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in

- Diagnostic and Interventional Radiology,
- Nuclear Medicine and
- Radiotherapy

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WORKING MATERIAL-CONTRIBUTED PAPERS

PART V

Papers: 251-304

and other new papers

To be presented on behalf of Toshiba Medical Systems, Nasu, Japan by:

Robert Eastick
Senior Manager – X-ray Systems Business Group
Toshiba Medical Systems Europe B.V.

DYNAMIC FLAT PANEL TECHNOLOGY MTF, NEQ AND RADIATION SENSITIVITY

With the advent of Dynamic Flat Panel (DFP) technology to compliment static flat panel technology (SFD) and computerized radiography (CR), the concept of a totally digital medical diagnostic imaging environment will soon be technically accessible, assuming the absence of final limitation.

Until digital image archiving capability was realized, permanent records still relied upon the performance of film and intensifying screens.

In the future, the mantle of responsibility for technology and products that limit radiation dose to both the patient and operator will transfer almost entirely to those companies involved with the development and manufacture of FPD systems, be they static or dynamic.

Companies involved with DFP technology are promoting advanced MTF performance, a dramatic improvement in dynamic range, and increased radiation sensitivity for the potential reduced of radiation dose during both digital fluoroscopy and fluorography.

While these claims may be true, even at this early stage different companies are presenting DFP technology that differs in design and performance characteristics.

Toshiba is involved in the development of selenium based direct-conversion flat panel detectors and has determined significant differences and benefits in technical performance relative to those of detectors that identify with indirect-conversion technology. Indirect-conversion technology employs the interaction with fluorescent material by X-ray photons to produce light, which in turn stimulate photodiodes.

Research in association with State University Hospital of New York, USA, has provided a direct comparison of selenium based direct panel detectors performance with that of image-intensifiers and CCD television cameras, in terms of MTF and NEQ (Noise Equivalent Quanta).

Toshiba's research engineering division has also conducted extensive evaluation of direct and indirect dynamic detector technology to establish relative performance in terms of MTF and radiation sensitivity, taking into account both fluorographic and fluoroscopic functionality.

The objective of this presentation is to present these facts and findings, to advance the understanding of the issues and challenges confronting this new aspect of dynamic imaging technology.

NEW PAPERS/using numbers were the input was duplicated or they have sent before only the announcement

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EXPOSICIÓN PRENATAL INJUSTIFICADA DURANTE LAS APLICACIONES MÉDICAS

Autores: Cárdenas Herrera J.[x] López Bejerano G[x]., Lamadrid AI.[x], García Lima O.[x], Díaz Bernal E.[x] , Freixas V.[x], Sánchez R.[xxx]
[x] Centro de Protección e Higiene de las Radiaciones
[xx] Hospital Clínico-Quirúrgico Miguel Enrique
[xxx] Hospital Obstétrico Ramón González Coro

ABSTRACT

The exposure to the radiation ionising of pregnant women , frequently constitutes motive of preoccupation for the expectant mother and the medical professionals taken the responsibility with its attention. The protection of the embryo-fetus against the radiation's ionising is of singular importance due to its special vulnerability, to this agent. On the other hand the diagnosis or treatment with radiations ionising beneficial i for the expectant mother, are only indirectly it for the embryo-fetus that is exposed to a hazard without perceiving anything. The present paper i exposes the experience obtained in the clinical and dosimetri evaluation from twenty-one patient subjected gestantes to diverse radiodiagnóstico procedures or nuclear medicine, during the years 1999 - 2000. The obtained results evidence that 24% of the patients was subjected to procedures of nuclear medicine with purposes diagnoses. While the period of pregnancy of the patients oscillated between 4 and 12 weeks. It could be concluded that in all the cases the doses received by the patients in the whole body didn't overcome the 2 mSv. When conjugating the period of pregnancy of the patients with the doses received dion't have any evidences of significant risks for the embryo-fetus. Paradoxically the physicians of assistance indicated their patients in all the cases to carry out the interruption of the pregnancy., demonstrating with this decision ignorance on the biological effects of the radiations ionising during the prenatal exposures.

1. Introducción:

En los últimos años se ha suscitado en la Comunidad Científica Internacional justificadas preocupaciones por la contribución de las aplicaciones médicas, a la exposición de las radiaciones ionizantes en la población mundial. En tal sentido organizaciones nacionales e internacionales encargadas de la regulación y control en materia de protección radiológica, han adoptado medidas para minimizar los riesgos derivados de las exposiciones médicas, tanto para los pacientes, como para el público en general. [1,2,3]. Sin embargo en estas regulaciones no siempre queda claro la especial protección que requiere el embrión-feto y el recién nacido durante los períodos de gestación y lactancia respectivamente.

El embrión-feto y los recién nacidos son muy vulnerables a los riesgos de las radiaciones ionizantes, que pueden llegar a producirles múltiples efectos de severidad variable y por otra parte estos no reciben beneficios directos de la exposición de su progenitora para fines de diagnóstico y tratamiento médico. Estas razones nos motivaron a llamar la atención sobre el comportamiento de las exposiciones médicas, con mujeres gestantes en instituciones hospitalarias.

El trabajo expone los resultados obtenidos en la evaluación clínico-dosimétrica de veintiuna pacientes sometidas a procedimientos médicos de medicina nuclear o radiodiagnóstico, realizados en instituciones hospitalarias de la Ciudad de la Habana, Cuba.

2. Materiales y métodos:

Para realizar la evaluación clínico-dosimétrica, a las pacientes que forman parte de esta investigación, estas son sometidas a un interrogatorio detallado, con el objetivo de conocer y precisar las causas y circunstancias de la exposición a que fueron sometidas. Con posterioridad se les realizan exámenes clínicos y de laboratorio y se determina la magnitud de la exposición a las radiaciones ionizantes mediante diversas técnicas de evaluación dosimétrica.

Finalmente, en todos los casos se prestó especial atención a brindarle consejos genéticos a las pacientes con el propósito de reducir su estrés y de facilitar la comprensión real del riesgo al que fueron sometidas.

3. Resultados y Discusión:

En el interrogatorio a las pacientes gestantes se trató de identificar y precisar los estudios que le fueron practicados y las dosis recibidas o actividades administradas en ellos, edad gestacional en el momento que estos se realizaron; así como factores de riesgos adicionales a esta exposición, como los relacionados con la edad y número de embarazos anteriores.

En el gráfico 1 se presenta la distribución de las gestantes incluidas en este trabajo, según su edad y número de embarazos, comprobándose que el 62% de ellas en el momento en que se les realizó el estudio, se encontraban en edad gestacional con bajo riesgo y sólo el 10% se encontraba en edad de mayor riesgo.

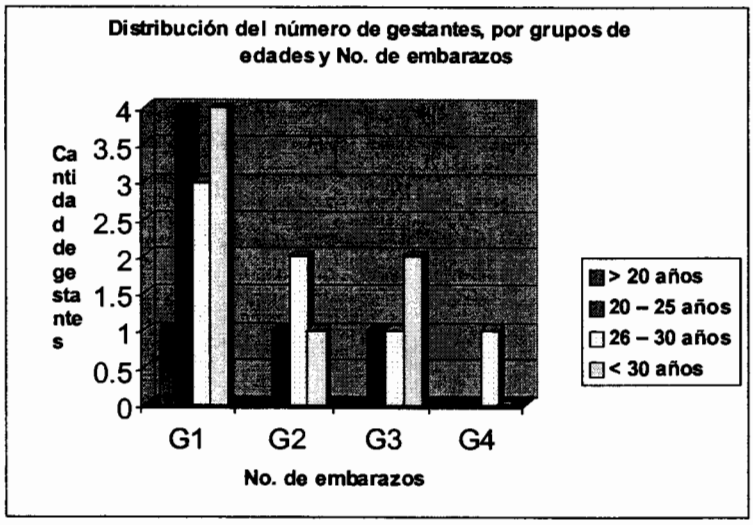

Figure 1 Distribución de las gestantes según edad y número de embarazo

Nota: La G en este gráfico significa el número de embarazos.

La distribución de las gestantes según el procedimiento médico y dosis de exposición a que fueron sometidas, se presenta en la tabla No.1. Como se muestra el 76% de las gestantes estuvieron sometidas a procedimientos de radiodiagnóstico, que incluyen desde estudios convencionales hasta estudios de tomografía computarizada, en dos casos. Los procedimientos de medicina nuclear se asociaban a estudios funcionales, especialmente de la glándula tiroidea.

Tabla No.1 Distribución de las gestantes según procedimiento médico y dosis de exposición

	Dosis de exposición (mSv)		
	< 1	1-2	hasta 3
Radiodiagnóstico	11 (52%)	5 (24%)	-
Medicina Nuclear	2 (10%)	2 (10%)	1 (5%)

Tanto en los procedimientos de radiodiagnóstico como de medicina nuclear las dosis recibidas por los pacientes en órganos o localizadas, no sobrepasaron los 3 mSv, exponiéndose el 62% de las pacientes a dosis inferiores a 1 mSv.

Aspecto a destacar es, que del interrogatorio realizado a las pacientes, se puso de manifiesto que en una buena parte de los casos, los prescriptores o ejecutores de los procedimientos no adoptaron las medidas elementales para determinar si las pacientes se encontraban embarazadas, violando de tal forma principios establecidos en materia de protección radiológica al paciente. Sólo el 39% de las pacientes fueron interrogadas al respecto, las cuales negaron la posibilidad de encontrarse en la condición antes citada, evidenciando de tal forma el desconocimiento que poseen de que el riesgo de embrión-feto durante la exposición prenatal a las radiaciones ionizantes se encuentra condicionado a la dosis de exposición y a la edad gestacional a la que esta se produce [1,4,5].

La tabla No.2 muestra que el 57% de las gestantes estudiadas se expusieron a dosis muy bajas, inferiores a los 3 mSv y en una etapa temprana del embarazo, factores estos, que determinaron la inexistencia de efectos determinísticos y la disminución de los estocásticos [1,4].

Tabla No.2 Distribución de las gestantes según edad gestacional y dosis de exposición

Edad gestacional	Dosis de exposición (mSv)		
	< 1	1-2	hasta 3
> 8 semanas	7 (33%)	5 (24%)	-
8-12 semanas	6 (29%)	2 (10)	1(5%)

Sin embargo inexplicablemente los médicos de asistencia de las gestantes indicaron a sus pacientes la interrupción del embarazo. Situación que somete a los pacientes a un riesgo adicional mayor al esperado por las radiaciones y por otra parte manifiesta falta de conocimiento sobre los efectos de las radiaciones ionizantes.

4. Conclusiones:

El estudio permitió conocer como con frecuencia, en las instituciones hospitalarias se violan procedimientos usuales y reconocidos en materia de protección radiológica al paciente. Demostrando además, la conveniencia de continuar desarrollando programas de capacitación en esta materia, dirigido esencialmente a los profesionales de la salud encargados de proteger y orientar a sus pacientes.

La limitación fundamental del trabajo, es la imposibilidad de darle un sistemático seguimiento epidemiológico a las pacientes expuestas, aspecto para el cual debe trazarse una estrategia.

5. Bibliografía:

[1]. Recomendaciones de la comisión Internacional de Protección Radiológica ICRP 60 1990,

[2]. Protección Radiológica y Seguridad en Medicina, Publicación 73 ICRP,

[3]. Implementacion of the Medical Exposure directive 97/43/ Euraton Radiatión Protección 102,

[4]. Genetic and Somatic,
Effects of ionizing Radiation United Nations Scientific Committec and the efects of Atomic radiation 1996 repolt to the general Asembly, Biologica effects of prenatal irradiacion,

[5]. Comisión Europea Madrid 1998. Guía para la Protección del Feto y los niños pequeños irradiados debido a la exposición médica de sus progenitores. Protección Radiologico 100 Comisión Europea.

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SITUACIÓN DE LA FÍSICA MÉDICA EN LATINOAMÉRICA Y LOS RECURSOS NECESARIOS PARA SU DESARROLLO EN EL SIGLO XXI

Carrizales Lila
Presidenta de la Asociación Latinoamericana de Física Médica. ALFIM.
Instituto Venezolano de Investigaciones Científicas. Unidad de Tecnología Nuclear. Laboratorio Secundario de Calibración Dosimétrica. Caracas. República Bolivariana de Venezuela.
Fax. 58-2-504.1546 e-mail: lcarriza@pion.ivic.ve

Introducción.

La presente charla trata de establecer de manera objetiva la situación actual de los países de Latinoamérica en referencia a las áreas de diagnóstico radiológico intervensionista, medicina nuclear y radioterapia cuya optimización está directamente vinculada con la existencia de personal altamente capacitado en dichas áreas capaz de impulsar Programas de Garantía de Calidad en los países de la región, como lo son los Físicos Médicos, quienes tienen están capacitados para aplicar conocimientos y técnicas de la física básica para optimizar la el diagnóstico o el tratamiento de patologías malignas o benignas en pacientes.

El área de la Física Médica es muy extensa y va desde la investigación y enseñanza de técnicas altamente especializadas, la implantación de las mismas en instituciones hospitalarias bien sea para la optimización de sistemas en la detección de patologías o en el tratamiento de las mismas. así como en la aplicación de sus conocimientos en la industria

En la consulta que ha realizado ALFIM en la región tenemos:

ARGENTINA	
Radiodiagnóstico	5 a 6 físicos dedicados a esta área en todo el país. No hay estadísticas del equipamiento
Medicina Nuclear	10 a 15 físicos. Hay aproximadamente 300 Laboratorios de Medicina Nuclear con aproximadamente 190 gamma cámaras planares y 160 SPECT.
Radioterapia	57 personas entre físicos e ingenieros No se obtuvo información sobre las estadísticas del equipamiento

Formación	Radiodiagnóstico: Tema poco tratado, eventualmente se dictan algunos cursos aislados, dictados por especialistas extranjeros. Medicina Nuclear: Existe un curso que dicta la Comisión Nacional de Energía Atómica (CNEA) para médicos y técnicos, el cual los habilita para trabajar con radioisótopos. Radioterapia: Existen dos cursos que dicta la Comisión Nacional de Energía Atómica (CNEA). El primero se dicta anualmente en Buenos Aires. Tiene una duración de un mes, contempla aspectos básicos de radioterapia, incluyendo cálculos básicos tanto para RT externa como para Braquiterapia. El segundo se dicta cada seis meses. Contempla aspectos de radioprotección, radiobiología, pasantías en el LSCD y braquiterapia, haciendo énfasis en planificación de tratamientos. La ARN y organismos oficiales de Protección Radiológica dicta diversos cursos durante todo el año en diversas áreas.

BRASIL	
Radiodiagnóstico	La Comisión Nacional de Energía Nuclear (CNEN), actúa como ente fiscalizador en esta área ya que existe una legislación que atribuye dicha tarea a la secretaría de Estado de Salud. Pocos de los Servicios poseen Programas de Control de Calidad y la eficiencia de la protección radiológica depende de las circunstancias locales. En 1988 el Ministerio de Salud emitió un decreto de la obligatoriedad de implantación de Programas de garantía de Calidad y supervisión en protección radiológica. Tienen estadísticas del equipamiento. No se obtuvo información sobre las estadísticas del equipamiento
Medicina Nuclear	Es una de las áreas más desarrolladas debido a la producción de radioisótopos. Sin embargo, en esta área no existe la obligatoriedad de contar con un Físico Médico en la instalación y la responsabilidad de la protección radiológica queda relegada al médico. Únicamente los grandes centros cuentan con este personal. La ABFM regula el titulo de especialista en MN para contribuir a mejorar la calidad de los servicios atribuyéndole la responsabilidad de la protección radiológica de los centros. No se obtuvo información sobre las estadísticas del equipamiento
Radioterapia	Desde que se inició la aplicación de la Radioterapia en Brasilia la Comisión Nacional de Energía Nuclear (CNEN), estableció normas que exigen la presencia de un Físico Médico especializado con la responsabilidad de velar por la protección radiológica de la instalación, planificación del tratamiento del paciente y la disimetría de los instrumentos. No todos los servicios de Radioterapia cuentan con FM especializados, en muchas ocasiones el FM es preparado por el propio servicio, realizando un trabajo de investigación en el área para licenciarse bajo la supervisión y asesoría del FM especialista responsable del Departamento. Sin embargo, persiste la necesidad de personal capacitado en esta área. No se obtuvo información sobre las estadísticas del equipamiento

Radiodiagnóstico	3 FM Apox 3000 equipos de radiodiagnóstico, 50 TC, 15 RMN, 270 mamógrafos 5 equipos de esterotaxia mamaria Se escribió la Norma de protección contra las radiaciones ionizantes de las fuentes externas usadas en medicina. Parte I. Radiodiagnóstico médico y odontológico. Dichas normas tienen con carácter de obligatoriedad la implantación de Programas de Garantía de Calidad en los servicios de radiodiagnóstico.
Medicina Nuclear	Ningún FM 17 sistemas 20 SPECT y resto planar. Está en proyecto la escritura de la normativa en Medicina Nuclear.
Protección Radiológica	3 FM, 4 TSU Se realiza un número alto de inspecciones de seguridad radiológica, y se dictan diversos cursos de Seguridad radiológica para oficiales de protección radiológica. Se adoptaron la Normas Básicas de Seguridad de la OIEA Reporte 115
Radioterapia	8 Físicos Médicos, 12 dosimetristas, 38 servicios de Rt 15 Co y 5 AL, 2 con posibilidades de Radiocirugía, 8 instituciones cuentan con sistemas de planificación de tratamientos. 20 centros con Barquiterapia 2 de ellos con alta tasa, 1 con media y el resto con baja. Existe un Programa de Control de Calidad y Calibración de unidades de RT con frecuencia anual al igual que se participa en la Intercomparación Postal de Dosis de la OPS/IAEA Se elaboraron normas para RT en las cuales se exige la presencia de un FM en los servicios así como la implantación de Programas de Aseguramiento de Calidad y se adoptó como norma el reporte TEC-DOC-1151. Aspectos físicos de la Garantía de la calidad en Radioterapia: Protocolo de Control de Calidad.
Formación	Actualmente se está en conversaciones para la jerarquización del cargo del FM El Ministerio de Energía y Minas exige una inspección de Aceptación de cualquier unidad de RT que se instale en el país para dar permiso de funcionamiento. Se han realizado diversos trabajos de investigación con la finalidad de determinar la realidad en el área del diagnostico radiológico y de le intervensionismo así como en la actualidad se esta impulsado una investigación en MN con el mismo fin. Se lleva un Programa de Maestría Nacional que esta formando a 6 FM dicho programa tiene las opciones de RT, RD y PR y está en su fase terminal. La IAEA aprobó y apoya la Maestría Regional cuyo primer grupo consta de 21 miembros participantes de toda la región de Latinoamérica y por segundo año estará coordinada en Venezuela y se esperan 12 estudiantes más.

En Conclusión

No existe la jerarquización del cargo del Físico Médico. Es imprescindible la formación inmediata de recursos humanos con un alto nivel en la FM Se espera que con el Programa de la Maestría Regional se preparen en seis años 160 FM.

No se tienen estadísticas fidedignas del equipamiento existente en Radiodiagnóstico, Medicina Nuclear.

Pocos países cuentan con Programas de Garantía de Calidad.

Ha y un gran número de Equipos obsoletos en todas las áreas.

Incursión de nuevas tecnologías sin contar con los FM necesarios para funcionar

Faltan radioterapeutas y técnicos especializados en especial en las áreas de Medicina Nuclear y Radioterapia.

Los programas de formación existentes difieren ampliamente en su mayoría por ello la creación de una maestría regional de manera tal que el profesional capacitado tenga un dominio uniforme de la

Radiodiagnóstico	En 32 Estados tienen: 3510 Establecimientos con 6633 equipos de Rayos-X. (76% convencionales, 15% fluoroscópicos, 5% mamográficos y 4% tomográficos 39% de los físicos tienen especialidad, 24% licenciatura, 2% Maestría, 0,5% Doctorado. (11920) 22% son técnicos radiólogos y 12% formación práctica Tienen un Programa Nacional de Protección Radiológica en el Diagnóstico Médico con Rayos-X Tienen cuatro normas oficiales Responsabilidades sanitarias en establecimientos de diagnóstico médico con Rayos-X Requisitos técnicos para las instalaciones en establecimientos de diagnóstico médico con Rayos-X Protección y seguridad radiológica en el diagnóstico médico con Rayos-X Especificaciones técnicas para equipos de diagnóstico médico con Rayos-X El Consejo Mexicano de Radiología e Imagen otorga certificación de 696 establecimientos en 21 estados 60% están verificados y 40% están en proceso. Tienen estadísticas completas en el área de RD
Medicina Nuclear	El área está reglamentada por la Comisión Nacional de Seguridad Nuclear y Salvaguardias Las estadísticas están en proceso de elaboración
Radioterapia	No se obtuvo información sobre las estadísticas del equipamiento
Formación	Actualmente dictan dos cursos de postgrado en FM, uno en la Universidad Nacional Autónoma y otro en la Universidad Autónoma del estado de México en conjunto con el ININ. Tienen un programa de Diplomado en Física Médica

PERÚ	
Radiodiagnóstico	No se obtuvo información sobre las estadísticas del equipamiento
Medicina Nuclear	No se obtuvo información sobre las estadísticas del equipamiento
Radioterapia	No se obtuvo información sobre las estadísticas del equipamiento
Formación	Maestría en FM con especialidad en física radiológica en la Universidad Nacional de Colombia El Pensum contempla aspectos de física moderna, radiobiología, radioprotección, modelos en radiologías y tesis Existe un programa apoyado por e OIEA donde en conjunto con el IPEN, una Universidad y el Instituto de enfermedades neoplásicas de ha creado una maestría la cual ya egreso el primer grupo

PARAGUAY	
Radiodiagnóstico	No se obtuvo información sobre las estadísticas del equipamiento
Medicina Nuclear	No se obtuvo información sobre las estadísticas del equipamiento
Radioterapia	2 FM, 1 dosimetrista Cuentan con un sistema completo de Planificación de tratamientos No se obtuvo información sobre las estadísticas del equipamiento
Formación	No existen programas de formación de FM, calibraciones periódicas, ni de control de calidad en RD, MN y RD

REPUBLICA BOLIVARIANA DE VENEZUELA

Protección Radiológica	1 FM No se obtuvo información sobre las estadísticas del equipamiento
Radioterapia	3 FM No se obtuvo información sobre las estadísticas del equipamiento
Formación	Solo dos tienen títulos de FM. No hay carreras universitarias para FM

CUBA	
Radiodiagnóstico	13 físicos dedicados a RD. No se obtuvo información sobre las estadísticas del equipamiento
Medicina Nuclear	38 físicos e ingenieros. Hay 2 cámaras planares y 8 SPECT.
Radioterapia	17 FM No se obtuvo información sobre las estadísticas del equipamiento
Formación	Existen tres escuelas de formación en Física, Física Nuclear e Ingeniería en Física Nuclear. Se tenía el proyecto de un programa para diplomado del FM pero no ha tenido curso y está en proyecto la elaboración de una maestría con opciones en RT. RD y MN

ECUADOR	
Radiodiagnóstico	1 FM, 500 centros de radiología No se obtuvo información sobre las estadísticas del equipamiento
Medicina Nuclear	1 FM, 10 servicios No se obtuvo información sobre las estadísticas del equipamiento
Radioterapia	7 FM 3 aceleradores lineales, seis unidades de Cobalto, un TAC simulador, Cinco simuladores, un equipo para barquiterapia de alta tasa de dosis, dos de media tasa y seis de baja tasa de dosis y tres equipos de radioterapia superficial. Un sistema computado de disimetría relativa, dos lectores de TLD, siete sistemas dosimétricos para disimetría absoluta y diversos sistemas para control de calidad .
Formación	Cuenta con una infraestructura de educación a distancia para participar en os seminarios organizados por el programa académico de la Wayne Satate university de Detroit, Michigan, USA La ley de seguridad radiológica de 1978 exige la vinculación de un especialista en FM por lo que SOLCA, la escuela politécnica del Litoral, y la Comisión Ecuatoriana de Energía Atómica crearon la Residencia-maestría en FM que se inició en enero de 1999. La AEFM tiene seis miembros y está impulsando la protocolización de los programas de Garantía de Calidad de FM en RT para lo cual desarrolla dos talleres nacionales. Están trabajando en la implantación de auditorias físicas, implantación de los protocolos nacionales de control de calidad en cobaltoterapia y braquiterapia de baja y alta tasa de dosis, así como para los aceleradores lineales

MÉXICO

Formación	Radiodiagnóstico: Existen cursos de maestría en 5 universidades dos de ellas en FM y tres en ingeniería nuclear con opción a hacer tesis en cualquier área de la FM. Medicina Nuclear: Idem Radioterapia: Los Físicos médicos que trabajan en Radioterapia son instruidos mediante cursos de especialización en dicha área, actualmente hay cuatro cursos en Río de Janeiro y en Sao Paolo, los cuales tienen una duración de dos años con dedicación exclusiva asociados a residencia médica en por lo menos tres hospitales o trabajando directamente en el hospital bajo la asesoría de un FM especialista sin programa definido pero directamente relacionado con el tratamiento del cáncer. El IRD o IPEN, la UFPE y la UERJ ofrecen cursos de corta duración en el área de la dosimetría y protección radiológica La CNEN en conjunto con la ABFN realizan la acreditación del Físico Médico emitiendo un certificado o titulo de especialista en RT. Algunos cursos de postgrado también preparan FM en RT bajo la figura de: Programas de Postgrado en tecnología nuclear IPEN/SP Programas de Postgrado en Ciencias Biológicas y Nucleares UERJ/RJ Programas de Postgrado en Ciencias Biológicas y Nucleares. Departamento de Energía Nuclear UFPE (Pernambuco). Cursos de doctorado en FM en dos universidades y dos en ingeniería nuclear con opción a FM

CHILE	
Radiodiagnóstico	No se obtuvo información
Medicina Nuclear	No se obtuvo información
Radioterapia	No se obtuvo información
Formación	Existe la carrera de tecnología medica con cinco especialidades: Radiología y Física Médica, el egresado está preparado para trabajar en radioterapia, medicina nuclear y radiodiagnóstico. La formación consta de cuatro semestres con asignaturas de ciencias básicas, al final de los mismos el estudiante selecciona la opción de radiología, física medica y realiza 5 semestres más en el área seleccionada la cual incluye tesis y practicas hospitalarias Laboratorio clínico, Hematología y Banco de Sangre, Histología y Oftalmología, Física Nuclear e Ingeniería en Física Nuclear.

COLOMBIA	
Radiodiagnóstico	No se obtuvo información
Medicina Nuclear	No se obtuvo información.
Radioterapia	No se obtuvo información
Formación	Maestría en FM con especialidad en física radiológica en la Universidad Nacional de Colombia El Pensum contempla aspectos de física moderna, radiobiología, radioprotección, modelos en radiologías y tesis.

COSTA RICA	
Radiodiagnóstico	1 FM No se obtuvo información sobre las estadísticas del equipamiento

información para enfrentar los mismos problemas ya que participan en dicho Programa todos los países de la Región.

Requisitos para el ingreso a la maestría.

Poseer titulo de Licenciado en física química matemática biología ingeniería electrónica mecánica o computación. Aprobación del examen de admisión y cursas materias de nivelación cuando así se requiera

El objetivo del postgrado es formar profesionales de alto nivel que a mediano plazo puedan enfrentarse y resolver los problemas propios de las instituciones hospitalarias, industrias y/o centros académicos

CD-ROM TRAINING COURSE IN QUALITY ASSURANCE IN DIAGNOSTIC IMAGING

Khoury, H.J; Machado, P.; Drexler, G.*
Departamento de Energia Nuclear-UFPE
Av. Prof. Luiz Freire-1000- Recife-Brazil
khoury@elogica.com.br
*Laboratório de Ciências Radiológicas-UERJ and
GSF- Forschungszentrum- Munich, Germany

Abstract: This paper discusses the CD-ROM elaborated to provide a continuous professional formation and a practical guidance on the implementation and operation of routine quality assurance (QA) programme for medical physicists, regulator authorities and for those personnel concerned with the daily provision of diagnostic radiology services. The CD-ROM contains topics on the basic concepts of QA in radiodiagnostic, and it also allows to the user to visualise effects on the variation of technical parameters (tube potential (kV) and current (mA), filtration) in the quality of the image. This possibility will contribute to the better understand of the phenomena associated with the quality of the image. Besides, the program contains the procedures for the execution of the tests of the equipment and the route of implantation of program of quality assurance. It is interactive with the user, it fills out a gap in medical physics area and it allows the student's continuous formation because it assists the beginner, with the basic concepts, and the professional, with the aid in the implantation of the program of QA. The presentation is in portuguese language.

1. Introduction

Use of X-rays for diagnostic examination needs to ensure that the exposure of patients is at the adequate level to achieve an image with quality to allow for the diagnostic [1]. To ensure diagnostic images of optimum quality with low exposures it is necessary to implement a quality assurance program in the institution. To do that it is necessary to have professionals with adequate education and practical training in radiation protection. They do not only require initial training but also continued education throughout their professional lifetime.
Quality assurance programmes and quality control initiatives in general diagnostic radiology has been developed in several European countries in the past 10years [2]. On other hand, in Latin America countries and especially in Brazil theses programs began to be implanted recently. Since in these countries there are a few professionals prepared to implement a QA programme in X-ray departments, a CD-ROM was prepared with the aim to contribute with the professionals' formation. The CD-ROM contains topics on the basic concepts of QA in radiodiagnostic, procedures for the execution of the tests of the equipment and the route of implantation of program of quality assurance. It assists the beginner, with the basic concepts, and the professional, with the aid in the implantation of the program of QA. It is intended to help in the implementation of recently published legal requirements on the use of X-rays in Brazil.

2. Materials and Methods

The scope of the CD-ROM was prepared so that the professional that is beginning to work with X-Ray equipment can find information about the legislation, the physical principles of x-ray equipment and of medical imaging. The CD also contribute for training of professionals on the implementation of the quality control tests. The figure 1 shows the main page where is possible to see the main topics of the CD.

Figure 1- Image of the main page of the CD-ROM

The main menu has the following five topics: Legislation , Equipment, X-ray Quality assurance, Test procedures and Reporting.

In the first item the user will find the information related to brazilian and international legislation and safety standards. In the topic **Equipment** the user will find three items: a) Function of x-ray equipment, b) Type of x-ray equipment, c) Automatic processors. In the first item it is presented an introduction and overview of the x-ray production, the tube x-ray components and its function. Technical aspects of radiation production are discussed. The information are associated with the images of the x-ray components. In the third item automatic film processors are presented and its components and function are discussed

In the topic **X-ray Quality Assurance** the geometric factors that affect the radiographic image are discussed. The effect of kilovoltage, time and current can be seen in a torax radiography by moving the cursor. The influence of radiographic grids, diaphragms and intensifying screens on the image quality are also described. This topic also present information about the radiographic receptors and the film sensitivity and contrast characteristics. This first part of the CD-ROM give to the user basic information about x-ray equipment and image characteristics and quality. This material will be useful for courses for medical physics, for technicians and radiologists.

The second part of the CD-ROM is for the professionals that have basic knowledge on physicals principles of medical imaging but want to improve their knowledge about specific quality assurance tests. The topic **Test procedures** discuss this subject.

In this topic are presented the general considerations of an X-ray quality assurance program and the procedures to perform collimation and beam alignment test, to check the changes in the performances of the x-ray tube and generator, to estimate the beam filtration and the exposure time. In this topic it is also presented the procedures to check the level of illumination provided by the viewing boxes and the protocol for a processor quality assurance program. All the description of the tests is associated with images that illustrate each stage of the procedure.

If the user has experience and doesn't need to study how to do the quality assurance tests, but wants to treat the data, he/she can do it with the last topic of the CD-ROM, the **Report**. In this part the program treat the data and compare the results with the tolerance levels and inform if they are adequate or note. It is possible to print the report of the test.

The entire structure is displayed in the Figure 2.

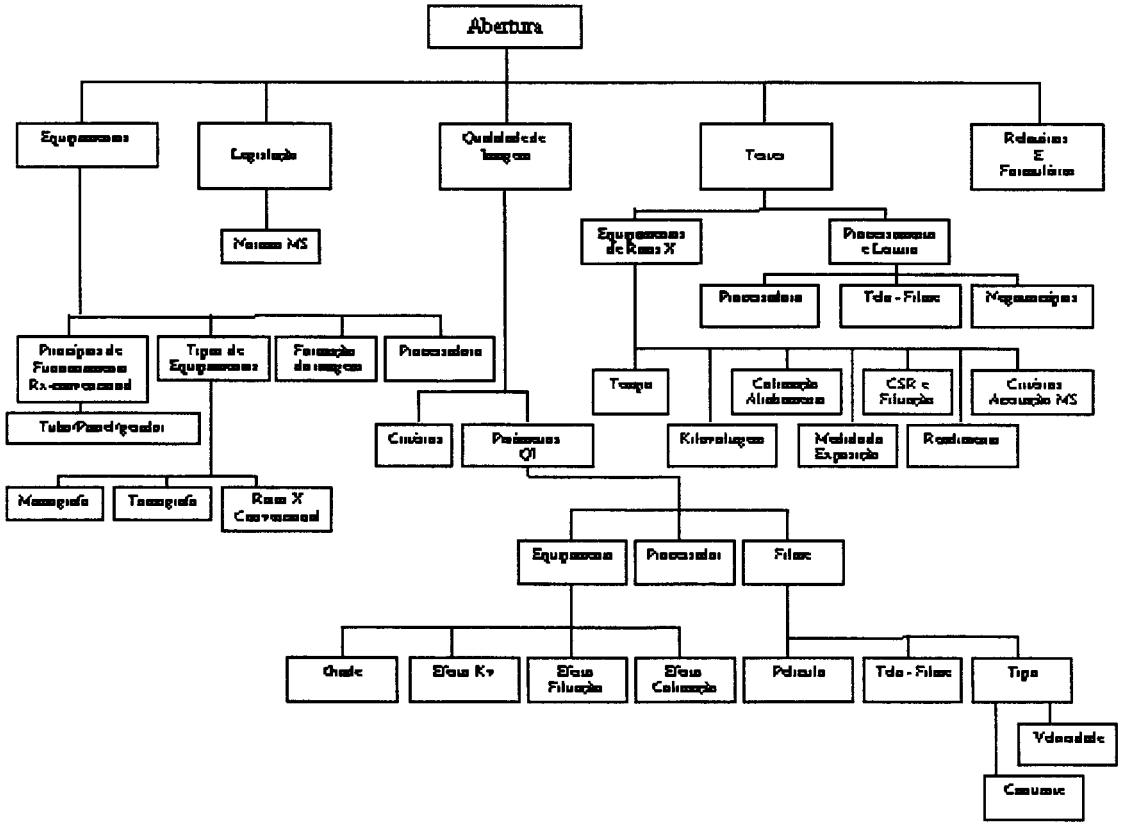

Figure 2- CD-Rom structure

PROGRAMME FOR REDUCING THE RISK FACTORS DUE TO PRENATAL EXPOSURE

L. Arranz, N. Ferrer, J.M. Sastre
Hospital Ramón y Cajal. E-28036 Madrid. Spain.
Email: larranz@hrc.insalud.es

ABSTRACT

When a patient is not aware of her pregnancy, the foetus/embryo may be inadvertently irradiated during a diagnostic exploration or therapeutic intervention.
The radiosensitivity of the foetus/embryo changes during the different periods of gestation. For this reason there are different risk factors for each moment at which the patient may suffer irradiation. In the past 7 years, the department of Radiophysics and Radiation Protection has been consulted 75 times for this reason, to evaluate the dose received in the uterus. Since the establishment of a programme to avoid inadvertent irradiation of the foetus/embryo, these consultations have been reduced.
This programme is based on informing the patients and on training the medical staff.

INTRODUCTION

The radiosensitivity of the foetus/embryo changes throughout the various stages of gestation.

It is unlikely that exposure of the embryo in the first three weeks after conception would cause deterministic or stochastic effects in the born infant. In this period practically the only risk is radioinduced death (all or nothing law). The risk factor is 1 per Gray (1‰ per mGy).

For the remainder of the organogenesis period, conventionally considered after the third week (until the 8th), malformations may occur in the organ which is developing at the moment of exposure. These effects are of a deterministic nature and a threshold of 100 mSv has been estimated with an associated risk of approximately 0.5 per Gy.

In the period between three weeks after conception and the end of gestation, it is likely that exposure to radiation could cause stochastic effects resulting in an increased probability of cancer in the live born infant. The risk factor is 0.02 per Gy, implying a risk between 2 and 3 times greater than for the general population.

The risk of serious metal retardation or loss in IQ is high between weeks 8 and 15 (0.45 per Gy) and low between weeks 16 and 25 (0.1 per Gy). For purposes of comparison, the ratio of serious mental retardation in born children is 1 in 200. [1 to 3].

ESTIMATE OF THE RISK IN RADIOLOGIC AND NUCLEAR MEDICINE

3. Conclusion

The CD-ROM prepared will strongly contribute for the professional's continuous formation and it fills out a gap in medical physics area. It can assists the beginner, with the basic concepts, and the senior professional, with the aid in the implantation of the program of QA. This training material is a practical guide to quality assurance in medical imaging .

4. REFERENCE

1. International Commission on Radiological Protection- Recomendations of the International Commission on Radiological Protection. ICRP 60. Ann. ICRP 21 (1-3), 1990.
2. Schneider, K. Evolution of quality assurance in paediatric radiology- Rad. Prot. Dosim. 57, 1-4, 119-123 (1995)

In our hospital 75 consultations have been received in the past 7 years to perform a in-uterus dosimetric study to evaluate foetal risk. Of these, 75% correspond to radiological studies and 25% to Nuclear Medicine (68% correspond to diagnostic explorations and 32% to therapeutic treatments with I-131). Patient ages vary from 18 to 42 years and declared gestation weeks vary from 1 to 14 (average of 4 weeks).

The "Effdose" program of the National Institute of Radiation Hygiene of Denmark, the in-uterus dose documentation of NRPB and ICRP-53 and the MIRD method were used for dosimetric studies.

A dose of 10 mGy on the foetus, which may be standard for certain types of abdominal radioexplorations and radionucleide explorations (bone and brain gammagraphs, microcardial perfusion gammagraphs with Tl 201, with Tc-99m MIBI and with Tc-99m TTF, etc.), will imply an increase in the risk of mental retardation of 4 0/00 when irradiation takes place between weeks 8 and 15 (the period of highest radiosensitivity), which when compared to the natural rate (5 0/00) could be considered as acceptable if the benefits of the exploration are important.

Foetal doses between 10 and 100 mGy or more may occur during complex or simple radioexplorations performed with poorly optimised equipment and protocols, as well as in certain explorations and treatments in nuclear medicine (gammagraphs with Ga-67 or Selenium-75, and therapeutic treatments using I-131, etc.). [3 to 7].

PROGRAMME FOR PREVENTING INADVERTENT IRRADIATION OF THE FOETUS/EMBRYO

In view of the results obtained and of interviews performed with several affected patients, it was decided to carry out a program meant to reduce prenatal risks due to irradiation based on:

Patient information

The prescribing physician should ask the patient if she is pregnant or if she has missed a menstruation. If there are doubts regarding the possibility of a pregnancy, the woman will be considered to be pregnant.

Posters were created with the cooperation of the Ministry of Health and Consumption and the Scientific Societies of Radiological Protection (SEPR), Nuclear Medicine (SEMN) and Radiology (SERAM), with a striking and simple design, encouraging the patient to inform the physician of her situation. These posters were placed next to the appointment windows and in all waiting rooms, in order to inform the patients in both situations: when requesting an appointment and prior to the exploration or treatment. The design of the Nuclear Medicine poster included a request to inform the physician of a lactation situation in order to prevent risk to the lactant.

Additionally, nurses were asked to inquire all women in fertile ages on behalf of the physician responsible for the exploration regarding the possibility of a pregnancy before

carrying out the exploration or treatment. In the event of a positive reply the physician was immediately informed.

Physician training

All prescribing physicians and specialist physicians in radiology and nuclear medicine shall receive information on the justification and optimisation criteria proposed by the ICRP and gathered in our legislation and in Directive 97/43/Euratom. [1,2,8,9].

The criteria indicated are as follows:

- Only when a diagnostic exploration is well justified do the benefits overcome the risks. It should also be kept in mind that the risk of not performing a necessary radiological study may be much greater than the risk caused by the radiation.

- If a pregnancy cannot be ruled out and the radiological study involves the abdominal or pelvis region, particular care shall be paid to the justification, and particularly to the urgency of said study. The ICRP and the EC recommend that diagnostic methods which involve exposure of the abdomen in possibly pregnant women should be avoided unless there are important clinical indications.

- Once the exploration is justified, the doses shall be kept as low as reasonably possible, in accordance with the diagnostic information required.

- Experience shows that for the same exploration there are great intervals of doses to the uterus depending on the equipment and protocol of exploration used, so that significant dose reductions can be obtained without affecting the quality of the diagnostic image.

If the patient declares a possible pregnant state, the following alternatives are suggested, which shall always be followed under the criteria of the physician responsible for the exploration or treatment:

- **Cancel the exploration,** considering other available methods (ultrasound or MR) which have the same objective but do not imply exposure to ionising radiation. The patient may also be asked about any similar studies which she has undergone recently.

- **Postpone for a later date**, if it is not urgent, if the patient is uncertain about her state of pregnancy, until being certain of said state or until after the child is born if the pregnancy is confirmed.

- **Modify the exploration,** (for radiology) to reduce exposure to radiation, reducing the number of images, selection of projections, reduced radioscopy time and collimation of the radiation beam.

- **Carry out the full exploration,** in all cases ensuring that technical conditions are optimal, using the minimum mAs, maximum possible collimation in radiology, as

well as the available protection means for adjacent areas which do not affect the image, and for Nuclear Medicine performing a careful choice of radiopharmacology and radionucleides and with the minimum compatible dose administered in order to minimise the dose to the foetus.

In any case, the decision should always be explained to the patient and her consent requested (the patient has a right to know the possible risks).

In the case of radiotherapy, before making a decision regarding treatment of the future mother the dose to the foetus shall be carefully calculated. It will normally be high, but treatment of the mother must in general prevail over said dose to the foetus. In discussion and decision regarding treatment the mother's decision will be considered.

CONCLUSION

With the execution of this program the number of cases consulted per year due to inadvertent irradiation of the foetus has been to less than 10%.

The cooperation of the medical personnel has been crucial for the success of this experience, so that inclusion of these measures in the continuous training programs has proved its usefulness and effectiveness.

REFERENCES

[1] INTERNATIONAL COMMISSION OF RADIOLOGICAL PROTECTION. 1990 Recomendations of the International Commission on Radiological Protection, ICRP. Publication 60. Ann ICRP, 1991.

[2] EUROPEAN COMMISSION; Guía para la protección del feto y los niños pequeños irradiados debido a la exposición médica de sus progenitores. Protección radiológica 100, OPOCE Luxemburg. 1999.

[3] NATIONAL RADIOLOGICAL PROTECTION BOARD. Diagnostic Medical Exposures: Advice on Exposure to Ionising Radiation during Pregnanty. Doc NRPB. 1998.

[4] EUROPEAN COMMISSION; Protección radiológica después de la terapia con Yodo-131 (exposiciones debidas al contacto con pacientes ambulatorios o dados de alta). Protección radiológica 97, OPOCE Luxemburg. 1998

[5] COHEN B.L. Catalog of risk extended and updated. Health Phys. 61: 317-335, 1991.

[6] UNITED NATIONS. Sources and Effects of Ionizing Radiation.United Nations Scientific Committee on the Effects of Ionizing Radiation, 1993. Report to the General Assembly, with annexes.United Nations sales publication E.94.IX.2. United Nations, New York, 1993.

[7] MOUNTFORD P.J. Evaluación del riesgo del paciente de medicina nuclear. Br J Radiol 70: 671-684. 1997.

[8] INTERNATIONAL COMMISSION OF RADIOLOGICAL PROTECTION. Radiological Protection and Safety in Medicine, ICRP Publication 73.Ann ICRP, 1996.

[9] EUROPEAN COMMUNITY. Council Directive 97/43/Eurotom of June 30 1997, on health protection of individuals against the dangers of ionising radiation in relation to medical exposures. Official J Eur Commun 1997; N.L 180/22.

TISSUE STANDARD RATIOS(TSR) FOR VARIAN'S CLINAC2100C RADIOTHERAPY ACCELERATOR

TinasheE. Makoni
Mpilo Hospital Radiation Therapy Dept. P.O. Box 2096. Bulawayo. Zimbabwe.
Email: kvmugabe@yahoo.com

1 INTRODUCTION

Since the advent of isocentrically mounted external therapy machines, there have basically been two main treatment geometries, namely fixed source to surface distance (SSD) and isocentric treatment. The dose calculation procedure for fixed SSD treatment is straight forward, involving the measurement and tabulation of beam data such as relative output factors(ROF), percentage depth dose(%DD) and the quoted output for the external radiotherapy unit, which may be a linear radiotherapy accelerator(LINAC) or a cobalt-60 unit. Dose calculation procedures for isocentric treatments, with varying SSDs depending on the patient's tumour depth however involve a number of correction factors to be applied and a measurement and tabulation of Tissue Phantom Ratios(TPRs), Tissue Maximum Ratios(TMRs) and/or Tissue Air Ratios (TARs). Depending on a particular radiotherapy clinic and the expertise within that clinic, dose calculation may be very complex and errors leading to misadministered radiation dose could arise. Our Department received its first LINAC in December 1996 from Varian Oncology Systems after years of using a cobalt-60 unit for external radiation therapy. In order to safely bring the LINAC into clinical service; the unit had to go through acceptance testing and finally commissioning. Commissioning is when the medical radiation physicist measures, analyses and tabulates the radiation beam data for treatment planning and treatment purposes. It is also when base level minimum standards are set for the Quality Control(QC) of the unit, so as to predict immediate service needs of the unit. In our Department, we decided to introduce and measure TSRs for isocentric treatment setups. We describe and present below our commissioning experience and a tabulation of the TSR data for Varian's Clinac2100C LINAC for 6MV and 10MV X-Rays.

2 MATERIALS AND METHODS

During commissioning the following data was acquired using the automated Wellhoffer Waterphantom Dosimetry Scanner with a C10 chamber.

1 %DD for field sizes 4x4 cm^2 up to 40 x 40 cm^2 and to a depth of 35cm
2 ROF
3 beam profiles
4 wedge transmission factors and blocking tray transmission factors.

For isocentric treatment setups, TSRs were measured using the Wellhofer Waterphantom Dosimetry Scanner. We define first what TSR is.

DEFINITION: A TSR is defined as the ratio of the dose at the isocentre for the depth, field size and shape and radiation quality to the dose at the isocentre for a $10x10cm^2$ field

at 10cm depth. See Figs 1 and 2.

In a radiation therapy clinic, use of TSRs would require knowledge of a reference measured dose. It is quite common in most deaprtments to calibrate a LINAC such that at the depth of maximum dose, dmax, for a 10x10cm^2 field at 100cm SSD is
D(10x10, dmax, Q, SSD=100cm) = 100.00cGy / 100U.
This is the reference dose, but for the isocentric treatment setup, the inverse of this dose at 10cm depth and for a 10x10cm^2 field would give us the monitor units(U) required to give 1Gy at the isocentre. This is the calibration factor (CF) for the radiation quality.
To measure TSRs, the LINAC is mounted vertically and all measurements were taken on the central axis (CAX) and at the isocentre for various field sizes ranging from 4x4cm^2 to 25x25cm^2. For each field size and depth set, the LINAC was set for 100U and point by point measurements at the isocentre taken with varying amounts of the waterhead above the isocentre. Measurements from 2cm up to20cm depth were made. The values so measured were normalised using the isocentric dose measured for a 10x10cm^2 field at 10cm depth at the isocentre also for 100U set. Measurements were done for 6 and 10mV X-Rays. A treatment data table was produced for the two X-Ray Qualities of 6mV and 10mV.
To confirm the measured data independently,another physicist repeated the measurements using perspex 30x30x1cm solid waterphantom sheets, and using an NE Farmer type chamber.One of the sheets had a hole to fit the chamber. Using the perspex method, and noting that the time required to take all data points is quite long, a record of temperature and pressure was kept to minimise drifts due to changing conditions.

3 RESULTS AND DISCUSSION

Tables 1 and 2 show the experimental data for 6 and 10mV X-Rays respectively. The data was collated from a mean of the waterphantom and the perspex phantom. Deviations less than 0.5% were recorded for the two phantoms at each measured point. As can be readily seen from the data, TSRs are a slow rising function of field size, depth and radiation quality. The BEAM ON monitor units to give a Tumour Dose(TD) at the isocentre can readily be calculated from

Beam On = CFxTD/TSR

For 6mV X-Rays, a calibration factor of 125U/Gy was measured, while that for 10mV X-Rays was found to be 115U/Gy.
In our clinic , we now readily use TSRs for isocentric set-ups. They are easier to use. They have eliminated the need to correct for inverse square law and ROF corrections and provide a quick QC of all isocentric treatment setups as the CFs can be easily checked using the geometry in Fig 1. Also using the perspex phantom and at any depth, the monitor units required to give a particular TD can be checked before beaming on.
Dose calculations obtained using the TSR method have been compared to those using other methods such as TMRs and we report agreement within 0.5%. For a Co-60 unit, the calibration factor would have munites/Gy, it being the time one would set at 10cm depth for a 10 x 10 cm2 in order to get 1Gy at the isocentre.

4 CONCLUSIONS

TSRs for Varian's Clinac 2100C Radiotherapy Accelerator have been experimentally determined for 6 and 10mV X-Rays. They offer a less error prone dose calculation procedure for isocentric treatment set-ups for the dose at the isocentre. We recommend the adoption for use of TSRs in small radiotherapy clinics which at times work without a full time medical radiation physicist. Their adoption in larger clinics is a matter of choice and the expertise in the clinic.

5 REFERENCES

1. A.R. HOUNSELL and J.M. WILKINSON – Tissue Standard Ratios for irregular shaped Radiotherapy Fields, British Journal of Radiology 1990,63, 629-634

PROTECCIÓN RADIOLÓGICA DEL PACIENTE EN EL TRATAMIENTO RADIOTERÁPICO DEL CÁNCER DE MAMA: ICRU 50 VS TRATAMIENTO CLÁSICO.

[1,2]F. Carrera; [1,2]C. Ojeda; [2]S. Velázquez; [1]I. Tort; [1]R. Ruiz-Cruces; [2]E. Bayo.

[1]Grupo de Investigación en Protección Radiológica de la Universidad de Málaga. SPAIN.
[2]Área Hospitalaria Juan Ramón Jiménez de Huelva.

ABSTRACT.

The goal of our investigation has been to compare breast cancer radiotherapy treatments prescribed according to classical and ICRU 50 methodology attending to the comparison of stochastic and deterministic risks of critical organs.
28 women were studied, 9 of them were plannified attending to ICRU 50 and 18 attending to the classical one. Patients were plannified using 3D planning system. The contralateral breast dose (CBD) were evaluated as a demonstrative of stochastic risks, and the volume closed by the reference isodose corresponding $TD_{5/5}$ which gave place to lung fibrosis. Every group were subdivided in only breast irradiated women and the one had been irradiated their supraclavicular fosa too.
When only breast was irradiated, a higher CBD was obtained with the ICRU 50 method. However, the lung toxicity was higher with the classical treatment. Studying the group which supraclavicular fosa was irradiated, we could notice that the classical method gets a higher CBD, but lower lung toxicity.
Beam size and arrangement were decisive in breast-irradiated women. When the supraclavicular field was involved, CBD was influenced by the beam size, although the lung risk seemed to be in dependence of the depth of normalization.

INTRODUCCIÓN.

La radioterapia complementaria en pacientes sometidas a MRM o a cirugía conservadora por cáncer de mama ha demostrado una reducción muy significativa de la tasa de recurrencia local y más recientemente también un beneficio en la supervivencia, sobre todo en pacientes premenopáusicas con ganglios axilares positivos [1-5]. A raíz de la publicación de los estudios sobre meta análisis de EBCTCG [6,7] la controversia se centró en torno al incremento de muertes tóxicas generadas por la irradiación y más concretamente de la irradiación de la cadena mamaria interna (CMI) como causa fundamental de toxicidad cardiaca. En la actualidad la irradiación de la CMI esta muy cuestionada [8], no obstante los campos tangenciales y claviculoaxilares, que constituyen nuestra practica habitual, no están exentos de toxicidad, sobre todo pulmonar que en algunos casos puede llegar a ser grave.

En los últimos años los sistemas de simulación virtual y planificación tridimensional nos han permitido conocer de una forma mucho más precisa la distribución de dosis en radioterapia, no solo en los volúmenes blanco sino también nivel de órganos críticos. Igualmente el desarrollo de la moderna radiobiología nos ha permitido un conocimiento más preciso de los límites de tolerancia de cada órgano crítico con relación a los distintos esquemas de fraccionamiento.

Por otro lado, desde la publicación del informe sobre prescripción, registro y elaboración de informes en terapia con haces de fotones, recomendados en el informe nº 50 [9] (en adelante la metodología recomendada por este informe se identifica como "ICRU 50") de la International Commission on Radiation Units and Measurements (ICRU), la definición de volúmenes de tratamiento se modifica significativamente respecto al sistema clásico, definiendo el volumen tumor macroscópico ("gross target volume", GTV) y volumen blanco clínico ("clinical target volume", CTV) siguiendo conceptos muy semejantes a los clásicos, pero estableciendo la definición de un tercer volumen, el volumen blanco de planificación ("planning target volume", PTV), cuyos márgenes respecto al CTV vienen definidos para cada localización en general y para cada sistema de trabajo en particular, incluyendo la incertidumbre en la definición del CTV respecto a un sistema de referencia de paciente [10], como consecuencia de la falta de reproducibilidad en el posicionamiento diario del paciente, de los movimientos fisiológicos del paciente, y de los errores de transferencia de datos geométricos que hayan podido producirse a lo largo de todo el proceso radioterápico. Para nuestro trabajo, y en tanto no terminemos un trabajo en curso [11] para la definición de nuestros propios márgenes de PTV, se toman de la bibliografía [12-16].

Aun manteniendo las mismas indicaciones de tratamiento locorregional, lo anteriormente expuesto supone una modificación de los volúmenes de tratamiento respecto al sistema clásico y también respecto a la toxicidad, que puede ser bien estudiada en virtud del más preciso conocimiento que aportan los sistemas de planificación tridimensional. El objetivo de este trabajo es, por tanto, comparar la incidencia de la metodología de prescripción y planificación del tratamiento utilizada en el riesgo para la paciente, entendido tanto como riesgo estocástico cómo determinista.

MATERIAL Y MÉTODOS.

Se escogieron aleatoriamente 27 mujeres que habían seguido tratamiento radioterápico en nuestra instalación, en el periodo 1998-2000, de las cuales en 9 (33%) se habían seguido los procedimientos ICRU 50, y en 18 (77%) se siguieron los procedimientos que en adelante identificaremos como "Clásicos", basados en la determinación de los campos de tratamiento utilizando referencias anatómicas.

Ambos grupos de tratamientos fueron objeto de simulación virtual [17] y planificación 3D utilizando un sistema de planificación Theraplan Plus 3.5 (Theratronics, Nordion). En todas las pacientes fueron contorneados como órganos críticos de interés la mama contralateral y el pulmón ipsilateral. En el grupo ICRU 50, además, el oncólogo radioterapeuta contorneó, en cada corte de tomografía computerizada el CTV y el PTV.

Se dividieron los dos grupos anteriores en otros dos subgrupos: aquellas mujeres que habían recibido sólo irradiación de la mama y las que además habían sufrido irradiación de la fosa supraclavicular, con el fin de aumentar la homogeneidad de las muestras.

Como parámetro de comparación del riesgo estocástico se eligió la dosis física a la mama contralateral (DMC). Existen multitud de referencias [18-20] sobre la misma, con relación a la probabilidad de aparición de un cáncer radioinducido secundario al tratamiento radioterápico. La dosis física se evaluó a partir del histograma diferencial del órgano, que representa el volumen que es irradiado a cada intervalo de dosis. Si llamamos v_{ij} al volumen del voxel i, en la resolución de cálculo utilizada por el sistema de planificación, que recibe una dosis

comprendida en el bin j del histograma, y D_j a la dosis máxima de ese bin, la dosis física al órgano viene dada por

Para evaluar el riesgo determinista, y dado que en la muestra de estudio no había suficientes tratamientos de la mama izquierda, se prescindió de la toxicidad cardiaca y se utilizó únicamente la pulmonar. Para ello, se calculó la superficie de isodosis que encierra el volumen de pulmón ipsilateral que supera la $DT_{5/5}$ (dosis que provoca la aparición del efecto en el 5% de los individuos irradiados a los 5 años) para fibrosis pulmonar, que dependerá, además, de la dosis prescrita, el fraccionamiento, la isodosis de prescripción, y α/β [21] del órgano. Posteriormente, y sobre el histograma acumulativo de cada paciente, se obtuvo el volumen fraccional de pulmón encerrado por la isodosis hallada.

RESULTADOS.

Los resultados obtenidos para la DMC, la dosis al pulmón ipsilateral (DPI) y el volumen fraccional encerrado por la isodosis de tolerancia de toxicidad en pulmón, y sus respectivos rangos, se presentan en la tabla I.

Tabla I. Dosis física a la mama contralateral (DMC) y dosis al pulmón ipsilateral (DPI) .

	Irradiación de la mama		Irradiación de la mama y de la FSC	
	ICRU 50	CLÁSICO	ICRU 50	CLÁSICO
DMC (cGy)	198.5 (277.3-140.4)	166.3 (301.8-77.0)	236.0 (389.6-167.5)	273.1 (1157.7-129.7)
DPI (cGy)	670.6 (1394.2-386.8)	896.5 (1914.6-270.1)	1705.5 (1955.4-1395.7)	1301.9 (1882.9-270.1)
* Pulmón (%)	7.6 (20.27-2.77)	12.3 (28.28-3.49)	24.9 (28,58-20.20)	16.0 (27.26-6.68)

Entre paréntesis se muestra el rango de dosis. * Volumen de pulmón con riesgo determinista.

DISCUSIÓN.

La exactitud del método de medida de la dosis a la mama contralateral depende del tamaño del intervalo de dosis del histograma diferencial, y este está fijado por el sistema de planificación (200 bins). No obstante, al interesarnos la comparación, siempre que trabajemos a la misma resolución no hay afectación de los resultados.

El método de determinación del riesgo determinista ha sido calculado por un método simple pero que consideramos es buen indicador a efectos comparativos. Si quisiéramos conocer el riesgo absoluto sería formalmente más correcto evaluar el NTCP [22] (normal tissue complications probability).

En el grupo de mujeres que habían recibido sólo irradiación tangencial, la mayor DMC para las que recibieron una prescripción según la metodología ICRU 50 está motivada porque en la técnica de irradiación clásica los límites de entrada de los haces permanecen constantes situándose aproximadamente en la línea axilar media para el haz externo y en la línea media para el haz interno, mientras que cuando de utiliza ICRU 50 todo el volumen mamario (CTV) debe ser incluido junto con el PTV correspondiente, para el nivel de dosis determinado. Esto supone que la entrada y salida de los haces, en términos generales, deberán ir más allá de los límites clásicos y por lo tanto incluir un más amplio volumen de mama contralateral, tal como efectivamente se comprueba en el análisis de nuestros resultados. Sin embargo, por esta misma razón, la dosis al pulmón ipsilateral es superior en el método clásico, dado que la metodología ICRU 50 permite una configuración de haces en orden a conseguir englobar el PTV con la isosuperficie de referencia, pudiendo ajustarse su angulación y punto de entrada para disminuir la irradiación del pulmón. En la metodología clásica, los puntos de entrada de haces están predeterminados, y el volumen de pulmón irradiado, de alguna manera, también.

Sin embargo, el efecto fue opuesto cuando se irradiaba con un campo supraclavicular: la DMC fue mayor en las pacientes planificadas según el método clásico, debido al mayor tamaño del mismo respecto a la metodología ICRU 50 y la influencia determinante del volumen irradiado en la radiación dispersa interna, principal responsable de la DMC. Para el pulmón ipsilateral, cobra preponderancia la profundidad de normalización adaptada al CTV, que provoca una mayor dosis en profundidad, frente a la prescripción clásica de ("50 Gy a 3 cm. de profundidad" versus un promedio de aproximadamente 5.5 cm.).

BIBLIOGRAFÍA.

[1] FISHER B, REDMOND G, FISHER E. Ten year results of a randomized clinical trial comparing radical mastectomy with or without radiation. N Engl J Med 312 (1985) 674-681,
[2] FISHER B, ANDERSON S, REDMOND CK. Reanalysis and results after 12 years of follow-up in a randomized clinical trial comparing total mastectomy with lumpectomy with or without irradiation in the treatment of breast cancer. N Engl J Med 333 (1995) 1456-1461.
[3] OVERGAARD M, HANSE PS, OVERGAARD J. Postoperative Radiotherapy in high-risk premenopausal women with breast cancer who receive adjuvant chemotherapy. N Engl J Med 337 (1997) 949-955.
[4] RAGAZ J, JACKSON SM, LE N. Adjuvant radiotherapy and chemotherapy in node positive premenopausal women with breast cancer. N Engl J Med 337 (1997) 956-962.
[5] CUZICK J, STEWART H, PETO R. Overview of randomized trials of postoperative adjuvant radiotherapy in breast cancer. Cancer Treat Rep 71 (1987) 15-29.
[6] CUZICK J, STEWART H, RUTQVIST L. Cause specific mortality in long term survivors of breast cancer who participated in trials of radiotherapy. J Clin Oncol 12 (1994) 447-453.
[7] EARLY BREAST CANCER TRIALIST'S COLLABORATIVE GROUP. Effects of radiotherapy and surgery in early breast cancer. N Engl J Med 333 (1995) 1444-1455.
[8] ROMESTAING P, ECOCHARD R, HENNEQUIN C. The role of internal mammary chain irradiation on survival after mastectomy for breast cancer. Results of a phase III SFRO trial. Proc 306. 19th Annual Estro Meeting. Istanbul, Turkey, 19-23 September, 2000
[9] INTERNATIONAL COMMISSION ON RADIATION UNITS AND MEASUREMENTS, Prescribing, registering and reporting photon beam therapy, Rep. 50, Bethesda, Maryland, USA (1993).
[10] INTERNATIONAL COMMISSION ON RADIATION UNITS AND MEASUREMENTS, Use of Computers in External Beam Radiotherapy Procedures with High-Energy Photons and Electrons, Rep. 42, Bethesda, Maryland, USA (1988).
[11] GÓMEZ-MILLÁN, J., VELÁZQUEZ, S., CARRERA, F., BAYO, E. 'Determinación de la incertidumbre geométrica para la aplicación eficiente de radioterapia conformada: propuesta de una metodología extrapolable a cualquier Centro de Radioterapia', proyecto financiado por el Fondo de Investigación Sanitaria.
[12] JACOBS, I., VANREGEMORTER, P., SCALLIET, P. Influence of respiration on calculation and delivery of the prescribed dose in external radiotherapy, Radiother. Oncol. 39(1996) 123-8.

[13] CREUTZBERG, C.L., ALTHOF, V.G.M., HUIZENGA, H., VISSER, A.G., LEVENDAG, P.C. Quality assurance using portal imaging: the accuracy of patient positioning in irradiation of breast cancer, Int. J. Radiat. Oncol. Biol. Phys. 25 (1992) 529-39.
[14] MCGEE, K.P., FEIN, D.A., HANLON, A.L., SCHULTHEISS, T.E., FOWBLE, B.L. The value of set-up portal films as an estimate of a patient's position throughout fractionated tangential breast irradiation: an on-line study. Int. J. Radiat. Oncol. Biol. Phys. 37 (1997) 223-8.
[15] POULLIOT, J., LIRETTE, A. Verification and correction of setup deviation in tangential breast irradiation using EPID: gain versus workload. Med. Phys. 23 8 (1996) 1393-8.
[16] FRASS, B.A., LASH, K.L., MATRONE, G.M., VOLKMAN, S.K., MCSHAN, D.L., KESSLER, M.L., LICHTER, A.S. The impact of treatment complexity and computer control delivery technology on treatment delivery errors. Int. J. Radiat. Oncol. Biol. Phys. 42 3 (1998) 651-9.
[17] VELÁZQUEZ, S., GÓMEZ-MILLÁN, J., CARRERA, F., SÁNCHEZ, J., GUTIÉRREZ, L., BAYO, E. Simulación virtual: Determinación de isocentro con láseres fijos, Oncología. 22(7) 1999:326-332 .
[18] BOICE J.D., HARVEY E.B., BLETTNER M., STOVALL M., FLANNERY M.S. Cancer in the contralateral breast after radiotherapy for breast cancer. N Eng J Med, 326 12 (1992) 781-786.
[19] ZUCALI R, LUINI A, DEL VECCHIO M, SACHINNI V, SVERZELLATI E, STUCCHI C, BANFI A, VERONESI U. Contralateral breast cancer after limited surgery plus radiotherapy of early mammary tumors. Eur J Sur Oncol, 13 (1987) 413-417.
[20] STORM HH, ANDERSSON M, BOICE JD JR, BLETTNER M, STOVALL M, MOURIDSSEN HT, DOMBERNOWSKY P, ROSE C, JACOBSEN A, PEDERSEN M. Adjuvant radiotherapy and risk of contralateral breast cancer. J Natl Cancer Inst 84 16 (1992)1245-50.
[21] STEEL, G.G., "Basic Clinical Radiobiology", Edward Arnold, London, 1993
[22] LYMAN, J.T. Normal tissue complication probabilities: variable dose per fraction. Int J Radiat Oncol Biol Phys 1992 22:2 247-50.

DOSIMETRÍA A PACIENTES EN PROCEDIMIENTOS DE CARDIOLOGÍA INTERVENCIONISTA

[1,2]F. Carrera; [1,2]C. Ojeda; [2]A. Sánchez; [1]I. Tort; [1]R. Ruiz-Cruces; [2]JF. Díaz.

[1]Grupo de Investigación en Protección Radiológica de la Universidad de Málaga. SPAIN.
[2]Área Hospitalaria Juan Ramón Jiménez de Huelva.

ABSTRACT.

Cardiovascular diseases are the first cause of dead in Spain. The most usual procedures in interventional cardiology are cornariography and PTCA. The first is a diagnostic technique, and the second one is interventional. Our goal has been to study procedures made during the first six months in the Interventional Cardiology Unit of the Juan Ramón Jimenez Hospital (Huelva-Spain), having in account radiation protection issues.
We've studied 178 patients; 145 of them were underwent coronariography, and 33 of the patients had PTCA too. Every case was analyzed having in account technical and dosimetric parameters.
We show parameters values gathered: Diagnostic techniques (valvular and non-valvular patients), and interventional techniques (coronariography and PTCA in different or in the same intervention.
Higher doses were obtained with valvular patients, although the number of frames was similar. Attending to therapeutic procedures, the highest values were gotten with the "double" interventions. Interventional procedures exceed in 60% doses got in diagnostic studies; this is because of the number of series and frames per serie. Similar values obtained by other authors have been got.

INTRODUCCIÓN.

Las enfermedades cardiovasculares son la primera causa de muerte en España (un 38 por ciento del total de los decesos: 44,4 por ciento mujeres y 32,5 por ciento hombres)[1]. Estas enfermedades se agrupan en tres grandes bloques: patología coronaria (angina de pecho, infarto de miocardio y muerte súbita), valvulopatías (procesos que afectan a las cuatro válvulas cardiacas: aórtica, pulmonar, mitral y tricúspide) y dolencias congénitas. Los procedimientos más habituales en un laboratorio de hemodinámica y cardiología intervencionista de pacientes adultos son: coronariografías, estudios de pacientes valvulares en los que se incluye casi siempre la coronariografía de forma asociada y finalmente los procedimientos intervencionistas de dilatación coronaria (angioplastia).

La coronariografía o estudio del árbol coronario con la ayuda de la radioscopia sigue constituyendo el patrón de referencia para estudiar la presencia y extensión de la enfermedad coronaria. Su realización estará indicada si la presencia de enfermedad coronaria va a determinar de manera significativa el manejo del paciente, cuando se quiera valorar las posibilidades de revascularización coronaria o identificar a aquellos pacientes que presentan alto riesgo de complicaciones isquémicas. El procedimiento de coronariografía diagnóstica implica la canulación selectiva de la coronaria derecha y de la coronaria izquierda y la inyección de contraste yodado con filmación en diversas proyecciones. Finalmente, con otro catéter, se opacifica con 40 cc de contraste el ventrículo izquierdo y se filma en proyección OAD. El procedimiento valvular suele incluir la coronariografía anterior y manipulaciones

adicionales con monitorización en radioscopia para mediciones fisiológicas. A veces se realiza además opacificación de la aorta ascendente con 60 cc de contraste.

La angioplastia coronaria transluminal percutánea (ACTP) se ha convertido desde 1992 en la técnica de revascularización miocárdica más frecuentemente utilizada en España[2,3]. Consiste en la dilatación de una o varias estenosis dentro de una o varias arterias coronarias. Según la complejidad se necesitan periodos variables de radioscopia y filmación coronariográfica. Habitualmente, la angioplastia precisa de un estudio coronariográfico previo completo que puede hacerse en una sesión aparte o bien en inmediata continuidad con la angioplastia.

La proliferación de ACTP es creciente[4], y ha venido acompañada de la descripción de casos de efectos deterministas, fundamentalmente en piel, debidos a las altas dosis de radiación involucradas en los procedimientos tanto diagnósticos [5] como terapéuticos [6].

En nuestro trabajo hemos pretendido caracterizar desde el punto de vista de la protección radiológica las intervenciones realizadas durante el primer semestre de funcionamiento del Laboratorio de hemodinámica del Área Hospitalaria Juan Ramón Jiménez de Huelva.

MATERIAL Y MÉTODOS.

Hemos analizado los datos de los procedimientos realizados sobre 178 pacientes, en el periodo comprendido entre el 22 de junio y el 29 de septiembre de 2000. De esos pacientes, 133 (74.7%) sufrieron únicamente coronariografía diagnóstica (identificados como "CORO"), 12 (6.7%) eran pacientes valvulares que sufrieron coronariografía (identificados como "VAL-CORO"), 20 (11.2%) fueron citados tras una coronariografía para una ACTP (identificados como "ACTP"), y 13 (7.3%) sufrieron la coronariografía y la angioplastia en la misma sesión (identificados como "CORO-ACTP").

De cada paciente se dispuso de los siguientes datos: Producto dosis-área (PDA) por radioscopia, por grafía y total; nº de series de grafía realizadas, y para cada serie, nº de imágenes, velocidad de adquisición, identificada por el protocolo de adquisición empleado ("ventrículo" con 25 imágenes por segundo, y coronario, con 12.5), kVp, mA y tiempo de exposición, ángulos cráneo-caudal y lateral del arco, distancia foco-receptor de imagen y tamaño de campo empleado.

RESULTADOS.

Se muestran, para cada uno de los cuatro grupos, los valores promedio, intervalos de incertidumbre al 90% de confianza, de acuerdo a una distribución t de Student salvo para el grupo "CORO" que suponemos se ajusta bien a una distribución normal, valores máximo y mínimo de todos los parámetros disponibles para cada estudio.

Se agrupan en coronariografías generales y de pacientes valvulares (CORO Y VAL-CORO) en la Tabla I, y pacientes coronariográficos que sufrieron posteriormente (ACTP) o en el mismo acto (CORO-ACTP) una angioplastia, en la Tabla II.

Tabla I. Coronariografías generales y de pacientes valvulares (CORO Y VAL-CORO) .

ESTUDIO	VAL-COROS				COROS			
	12 Pacientes				133 Pacientes			
	Med.	Inc.	Máx.	Min.	Med.	Inc.	Máx.	Min.
PDA Radioscopia	20.0	21.2	45.5	3.6	8.2	6.1	31.7	0.6
PDA Radiografía	21.3	29.4	50.8	4.9	19.6	9.9	66.6	0.3
PDA Total	41.3	48.5	96.3	8.5	27.8	15.9	98.3	0.9
t Radioscopia.(min.)	10.7	8.2	22.3	4.5	4.4	2.8	18.4	1.5
N° Series	12	9.0	28	7	11	4	36	1
N° Imágenes	723	517.3	1551	276	758	325	2114	32
kVp	73.8	10.0	89.0	64.8	72.7	4.0	86.9	60.0
mA	621.8	151.4	752.3	433.4	620.2	77.6	789.9	315.0
Edad	68.9	129.8	84.6	42.3	62.0	90.3	99.9	38.8
Uso APR "Ventrículo"	1.1	1.8	4.0	0.0	0.9	0.8	7.0	0.0
Uso APR "Coronario"	11.3	10.0	28.0	3.0	10.3	4.3	36.0	0.0
Distancia FR	105.1	5.2	110.7	99.7	103.7	2.5	115.4	98.1
Uso lupa 17	7.1	10.3	28.0	0.0	8.1	4.4	19.0	0.0
Uso lupa 23	5.3	5.6	13.0	0.0	3.2	3.9	29.0	0.0

Med. Media; Inc. Incertidumbre; Máx. Máximo; Min. Mínimo; PDA.- Producto de la dosis por el área irradiada.

Tabla II. Pacientes coronariográficos más angioplastia posterior (ACTP) o en el mismo acto (CORO-ACTP) una angioplastia.

ESTUDIO	ACTP-H				CORO-ACTP			
	13 Pacientes				20 Pacientes			
	Med.	Inc.	Máx.	Min.	Med.	Inc.	Máx.	Min.
PDA Radioscopia	22.8	29.9	53.3	3.9	19.1	30.8	84.3	6.6
PDA Radiografía	28.2	35.8	59.3	8.2	48.1	45.2	126.2	15.6
PDA Total	51.0	60.6	112.6	12.1	67.2	74.0	210.5	26.1
t Radioscopia.(min.)	11.1	10.7	27.6	3.4	7.5	6.7	14.9	3.2
N° Series	28	21.5	51	9	20.9	11.5	38.1	12.2
N° Imágenes	923	795.1	2304	366	1191.3	787.9	2183.8	478.7
kVp	76.2	8.3	87.2	69.4	60.2	5.8	68.6	55.0
mA	703.1	113.8	815.8	576.5	539.5	102.2	632.2	423.0
Edad	61.9	126.1	89.0	43.7	47.7	118.2	61.4	0.1
Uso APR "Ventrículo"	0.1	0.4	1.0	0.0	1.3	3.9	7.3	0.0
Uso APR "Coronario"	27.8	21.6	51.0	8.0	19.7	14.3	37.3	6.5
Distancia FR	105.3	6.6	113.6	97.2	84.8	3.0	88.7	82.4
Uso lupa 17	26.0	24.5	51.0	0.0	18.1	12.8	37.3	5.7
Uso lupa 23	1.9	8.7	22.0	0.0	2.9	4.1	8.9	0.0

Med. Media; Inc. Incertidumbre; Máx. Máximo; Min. Mínimo; PDA.- Producto de la dosis por el área irradiada.

DISCUSIÓN.

Para procedimientos exclusivamente diagnósticos, en pacientes valvulares se ha obtenido una dosis a paciente similar por radioscopia que por grafía, con un PDA total de 41.3 Gy·cm^2. Para pacientes no valvulares, el tiempo y la dosis por radioscopia es aproximadamente la mitad, con la consiguiente reducción en el PDA (27.8 Gy·cm^2). El número de series y el número de imágenes por serie, en promedio, son prácticamente iguales en ambos tipos de pacientes.

Para pacientes que sufren angioplastia, se observan valores superiores de PDA por grafía en aquellos en los que se realiza la misma a continuación del estudio diagnóstico, como es de esperar al tratarse de un estudio "doble". Los valores de radioscopia son similares, e incluso los de número de series, pero no así el de imágenes por serie, que es casi de 300 imágenes superior, en promedio, para el procedimiento extendido.

Comparando procedimientos terapéuticos frente a diagnósticos, se evidencia una mayor dosis a paciente en los primeros, de casi un 60% superior en promedio, debido fundamentalmente a que se duplican las series por paciente, y el número de imágenes por serie, que es superior en promedio en unas 300 imágenes.

En todos los procedimientos son mayoritarios el uso de tamaño de campo de 17 cm. y velocidad de adquisición de 12.5 imágenes por segundo.

En la Tabla III comparamos nuestros valores (en cursiva) con valores de otros autores, encontrando buena correspondencia.

Tabla III. Análisis comparativo de nuestros resultados con los obtenidos por otros autores.

Tiempo de radioscopia (min.) media (min.-máx.)		PDA (Gy·cm^2)		Nº de imágenes	
Coronariografía	ACTP	Coronariografía	ACTP	Coronariografía	ACTP
4.4 (1.5-18.4)	**11.2 (3.4-27.6)**	**27.8 (0.9-98.3)**	**51 (60.6-112.6)**	**758 (32-2114)**	**923 (366-2304)**
0.35 [7]	12 (7-35) [8]	72.18 [7]	100 [8]	1550 [7]	450 [7]
3.55 [9]	12.8 (0.1-180) [10]	39.3 [9]	81.68 [11]		1434 [9]
	15.5 (2.63-61.1) [7]		93 (33-402) [12]		
	18.6 [9]		28.5 (20-50.5) [13]		
			110 (40-340) [16]		
			87.5 (67-122) [15]		
			58 (0.5-810) [10]		
			101.9 [9]		
			93.3 [7]		
			91.8 [17]		
			42.0 [14]		
			60.0 [18-19]		

Entre paréntesis el rango.

Es oportuno destacar, como queda de manifiesto en este trabajo, las cada vez mayores posibilidades que ofrecen los equipos dedicados a estudios hemodinámicos, a la hora de caracterizar de forma precisa la dosis efectiva al paciente, como resultado de la identificación exhaustiva de las proyecciones y tamaños de campo empleados, como de los PDA obtenidos.

Queda, para completar un nivel superior de información del detrimento radiológico al paciente, de acuerdo a la clasificación del grupo de expertos del Artículo 31 de la Directiva MED [20], la implementación de métodos asumibles [21] para la determinación de la dosis a órganos y dosis efectiva, que, en cardiología intervencionista, es especialmente complicado por la profusión de proyecciones no coplanares.

BIBLIOGRAFIA.

[1] FUNDACIÓN ESPAÑOLA DEL CORAZÓN. Revista Corazón y Salud, 16 (2000).
[2] SORIANO J, ALFONSO F, CEQUIER A, MORÍS C. Registro de actividad de la sección de hemodinámica y cardiología intervencionista del año 1997. Rev Esp Cardiol (1998); 51: 927-938.
[3] IGUAL A, SAURA E. Cirugía cardiovascular en España en el año 1996. Registro de intervenciones de la Sociedad Española de Cirugía Cardiovascular. Cir Cardiovas (1998); 5: 115-124.
[4] UNGER F. Cardiac Interventions in Europe 1996: Open Heart surgery and coronary revascularization. Report of the European Heart Institute of the European Academy of Sciences and Arts. Cor Europeum (1998); 7: 81-93.
[5] LICHTENSTEIN D.A., KLAPHOLZ, L., VARDY, D.A., LEICHTER, I., MOSSERI, M., KLAUS, S.N., GILEAD, L.T. Chronic radiodermitis following cardiac catheterization. Arch Dermatol 132, 663-7.
[6] SOVIC, E., KLOW, N.E., HELLESNES, J., LYKKE, J. Radiation-induced skin injury after percutaneous transluminal coronary angioplasty.
[7] MACCIA, C. An optimization study of cardiac interventional radiology procedures: an experience in France. Proceedings of the ERPET Course "Radiation Protection in Interventional Radiology"(1997) Madrid - Spain.
[8] ZEITLER, E. Joint WHO/Institute for Radiation Hygiene Workshop on efficacy and radiation safety in Interventional Radiology. Proceedings of the ERPET Course "Radiation Protection in Interventional Radiology", (1997), Madrid - Spain.
[9] PADOVANI, R. Experience in Italy: Cardiological and neuroradiological data. Proceedings of the ERPET Course "Radiation Protection in Interventional Radiology" (1997) Madrid - Spain.
[10] SCHMIDT, T. Personal Communication (1995).
[11] VAÑÓ, E., GONZÁLEZ, L. Patient dose: Reference Values for I.R. Possibilities and advantages. Proceedings of the ERPET Course "Radiation Protection in Interventional Radiology" (1997) Madrid (Spain).
[12] NEOFOTISTOU, V. Personal Communication. (1995).
[13] FAULKNER, K., LOVE, H. G., SWEENEY, J. K., BARDSLEY, R.A. radiation dose and somatic risk to patients during cardiac radiological procedures. Br J Radiol 59 (1986) 359-363.
[14] HUYSKENS, C.J., HUMMEL, W.A. data analysis on patient exposures in cardiac angiography. Radiation Protection Dosimetry, 57 (1995) 475-480.
[15] BERNHARDT, J., VEIT, R., BAUER, B. Erhebungen zur effektiven Dosis und zur Kollektivdosis bei der Röntgendiagnostik in den alten Bundesländern. Veröffentlichungen der Strahlenschutzkommission, Bd 30. Gustav Fischer Verlag. (1995).
[16] BAKALYAR, D.M., CASTELLANI, M.D., SAFIAN, R.D., TIMMIS, G.C. Radiation exposure to patients during diagnostic and interventional cardiac catheterization procedures. catheterization and cardiovascular Diagnosis, 52 (1994), 94.
[17] MACCIA, C. CEC Research Project. Contract: F13PCT930070, (1992-1994).
[18] HEINRICH, K.W. Personal Communication.
[19] GLEINCHMANN, U., MANNEBACH, H., LICHTIEN, P. Bedcht Cjber Struktur und Leistungszahien der Hertzkatheterfabors in der Bundesrepublik Deutschland. Z. Kardiol. 82 (1993) 46-50.
[20] WORKING PARTY ON MEDICAL EXPOSURE. GROUP OF EXPERTS OF THE ARTICLE 31 OF THE EURATOM TREATY. Reference Levels for Interventional Radiology. Ref. IR (EC99c). Document. 1999
[21] VAÑÓ, E., GUIBELALDE, E., FERNÁNDEZ, J.M., GONZÁLEZ, L., TEN, J.I. Patient dosimetry in interventional radiology using slow film systems. British Journal of Radiology, 70 (1997) 195-200.

DOSIS EN ORGANOS EN TC DE TORAX: CORTES DISCRETOS VERSUS HELICOIDALES.

[1,2]C Bodineau Gil; [2]J. Macías Jaén; [1]I Tort Ausina; [1]R Ruiz-Cruces; [2]P Galán Montenegro; [1]A Díez de los Ríos.

[1]Grupo de Investigación en Protección Radiológica de la Universidad de Málaga. Spain.
[2]Radiofísica Hospitalaria. Complejo Hospitalario Carlos Haya. Málaga.

Abstract:

Helical scanning introduces additional choices in technical parameters and has an impact on how much radiation dose a patient receive. Helical scanning allows the entire thorax to be scanned within a single breathold, reducing slice registration due to breathing artifacts.
Organ doses from thoracic computed tomography have been estimated in an anthropomorphic phantom by using thermoluminescence dosimeters.
With a very similar radiological techniques in helical and axial scanning the absorbed dose in organ measured more relevant were in lung 12,0 ± 2,0 mGy and 11,0 ± 2,0 mGy respectively; in heart 9,0 ± 4,0 mGy and 9,0 ± 5,0 mGy.
Our results show that contiguous helical CT scans acquired with the same technical factors as contiguous axial scans, give approximately the same radiation dose.

1. INTRODUCCIÓN.

Principios del Tomógrafo Computarizado helicoidal

Los Tomógrafos Computarizados Helicoidales (TCH), permiten una adquisición continua del volumen corporal, en vez de la forma tradicional de cortes sucesivos. Se va imponiendo ampliamente sobre las generaciones anteriores de tomógrafos, tal que actualmente TC se considera sinónimo de TCH o de reconstrucción volumétrica[(1)].

La génesis de imágenes con gran calidad implica una inmovilización del paciente durante el proceso de adquisición, evitando la aparición de efectos no deseables desde el punto de vista técnico:

1. la falta de nitidez de la imagen (igual que ocurre en la radiografía clásica), y
2. los artefactos de movimientos (inherentes a la reconstrucción de imágenes en tomografía computarizada cuando el sistema recibe datos inconsistentes).

Para evitar dichos efectos son deseables tiempos de exposición cortos en los cortes tomográfico simples y también, en los tiempos totales de cada exploración. Asimismo debe tenerse presente el movimiento de la mesa entre cortes, ya que puede conllevar a omitir detalles anatómicos.

El TCH tiene un proceso de exploración volumétrico realizándose la adquisición mediante varias rotaciones del tubo con el paciente sobre una mesa que se desplaza de forma continua y simultánea al movimiento del tubo a través del gantry. Mientras el sistema tubo detectores giran alrededor del paciente no cesa la adquisición.

Los parámetros básicos para la selección de una exploración volumétrica son básicamente los mismos que para una exploración convencional, la principal diferencia estriba la definición de la hélice respecto a los cortes discreto.

Beneficios clínicos del TC helicoidal

Las principales ventajas de esta técnica son:

1. la eliminación de artefactos de movimiento,
2. el uso de menos medios de contraste,
3. la reducción del tiempo de exploración,
4. las nuevas reconstrucciones y presentaciones

Aplicaciones: Exploraciones pulmonares[2].

La reducción significativa de artefactos de movimiento causados por la respiración, hace recomendable el TC helicoidal para estudios torácicos, en particular en casos que requieran localización y evaluación de pequeñas lesiones en los pulmones, como los nódulos solitarios. Con el TCH se puede capturar la imagen de los pulmones y las costillas, así como los vasos pulmonares y el árbol bronquial.

MATERIAL Y MÉTODO.

Dosímetros de termoluminiscencia.

Para determinar las dosis en los órganos se han utilizado dosímetros de termoluminiscencia tipo TLD-100 (FLi:Mg,Ti con 7,5% de ^{6}Li y 92,5% de ^{7}Li). La morfología seleccionada ha sido la cilíndrica (1mm de diámetro y 6 mm de altura), para que la distribución de la radiación recibida sea homogénea.

La calibración de los citados dosímetros se realizó con el código D-120 para una tensión de 120 kV, una energía media de 54 keV, siendo la primera capa hemirreductora de 4,33 mm de Al y la segunda de 6,84 mm de Al, según programa seleccionado por el Centro Nacional de Dosimetría de Valencia (España). La dosis suministrada fue de 10,14 ± 0,36 mGy de kerma en aire en el seno de aire sobre la superficie de un maniquí de 295 x 295 x 153 mm^3, sobre la superficie del maniquí, y en ausencia del mismo.

El equipo de tratamiento dosimétrico estuvo compuesto por un Horno TELDO (PTW-Freiburg, Germany) con perfiles de calentamiento seleccionables en el panel frontal de control y por un Lector Harshaw 5500 (Bicron-Harshaw, USA) más su software conectado a un PC.

Se emplearon un total de 243 dosímetros TLD en cada una de las exploraciones de tórax realizadas.

Rando Antropomórfico.

Para determinar las citadas medidas de radiación se ha utilizado un maniquí del tipo Rando (New York Laboratory), como modelo de paciente y construido en material plástico que contiene un esqueleto simulando cavidades y órganos internos de interés.

El material plástico que simula tejido blando tiene un número atómico efectivo de 7,30 y densidad de 0,985 g cm^{-3}. Pesa 73,5 kg y mide 175 cm. Este maniquí permite la colocación de dosímetros en su interior para el estudio de la distribución de dosis.

Los dosímetros TLD-100 se ubicaron en los orificios inmersos en portadosímetros transparentes de polimetil de metacrilato diseñados por el Grupo de Investigación PRUMA, con ajuste perfecto en orificios del Rando y ubicación central exacta de los TLD-100 cilíndricos.

Además, en ambas modalidades (axial y helicoidal) se colocaron TLD-100 en la superficie corporal del maniquí, coincidiendo con el centro longitudinal de la zona explorada.

Exploraciones y equipamiento.

Se han estudiado exploraciones de Tórax en un TC Tomoscan AV, de tecnología helicoidal utilizando la técnica optimizada recomendada por el fabricante para la reconstrucción volumétrica y para cortes axiales. Las técnicas recomendadas se muestran en la tabla 1.

Tabla 1.- Técnicas para exploraciones de tórax con cortes axiales.

Característica	Valor seleccionado
Número de cortes	20
Grosor del corte	10 mm
Avance de mesa	10 mm
Kilovoltaje	120 kVp
Miliamperaje-segundo	280 mAs

En CT helicoidales la distancia entre cortes se define por un factor de paso de rosca ("pitch") que es el cociente entre el avance de la mesa por rotación completa y el espesor nominal del corte en el eje de rotación. El total de la carga utilizada en la exploración es la indicada en la Tabla 2, mientras que para los cortes discretos los mAs se fijan para un único corte.

Tabla 2.- Técnicas para exploraciones de tórax con reconstrucción volumétrica.

Característica	Valor seleccionado
Longitud explorada	20 cm
Grosor del corte	10 mm
Paso de rosca	1
Kilovoltaje	120 kVp
Miliamperaje-segundo	5600 mAs

RESULTADOS

En la tabla 3 se presentan los resultados obtenidos en las exploraciones analizadas, comparando la dosis absorbida en órganos (mGy) en cortes discretos versus cortes continuos:

Tabla 3.- Dosis absorbida en órganos (mGy)*.

Órganos	Cortes discretos	Cortes continuos
Tiroides	2,4 ± 0,7	2,5 ± 0,6
Esófago	5,8 ± 0,5	7,4 ± 0,6
Columna vertebral	7,0 ± 4,0	7,0 ± 5,0
Esternón	14,2 ± 1,3	14,6 ± 1,1
Costillas	12,0 ± 2,0	11,0 ± 2,0
Corazón	9,0 ± 4,0	9,0 ± 5,0
Línea media	14,0 ± 5,0	14,0 ± 5,0
Pulmón	11,0 ± 2,0	12,0 ± 2,0
Superficie (piel)	23,0 ± 3,0	21,0 ± 2,0

* Promedio ± desviación estándar

Los resultados obtenidos están en acuerdo con los referenciados por McNitt-Gray y cols [3]

Nuestros resultados demuestran que cortes contiguos en exploraciones helicoidales suministran aproximadamente la misma dosis de radiación que cortes axiales contiguos adquiridos con la misma técnica.

Se recomienda por tanto, la utilización de TCH para cualquier caso que sea necesario, ya que el beneficio de esta técnica iguala o supera al realizado por TC convencional, con respecto a la dosis recibida por el paciente.

BIBLIOGRAFÍA.

[1] KALENDER, WA. Principles and Performance of Spiral CT. AAPM Summer School, (1995).
[2] COSTELLO, P. Thoracic helical CT. Radiographics 14 (1994) 913 - 918.
[3] MCNITT-GRAY MF, CAGNON CH. Radiation dose in Spiral CT: The relative effects of collimation and pitch. Med Phys 26 (1999) 409 - 414.
[4] EUROPEAN COMMISSION; Quality criteria for Computed Tomography. EUR 16262, EC, Luxembourg (1999).
[5] HUDA, W., SCALZETTI, E.M., ROSKOPF, M.L., Effective doses to patients undergoing thoracic computed tomography examinations, Medical Physics 27 (2000) 838 - 844.
[6] ROTHENBERG LN, PENTLOW KS. Radiation dose in CT. Radiographics 12 (1992) 1225 - 1243.
[7] SHRIMPTON, P.C., EDYVEAN, S., CT scanner dosimetry, British Journal of Radiology 71 (1998) 1 - 3.

RADIATION EXPOSURE OF CHILDREN DURING RADIODIAGNOSTIC EXAMINATIONS OF CHEST IN SLOVAKIA

M. Horváthová[1], D. Nikodemová[2]

1/ Faculty of Health and Social Care, Trnava University, 918 43 Trnava, Slovakia, mhorvath@truni.sk

2/ Institute of Preventive and Clinical Medicine, Bratislava, Slovakia

Higher individual somatic radiation risk in the younger age groups has been until now inadequately considered in radiation protection. It is therefore essential to develope appropriate radiation protection measures also in the field of diagnostic radiology for paediatric patients.

The European Communities elaborated Guidelines on quality criteria for radiodiagnostic radiographic images in paediatrics. Reference dose values for selected types of examinations and for 5 year old child were proposed.

In our contribution we have tried to estimate the radiation load of children to 15 years, which undergone chest radiodiagnostic examinations during 1996 in a Slovak district. Our data of entrance surface doses were collected using measurements with TLD for 149 patients divided in 5 age categories at nine radiodiagnostic departments.

The calculations of the total absorbed dose were performed using the measured ESD values integrated over the X-ray beam area, the conversion factors between the imparted energy and the dose-area product and the known irradiation parameters (kV, HVL, mass, etc.).

The analysis of the obtained absorbed doses as a function of age for chest PA radiodiagnostic examinations has shown, that the investigated Slovak radiodiagnostic centres use rather lower voltage techniques and the entrance surface doses are much higher than the proposed value of EC.

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M. Horváthová[1], D. Nikodemová[2]

1/ Faculty of Health and Social Care, Trnava University, 918 43 Trnava, Slovakia, mhorvath@truni.sk

2/ Institute of Preventive and Clinical Medicine, Bratislava, Slovakia

Introduction

Risks to pediatric patients from radiation exposure are aknowledged to be greater than for adults. It is supported by the fact that for certain detrimental effects has the radiation exposure in the first ten years of life, 3 to 4 times greater attributable lifetime risk than exposures between ages of 30 to 40 years, and 5 to 7 time greater when compared to exposures after the age of 50 years. It is therefore essential to develope appropriate radiation protection measures also in the field of diagnostic radiology for paediatric patients. Available data on paediatric doses are limited and comparisons are complicated by range of patient size.

Commision of the European Communities (EC) contributed to this problem giving special attention to the control measures, analysis of patient doses and quality criteria for radiodiagnostic procedures of children.[1] In 1996 EC adopted Guidelines on quality criteria for radiodiagnostic images in paediatrics [2] contain reference entrance surface doses for various diagnostic examinations and for 5 years old children. The patient doses obtained on individual radiodiagnostic departments can be compared with this given standards.

In our paper we surveyed the entrance surface doses, measured during chest examinations of 149 patients (with ages to 15 years) and results of measurements of dose area product for assessment of absorbed doses. The calculations of absorbed doses were performed using the conversion factors between the energy imparted and the dose area product at the known irradiation parameters (kV, HVL, mass of the patients, etc.)

The analysis of the obtained data and their comparison with reference values of EC demonstrate that the entrance surface doses (mainly due to the lower used voltages) are several times higher than recommended.

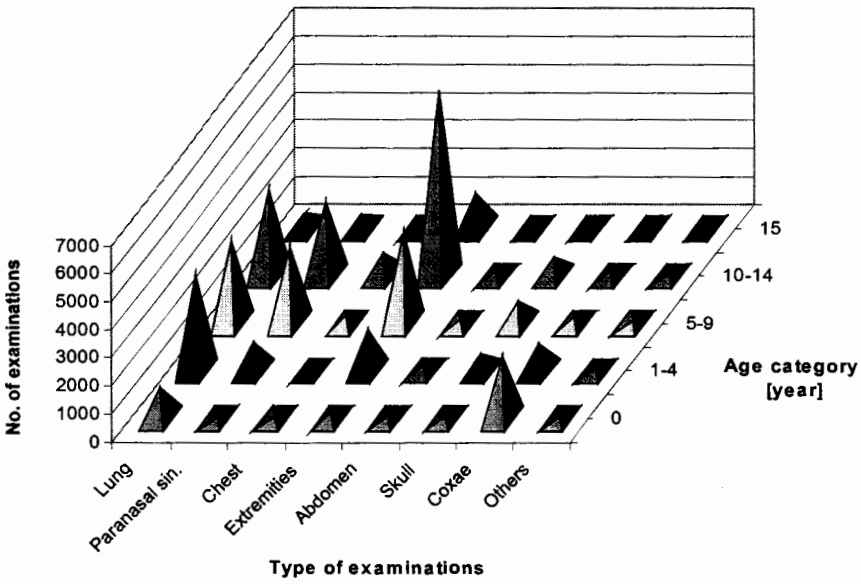
The results are proposed for application as an indicator of radiation risk for optimisation of diagnostic procedure and hence for reduction of children's radiation load.

Materials and methods

Our data were collected for 9 paediatric radiodiagnostic departments in the county of Trnava, where NPP is working . There are 590 996 people living, including 118 974 children, aged to 15 years. Children undergoing radiographic examinations (39 096) in the year 1996 were split into 5 categories: 0-1 year, 1-4 years, 5-9 years, 10-14 years and 15 years old.

Detailed information obtained through questionnaires allowed us to select as the most frequent examination (fig. 1) – the chest PA projection. To provide information on paediatric dose levels during chest examination a combination of direct measurements using LiF-700 Harshaw thermoluminiscent dosemeters (TLD) and indirect measurements using a dose-area product meter was used. TLD?s used to determine the entrance surface dose were calibrated at Slovak Metrological Institute using an X-ray equipment (50 kV, 2mA, 3 mm Al). They were annealed for 60 min at 400°C and by 120 min at 100°C in an automatic TLD oven. All readings were realised with Harshaw 3500 reader, the readout temperature was 300°C. The dose-area product was measured with a Diamentor (PTW Freiburg) type E using a light transparent ionisation chamber (type 57523-B). Conversion factors published by Persliden [3] were used to determine the energy imparted to paediatric patients of different ages from the dose-area product.

Fig.1. Frequency of radiodiagnostic examinations in paediatric department of Trnava county



Results and discussion

Determination of effective doses for paediatric radiological examinations is difficult, time consuming and due to diferent sizes of patient also uncertain. Therefore we used the procedure proposed by Huda [4] using the energy imparted to the patient for absorbed dose E_a calculation. The values of E_a were calculated by following equation

$$E_a = (ESD \times A \times C_a) / M$$

A = the irradiation beam area in m^2

ESD = the measured entrance surface dose in mGy

C_a = the conversion factor (kg/m^2) between the imparted energy and dose area product [3]

M = the mass of patient in kg

Conversion factors C_a were calculated taking into account the age of patient and the total filtration (HVL in mm of Al), applicated during the examination.

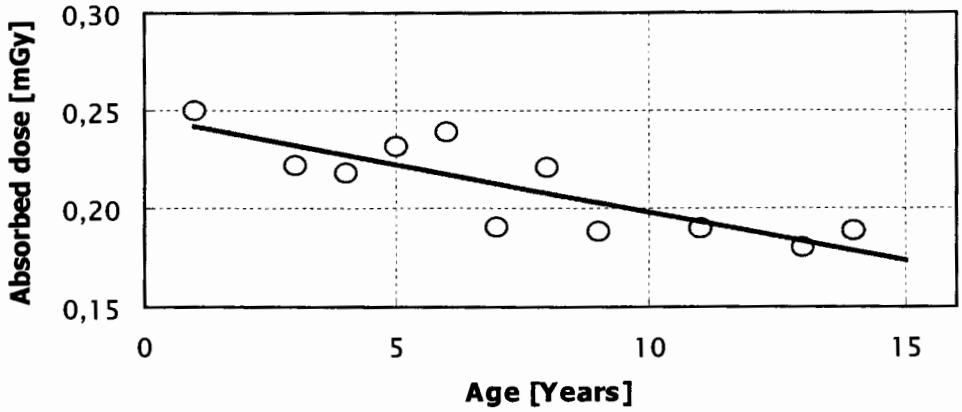


Fig.2. shows the relationship between E_a and the age of patient.

Fig.2. Absorbed dose E_a vs. age of patient

In the table 1. technical parameters and adequate ESD for chest examinations of children are shown.

Tab.1. Technical parameters and entrance surface doses for X-ray examinations of chest (children 5-9 ages)

Hospital	**Used equipment**	**Technical parameters**		**FSD**	**HVL**	**ESD**
		kV	**mA.s**	**cm**	**mmAl**	**μGy**
1	chiralux 2	38-46	24-42	100-150	3	586
2	chiralux 2	50-53	18	100-150	2,8	562
3	MP 15-chirana	55-60	4-6	150	2,8	403
4	chiralux 2	50	18	150-200	2,2	431
5	chiralux 2	50	13-18	150	2,85	443
6	durolux	71-73	5-12	150-200	2,6	432
7	chiralux 2	40-44	24	150	2,8	305
8	chirodur 125C	45-47	8-13	150	2,8	488
9	chiralux 2	42-46	18	110-150	2,8	326

Total filtration 3 mmAl

Comparison of our results with reference values published in EC document indicate that in the case of chest PA of 5-9 years old children, the reference value for

ESD of 0,1 mGy was defined for "high kV technique" and therefore for penetration of the X-ray beam. As it is shown in the table the radiological departements, investigated in our study, used fot chest examinations rather "low kV technique" leading to several time higher ESD.

Tab.2 Entrance surface dose of 5-9 year old children for the chest PA/AP examination

	ESD[μGy]		
	min-max	median	ratio of min:max
departments of Trnava county	253-708	414	1:3
European hospitals	19-1347	67	1:71

The requirements of good radiographic technics given in the EC Guidelines are fulfilled only in 10% of chest examinations.

We are following this study in all counties of Slovakia, which should be the basis for establishing reference values of chest examinations in paediatric radiology and implementation of QA programme for children dose reduction.

References

1. Directive 84/466 EURATOM: Basic measures for the radiation protection of persons undergoing medical examination or treatment, September 1984
2. EUR 16261- European guidelines on quality criteria for diagnostic radiographic images in pediatric, Luxemburg, 1996-IX, 61
3. Persliden, J., Sandborg, M.: Conversion factors between energy imparted to the patient and air collision kerma integrated over beam area in paediatric radiology, Acta Radiologica 1993; 34: 92-98
4. Huda, W., Gkanatsisos, N.A.: Effective dose and energy imparted in diagnostic radiology, Med. Phys. 1997; 24: 1311-1316
5. Nikodemová, D., Horváthová, M., Vladár, M.: Radiation load connected with some radiodiagnostic examinations in paediatrics; Book of abstracts, IRPA regional congress on radiation protection in central Europe, Budapest, August 22-27 1999

RADIOLOGICAL PROCEDURES: QUALITY CRITERIA AND DOSE OPTIMISATION. FRENCH STATUS

Authors:
Philippe GRENIER (1), Michel BOURGUIGNON (2), Elisabeth MARSHALL-DEPOMMIER (1), Hélène BEAUVAIS-MARCH (2), Marc VALERO (2), Jean-François LACRONIQUE (2), Guy FRIJA (1).

Scientific establishments in which the work has been completed:

(1) Société Francaise de Radiologie (SFR), 20, Avenue Rapp, 75007 Paris, France
(2) Office de Protection Contre les Rayonnements Ionisants (OPRI) : 31, Rue de l'Ecluse, 78116 Le Vésinet Cedex, France.

Author who will present the paper :
As it is a contributing paper, this question is not applicable. In any other case, the presenting author would be Ms E.Marshall-Depommier, M.D.
E-Mail address: edepomm@club-internet.fr

Summary:

The Council Directive 97/43/Euratom of June 30th 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure has come into force on May, 13th 2000. French health directorate has entrusted the "Office de Protection contre les Rayonnements Ionisants (OPRI)" together with the "Société Française de Radiologie" (SFR) to implement the article 6 related to radiological procedures, in order to bring into operation the principle of optimisation. The most frequent diagnostic radiology and interventional procedures (120 protocols) have been standardised in writing. Corresponding patient dosimetry have been determined from measurements on site, calculations and literature review. The criteria for optimisation have been highlighted for each protocols. With the help of the French Society of Medical Physicists (SFPM), measurements are being collected on a large scale in France. Then, knowing more precisely the patient dosimetry of each protocol, referral criteria will be reviewed and prioritised to implement the principle of justification. The authors will present and explain the chosen methodology (methodology of the Accreditation and Evaluation in Health Agency: ANAES) for completing this two years workload program, and will demonstrate clinical examples as well.

Introduction

The Council Directive 97/43/Euratom of June 30th, 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure has come into force on May 13th, 2000 date of application of Directive 96/29 Euratom on the basic safety standards to which it is linked.

To implement articles 4 and 6 of the Directive, the French health directorate (Direction Générale de la Santé) entrusted its radiation protection agency (Office de Protection contre les Rayonnements Ionisants – OPRI) with the specific request of working with relevant scientific and professional societies.

For the domain of medical investigations with X rays, the corresponding work has been carried out with the radiologists represented by their national scientific society, i.e., Société Française de Radiologie (SFR).

Steering Committee

A Steering Committee has been created and brings together SFR members and OPRI specialists in charge of the mission. The Steering Committee established its proper rules of functioning to accomplish the mission:

- To obtain the co-operation and agreement of the accreditation and evaluation in health agency (Agence Nationale d'Accréditation et d'Evaluation en Santé - ANAES) on a proposed method.
- To obtain the co-operation of radiologist experts dedicated to every main radiological specialty (chest, pediatry, neuroradiology...)
- To obtain a broad and representative view of radiological practices in France by selecting contributing experts from university hospitals, general hospitals, private practice with the advice of the national union of French radiologists (Fédération Nationale des Médecins Radiologistes -FNMR)…
- To obtain the co-operation of experts in medical physics (Société Française de Physique Médicale)
- To use the expertise of radiology technicians (Association Française du Personnel Paramédical d'Electroradiologie)
- To use European guidelines if applicable and to liaise with European experts groups (European Commission MED Working Party)
- To report regularly to the French directorate of health for critical follow up from administrative advisors
- To meet regularly for reviewing and validating all updated documents and to make arbitration when necessary

Methods

Since the article 6 of the Directive requires that written procedures have to be established for each type of radiological practice and since such documents are needed for accrediting radiology departments, the Steering Committee has decided to launch a complete standardisation of radiological procedures at the national level with the following steps:

- To identify all diagnostic radiology and interventional protocols starting with those contributing mostly to both individual and collective dose, i.e., the most frequently used protocols and those delivering significant doses.
- To write down radiological procedures for all of the above protocols. So far 120 examinations have been identified and precisely documented along the following lines:

- To define for each radiological examination the quality criteria expected of the outcome, i.e., what is to be seen in images for each clinical situation. Patient dose optimization has to be obtained in a context of sufficient diagnostic information to conclude and answer the clinical question which has priority. The goal is to avoid useless exposures, e.g. exposures with such a reduced dose that medical useful information may be lost, leading subsequently to exposing the patient again to get the needed information. There is no optimisation of the exposure without a good medical outcome.
- To precisely define technical parameters used, e.g. X ray tube voltage, tube current and exposure time product, total filtration, geometric parameters of the examination (distance, exposed area, angle…)
- To discuss and select the dosimetric quantities to be used as National Diagnostic Reference Levels taking into account European choices: - in conventional radiology, the entrance surface dose for single exposure and the dose area product for complete examination, - in computed tomography, the weighted CT Dose Index per slice and the Dose Length Product for a complete CT examination, - in interventional radiology the choice of dosimetric quantities is still subject to discussion. The dosimetric quantities already selected are clearly defined, can be easily measured and consequently can be easily used in all radiology departments.

- To establish for each protocol the corresponding dosimetry according to its physical parameters and to evaluate the influence of each parameter individually and of various combination of parameters on dosimetric values. These evaluations are keystones of the optimisation process.
- To obtain the agreement of the scientific experts on a national basis on all criteria and parameters by using ANAES methodology of experts consensus. The first draft of each protocol was written by a working party of organ dedicated experts (15 groups) lead by three experts, one being member of the Steering Committee. Each written protocol was then reviewed by groups of 10 to 12 readers carefully chosen by the SFR and FNMR to keep an appropriate balance between all types of practice, and from large cities to country towns. The selection of reviewing groups has been an essential step to ensure the acceptance and the validity of the protocols as truly representing the daily practice.
- To review each protocol with the Steering Committee, the aims of the critical analysis being the validation of each procedure. The Steering Committee has set up an editorial committee in charge of the realization of the reports, with a special task of harmonization of the presentation of the different procedures. Whenever necessary, the protocols have been sent back for further discussion and an iterative method applied.
- To finally establish National Diagnostic Reference Levels in France for all defined protocols, subsequently named "SFR protocols".

Indeed, each expert has contributed primarily in his/her field of expertise (SFR, the radiologists and technicians to the definition and description of the procedures, OPRI and the physicists to all dosimetric issues), with a fruitful interaction between all of them.

Current status

Two preliminary reports were published in November 1999 and July 2000 and approved by the French health directorate.

The report is being completed for a publication during the first quarter of 2001. This report will be the first complete set of recommendations for good practice in radiology in France,

established and approved by SFR. Validated by more than 150 French radiologist experts, these protocols represent the national current consensus for radiology practice in France.
Dosimetric evaluations corresponding to the "SFR protocols" have been obtained by OPRI and SFPM physicists by different means: values calculated from the technical parameters, measurements already available from experiments performed in a number of radiology departments according to the protocols, and values from critical review of literature. All these values indicate that medical exposures to X rays in France for the main diagnostic examinations are in the range of the published European Reference levels. Consequently, these European Reference levels can be adopted as starting points in France.

Future developments for assessing French Reference Levels

Reference Levels in radiology have to be determined in the near future in France with wide scale surveys of typical doses for common procedures, allowing the determination of third quartile values as recommended by the European Commission.
Thus the Steering Committee has decided to launch for 2001 a large campaign of measurements with the following rationale. Methods of measurements are established by the medical physicists of SFPM for the selected protocols and approved by the Steering Committee. Measurements are carried out on a large scale in the country, collecting data for all types of equipment, in departments representative of radiology practice in the country. Since the "SFR protocols" define the new standards of diagnostic radiology practice, it is assumed that the corresponding Reference Levels represent a fair view of the exposures yielding to images fulfilling quality criteria for diagnosis.
The Steering Committee expects that within the year 2001 enough data will be collected allowing to build up French Reference Levels to be subsequently used by all radiologists.
According to the Directive, these Reference Levels will serve for optimization for all radiologists. All practitioners will be encouraged to measure dosimetric quantities corresponding to the "SFR protocols" used on their equipment, to compare the results with the Diagnostic Reference Levels nationally established and to act consequently. In case of discrepancy, investigations will be necessary to fully understand the possible causes. Situations where patient doses are unusually high will lead to review of procedures and equipment if necessary.

Perspectives on French medical exposures

The French health directorate and OPRI plan to collect all measured dosimetric values in a national database in order to ensure the perenniality of the national Reference Doses and to facilitate their periodic review in a continuous process of optimization and reduction of unnecessary doses. The French health directorate is currently enforcing quality assurance surveys of radiological equipment which is also a key factor of limitation of medical exposures to ionizing radiation.
It is the intention of the Steering Committee to continue to update the protocols along the lines of the improvement of radiological technology in the future and with the approval of the French health directorate. The annual publication of an updated document is considered.
Ultimately, patient dosimetry of each diagnostic radiology protocol will be used to review the referral criteria for imaging to implement the principle of justification of medical exposures to ionising radiation.

QUALITY ASSURANCE IN RADIOTHERAPY

S. Groth, A. Meghzifene, H. Tatsuzaki, V. Levin, J. Izewska
Division of Human Heath, International Atomic Energy Agency

ABSTRACT

Quality assurance in the management of a patient receiving radiation therapy and the role of the radiation oncologist and medical physicist in this process is described. The constraints on available personnel is recognised and the need for further education resources and IAEA activities in education for both groups described.

IAEA activities in the clinical and dosimetric aspects and the resultant publications and education have contributed to a culture of quality assurance.

1 INTRODUCTION

Radiotherapy involves the use of ionizing radiation in the treatment of cancer patients. It is a multi-disciplinary speciality involving the use of complex equipment and procedures. It includes many phases, from diagnosis to clinical decision to undertake treatment, treatment delivery and follow-up. A systematic and comprehensive approach to quality assurance (QA), covering all these phases, is of vital importance to ensure optimum treatment of patients. Such QA programmes have been recommended by many professional bodies such as ESTRO [1] and AAPM [2], and should follow the guidelines given in the Basic Safety Standards (BSS) [3] and by WHO [4]

The main rationale and justification for quality assurance in radiotherapy is to ensure that not only does the patient receive good quality treatment but is also protected from accidents and errors (random and systematic). QA aims at minimizing the occurrence of random errors and at eliminating large systematic errors, contributing to the minimization of the morbidity rate and maximization of the cure rate of radiotherapy patients. This concept is emphasized in the BSS [3]. Patient safety is therefore integrated within the overall QA programme of radiotherapy [5].

At the national level, the establishment of a QA programmes should take into account international recommendations and existing national guidelines. To ensure that radiation therapy centres have a common basis for developing and implementing their quality assurance programmes, professional bodies representing radiation oncologists, medical physicists and medical radiation technologists should develop national guidelines or standards for radiation therapy quality assurance and set out a uniform quality assurance program to be adopted by all radiation therapy centres, taking into account the level of practice in the country. Several major issues should be considered before the establishment of a national quality assurance program for radiation therapy, including the licensing and regulation of radiotherapy equipment, the accreditation process, if it exists, the problems with the review process and compliance, the cost-benefit analysis of setting up an independent external quality assurance programme, the need to maintain confidentiality of patient records and the need to respect professional standards.

The IAEA assists its Member States to establish and implement national QA programmes through its programmatic activities and Technical Cooperation projects. The IAEA assistance is directed to national regulatory bodies for the establishment of a regulatory framework, which complies with the BSS, to standards laboratories for metrological traceability, and to end users at hospitals for the development and implementation of QA programmes. Traceability of radiation measurements for radiotherapy dosimetry and quality audit services, run jointly with WHO, such as the IAEA/WHO postal TLD service for the verification of the clinical beam output, are also offered by the IAEA to the Member States. To coordinate its activities in QA in radiotherapy, close cooperation is maintained with other international organizations and professional bodies such as WHO, ICRU, ESTRO and IOMP.

2 REQUIREMENTS FOR QA

QA in radiotherapy encompasses all procedures which aim to ensure a consistent and a safe fulfilment of dose prescription to the target volume while minimizing the dose to normal tissue, minimal exposure to personnel and the public. It involves all clinical, physical and technical, and safety procedures. The QA programme should be established by professionals working in the field of radiotherapy, taking into account the level of practice in the country and following international recommendations and guidelines. Either voluntary quality assurance guidelines or mandatory regulations could be used to achieve national uniformity. In both cases, however, a peer review program to audit the compliance with the national standards, if they exist, or international guidelines, should be established. If necessary, compliance with the national standards can be made as a condition of the licensing process.

The IAEA has established guidelines, taking into account clinical, medical physics, radiation protection and safety considerations, for designing and implementing radiotherapy programmes at the national level [5].

2.1 Staff requirements

The clinical use of ionizing radiation is a complex process, involving highly trained personnel. It is important that all staff dealing with patients, radiation sources and equipment have the necessary education background, adequate training and recognition of their status. The main categories of staff required and their responsibilities and training requirements are given elsewhere [2, 6, 7].

The shortage of professionals in the field of medical physics in developing countries is fully recognized. In the northern part of Africa, the number of medical physicists in radiotherapy per million population, is less than 0.3 whereas it fluctuates from 2 to 15 in Europe (according to data published by the European Federation of Organizations of Medical Physicists in Europe (EFOMP) [21]). In addition, the competency and qualifications of medical physicists in Europe are wellcontrolled through national regulations and the European Directive [22]. This is not the case in many developing countries where in reality the number of "qualified medical physicists" may be even lower. Consequently, the development and implementation of QA programmes in radiotherapy in many developing countries can be severely hampered by the lack of professionals in the field of medical physics.

A similar situation exists in the clinical field where, in some developing countries, a radiation oncologist may be responsible for upwards of 500 new patients per year in contast to 250 in developed countries.

2.2 Radiation protection and safety aspects

The general requirements include the review and approval by the regulatory authority aiming at ensuring radiation protection and safety of sources. These requirements cover all aspects described in the BSS and regulatory guidance [19]. In addition to administrative requirements, the control of exposure (occupational, medical and environmental), the safety of sealed radiation sources and equipment, including accessories, require conformity with ISO [10, 11, 12] and IEC standards [8, 9], respectively.

National regulatory bodies should apply the requirements of the BSS, together with national regulations, to review radiotherapy practice.

Radiotherapy centres can use the guidance provided in the BSS or propose alternative measures with an equivalent level of protection and safety [19].

2.3 Clinical aspects

This process commences with patient registration. Besides the domiciliary and medical records, the pathological diagnosis should be part of a national and institutional cancer registry. Pre-treatment evaluation with combined clinical assessment has a vital role in selecting the optimal management strategy within the limitations of resources. The patients' rights through informed consent must be

respected. Psychosocial problems need to be addressed during and after treatment, both for the patients' benefit and to assure their compliance. Treatment planning and daily treatment need to be accurate and to be recorded. During the treatment period, the patient must be examined periodically and the treatment plan modified if required. Finally, an established patient follow-up procedure is required to pre-empt or manage complications and as a long-term assessment of the efficacy of management.

The two major tools to assist in achieving this clinical quality assurance are: firstly an institutional protocol manual clearly identifying the clinical management practice for the institution in all its multidisciplinary aspects, respecting the constraints within an institution, and secondly a departmental procedure manual, covering both clinical (immobilisation, simulation) and physical procedures.

2.4 Physical and technical aspects

The physical and technical aspects of the QA programme are usually performed under the responsibility of the medical physicist and cover the following areas: quality control of equipment including acceptance testing and commissioning; beam dosimetry including traceability of measurements and use of a code of practice; treatment planning and patient treatment including final verification of the accuracy of the delivered dose. The details of such QA programmes are described extensively by IAEA [5], AAPM [2] and ESTRO [1].

2.5 Organizational relationship and responsibility for quality

At the institutional level, the organizational structure of a radiotherapy centre should be well defined. An essential element is the establishment of an organizational chart, which should clearly show all hierarchical, functional and operational relationships. All responsibilities, tasks and competencies of each staff member must be clearly defined. For each task, a responsible person must be designated. In particular, the organizational structure should indicate who could stop radiotherapy treatments. It is a general practice to have the medical practitioner (radiation oncologist) be the responsible person for the medical exposure [20], including the protection of the patient. It is also usual practice for the medical practitioner to delegate parts of this responsibility to qualified persons. The medical physicist usually takes responsibility for the physical and technical aspects of QA [2, 5, 7].

At the multi-institutional level, there is a need to coordinate activities related to the external QA programme. It is well established that metrology institutions, such as Secondary Standards Dosimetry Laboratories (SSDLs), are usually competent to check the beam calibrations. External QA groups which include experts from the metrology institution and radiotherapy centres should be set up at the national level. The IAEA has helped 12 countries to establish External Audit Groups (EAGs) through a Research Coordinated Project [23].

3 IAEA ACTIVITIES IN SUPPORT OF QA IN RADIOTHERAPY

The IAEA activities in support of QA in radiotherapy cover a large spectrum. In particular, the IAEA Division of Human Health provides:

- services to Member States for metrological traceability and external quality audits to radiotherapy centres, in collaboration with the IAEA Laboratories in Seibersdorf,
- research and development to foster exchange of information and help in the transfer of know-how in the field of QA in radiotherapy, covering clinical, physical and technical aspects, and
- support to technical cooperation projects in the field of radiotherapy and medical radiation physics, including training and education of staff.

Through its research and development activities in the clinical aspects of QA, both potentially optimal treatments and resources-sparing treatments are investigated. In the physical and technical aspects of QA, the IAEA Division of Human Health promotes standardization and harmonization of codes of practices and procedures used in QA, in close cooperation with other international organizations and professional bodies.

Education is the foundation for all quality assurance. To this end, the IAEA is in the process of developing a distance-learning programme to assist in the training of the basic sciences of radiation oncology intended primarily for radiation oncologists and therapy technicians.

3.1 Traceability and quality audit services

In the framework of the international measurement system the IAEA, in collaboration with the Bureau International des Poids et Mesures (BIPM), provides the metrological link through its IAEA/WHO network of Secondary Standard Dosimetry Laboratories (SSDLs) for traceable calibrations needed in radiotherapy. The IAEA's support is accomplished with the transmission of calibration factors for national measurement standards from the BIPM or Primary Standards Dosimetry Laboratories (PSDL) linked to the international measurement system. Each year, the IAEA provides traceability for radiotherapy dosimetry to about 20 Member States, mainly to those countries who are not members of the "meter convention" and do not have access to a PSDL. As a second step, dose quality audits and follow-up programmes are implemented to help the Member States ensure that the standards transmitted to hospitals are kept within the levels required by the international measurement system [14]. These programmes include intercomparisons of ion chamber calibrations made by SSDLs and dose quality audits using mailed Thermo Luminescent Dosimeters (TLDs). The intercomparison programme is available to the member laboratories of the IAEA/WHO SSDL Network, while dose quality audits are provided to radiotherapy centres through the IAEA/WHO TLD postal dose service. Both programmes are essential for assuring high accuracy in clinical dosimetry.

Ionization chambers are used in the intercomparison programme to assess the ability of the SSDLs to calibrate their own as well as hospital's dosimeters. About 40 SSDLs participated in this programme with 90% of the results within the acceptance level of ±1.5%. The TLD programme for SSDLs annually checks about 80 beam calibrations by 60 laboratories with 95% of the results within the acceptance level of ±3.5%. The TLD programme for hospitals aims at ensuring proper calibration of radiotherapy beams. The IAEA is responsible for the technical aspects of the service and WHO (or PAHO) takes care of the mailing and distribution of the TLD capsules to radiotherapy hospitals. This service checks approximately 400 clinical beams per year and has checked a total of more than 3500 radiotherapy beams in approximately 1000 centres. At present, about 80% of the results are within the acceptance level of ±5%, compared to 65% in the past. Subsequent follow-up actions in centres with poor results have helped the radiotherapy centres resolve the discrepancies, thus preventing further mistreatment of patients.

3.2 Codes of Practice

The IAEA has maintained an interest in standardization and development of Codes of Practice (CoP) for radiotherapy dosimetry going as far back as the seventies, resulting in several publications in the field. The IAEA has published the first CoP in 1970 [15], followed by "Absorbed Dose Determination in Photon and Electron Beams" (TRS-277) in 1987 and updated in 1997 [16]. Another Code of Practice (TRS-381) for radiotherapy dosimetry on "the Use of Plane-Parallel Ionization Chambers in High-Energy Electron and Photon Beams" was published in 1997 to update TRS-277 and complement it in the field of parallel-plate ionization chambers [17]. Following the world trend in radiation dosimetry, the IAEA had developed a new Code of Practice, based on absorbed dose to water standards, under the framework of a Co-ordinated Research Project. This CoP has been endorsed by WHO, PAHO, and ESTRO and will be published soon by the IAEA on behalf of these organizations as TRS-398 [18].

The Codes of Practice developed by the IAEA on absorbed dose determination in radiotherapy beams [TRS-277, TRS-381] are presently used by many physicists involved with dosimetry in radiation therapy, and have been adopted by several countries as their national dosimetry protocol.

3.3 Technical cooperation projects

The IAEA's Technical Co-operation Programme is based on an assessment of the development priorities

and conditions in each specific country or region. The programme also includes regional and interregional projects that are developed to improve the efficiency of implementation or to utilize better the collective experience and resources of multiple Member States. During 2000, the IAEA Division of Human Health provided technical assistance to 64 national projects to support the establishment of radiotherapy services or to improve QA of the operational radiotherapy centres in the Member States. In addition, 10 regional projects, aiming at solving common problems in the geographical region mainly through training courses or workshops were also supported. Twelve IAEA Regional Training Courses, covering clinical, physical and technical aspects of QA in radiotherapy, were organized during 2000.

Taking into account the shortage of medical physicists in developing countries, support for the development of university degrees in medical radiation physics has become an important goal. This has been implemented with success, under a technical cooperation project in the Latin American Region and may be extended to East Asia and Africa. In addition, training courses and workshops, covering all aspects of QA, are organized each year by the IAEA. These training courses are directed towards radiotherapy staff, i.e. radiation oncologists, medical radiation physicists, maintenance engineers, and radiographers, including technicians. In addition, attendance at training courses provided by ESTRO is supported by the IAEA.

Through training courses on clinical topics, the IAEA promotes an awareness of the best evidence-based standards of management of clinical problems and encourages subsequent development of the relevant protocol and procedure manual entries. Concerning the physical and technical aspects, the training courses and workshops provide a unique opportunity to physicists to harmonize procedures and for continuous upkeep of knowledge and exchange of experience in QA.

4 CONCLUSION

There are many indicators that the IAEA through its different activities is assisting the Member Sates in the development and implementation of QA programmes in radiotherapy. These activities also help disseminate not only the technical knowledge but also the basic ingredient of the QA culture. The IAEA maintains close contacts and cooperation with other international organizations and QA networks to coordinate its activities and avoid duplication of efforts.

REFERENCES

1. European Society for Therapeutic Radiology and Oncology, Quality Assurance in Radiotherapy, Report to the European Union for the "Europe Against Cancer Programme", (1994)
2. American Association of Physicists in Medicine, Comprehensive QA programme for radiation oncology: Report of AAPM Radiation Therapy Committee Task Group-40, Med.Phys. 21 (1994) 581-618
3. International Atomic Energy Agency, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).
4. World Health Organisation (1988) Quality assurance in radiotherapy. WHO, Geneva
5. International Atomic Energy Agency, Design and Implementation of a Radiotherapy Programme: clinical, medical physics, radiation protection and safety aspects, (IAEA-TECDOC-1040). IAEA, Vienna (1998)
6. Inter-Society Council for radiation oncology in integrated cancer management (blue book), report of the ISCRO, 1991.

7. S. Belletti & al, "QA in radiotherapy; the importance of medical staffing level", Recommendations from an ESTRO, EFOMP joint task group, Radiotherapy &. Oncology. 41 89-94, (1996).
8. International Electrotechnical Commission, Medical Electrical Equipment. Part 1: General requirements for safety, Pub. IEC-601-1, IEC, Geneva, (1988).
9. International Electrotechnical Commission, Medical Electrical Equipment. Part 2: Particular requirements for the safety of radiotherapy simulators, Pub. IEC-60601-2-29, IEC, Geneva, (1993).
10. International Organization for Standardization, Sealed radioactive sources-General, ISO-1677-1977, ISO, Geneva, (1977)
11. International Organization for Standardization, Sealed radioactive sources-Leakage test methods, ISO/TR 4826, ISO, Geneva, (1979)
12. International Organization for Standardization, Sealed radioactive sources-Classification, ISO-2919-1980, ISO, Geneva, (1980)
13. Quality Assurance in radiotherapy, Rad Onc 35, 61-73, 1995 (10)
14. P. Andreo & al, IAEA Dosimetry Programme: Report on Activities in 197-1998, CCRI (1), 1999
15. International Atomic Energy Agency, Manual of Dosimetry in Radiotherapy, (TRS-110), IAEA, Vienna, 1970
16. International Atomic Energy Agency Absorbed dose determination in photon and electron beams: An international Code of Practice, 2nd edn. (TRS 277). (1997), IAEA, Vienna
17. International Atomic Energy Agency The use of plane parallel ionization chambers in high energy electron and photon beams (TRS 381). (1997), IAEA, Vienna
18. International Atomic Energy Agency, Absorbed Dose Determination in External Beam Radiotherapy: an International Code of Practice for Dosimetry based on Standards of Absorbed Dose to Water, (TRS-398), IAEA, Vienna in press.
19. International Atomic Energy Agency, Regulatory Guidance: Radiation Protection and Safety in Radiotherapy, to be submitted for publication as Interim Report for Comments, IAEA, Vienna
20. European Commission, Implementation of the "Medical exposure directive" (97/43 Euratom), Proceedings of an International Workshop, Madrid, 27 April 1998.
21. K.A Jessen, the role of EFOMP in the European structures, for implementation and harmonization of QA programmes in radiotherapy, Proceedings of an IAEA-ISRO joint meeting, 8-9 May 1995, IAEA TECDOC-989, (1997), IAEA, Vienna
22. European Communities Council. Directive 84/466/Euratom, 3 September 1984. Off. J. Eur. Commun. 5 October 1984, 27, L 265/1.
23. Report of the first Research Coordination Meeting for the Coordinated Research Project on Development of a Quality Assurance Programme for Radiation Therapy Dosimetry in Developing Countries, SSDL Newsletter No. 39, (July 1998), IAEA, Vienna.

Medical Physics Dept.,
Faculty of Medicine
Mashad University of
Medical Sciences
Daneshgah Str.,
Mashad IRAN
Fax : + 9851 819805
14Th Nov 2000
E-mail : mbahreyni@Yahoo.CO.UK

PATIENT DOSE ARISING FROM COMMON DIAGNOSTIC X-RAY EXAMINATIONS IN GHAEM HOSPITAL MASHAD- IRAN

M.T.Bahreyni Toossi (M. Sc., Ph.D)& M.Hajizadeh Saffar (M.Sc., Ph.D)
Medical Physics Department Faculty of Medicine , Mashad University of Medical Sciences Mashad - Iran.

Patient dose is of great importance in diagnostic X-ray examinations . Although everywhere radiographeres try to use standard techniques but wide variations in patient dose for identical X-ray examination have been observed not in different hospitals but in different units of one X-ray department . In the developed countries more attentions have been paied to this problem and quite a few papers have been published . But there are very few reports form developing countries.
In Iran non or very few reports are avilable . The aim of this study was to assess the organ dose and effective dose of patients undergoing the most common X-ray examinations in Ghama hospital . 385 paients (185 male and 200 femal) were examined . The diagnostic examinations included in this research were Chest (PA) , Pelvic (AP) , Waters , Cervical Spine (AP , Lat), Lumber Spine (AP, Lat). Lumbo Saceral (AP, Lat) , Skull (PA, Lat) . To calculate absorbed dose of 26 organs as well as effective dose ODS - 60 softwere was employed . The organ dose varied with the type of examination e.g . the highest gonadal dose of male patients was equal to 9.62 ± 1.89 mGy and resulted from pelvic (AP) examination . While Lumbo saceral spine examination produced the highest gonadal dose equal to 4.21 ± 1.59 mGy to female patients . Maximum bone marrow dose delivered to male and female patients were 3.25± 0.62 mGy and were caused by Lumbo Saceral . Average effective dose (3.68 ± 0.91 mSv) is related to the radiography of Lumbo Saceral (Lateral view) of male patients.

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EL PASTOR MENTIROSO Y OTROS MOTIVOS POR LOS QUE LOS ACCIDENTES SEGUIRÁN OCURRIENDO

Sánchez G.* Álvarez P.**
Universidad Nacional de General San Martín
Buenos Aires - Argentina

Abstract

The attitudes of the people are conclusive for preventing and detecting incidents, and to carry out the necessary corrective actions as well. These attitudes are not only defined by people's knowledge and training, but also by some non-rational concepts and ideas –named "myths" by the authors-; an example of this is assuming that an alarm is failing, just because of the fact that it is ringing.

The most ordinary myths and their influence in accidents that have already happened are analized; the difficult stages to get over them are shown in the current work.

We arrive to the conclusion that the accidents that will surely take place in the future, are going to be because of one –or more than one- of the reasons mentioned here; and they will also be future "learnt lessons"

1. Introducción

Los accidentes (no solo radiológicos) comienzan con un evento iniciador ("incidente") originado en fallas de equipos, de procedimientos o –más comúnmente- una combinación de ambas. Pero si ese "incidente" deriva en un "accidente" es siempre como consecuencia de fallas humanas, ya sea por acción u omisión.

Estas fallas pueden demorar la detección del incidente y/o traducirse en una intervención inadecuada que hará que las consecuencias sean más graves que lo que el evento iniciador podría sugerir.

Las "Lecciones aprendidas" de los accidentes documentados se han volcado en Criterios y recomendaciones, como por ejemplo los conceptos de *Cultura de la Seguridad* y *Defensa en Profundidad*; también en Normas y Regulaciones específicas: por ejemplo, en Argentina la exigencia de contar -en las instalaciones de Cobaltoterapia- con una alarma que detecte la condición de fuente expuesta en base a un monitor de radiación, se impuso como norma luego de un evento en el que el personal no advirtió que la fuente había quedado trabada. La difusión de la información referida a accidentes, merced a la acción de entidades académicas y sociedades de radioprotección contribuye asimismo a que estas lecciones sean aprendidas por la mayor cantidad posible de personas.

Sin embargo las *actitudes* de los actores (médicos, técnicos, físicos, etc.) respecto de la prevención, detección e intervención están condicionadas por factores no racionales que muchas veces hacen olvidar las lecciones aprendidas. *"El hombre es un ser anfibio que vive simultáneamente en dos mundos: el árido mundo de los hechos y el mar de los símbolos. En*

* Email gustavo.sanchez@unsam.edu.ar
** Email paola.alvarez@unsam.edu.ar

realidad, los hechos deberían predominar a los símbolos, pero a menudo sucede lo contrario[1]"

Podemos preguntarnos: Las "lecciones aprendidas" ¿son realmente aprendidas por quienes corresponde? ¿Podemos identificar algunos de los símbolos o "mitos" que contribuyen a que ocurran los accidentes o se agraven sus consecuencias? ¿Tenemos argumentos para refutar esos mitos? ¿Podemos hacer algo para que las "lecciones aprendidas" se traduzcan en "actitudes aprehendidas"?. A continuación se plantean algunas aproximaciones a esta problemática..

2. Mitos y Creencias

2.1. Caso 1

Durante la Conferencia de la European School of Oncolgy (Buenos Aires – abril de 2000) el orador (Director de un importante centro de terapia Radiante de Italia) comparaba la Braquiterapia de Pulsada (PBT) con la Braquiterapia de Alta Tasa de Dosis (HDR). Un médico canadiense, miembro del auditorio, le hizo referencia a que en Estados Unidos la NRC (Comisión Reguladora Nuclear) requiere la presencia de un oficial de seguridad cada vez que se efectúa una aplicación, como consecuencia del accidente ocurrido en 1992 con un equipo de HDR que provocó la muerte de un paciente y sobre exposición a varias personas [2]; este médico preguntó al orador cómo implementar esto en PBT, ya que esta técnica implica muchas aplicaciones por día por cada paciente, y en cualquier horario.

Las respuestas del orador pueden considerarse paradigmáticas:

"El diseño de nuestra máquina es mejor, ese accidente no nos puede ocurrir" **Mito 1:** Podemos confiar ciegamente en la tecnología, con tal que esta sea buena.

"Hemos efectuado muchas aplicaciones y NUNCA OCURRIO NADA" **Mito2**: el riesgo de que ocurra un accidente es directamente proporcional al tiempo de trabajo sin problemas, independientemente de las medidas de seguridad implementadas

Corolario 1 *Las regulaciones de Estados Unidos son excesivas*. Corolario 2:*Todas las regulaciones son excesivas.*

2.2. **Mito 3**: *"E Pastor Mentiroso"*

En el accidente fatal referido en el punto anterior, donde una fuente de ^{192}Ir de 137GBq (3.7 Ci) se desprendió y fue dejada dentro del paciente, tres técnicos advirtieron las señales de alarma (sonora y lumínica) generada por el detector de radiación en el interior de la sala de tratamiento, y *"decidieron"* que el instrumento estaba funcionando mal, sin efectuar comprobaciones adicionales. Existen muchos otros ejemplos de esta actitud, probablemente debida a anteriores falsas alarmas, entre los cuales podemos destacar:

Desde el punto de vista de la *"Defensa en Profundidad"* en el accidente en el Hospital Clínico Universitario de Zaragoza la última barrera de detección del problema fue el indicador de energía en el comando del equipo, que funcionaba correctamente pero el valor anormal de su indicación fue atribuido a un mal funcionamiento del monitor.

El accidente en la planta de irradiación de El Salvador es un ejemplo extremo: el sistema de detección de posición de fuente fue directamente eliminado, y los interlocks puenteados.

Buenos Aires, agosto de 1999: Un avión se estrelló al no lograr despegar. En la grabación de la "caja negra" puede escucharse claramente la alarma que indicaba que las alas no estaban configuradas para el despegue. Se especula con que la alarma solía sonar en forma espuria y por lo tanto los pilotos no la tuvieron en cuenta cuando estaba indicando un problema real.

2.3. Algunas otras creencias que afectan negativamente la seguridad

A los fines de la seguridad es suficiente con cumplir con los límites de dosis.
La Garantía de Calidad es algo que hace el Físico por las noches y los fines de semana.
La Garantía de Calidad consiste en controlar el funcionamiento de los equipos.
Hacer un doble control (por ejemplo en la dosimetría de los pacientes o en la performance de los equipos) implica desconfiar de la idoneidad de quien hizo el trabajo original.
Los viernes -o vísperas de feriado- por la tarde son días como cualquier otro (los accidentes de Zaragoza, del Reactor RA2 en Argentina, y muchos más ocurrieron viernes por la tarde).

3. Comentarios y Refutaciones

3.1. Mito 1

Cuanto más sofisticado es un equipo o un sistema mayor es la variedad de fallas que pueden ocurrir. Por lo tanto mayor será la cantidad y complejidad de los procedimientos operativos destinados a verificar su correcto funcionamiento. El simple hecho de que un equipo u aparato sea, en términos relativos, más seguro que otro no lo hace absolutamente seguro.

3.2. Mito 2

Muchos accidentes se han producido, no "a pesar de" sino "como consecuencia de" la experiencia de los operadores y el consecuente relajamiento de las medidas de seguridad. El único accidente radiológico mortal ocurrido en Argentina (Centro Atómico Constituyentes, Buenos Aires, 1983) tuvo como protagonista a un operador sumamente experimentado. Se pueden dar muchos ejemplos más.

3.3. Mito 3

Siempre que se relatan (en nuestras clases, en una conferencia, etc.) casos en los que una señal de alarma no fue tenida en cuenta, asumiendo un mal funcionamiento de la misma, la reacción del auditorio es de sorpresa y nunca faltan los comentarios despectivos respecto del nivel intelectual de los protagonistas. Esta puede ser la explicación última en muchos casos, pero este es un punto que debería analizarse desde un enfoque psicológico, pues esta tendencia a negar los problemas es mucho más común de lo que una primera lectura podría sugerir.

4. Conclusiones:

4.1. Los problemas planteados no pueden analizarse solamente desde un punto de vista racional; los factores involucrados se encuadran mejor dentro del campo de la psicología y la sociología. Excluir estas ciencias del análisis de accidentes significa cerrar una puerta a la posible solución los problemas.

4.2. Las "lecciones" que nos dejan los accidentes generalmente son "aprendidas" sólo por un sector de los actores involucrados: los organismos reguladores o instituciones científicas especializadas. En la formación de médicos, tecnólogos, físicos (al menos en Argentina) muy pocas instituciones tienen en su Currícula la materia Seguridad Radiológica.

4.3. Nuestros alumnos de las carreras de Física Médica y Diagnóstico por Imágenes deben "aprender las lecciones" que nos dejan los accidentes. Creemos que al menos durante un tiempo tendrán tanto la formación como la conciencia y actitudes para prevenir, detectar e intervenir en accidentes, pero nuestra pregunta (y nuestro temor) es: ¿Cuánto tardarán en ser imbuidos por los "mitos y creencias" mencionadas en el presente trabajo...?

4.4. A lo largo del presente trabajo se utilizó el término "mito" pues se refiere a creencias que no soportan un análisis crítico pero son difíciles de desarraigar, puede tener un lejano trasfondo de verdad , se transmite por fuera de los ámbitos académicos y se realimenta continuamente a sí mismo. Para ilustrar esto final se describen las "reglas para crear un mito [3]:

1- *los conceptos se vinculan por analogía.* Por ejemplo: Gobierno-Ineficiencia-Normas-Burocracia da como conclusión: las normas son inútiles.
2- *Si tout se tient, tout se tient.* No es necesario que un concepto se concluya necesariamente de otro, es suficiente con que no haya contradicciones (esto en lógica se llamaría falacia de afirmación del consecuente) Por ejemplo para llegar a las conclusión de que las normas son inútiles es suficiente conque "algunos" gobiernos sean ineficientes, y no todos ellos...
3- *Las conexiones deben haber aparecido una vez y mejor si han aparecido muchas veces*: cuantos más gobiernos ineficientes, burocracia, normas inadecuadas o incumplibles, más fuerza tendrá la conclusión de que las normas son inútiles.

4.5. Casi con certeza durante el presente año ocurrirán accidentes que tendrán entre sus causas algunas de las aquí mencionadas. Estos accidentes serán analizados y nos permitirán aprender nuevas lecciones. O al menos nos permitirán repasar las ya estudiadas...

5. Referencias

[1] PRETE, S. Átomo, simbolismo y sociedad. Revista de la Sociedad Argentina de Radioprotección. N° **18** (2000) pag 34-48.

[2] OSTROM L.T., LEAHY T.J., NOVACK S.D., Summary of 1991-1992 Misadministration Event Investigations, págs. 19-21, NUREG/CR-6088 EGG-2707, (1994)

[3] ECO H., El Péndulo de Foucault, Ed. Bompiani Lumen de la Flor 1989. Buenos Aires. Pág. 558

INITIAL EVALUATION OF A FULL BREAST DIGITAL SYSTEM

E. VAÑÓ[1,2], M. CHEVALIER[2], P. MORÁN[2], J.M. FERNÁNDEZ[1,2], T. CEPEDA[3], A. FABRA[3], C.S. ALVAREZ PEDROSA[3]

[1] Medical Physics Service. San Carlos University Hospital. 28040 Madrid. Spain. (eliseo@eucmax.sim.ucm.es).
[2] Radiology Department. Medicine School. Complutense University. 28040 Madrid. Spain.
[3] Diagnostic Radiology Service. San Carlos University Hospital. 28040 Madrid. Spain

ABSTRACT

Full-field digital mammography systems have been developed for overcoming the limitations of the screen-film mammography. This work is focused on the system from GE Medical Systems (Senographe 2000) which has been recently installed in our institution. The imager consists of a thin Ics:Tl scintillator which is in narrow contact with an array of amorphous silicon detectors mounted in a single panel. The flat-panel detector is integrated in a x-ray system with a high-frequency generator Senographe DM and dual track anode of Mo and Rh with Mo and Rh filtration. The aim of this work is to analyse the defaults exposure factors set at the installation of the x-ray unit. The image quality has been evaluated by using one of the two phantoms recommended in the ACR Accreditation Program. Phantom images were obtained at each of the three available imaging modes: contrast (CNT), standard (STD) and DOSE. While maintaining the defaults of kilovoltage and anode/filter combination, phantom images were obtained at lower dose vales. The contrast noise ratio (CNR) was calculated for each of the low contrast objects (masses) of the phantom images and the details visibility was also evaluated. The results obtained for both parameters reveal that similar image quality can be obtained with significant reductions of the average glandular dose.

1. INTRODUCTION

The development and application of digital technologies in mammographic x-ray systems has been the subject of many investigations, which have addressed the capability of such systems for overcoming the limitations of screen-film mammography. The first digital mammography systems introduced were for the guidance of stereotactic biopsy procedures [1] but these systems use small-format devices that are not directly applicable to full-breast mammography. To overcome this limitation, four manufacturers have been working in development of prototypes that accomplishes the requirements of full-field digital mammography. Now, the system from GE is commercially available and we present in this work the results obtained in a preliminary evaluation of the Senographe 2000D. This digital mammography system is based on a multipulse high frequency generator (Senographre DMR, GE Medical Systems, Milwaukee, USA). It is equipped with a dual track target (Mo and Rh) with selectable filtration of Mo or Rh and a non-stationary grid. The full breast digital imager is composed of a thallium-doped caesium iodide (CsI:Tl) scintillator in contact with a two dimensional amorphous silicon photodiode array manufactured in a single module. The array is formed by a matrix of 1800x2304 detector elements that are 100 μm in pitch. The electrical signals of each pixel are individually read out and digitised to 16 bits digital values. The important physical properties (dynamic range, presampling modulation transfer function (MTF), noise power spectrum (NPS), detective quantum efficiency (DQE) and noise equivalent quanta (NEQ)) of the flat panel detector were evaluated with a clinical prototype and the results were recently published [2]. These results indicate that the DQE is improved with the flat panel imager (mainly for the frequencies involved in the low-contrast lesions imaging) and the spatial resolution is higher with screen-film systems. The lower spatial resolution can be overcame by contrast enhancement of digital data as it is suggested in some studies [3].

3. MATERIAL AND METHODS

The default exposure techniques established by the manufacturer during the installation of the facility have been evaluated in terms of dose and image quality. Tube output at each kVp and anode/filter combination were measured by using an ionisation chamber (4000 M Plus, Victoreen Inc., Cleveland, USA) calibrated and traceable to a secondary standard. The chamber was positioned at 52 cm from the tube focus, and the compression paddle was in place at 10 cm above the chamber. Entrance surface dose (ESD) was calculated from tube output measurements and the current tube time product needed for obtain each phantom image. Image quality was evaluated with the Nuclear Associates model 18-220 phantom (Nuclear Associates, New York, USA) which is one of the two phantoms approved by the ACR Mammography Accreditation Programme [4]. The 18-220 phantom is equivalent to approximately 42 mm compressed average breast (50% adipose/50% glandular composition) and was placed on the breast table with its chest-wall edge aligned with the chest-wall side of the imager. Two phantom images were acquired at the three different automatic imaging modes that are available in the mammographic system: contrast (CNT), standard (STD) and dose (DOSE). The default exposure factors (kVp, mAs, anode/filter combination) together with the ESD and the average glandular dose (DG) displayed at the acquisition workstation monitor were recorded for each image. Subsequently, several images were acquired at the manual mode by reducing to the half the mAs while maintaining the kVp and anode/filter combination. The image quality was estimated in terms of contrast noise ratio (CNR) and detail visibility for the processed phantom images. The CNR was evaluated for the low contrast test objects included in the phantom simulating masses. This parameter was calculated through the following expression [5]:

where μ represents the mean and σ the pixel to pixel standard deviation of a region of interest (ROI). The subscript "in" refers data collected from the ROI within the low contrast objets and "out1" and "out2" refers data collected from two ROI adjacent to the test objects. The ROI area was 350 pixel side for the in and out ROIs. An experienced observer evaluated the detail visibility over the processed images displayed in a high-resolution monitor. Window, level and magnification settings were set to maximise visualisation of fibers, specks, and masses. The number of each type of details visualised was compared with the acceptable scores proposed in the Stereotactic Breast Biopsy Accreditation Program (ACR-SBBAP) [6] introduced by the ACR for digital systems.

3. RESULTS

The ESD values estimated from measurements with the ionisation chamber were approximately 10% lower than the values calculated and displayed by the system. This difference is of the same magnitude that the measurement errors.

3.1. Contrast noise ratio (CNR)

The CNR values of the masses calculated according to the above expression are represented in Fig. 1(a). Each curve corresponds to the default exposure conditions displayed for the three imaging modes (CNT, DOSE and STD). As it can be seen, similar CNR values were found for the CNT and STD modes while the DG value was 10% lower for the STD mode. CNR values decreased for all the masses when DG values were progressively reduced to the half, excepting in the CNT mode (Fig. 1 (b,c,d)). In this case, the highest CNR values correspond to the lowest DG value.

3.2. Detail visibility

Table I show the scores given to the phantom images together with their corresponding DG values. The images obtained at the default conditions (highest DG values) accomplished the acceptable scores proposed by the ACR-SBBAP [6] (5 for fibers, 4 for specks and 3.5 for masses) excepting the one obtained at the DOSE mode. With this imaging mode, the scores are highest for the image with a half DG value of the default image. This result is in agreement with CNR curves show in Fig. 2(b). The results also demonstrate that images with similar quality can be obtained at lower DG when the system is operating at the CNT mode. At the STD mode, the scores given to the fibers do not meet the acceptable value. However, similar image quality is also obtained with a DG vale half of the default one.

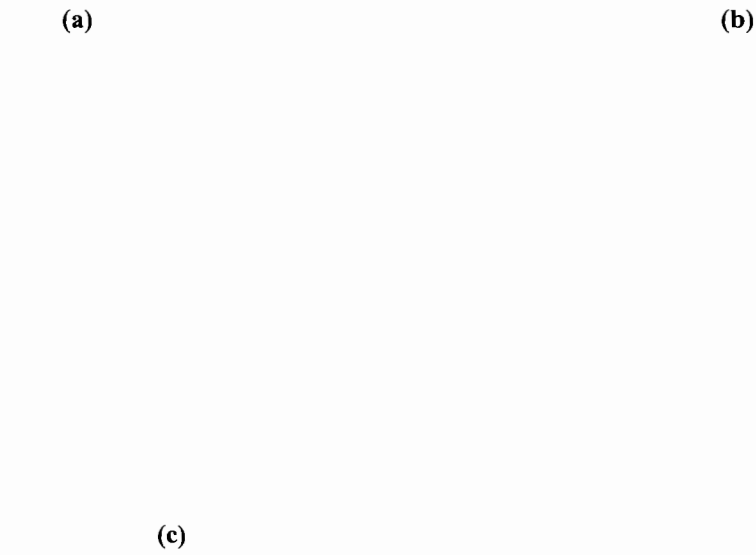

Figure 1. Contrast noise relation (**CNR**) versus low contrast details (masses) inserted inside the phantom. **(a)** Comparison of the CNR values obtained at the exposure conditions set at each imaging mode; Effects of reducing the average glandular dose on the CNR values at **(b)** DOSE mode (Mo/Rh, 31 kV); **(c)** Standard (STD) mode (Mo/Rh, 28 kV); **(d)** Contrast (CNT) mode (Mo/Rh, 26 kV).

Correlation between CNR and detail visibility was analysed by considering the CNR values calculated for the last mass detected in most of the phantom images (4^{th} mass). Fig. 2 shows that there exists a positive correlation between CNR and the total score obtained by adding the particular scores given to each type of detail.

Figure 2. Correlation between total score and contrast noise ratio (CNR).

4. CONCLUSIONS

From this initial evaluation could be concluded that enough image quality could be obtained with a dramatic reduction of the DG values associated to the default exposure conditions (Fig. 3). The correlation between the total score and CNR show that the latest is a robust parameter for evaluating the image quality in terms of a non-subjective magnitude.

It is also concluded that it is necessary a deeper analysis of the imager behaviour, since the results for the CNT imaging mode are not in agreement with the linearity conditions found for this system in previous studies [3]. Moreover, similar results were obtained with another image quality phantom that are not here presented.

Table I. Effects of decreasing average glandular dose (**DG**) values (photon fluence) on detail visibility for each imaging mode. The values in the shaded cells correspond to the default exposure conditions.

	CNT Mo/Rh, 26 kVp			**STD Mo/Rh, 28kVp**					**DOSE Mo/Rh, 31 kVp**		
DG	0.6	1.08	2.24	0.12	0.25	0.5	1.01	2.02	0.5	0.95	1.9
FIBERS	5	5	5.5	3	3	4.5	4.5	4,75	4	5	4.75
SPECKS	4	4	4	2	2	3	4	4	3	4	3.5
MASSES	5	5	5	4	4	4.5	4.5	5	4	4	4.75

5. REFERENCES

[1] Roerigh, H., Yu, T., Schempp, W.V., Performance of x-ray imaging systems with optical coupling for demagnification between scintillator and CCD readout, Proc. SPIE **2279** (1994) 388 a 401.

[2] Vedantham, S., Karellas, A., Suryanarayanan, Albagli, D. et al., Full breast digital mammography with an amorphous silicon-based flat panel detector: Physical characteristics of a clinical prototype, Med. Phys. **27** 3 (2000) 558 a 567.

[3] Nishikawa, R.M., Mawdsley, G.E., Fenster, A. and Yaffe, M.J., Scanned-projection digital mammography, Med. Phys., **14** (1987) 717 a 727.

[4] AMERICAN COLLEGE OF RADIOLOGY, Mammography quality control manual. Reston, Va: American College of Radiology (1999).

[5] Kimme-Smith, C., Lewis, C., Beifuss, M., Williams, M.B. and Basset, L.W., Establishing minimum performance standards, calibration intervals, and optimal exposure values for a whole breast digital mammography unit, Med. Phys. **25** 12 (1998) 2410 a 2416.

[6] AMERICAN COLLEGE OF RADIOLOGY, Stereotactic Breast Biopsy Accreditation Program. Reston, Va: American College of Radiology (1999).

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RADIATION ABSORBED DOSES AND SAFETY OF THE HUMANIZED MONOCLONAL ANTIBODY H-R3 LABELED WITH 99MTC

Leonel A. Torres, Maria E. Solano, Alejandro Perera, Juan F. Batista, Abel Hernandez, Tania Crombet, Marilyn Perez, Mayra Ramos, Elvia L Sanchez, Susana Romero, Vicente Aguilar, Normando Iznaga.
Center for Clinical Research
Principal Author: Leonel A. Torres Aroche
Telefax: 537243298, e-mail: leonel@infomed.sld.cu

Abstract

Introduction. Labeled humanized monoclonal antibodies (Mab) for the diagnosis and treatment of tumors using Nuclear Medicine procedures have contributed to decrease the immunogenicity and HAMA response of murine MAbs, increasing the effectiveness and usefulness of radioimmunoscintigraphic procedures. The objective of this study was to evaluate the internal radiation dosimetry and safety of the 99mTc-labeled H-R3 Mab, in humans. *Material and methods*: Ten patients with suspicions of epithelial tumors were included on this study. They received 1110 MBq of 99mTc H-R3, intravenously. Multiple blood, urine samples and sequential whole-body images were collected at different times. The internal radiation dosimetry was estimated using the Medical Internal Radiation Dosimetry (MIRD) Committee methodology. Biodistribution was computed from the scintigraphic images and regression analysis of the time-activity curves was employed to compute the residence times of the source organs. Hematological toxicity and adverse effects were evaluated using the WHO classification

Results: Liver received the higher absorbed dose (4,90E-02mGy/MBq), followed by the kidneys (1,60E-02mGy/MBq) and gallbladder wall (1,53E-02mGy/MBq). The effective dose and the effective equivalent dose were 0,0143 mSv/MBq and 0,0190 mSv/MBq, respectively. The main source organs of this radiopharmaceutical were liver, spleen, kidneys and heart. No significant changes were observed in the hematological parameters and only two patients showed mild and moderate adverse effects, solved during the studies and not related with radiation exposures.

Introduction.

Almost 90% of malignancies are epithelial derived tumors. Cancer of epithelial origin constitutes one of the first causes of death world-wide [1]. Tumors of epithelial origin, like cancer of lung, digestive tract, breast and others, have an overexpression of the epidermal growth factor receptor (EGF-R) [2]. This fact is often related to malignancy and poor prognosis of the disease [3]. Clinical trials have shown that anti-EGF-R monoclonal antibodies (MAbs) could be useful for immunoscintigraphic diagnosis of epidermal tumours [4,5].

In order to decrease the immunogenicity and HAMA response to the murine MAbs, and increase the half-live of the molecule in the patient, it was developed a reshaped humanized monoclonal antibody H-R3. This study include the preliminary results of the internal radiation dosimetry, biodistribution and safety of the 99mTc-labelled H-R3 used for radioimmunodiagnosis of tumors of epithelial origin.

Material and Methods.

Antibody Labelling and Quality Control.

Freeze-dried kits with 3 mg of humanised MAb H-R3 (Centre of Molecular Immunology, Havana, Cuba) were reconstituted with 1295 MBq of pertechnetate from a $^{99}Mo/^{99m}Tc$ generator (CIS-BioInternational, France). Labelled product was subjected to ascending paper chromatography. Radiochemical purity higher 90% was considered satisfactory for patient's administration.

Studied Patients

Ten adult patients (6 females and 4 males) were enrolled on this study. They received 3 mg of MAb labeled with 1110 MBq of 99mTc. All patients were suspected of having either primary or recurrent cancer of epithelial origin and had undergone CT scanning, x-ray and other determinations. Histopathological findings were considered as a confirmation criterion (gold standard). All studied patients gave their written informed consent previously to be included in the clinical trial.

Biodistribution studies and internal radiation dosimetry analysis.

Anterior and posterior whole body images were acquired at 5 min, 1 h, 3 h, 5 h and 24 h after administration of radiopharmaceutical, using a gamma camera (SOPHYCAMMERA DS7, France). The gamma camera head was fitted with a diverging parallel-hole collimator to increase the lateral viewing aspect. A 20% window centered on the 140 keV emission peak of the ^{99m}Tc was employed. On the gantry movements were used a speed of 20 cm/min. All whole-body images were stored in the computer in 2048x512 byte mode matrix.

All images were processed in a SOPHY-20P system using the software BioDose v1.0, developed at the Centre for Clinical Research. Geometric mean images were computed from the anterior and posterior whole-body scans. They were reviewed to determine the subjective biodistribution of ^{99m}Tc-H-R3 and to select which organs and tissues were clearly visible in the total image series. Such organs were considered as source organs.

Regions of interest (ROI) were drawn over heart, liver, spleen, small intestine, kidneys, upper large intestine (ULI), lower large intestine (LLI) and urinary bladder. Total counts were computed for each one, at the different time intervals. For each source organ count values were converted to activity, corrected for decay and expressed as percentage of the total administered activity. Whole-body activity was initially 100 % following a exponential clearance by biological removal and physical decay of activity.

The MIRD Committee method was used to assess the internal radiation dosimetry. Time-activity curves for each source organ and the remainder of the body tissues were obtained and fitted to exponential disappearance curves. Cumulative activities and residence times for each source organ were estimated integrating the time-activity curves. The absorbed doses to whole body and organs were estimated using the residence times and the modified "S" values reported on MIRD Pamphlets [6,7]. Based on the results of the absorbed dose estimated to various target organ the effective dose was calculated

Clinical laboratory analysis and safety studies.

Complete blood cell counts with differential and platelet counts, chemistry panel evaluation, liver function test and urinary analysis were performed 1-7 days before and 24 h after antibody administration. Patients did not have any food for 12 hours before blood collection. Fifteen millilitres of blood were withdrawn from a patient's vein 1 week before and 24 h after 99mTc-H-R3 administration. Five millilitres of blood were carefully added to a brand collection tube with 50 μL of 15% EDTA (K_3) solution (Vacutainer, Becton Dickinson, USA) for haematology. One drop of blood was extended in a microscope slide (Shanghai Company,

China) for differential leukocyte counting. Five millilitres of blood were added to a centrifuge tube and were incubated at room temperature for 1 h. After that, sample was centrifuged at 3000 rpm for 10 min and two 1mL-specimens of serum were added in Eppendorf tubes for analytical chemistry tests. On the other hand one hundred millilitre urine sample of the first morning urination was collected in a sterile container to test it.
All patients were monitored up-to 24 h after injection in order to detect any adverse reaction.

Results.

Biodistribution and Internal Radiation Dosimetry

The computed biodistribution of the 99mTc-MAb H-R3 is presented in table I.

Table No.I. 99mTc-H-R3 Human biodistribution. Data corrected by decay (Mean ± SD).

H-R3 Biodistribution .					
Organs	10 min.	1 hours	3 hours	5 hours	24 hours
Heart	2,79 ± 0,89	2,12 ± 0,6	1,99 ± 0,67	1,93 ± 0,67	0,14 ± 0,16
Liver	50,79 ± 6,42	53,31 ± 8,01	45,23 ± 7,61	43,46 ± 8,6	17,74 ± 8,03
Spleen	1,92 ± 1,44	1,6 ± 1,05	1,39 ± 0,82	1,32 ± 0,69	1,45 ± 1,96
Kidneys	1,08 ± 0,58	1,13 ± 0,45	1,9 ± 1,03	2,51 ± 1,5	6,6 ± 7,81
U. Bladd	0,41 ± 0,18	1,41 ± 0,64	3,17 ± 1,31	4,1 ± 2	1,11 ± 1,48
T.Body	100 ± 0	97,65 ± 6,79	96,81 ± 7,73	91,01 ± 17,31	35,77 ± 12,73
R.Body	42,93 ± 5,28	37,87 ± 4	42,03 ± 4,93	35,94 ± 16,54	6,84 ± 5,07
L.Intest					3,41 ± 1,86

The assessed absorbed dose of 8 target organs (mGy/MBq or rad/mCi) after the injection of ^{99m}Tc- MAb ior H-R3 are presented in Table No II. The absorbed dose for the whole body and the effective dose are also reported. The highest absorbed dose was received by the liver with a value of approximately 4,90E-02 mGy/MBq and the kidneys 1,60E-02mGy/MBq). The effective dose and the equivalent effective dose were 0,0143 mSv/MBq and 0,0190 mSv/MBq respectively. The main contributor organs to the absorbed dose per organ were the hepatic tissues.

Table No.X. Normal organ dosimetry for the labelled MAb ^{99m}Tc-H-R3 kit.

TARGET ORGAN	mGy/MBq		Rad/mCi	
	Mean	SD	Mean	SD
Brain	1,68E-03	2,28E-04	6,23E-03	8,42E-04
Gallbladder Wall	1,53E-02	2,38E-03	5,65E-02	8,77E-03
Heart Wall	8,87E-03	1,74E-03	3,28E-02	6,42E-03
Kidneys	1,60E-02	5,89E-03	5,93E-02	2,17E-02
Liver	4,90E-02	9,53E-03	1,81E-01	3,55E-02
Spleen	1,41E-02	5,46E-03	5,17E-02	2,05E-02
Thyroid	2,13E-03	2,56E-04	7,83E-03	9,99E-04
Urin Bladder Wall	1,54E-02	5,21E-03	5,69E-02	1,93E-02
Total Body	4,64E-03	5,68E-04	1,72E-02	2,09E-03
EFF DOSE EQUIV	1,90E-02	2,88E-02	3,48E-02	4,24E-03
EFF DOSE	1,43E-02	1,95E-02	2,86E-02	6,04E-03

Safety

Only two patients (20%) showed adverse reactions. Reactions were clasified as follows: Patient No.7, acute rhinitis at 30 minutes after injection. It was maintained for 6 hours, responding partially to the treatment with intramuscle Benadryl. According to the WHO criteria it was considered as moderated reaction. On this patient the hematological analysis showed normal results. Patient No.9, Chills that no required medication and disappeared at a few minutes. It was considered as mild reaction (grade 1). The complementary blood examinations had alterations in two parameters: glucose=21 milimols/L and alcalinephosphatase=312 u/L. These blood samples were obtained a day after the injection of the product. We cannot establish the causes of such abnormalities because no other patient injected had such abnormal parameters. On the other hand, no significant changes of the vital signs were detected in any of the studied cases after the injection of the radiopharmaceutical and anyone patient showed adverse events at the administration site.

Clinical laboratory parameters before and 24 h after intravenous injection of the ^{99m}Tc-h R3 were assessed and no significant changes were observed. Additionally did not exist any abnormality repeated in more than one patient. There were not hematologic and biochemical abnormalities with clinical significance that could be produced by the MAb or by radiation exposure.

Conclusions.

The obtained results of Biodistribution and Dosimetry of ^{99m}Tc-labeled Monoclonal Antibody H-R3 have shown that liver is the target organ of this product and presented an uptake peak at 1hr post-injection with a high retention. This organ also received the higher absorbed dose. These results should be taking into account for a future use of this compound for therapeutical purposes and for its current use in diagnosis procedures.

References.

1. Sheryl L. Parker Sl, Tong T, Bolden S, Wingo PA. Cancer Statistics. Ca. A. Cancer Journal for Clinicians. CA 1996, 46: 15-27.
2. Modjtahedi H, Eccles S, Sandle J, Box G, Titley J and Christopher D. Differentiation or immune destruction. Two pathways for therapy of squamous cell carcinomas with antibodies to the epidermal growth factor receptor. Cancer Res. 1994; 54: 1695-1701.
3. Fontanini G, Vignati S, Bigini D, Mussi A, Lucchi H, et al. Epidermal growth factor receptor (HEGF-R) expresion in non-small cell lung carcinomas correlates with metastatic involvement of hilar and mediastinal lymph nodes in the squamous subtype. Eur. J. Cancer. 1995; 31A: 178-183.
4. Ramos-Suzarte M, Rodriguez N, Oliva JP, Iznaga N, Perera N , Morales A, et al. ^{99m}Tc-Labeled Antihuman Epidermal Growth Factor Receptor Antibody in Patients with Tumors of Epithelial Origin: Part III. Clinical Trials Safety and Diagnostic Efficacy. J Nucl Med 1999; 40 768-775.
5. Iznaga-Escobar N, Torres LA, Morales A, Ramos M, Rodriguez N, Perez N, et al. 99mTc-Labeled-anti-human epidermal growth factor receptor antibody (ior egf/r3) in patients with tumor of epithelial origin: II. Pharmacokinetics and clearances. J Nucl Med 1998; 39: 1918-1927.
6. Sorenson J.A., Phelps M. E. Physics in Nuclear Medicine. Second Edition, Orlando, Florida. Grune an Stratton, 1987.

7. Snyder WS., Ford, MR. et al. "S" absorbed dose units cumulated activity for selected radionuclides and organs. MIRD pamphlet no. 11. New York: Society of Nuclear Medicine, 1975.

NEW PAPERS/starting from **Nr.: 251**

PATIENT DOSE FROM PHOTONEUTRONS IN A 18 MV LINAC

Barquero R.*, Méndez R.** and Iñiguez M.P.**
* Servicio de Radiofísica y Protección Radiológica, Hospital Universitario Río Hortega de Valladolid, Spain, email: rbarquero@hurh.insalud.es
** Departamento de Física Teórica y Atómica Molecular y Nuclear, Universidad de Valladolid, Spain

SUMMARY

We have estimated by measurements and Monte Carlo simulations, the photoneutron dose equivalent to patients in a Siemens KD-S radiotherapy accelerator operating at 18 MV. The beam was collimated to 40 cm x 40 cm and angles of 0° and 180° for the rotating gantry where considered. The measurements were made with pairs of TLD600-TLD700 thermoluminescent dosemeter chips inside a 25 cm diameter moderating sphere. The calibration of the instrument was performed in a bare Am-Be neutron source. On the other hand the Monte Carlo simulations of the fluence and energy spectra were made by using a simplified model for the neutron source and taking into account neutron scattering from the concrete walls surrounding the room. The agreement between the two approximations was good with a resulting dose to patient of 0.6 mSv per treatment Gy that fits well to reported values in the literature.

INTRODUCTION

In electron linear accelerators operating at high energies neutrons are produced as a consequence of photonuclear reactions in the target, field-flattening filters and beam collimators. These neutrons deliver an unwanted extra dose to patients, a fact constituting a very active research topic from the 1970's [1,2] which is of special relevance in the case of pregnant patients [3]. Experimental techniques to quantify the neutron dose to patients are limited by many reasons. For example pulse counters are discarded because dead time and pile up effects in the very intense and pulsed radiation field of a linac. On the other hand the high gamma intensity of the therapy beam makes it difficult to extract the relatively small neutron component if detectors sensitive to both radiations are used. Passive neutron activation [4], thermoluminescent TLD [5,6] and superheated drop detectors [7], which have not the pulse counters disadvantages, have been used to measure quantities wich are more or less closely related to the relevant dose equivalent depending on the particular technique.
Monte Carlo simulations can alternatively evaluate the transport of neutrons in the different components of the accelerator and through the room. What has to be calculated is a formidable task with an enormous neutron producing gamma and inversely gamma producing neutrons reactions all of them necesary in principle to correctly describe the resulting mixed neutron-gamma field. However it is much more frecuent to make some simplifications on the neutron source in addition to approximations of the detailed geometry and to neglect nuclear reactions that contribute less to the dose equivalent. In the simulations one obtains the neutron fluence and energy spectra and after that by using the appropriate conversion factor the neutron dose equivalent is estimated.
Some authors [5,6] have obtained the dose equivalent around linacs from the neutron spectrum measured by means of a Bonner spectrometer with TLD's [8,9]. This system consists of a bare detector and six polyethylene moderating spheres with diameters varying between 5 and 30 cm. Differently, in this work we report on results of TLD dosemeters but only inside a special sized sphere 25 cm diameter whose response versus neutron energy fits the quality factor behaviour [8,9] for the energy range of interest. The results of the measurements are compared with MonteCarlo calculations in which the source is assumed to be punctual and surrounded by a shielding sphere.

MATERIALS AND METHODS

Thermoluminescent LiF:Mg,Ti chips of 3x3x1 mm are located in the paraffine sphere center inside a methacrylate cylindrical box that contains four TLD600 and four TLD700. The responses of the

TLD600 are associated to gamma and neutron radiations whereas the corresponding to TLD700 only have gamma contribution. An identical gamma response of TLD600 and TLD700 will be assumed so the neutron contribution follows as a simple sustraction between the responses of the two types of dosemeters. The readout apparatus was a Victoreen 2800M model, and the lectures were obtained in a two steps way, a heating during ten seconds at 160 °C followed by another ten seconds at 300°C and taking the intensity emitted in the second time interval. The neutron contribution to the TLD600 reading is converted to dose equivalent by means of a calibration in an Am-Be isotopic neutron source. For this task we proceed to measure the neutron dose equivalent at different distances from the 3Ci bare source (50, 60, 70, 80 and 100 cm) with a scintillation pulse counter LiI (Eu) inside a 30 cm diameter poliethylene sphere [8]. At the same points our TLD-sphere system is irradiated and the neutron contribution of TLD600 is correlated to the LiI (Eu) remmeter response [9]. Then the correlation factor obtained in this way is assumed to be valid for the neutron field existing around the linac. For the irradiations in the accelerator two positions of the rotating gantry where chosen at angles 0° (anteroposterior AP) and 180° (posteroanterior PA) with a field size of 40 * 40 cm delivering 12.5 Gy at the isocenter ic.

The version 4B of the MCNP [10] code was used for the Montecarlo simulations. As the input we have considered an isotropic punctual neutron source with a maxwellian evaporation spectrum

$$p(E) = \frac{E}{T^2} * \exp(-\frac{E}{T}) \qquad (1)$$

and a temperature T = 0.5 MeV corresponding to photoneutron production in the tungsten material of the target. This source is surrounded by a shielding tungsten sphere 10 cm radius as if collimators where closed. The room walls are described as paralelepipedic concrete 2.3 g/cm^3 density with a mass percent composition of 17% hidrogen, 56% oxigen, 20% silicon and smaller proportions of Al, Ca, Mg, K, Fe and C. A number of 50000 neutrons in 12 energy groups, from [0, 4E-7] to [5, 7] MeV are transported up to ring detectors at the experimental positions or up to a punctual detector for the point in the beam. Prompt gamma rays produced in capture reactions were neglected. Since MCNP calculated fluence is normalized per neutron source, it is the neutron yield Q in the accelerator head that is required. We obtain Q in a semiempirical way, by assuming that the thermal fluence Φ_{th} is uniform and proportional to the source strength [11]. The proportionality constant is obtained from the MCNP normalized thermal fluence. Then by an independent measure of the thermal fluence Φ_{th} in the room (with bare and Cadmium shielded TLD) a neutron yield of 2.6 ** 10^{11} neutrons per treatment Gy is obtained, the value of Φ_{th} being 8.1 ** 10^5 n/cm^2 Gy.

The dose equivalent h results multiplying the group fluences Φ_i by the conversion factors $FCONV_i$ in ref. [12] as follows

$$h = \sum_{i=1}^{12} FCONV_i * \Phi_i . \qquad (2)$$

RESULTS

The investigated region near the beam is shown in Fig.1, where for completeness a sketch of the accelerator room is also given. The points labelled A, B, C and D are in the patient plane at respectively 30, 25, 25 and 80 cm from the isocenter ic and correspond to AP gantry position. In the measurements the center of the sphere is at those distances whereas in the calculations ring detectors around ic are used. Those same points in the patient plane are calculated for PA gantry position. The point ic is just in the beam center and the points labelled from E to J are in the electron gun plane at distances from ic appearing in Table I bellow. In the last case ring detectors around the source where used to calculate neutron fluence. The point K located at 125 cm from ic is where the thermal fluence Φ_{th} was measured to obtain Q as indicated above.

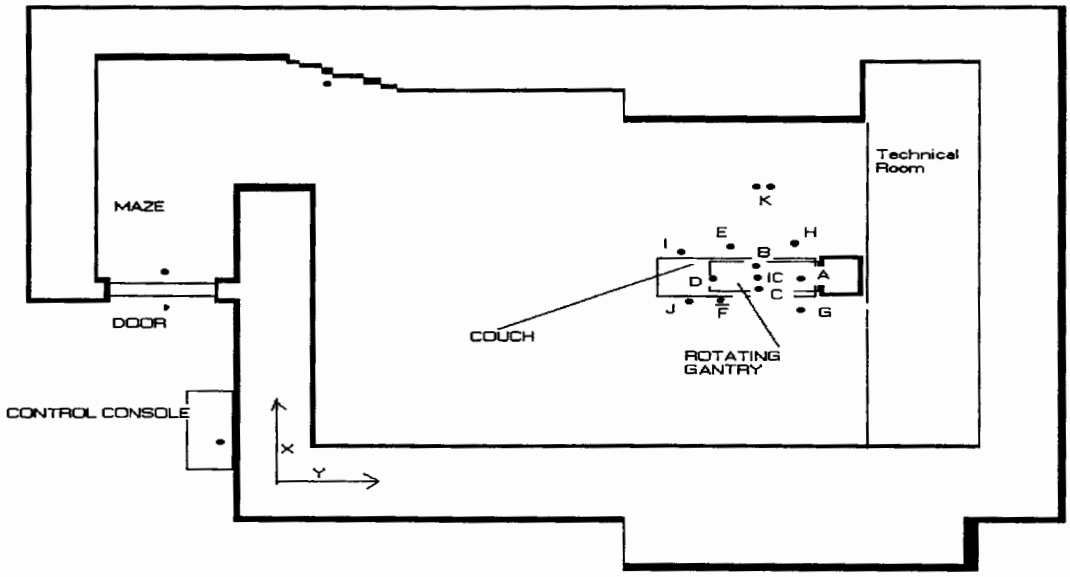

Fig.1 Sketch of the acelerator room with the studied points.

Table I shows the experimental and calculated results in miliSievert per treatment Gray. The calculated values for the points A to D corresponding to patient PA coincide with the values for patient AP and are not given in that Table. This is not extraneous because the room is rather symmetrical and the variation of distances to ceiling and floor does not affect at all. The point ic in the beam is calculated but it is not measured because the strong gamma content of our TLD dosemeters that makes it impossible to induce any value for neutron dose. The mean average among the points located out of the beam is 0.55 mSv/Gy with standard deviations of 40% and 20% for respectively the measured and calculated values.

Plane and position	Point, cm from ic	Measured dose mSv/Gy	Simulated dose mSv/Gy
Patient AP	A 30	0.35	0.60
	B 25	0.86	0.61
	C 25	0.64	0.61
	D 80	0.34	0.44
Patient PA	ic 0		0.63
Electron gun PA	E 104	0.44	0.62
	F 125	0.51	0.45
	G 131	0.36	0.42
	H 131	0.69	0.42

	I 160 J 82	0.66 0.55	0.30 0.95

Our resulting dose equivalent is inside the range of values reported in the literature [4,7] although some differences exist among different accelerator models. The thermal neutron dose represents only a small contribution two orders of magnitude smaller than the total dose. The experimental method we have used here has limitations to measure neutron doses very near to the beam and then as we have shown the Monte Carlo simulations could help in evaluation of doses for those points of interest. Finally we want to note that neutron dose reduction studies by adequate shields for fetus protection, whose importance has been stressed in refs. [3,7] can be accomplished with the methods used in this work.

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REFERENCES

[1] NCRP REPORT No. 79, Neutron contamination from medical electron accelerators (1984).
[2] AAPM American Association of Physicist in Medicine REPORT No 19, Neutron measurements around high energy x-ray radiotherapy machines (1986).
[3] ROY, S.C., SANDISON, G.A., Shielding for neutron scattered dose to the fetus in patiens treated with 18MV x-ray beams, Med. Phys. 27 (2000) 1800-1803.
[4] SANCHEZ, F., MADURGA, G., ARRANS, R. Neutron measurements around an 18 MV linac, Radiot. and Oncol. 15 (1989) 259-265.
[5] HOLEMAN, G.R., PRICE, K., FRIEDMAN, L.F., NATH, R. Neutron spectral measurements in an intense photon field associated with a high energy x-ray radiotherapy machine, Med. Phys. 4 (1977) 508 -515.
[6] VEINOT, K.G., HERTEL, N.R., BROKKS, K.W., SWEEZY, J.E., Multisphere neutron spectra measurements near a high energy medical accelerator, Health Physics 75 (1998) 285-290.
[7] D'ERRICO, F., NATH, R., SILVANO, G., TANA, L. In vivo neutron dosimetry during high-energy bremsstrahlung radiotherapy, Int. J. Radiation Oncology Biol. Phys., 41 (1998) 1185-1192.
[8] BRAMBLETT, R.L., EWING, R.I., BONNER, T.W., A new type of neutron espectrometer, Nuclear Instruments and Methods 9 (1960) 1 a12.
[9] VEGA-CARRILLO, H.R., WEHRING, B.W., VEINOT, K.G., HERTEL, N.E., Response matrix for a multisphere spectrometer using a ^{6}LiF thermoluminiscence dosemeter, Radiat. Prot. Dosim. 81 (1999) 133-140.
[10] MCNP A General Monte Carlo N-Particle Transport Code, Version 4B, LA 12625, (1997), Judith F. Briesmeister, Editor.
[11] Mc CALL, R.C., Neutron yield of medical electron accelerators, Stanford Linear Accelerator Center Report No SLAC-PUB-4480 (1987).
[12] SIEBERT, B.R.L., SCHUHMACHER, H., Quality factors, ambient and personal dose equivalent for neutrons, based on the new ICRU stopping power data for protons and alpha particles, Radiation Protection Dosimetry 58, No.3 (1995) 177 a 183.

PATIENT DOSE ESTIMATE AT CELLULAR LEVEL IN NUCLEAR MEDICINE USING MONTE CARLO NUMERICAL EXPERIMENTS BY FOTELP/EM CODE (Poster)

Rajko Spaic, Medical Military Academy, Crnotravska 17, 11000 Belgrade, Yugoslavia
Radovan Ilic, Institute of Nuclear Science "Vinca", Belgrade, Yugoslavia
Bratislav Petrovic, Sasha Dulic, Tihomir Vujnovic, Darko Krulj, Faculty of Organisational Sciences, Belgrade, Yugoslavia

ABSTRACT

This paper presents some part of the software package for Monte Carlo numerical experiments in medical physics. The first part of job is that FOTELP/EM code, which is developed in Belgrade for Monte Carlo simulation with photons, electron and positrons be prepared for use in medical physics, and also that use of FOTELP/EM software be simplified. Because of that, we developed FOTELP Wizard to facilitate FOTELP/EM code. The FOTELP Wizard includes built-in modules for automated preparing the input files, launching the Monte Carlo simulation, and processing the graphical presentation of the simulation results (2D and 3D). Next step is that software application for calculation absorbed dose in nuclear medicine, radiotherapy and radiology be developed. After that also will be developed others applications of this package in medical physics.
In nuclear medicine, especially in internal radiotherapy, Monte Carlo simulation open new possibilities, such us calculations absorbed dose at cellular level. Using pathomorfological data like the cell size of labelled and non-labelled cells and cell density, part of programme for microdosimetry calculation was developed.

INTRODUCTION

The estimation of the absorbed dose at the cellular level, in the nuclear medicine was very important. Conventional dosimetry in diagnostic nuclear medicine, using MIRD methodology, report individual organ absorbed doses and total body absorbed doses. In internal radiotherapy conventional dosimetry, using same methodology, absorbed dose of tumour, critical organ, and whole body have been estimated. These absorbed dose values are calculated with assumption that the distribution of radioactivity is uniform in tumour, organs, and body. However, in reality distribution of this radioactivity is mostly nonuniform. Distribution of radiopharmaceutics in organ isn't homogenous, so some part of the organ gets more doses then others. In the lot of cases, specially in internal radiotherapy, it is very import to know absorbed doses on the cellular level (1). Maybe, Monte Carlo simulation is only possibly way to perform these calculations. Modern general-purpose programming packages for Monte Carlo simulation of the particles transport usually have two programs. Firstly, an appropriate input data must be generated to describe the cross-section and energy-angular distributions, while the simulation is performed by second program. This includes data preparation about materials and geometrical forms of source and irradiated region and is both time-consuming and error prone in the simple cases.
The application of Monte Carlo simulation programs to medical physics is very complex, especially the description of materials and geometrical forms of source and irradiated region (2). Consequently, without some form of automation of simulation steps, the application of

the Monte Carlo methods is difficult to achieve. Therefore, we have developed FOTELP Wizard to facilitate the use of own Monte Carlo FOTELP/EM code (3,4).

The simulation package FOTELP/EM consists of two programs: FEPDAT for preparing of cross-section and energy-angular distributions and FOTELP performing simulation of photon, electron and positron transport by Monte Carlo methods.

The input file FEPDAT.INP contains data about materials, energies and FOTELP working conditions; RFG.INP - the description of the irradiated region geometry using first and second order surface; FOTELP.INP - the position of material into the given geometrical forms, numerical experiment conditions and data for 2D/3D representation of results.
The aim of this paper is to present applications made in FOTELP Wizard which are specially design for calculation absorbed doses in nuclear medicine.

METHODS

FOTELP Wizard is a specialised integrated environment in which we can define geometrical forms and describe properties of chosen objects. With FOTELP Wizard, users can quickly start programs of FOTELP/EM packages, test definitions of geometrical areas (Fig. 1), data preparation about materials, and start programs for visualisation of the simulation results. In fact, FOTELP Wizard is a graphical shell, which is designed to facilitate the use of FOTELP/EM package, whose programs are executed from the command line by well-trained person.

The FOTELP Wizard includes built-in modules for:

(i) automated preparing the RFG.INP and FEPDAT.INP files,
(ii) launching the Monte Carlo simulation, and
(iii) processing the graphical presentation of the simulation results.

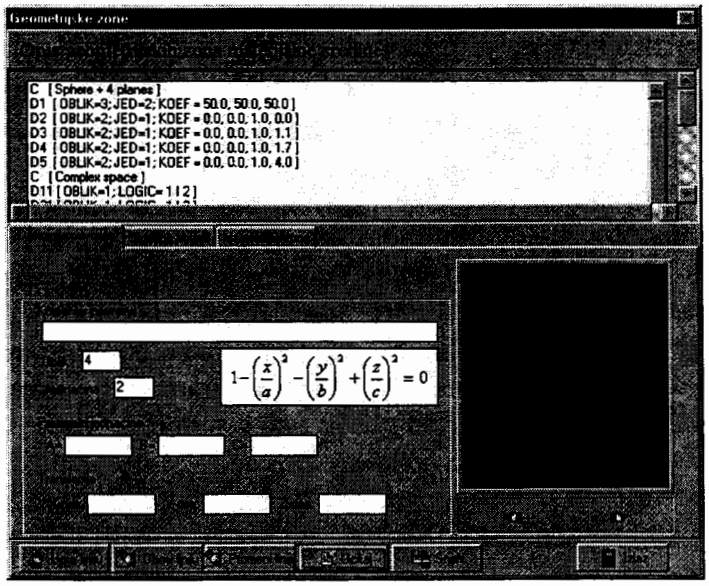

Fig. 1 Preparation of geometry data

RESULTS

The FOTELP Wizard provides an easy-to-use graphical user interface for building and deploying complete simulation as a project. You can add and remove components, change the components hierarchical ordering, and modify component attributes. The graphical part of package contains two programs (F2D and F3D), that generate 2D and 3D image display of the simulation results. Programs can be started from within FOTELP Wizard's main menu or from command line. Processing the FOTELP/EM output file SLIKA.DAT and file FOTELP.INP, the aforementioned programs yield a file DOSE.DAT and file PREGRAF.DAT (containing position data and corresponding energy levels) and visualise obtained data. A picture can be interactively magnified, extenuated and rotated (3D). The picture can be saved in standard graphical formats (e.g. JPEG, BMP or WMF). FOTELP Wizard is developed by using Delphi 5 compiler and TeeChart graphical library (5).
Now is possible with these programs to simulate conventional dose experiments in nuclear medicine using standard geometry for different organ. But, our goal is to develop radiology referent men in voxel space, and to make some improvements for this kind of the Monte Carlo simulations studies. Some of conventional dose measurements in these programs can be compared with same made with MIRD protocols.
Second part of software made in FOTELP Wizard, are calculations in Monte Carlo for microdosimetry measurements in nuclear medicine. For input data we used morphopathologic data and data from scintigraphic study and other medical imaging.

CONCLUSION

The FOTELP Wizard is developed to provide an easy-to-use graphical user interface for building and deploying complete simulation in medical physics.

Also, with specially designed applications for nuclear medicine conventional and microdosimetry dose calculations, the FOTELP Wizard was available for these clinical purposes.

The goal of this applications in FOTELP Wizard are to improve the effectiveness of nuclear medicine in the diagnosis and treatment of cancer and to enable new treatment modalities in internal radiotherapy using dose calculations at cellular level.

REFERENCES

1. Spaic R, Ilic R: Conventional Internal Dosimetry and Dosimetry at the Cellular Level in Diagnostic Nuclear Medicine, Proceedings of Yugoslav Society Conference, YUNSC-96, 563-566, (1996).
2. PEREGRINE Dose Calculation Program, Department of Energy's Lawrence Livermore National Laboratory, UCRL: MI-124425, (1999).
3. Ilic RD: Tehnike Monte Karlo u transportu cestica, Naucna knjiga, Beograd, (1991).
4. Ilic RD: Software FOTELP – Introduction for Installation and Usage, Report Vinca, Belgrade, NET – 87, (1995).
5. Petrovic B, R Ilic, R Spaic, S Dulic,T Vujnović, D Krulj: Material input geometry data editor-wizard for Monte Carlo numerical experiments in medical physics using FOTELP/EM code, Proceedings of Yugoslav Society Conference, YUNSC-2000, (in press)

OCCUPATIONAL HAND DOSES IN INTERVENTIONAL RADIOLOGY

Vesna Spasic Jokic, Federal Bureau of Measures and Precious Metals, Beograd, Mike Alasa 14, fax: +38-11-181-668, Yugoslavia
Branka Djurovic, Military Medical Academy, Beograd, Yugoslavia
Stevan Lukac, Military Medical Academy, Beograd, Yugoslavia

ABSTRACT: In this paper we present a case of radiologist working interventional procedures. Radiologist works numberes interventional procedures, but we reported only percutaneous nephrostomy and percutaneous biliary drainage which represent about 30 % of his occupational exposure. Radiologist is occupationally exposed for eighteen years and from 1995 has radiation injuries. From 1999. art. hypertension, cataracta complicata incip.ou., onychodystrophia and hyperceratosis mani bill. The most important are hands skin injuries. In ordinary dosimetric controle low doses, less than 10 mGy per year, were recorded , so personal dosimetry results and biological results are not in accordiance. For that reason we performed additinal measurements during meny procedures and in this paper we present results for two chosen procedures. Radiation exposure of radiologist hands during 200 percutaneous nephrostomy and 63 percutaneous biliary drainage per year are reported. Exposures were measured with thermoluminescent dosemeters (TLD) type CaF_2:Mn. Hands doses of equivalent of 221 μSv in average per drainage and 31 μSv in average per nephrostomy were recorded.

INTRODUCTION

Different radiologists at the same procedures show variation in their personal doses, specially the hand and finger dose in interventional radiology. Factors influencing the doses are: factors related to patients (age, sex, weight ...), factors related to eqipement and factors related to radiologists (technique, screening time, number of procedures, type of procedures...).

Medical staff radiation exposure is under physical and biomedical monitoring due to radiologist protection. Sometimes, for different reasons, results of these two monitoring techniques are not in accordiance.

In this paper we present a case of radiologist working interventional procedures, as percoutaneus nephrostomy (unilateral, bilateral, change of a nephrostomy catheter), biliary drainage, percutaneous apscess/pseudocyst drainage and placement of an ureteric stent. Percutaneous nephrostomy and percutaneous biliary drainage represent about 30 % of his occupational exposure.

This radiologist is occupationally exposed in interventional radiology for 18 years. According to medical documentation in his family there were not hereditary important deseases. He was healthy and had no visible (or clinical) signs of radiation leasions untill 1993. Medical examination from 1993 showed regular biochemical and hematological parameters, exept lower white blood cells (but still in the range of expected values). The same year physician regestrated dry skin of the hands. From 1995 the radiologist was not answering the calls for medical examinations untill 1999. when we found: art. hypertension, cataracta complicata incip. ou., onychodystrophia and hyperceratosis mani bill. The most important were skin changes which can be considered as precancerogenes

lesions. We tried to reevaluate this radiologist occupationally exposure because these changes can be considered as late effects of cumulative occupational doses.
Cytogenetics tests results didn't show unstable chromosomal aberations as parameter of recent irradiation. Micronucleus test showed signifficantly high rate - 46/1000. In vitro radiosensitivity was normal (micronucleus rate was 198/1000). All these results can be considered as late effects of ionizing radiation exposure.
Previous whole body exposure mesurements were performed by TLD typeCaF_2:Mn worn under the lead apron. Under these circumstances, personal monitor located under the apron on the trunk of the individual indicates the dose equivalent to the shielded trunk of the body. Our measurements included nine dosemeters at unshielded and shielded parts of the body.

MATERIALS AND METHODS

All measurements were performed by calibrated TLD typeCaF_2:Mn.
Calibration of the intensities of the radiation fields is traceable to the Federal Bureau of Measures and Precious Metals (further: FBMPM). The ionization chambers and electrometer used for field calibration are owned by national metrological institution FBMPM and are traceable to primary Yugoslav standards as well as to international standards. The intensity of the field is assessed in terms of air kerma with the field collimated to minimize unwanted scatter. Conversion coefficients from air-kerma to the dose equivalent vary as a function of photon energy, angle of incidence and size and shape of backscatter medium. Personal monitors are irradiated to a known value of dose equivalent while mounted on 30 x 30 x 15 cm slab (polymethylmethacrylate) PMMA phantom. An anterior to posterior radiation condition is simulated. Multiple personal monitors are irradiated to obtain informations on accuracy and precision. As there are limitations when we use radiation qualities as metrological standards which often differ from the radiation qualities that personal monitors encounter in the working circumstances which often cannot be fully characterized we used users beam for the calibration purposes. We also simulated working conditions from the stand point of distances from the beam focus as well as appropriate holders and all elements which can be found in roentgen room. All dosimeters were put in tissue equivalent folies when we irradiated them in free-air with well known air kerma.
We put personal monitors at seven places where we expected higher doses (right and left eye, thyroide, neck , right shoulder, left and right hand) as well as on two places where ordinary low doses (chest and gonades) were expected. In estimation of effective dose we looked up them as single personal dosimeter at one specific place. We also used direct reading electronic device type PDM -102 Aloka placed on chest under the lead apron.
Medical exeminations were performed according to recent regylatory papers for occupational exposure.
All measurements were performed on SHIMADZU X-ray apparatus type IDR-1000, model F-2 with 1mm Al equivalent and maximume tube voltage of 150 kV. In this work X-ray scatter radiation was produced at various X-ray tube potentials in the range of 85 to 90 kVp with X-ray tube in the overtable position. Medical staff were in proximity of patient undergoing a procedure.
In the two chosen procedures duration of the procedure nephrostomy was 15 min in average and drainage 20 min in average.
We used NCRP Rep.122 as well as ICRP Rep.47 for estimating H_E in practice using personal monitors. [1,2]

RESULTS

Mean dose in conventional TL dosimetry was 10.52 mGy per year with dosemeter worn under the protective apron.
Electronic device recorded about 9 μSv per procedure also worn under the apron.

Results of individual hand doses are given in table I.

Table I Radiologists individual hand dose measurements results

procedure	biliary drainage	nephrostomy
mean hand dose per procedure [μSv]	221	31
number of procedures per year	63	200
screening time [min]	20	15
total hand dose per year [mSv]	13.9	6.2

Our measurements results are comparable with other authors results who reported similar cases.[3,4,5]
Estimated cumulative hand dose for eighteen years occupational exposure, based on measurements of these two procedures taking into account that they represent 30 % of total exposure, is about 3.3 Gy. This dose can be reduced by improving tehnique and reducing the number of procedures per radiologist.

CONCLUSION

In interventional radiology total doses at the unprotected parts of the body, especially hands, can exceed the dose limits recommended by ICRP. Our results showed that hand doses for mentioned two procedures did not exceeded recommended dose limits but taking into account cumulative dose effects can couse radiation skin injuries and substantiate the need for both, medical and physical, monitoring in aim to keep doses as low as possible.

REFERENCES

1. NCRP Report No.122: Use of personal monitors to estimate effective dose equivalent and effective dose to workers for external exposure to low-LET radiation, NCRP, Bethesda (1995).
2. ICRU Rep. No.47 Measurement of Dose Equivalents from External Photon and Electron Radiations, ICRU, Bethesda (1992).
3. M.L. Ramsdale, W.J. Walker, P.W. Horton: Extremity doses during interventional radiology, Clin.Radiol.41(1) (1990) 34-36
4. E.Vano,L. Gonzales, E.Guibelalde,J.M.Fernandez,J.I.Ten: Radiation exposure to medical staff in interventional and cardic radiology, Br.J.Radiol. 71(849) (1998) 954-960
5. T.Vehmas: What factors influence radiologist' finger doses during percutaneous drainages under fluoroscopic guidance, Health Phys. 65(2) (1993)161-163

INTERNAL RADIATION DOSIMETRY, PHARMACOKINETICS AND BIODISTRIBUTION OF THE ^{99M}TC LABELED IOR EGF/R3 MONOCLONAL ANTIBODY

Leonel A. Torres, Alejandro Perera, Mayra Ramos, Abel Hernández, N. Iznaga, Maria E. Solano, Ivette Alvarez, José L. Rodríguez.

Center for Clinical Research

Principal Author: Leonel A. Torres Aroche
Telefax: 537243298, e-mail: leonel@infomed.sld.cu

ABSTRACT

The aim of this work was to assess the internal radiation dosimetry, human pharmacokinetics and biodistribution of the ^{99m}Tc-labeled murine monoclonal antibody (MAb) ior egf/r3, used for diagnosis of epitelial tumors. Five patients were included in this study. Multiple blood and urine samples were collected and sequential anterior and posterior whole-body scintigraphies up to 24 hr post-injection were acquired from all patients. The internal radiation dosimetry was estimated using the methods developed by the Medical Internal Radiation Dosimetry (MIRD) committee. Raw data were computed from operations between scintigraphic images and regions of interest (ROI). The residence times of the activity on the source organs were computed to assess the absorbed dose by 24 target organs. The dosimetric results showed that liver, gallbladder and spleen received the higher absorbed dose. The computed mean values were 0.69 mGy/MBq, 0.19mGy/MBq and 0.37 mGy/MBq, respectively. The mean value of effective dose was 1,2E-01 mSv/MBq and the effective equivalent dose was 9,2E-02 mSv/MBq. The Pharmacokinetics and Biodistribution results showed that this compound have a biexponential plasmatic and blood clearance with a rapid biodistribution phase and a slower elimination phase. This compound was excreted by the urinary and hepatobiliary systems. Liver was the principal target organ of this product showing a great retention of the MAb. These dosimetrics results have allowed to use the ior egf/r3 kit in a safe and controlled way.

INTRODUCTION

Nowadays the cancer of epithelial origin constitutes one of the first causes of death all around the world. That kind of tumors, like cancer of lung, digestive track, breast and others, have a 10-30-fold overexpression of the epidermal growth factor receptor (EGFr). On the basis of these findings, monoclonal antibodies (MAbs) able to recognize the EGFr and to block its kinase activation, have been developed for the therapy and diagnosis of that kind of tumors [1]. The 99mTc labeled MAb ior egf/r3 developed in the Center of Molecular Immunology have showed potentiality for the diagnosis of tumors from epithelial origin.

To estimate the value of the antibody it is important to consider not only the detection of the tumor but also the radiation exposure of the patients. Methods developed by the Medical Internal Radiation Dose (MIRD) Committee (Loevinger et al, 1988) were used to calculate mean doses to models representing various organs and tissues in order to allow the evaluation of the risks associated to the administration of radiopharmaceuticals for diagnostic purposes. The main aim of this study was to assess the human radiation dosimetry, pharmocokinetics and biodistribution of the ^{99m}Tc- MAb ior egf/r3.

MATERIALS AND METHODS

Patients.

The 99mTc-ior egf/r3 was administered to five patients (4 females and 1 male), aged from 58 to 69 years (mean age 63.0±4.2 years). The weight and height mean values were 71.6±14.1 Kg and 161±66cm, respectively. All patients gave informed consent. Three of them had primary tumor without treatment and two were suspected of having recurrences after surgery. All lesions were confirmed by biopsy (4 adenocarcinomas of rectum and one carcinoma of annal canal).

Monoclonal Antibody Kit and Radiolabeling.
The ior-egf/r3 MAb kit contains a highly specific murine IgG2a isotype antibody, which recognizes human epidermal growth factor receptor (h-EGFr). It was produced in the Center of Molecular Immunology (Havana, Cuba) by standard hybridoma techniques as previously described Fernandez et al., 1989 [1]. The freeze dried, sterile and pyrogen free kit was obtained according to the Schwarz's method [2,3]. Each vial contained 3mg of MAb. Kits were labeled with 1.66 GBq of pertechnetate from the $^{99m}Mo/^{99m}Tc$ generator (Amertec II, Amersham, UK) and activity was measured in a dose calibrator (Comp-U-Cal II, Victoreen Inc, USA.)

Quality Control and Radiopharmaceutical administration.
The labeling efficiency was assessed by ascending chromatography. The samples were applied on Whatman 3MM 1x10 strips and immediately placed in development tanks. After that, the strips were dried and the distribution of activity was determined using a ratemeter (SR8, Nuclear Enterprises, UK). The radiopharmaceutical was injected intravenously through an antecubital vein. The administrated dose was 1485.1 ± 86.3 MBq (mean ± SD).

Pharmacokinetics and excretion analysis.
Following intravenous injection, 3-4 ml of blood samples were collected from an antecubital vein opposite to the injection side at different time intervals. A bicompartimental model was applied in order to perform the pharmacokinetics analysis. Complete urine samples were also collected up to 24 hrs postinjection [4]. The radioactivity in blood, plasma and urine (0.3 ml) samples in duplicate was determined using a ratemeter (SR8, Nuclear Enterprises, UK) and expressed as a percentage of administered activity. Appropriate corrections were made for decay with time of injection as reference time.

Imaging.
Whole body images were performed using a Sophy Gamma Camera (Sopha Medical inc., Canada) fitted with a low-energy high-resolution, diverging parallel-hole collimator to increase the lateral viewing aspect. Anterior and posterior whole-body images were acquired using a 20% window centered on the 140 KeV emission from ^{99m}Tc at 10 min, 1, 3, 5 and 24 hr post-injection using a gantry speed of 20 cm/min. All whole-body images were stored on the computer in 2048x512 word mode matrix.

Biodistribution and Dosimetry.
All images were processed in a SOPHY-20P system. The geometric mean of anterior and posterior images was obtained. Regions of interest (ROI) were drawn over heart, liver, spleen, bladder, upper large intestine (ULI) and low large intestine (LLI), which were considered as the source organs and total counts were computed. Whole body and source organs activity was expressed as percent of the total administered activity remaining in each one at selected time intervals. The MIRD Committee method for determining absorbed dose was used [5,6]. The time-activity curves for each source organ and the remainder of the body tissues were calculated from the percent of injected dose values and fitted to exponential disappearance curves to estimate initial organ uptakes and clearance half times. Whole-body activity was initially 100 % following an exponential clearance by biological removal and physical decay of activity. Cumulative activities and residence times for each source organ were estimated from the integral under the time-activity curves. ***Absorbed dose***: The absorbed doses to whole body and normal organs were estimated using the computed residence times and the modified S values from MIRD Pamphlet No. 11. The mean absorbed dose per unit of administered activity was computed according to the method described in the MIRD Primer . The effective dose was calculated based on the results of the absorbed dose estimates to various target organs.

Statistical analysis.

Mean and standard deviation (SD) values were calculated. Curves were fitted to a biexponential model by using non-linear regression method. Data were processed using SPSS for Windows and the Microcal Origin software [7].

RESULTS.

Pharmacokinetics and excretion.

Counts versus time curves from blood and plasma samples were computed and fitted to a biexponential equation ($A*\exp(-\lambda t) + B*\exp(-\lambda t)$). From the rate constants of these curves, the half-life of the fast and slow components, were computed. Fitted curves showed a half-life of the initial fast component (distribution phase) of 9.1 ± 8.4 min (plasma) and 12.2 ± 4.4 min (blood) and a half-life for the predominant late slow component (elimination phase) of 6.6 ± 1.6 hrs (plasma) and 10.8 ± 6.8 hrs (blood). The percent of injected dose excreted by urine under physiological conditions, up to 24 hours post-injection, was 4.7 ± 0.4 %. On the other hand, it was excreted 9.9 ± 1.8 % of the injected dose by the hepatobiliar system.

Biodistribution

The biodistribution patterns of the ^{99m}Tc labeled MAb ior egf/r3 in humans is due to a combination of biological behavior of the MAb itself and its target antigen. Quantitative biodistribution data from all patients were very similar for all the source organs. Biodistribution data are presented in Table No.1 (values corrected by decay). The most notable tissue localization occurs in the liver, spleen and heart. Liver uptake was rapid with a peak at 1h post-injection (61.2%) and a great retention (T½ eff = 5.3 hr, T½ Biol.= 45.0 hr) because of the high number of human epidermal growth factor receptors (hEGFr) present in it. The ULI and LII were found as source organs due to the hepatobiliary system is the most important excretion way of this compound. Approximately 60.2% of the injected MAb remain in the total body at 24 hr postinjection, showing an effective and biological half-life of 5.61 and 84.8 hrs respectively.

Table No.1. ^{99m}Tc-ior egf/r3 Human biodistribution for the source organs (% of administered activity, mean ± SD)

	Time (Hrs)				
Source Organ	*0*	*1*	*3*	*5*	*24*
Heart	3.5	2.1	1.9	1.7	0.4
Liver	48.8	61.2	58.3	59.3	41.2
Spleen	4.2	4.6	4.2	1.9	0.7
ULI	0	0	0	1.0	4.7
LLI	0	0	0	1.2	5.2
Bladder	0.5	0.5	1.2	1.2	0
Whole body	100	95.2	93.6	88.9	60.2

* There was no statistical difference ($p < 0.05$ paired t-test) between all patients.

Intrenal Radiation Dosimetry.

The radiation dosimetry calculations were made using the residence times obtained from the biodistribution data. The assessed absorbed dose of 24 target organs and the effective dose after the injection of the Labeled MAb ior egf/r3 are presented in Table No.2. The liver (0.69 mGy/MBq), the gallbladder wall (0.19mGy/MBq) and the spleen (0.37 mGy/MBq) received the highest absorbed doses. The effective dose and the equivalent effective dose were of 0.12 and 0.092 mSv/MBq respectively. Liver was the principal contributor organs to the absorbed dose per organ.

Table No.4. Normal organ dosimetry for the labelled mAb ^{99m}Tc-ior egf/r3 kit (mGy/MBq)

TARGET ORGANS	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Average
Adrenals	0,0959	0,1220	0,1230	0,1290	0,0758	0,1100

Gallbladder Wall	0,1780	0,2120	0,1970	0,2380	0,1350	0,1900
LLI Wall	0,1270	0,0475	0,1330	0,0999	0,0452	0,0910
Small Intestine	0,0481	0,0537	0,0751	0,0554	0,0304	0,0530
ULI Wall	0,0967	0,0753	0,2240	0,1040	0,0432	0,1100
Heart Wall	0,0836	0,0964	0,0981	0,0935	0,0739	0,0890
Kidneys	0,0683	0,0897	0,1030	0,0923	0,0556	0,0820
Liver	0,6630	0,7680	0,6550	0,9020	0,4690	0,6900
Red Marrow	0,0270	0,0382	0,0363	0,0328	0,0218	0,0310
Spleen	0,1050	0,2230	1,1100	0,2500	0,1840	0,3700
Urine Bladder Wall	0,0581	0,0883	0,0945	0,0996	0,0516	0,0780
Total Body	0,0434	0,0577	0,0560	0,0560	0,0333	0,0490
EFF DOSE EQ.	0,0943	0,1170	0,1730	0,1270	0,0731	0,1200
EFF DOSE	0,0848	0,0907	0,1280	0,1030	0,0554	0,0920

CONCLUSIONS.

The pharmacokinetics and biodistribution of ^{99m}Tc-labeled Monoclonal Antibody ior egf/r3 have shown that this compound has a biexponential blood and plasmatic clearance with a rapid biodistribution phase and a slower elimination phase. Liver is the target organ of this product and presented an uptake peak at 1hr post-injection with a high retention. The dosimetric results showed that liver, gallbladder and spleen received the higher absorbed doses and it were also reported these values for 24 target organs. These results allow to use this radiopharmaceutical in a safe and controlled way.

REFERENCES.

1. Fernández, A.; Pérez, R.; Macias, A.; Velandia, A.; Alvarez I., Ramos, M. and Veloso, A. (1989). Generación y caracterización primaria de anticuerpos monoclonales contra el receptor del factor de crecimiento epidérmico. Interferón y Biotecnología, 6(3), 289.

2. Mather, S. J. and Ellison, D. (1990). Reduction-mediated ttechnetium-99m labeling of monoclonal antibodies. J. Nucl. Med. 31, 692.

3. Schwarz, A. and Steinstrasser, A. (1987). A novel approach to Tc-99m-labeled monoclonal antibodies. J. Nucl. Med. 28, 721 (abstract).

4. Yamaoka, K.; Nakagawa, T.; Uno, T. et al. (1978). A nonlinear multiple regression program, MULT(2)(Bayes), based on a Baye(s) algorithm for microcomputers. J Pharmacobio Dyn 8: 246-256.

5. Snyder, WS.; Ford, MR. et al. (1975). "S" absorbed dose units cumulated activity for selected radionuclides and organs. MIRD pamphlet no. 11. New York: Society of Nuclear Medicine.

6. Loevinger, RL.; Budinger, TF; Watson EE.(1988). Eds. MIRD primer for absorbed dose calculations. New York: Society of Nuclear Medicine.

7. Yamaoka, K.; Nakagawa, T.; Uno, T. (1978). Statistical moments in pharmacokinetics. J Pharmacokin Biopharmaceutics 6: 547-558.

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PATIENT DOSE SURVEYS AND THE USE OF LOCAL AND NATIONAL DIAGNOSTIC REFERENCE LEVELS

Ramsdale M L, Peet D, Hollaway P, and Rust A.
Regional Radiation Protection Service
Royal Surrey County Hospital
Guildford, Surrey, UK *radprot@royalsurrey.nhs.uk*

Abstract
Patient doses have been assessed routinely as part of quality assurance programmes in a group of National Health Service and private hospitals in a southern English health region. Surveys of patient dose have been conducted in plain film radiography, fluoroscopy, computed tomography, mammography and dental radiography. In keeping with national guidance, dose parameters used were entrance skin dose for radiography, dose area product for fluoroscopy, effective dose and dose length product for computed tomography (CT), mean glandular dose for mammography and air kerma and dose width product for dental intra-oral and orthopantomography (OPG) respectively. Comparison of results against recommended standards showed that in plain film radiography and fluoroscopy, doses were well below national reference levels and corresponding local reference levels were adopted at about 75% of the national figures. Elsewhere in CT, mammography and dental radiography, doses were generally in line with national trends. Overall, as an integral part of the QA programme, the dose surveys have contributed greatly to the users understanding of patient dose and in several instances has led to real optimisation.

Introduction

As part of the provision of a radiation protection and diagnostic radiology physics service to around 50 hospitals, 30 mammography units and 130 dental practices in the South East of England, sampling of the doses received by patients during common X-ray examinations is undertaken. Results are compared to relevant Diagnostic Reference Levels (DRLs) as an aid to optimisation and in compliance with the EC Directive [1] and UK legislation [2] on the protection of the patient.

Methods

Patient dose surveys for plain film radiography and fluoroscopy have been undertaken periodically in accordance with the national dose protocol which recommends that such surveys are carried out at least once every 3 years [3]. Surveys of patient dose have also taken place in computed tomography, mammography and dental X-ray.

For plain film radiography, the patient dosimetry programme started in 1993 and two cycles were completed covering 64 and 77 X-ray departments respectively. In accordance with the recommended protocol, thermoluminescent dosemeters (TLDs) were used to measure entrance skin doses for 5 common examinations; chest, skull, lumbar spine AP, lateral lumbar spine and pelvis. Only standard size patients (60 to 80 kg) were used in the study with generally 10 patients per examination.

Dose area product (DAP) is the recommended dose parameter for complex examinations including fluoroscopy. Since 1995 DAP data have been collected for barium studies, angiography and interventional procedures covering 37 screening rooms in 23 hospitals involving about 10,000 patients.

In CT the effective dose for common examinations has been assessed from knowledge of exposure protocols and measured computed tomography dose index (CTDI) values utilising published CT scanner data [4]. An initial patient dose survey of 8 CT scanners was undertaken in 1996 and subsequently repeated in 1999/2000 for 7 of the original units plus 3 new scanners. In keeping with the European protocol [5], doses are now also compared to the parameter dose length product (DLP).

The Service undertakes routine performance measurements on 30 mammography units locally including 12 in the national breast screening programme and 18 located in the symptomatic mammography sector. In accordance with the recommended protocol [6] assessment of mean glandular dose is undertaken routinely every 6 months for the 'standard breast' model. Calculation of mean glandular dose using exposure and breast thickness data from samples of patients undergoing mammography is also carried out periodically.

Radiation protection and performance measurements are undertaken on all dental X-ray on a 3-yearly cycle. Since 1997 doses have been assessed on 357 intra-oral and 70 OPG X-ray units using measurements of radiation output. In keeping with national guidance [7] dose parameters used were skin entrance dose for intra-oral and dose width product for OPG.

Results

The results of two rounds of patient dose surveys for plain film radiographic examinations carried out over 1992-1995 and 1996-1999 respectively is summarised in table I. The mean values presented across all hospitals for the common examinations studied are compared to the national reference doses published in 1992. The local doses were well below national levels and local reference doses, also shown, were derived from the first round of local dose measurements.

Table I. Skin entrance dose for plain film radiography

	No of pts	Mean dose (mGy)		% National Reference Dose		Local ref dose (mGy)
		92-95	96-99	92-95	96-99	
Abdo AP	682	5.1	4.8	51	48	7
Chest PA	1601	0.14	0.12	50	40	0.2
L spine AP	866	5.9	5.2	59	52	7
L spine Lat	876	15.3	13.2	51	44	20
Pelvis	638	5.2	4.0	52	40	7

The results of DAP measurements for more than 7500 patients are summarised in table II, highlighting the mean DAP for barium enemas and meals across 30 screening rooms. In the 1992 dose protocol these were the only examinations commonly undertaken in local screening rooms where reference doses were provided. Again, local doses were generally well within national figures and consequently local reference doses based on these values were adopted. The relative impact of local and national reference doses for barium enemas is illustrated in the distribution of doses in Figure 1.

Table II. Dose area product values for fluoroscopy examinations

Examination	Nos of patients	Mean DAP Gy cm2	% National Ref Level	Local Ref Dose Gy cm2
Ba Enema	3242	31.8	53	40
Ba Meal	1032	11.7	47	15
Ba Swallow	540	7.5	-	10
Ba FT	184	13.7	-	20
Femoral Arteriogram	676	54.6	-	80
Coronary Angiogram	372	35.9	-	50
Coronary Angioplasty	88	34.8	-	35
Venogram	558	4.4	-	5
ERCP	399	11.1	-	12
HSG	216	5.9	-	8
Nephrostomy	92	11.9	-	16
Fibroid embolisation	255	84.0	-	105

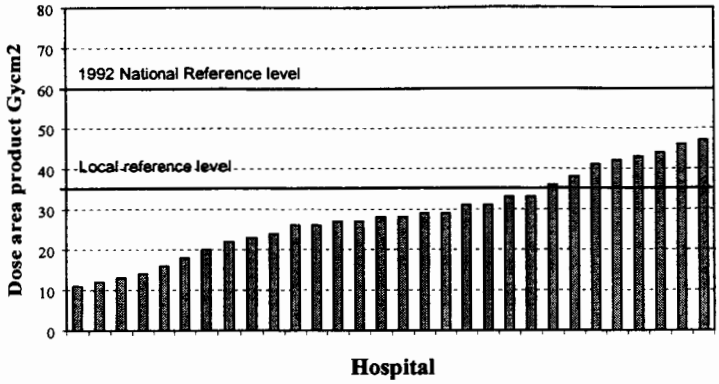


Figure 1. Dose area product for barium enemas

Table III Effective and dose length product for computed tomography examinations

Examination	Dose (mSv)		Dose-length Product (mGy cm)			
	Mean	NRPB Mean	Minimum	Maximum	Mean	EC Ref
Brain	2.08	1.78	316	2196	870	600
Neck	2.35	-	143	1107	552	-
Pelvis	6.93	7.12	216	655	423	600
Abdomen	7.01	7.58	469	989	414	800
Chest (normal)	9.04	7.80	162	790	409	650
Liver	6.00	7.17	151	723	364	-
IAM	0.63	0.35	100	641	298	-
L-spine	4.64	3.33	56	450	292	-
Chest (high resolution)	1.34	-	30	104	92	-

The mean effective dose for common CT examinations, based on a standard patient model, is shown in table III. These values are also compared to the means from a national survey conducted by the National Radiological Protection Board (NRPB) [8]. The corresponding range and mean of DLPs is also presented for the same nine examinations.

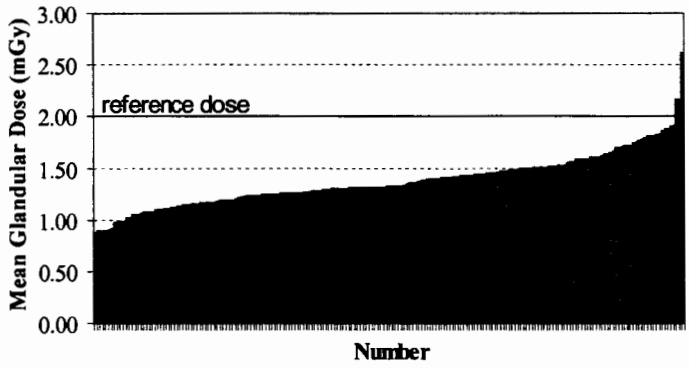


Figure 2. Mammography Dose to the "standard breast"

The results for mammography in Figure 2 indicate variation in dose due to equipment factors only as a 'standard breast' is defined. Variations in X-ray equipment design, speed of the film and screen combination and variation in film optical density are the main factors affecting the distribution of patient dose. The reference dose indicated on the graph is used as a maximum recommended level, above which further optimisation of the system is indicated or justification for continued use is required. Surveys of patient dose based upon exposure factor data for real examinations additionally include variations due to the size and composition of the breast and also operation of advanced automatic exposure systems with the capability to modify X-ray beam quality.

Patient doses in dental radiology are illustrated in figs 2 and 3 for mandibular molar intra-oral and OPG examinations respectively.

Figure 2:
Dental Intra-oral doses (Mandibular Molar) mGy

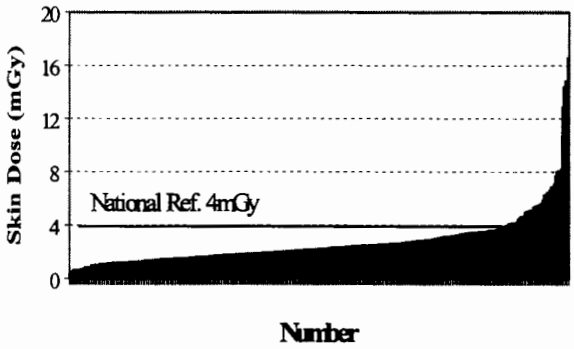
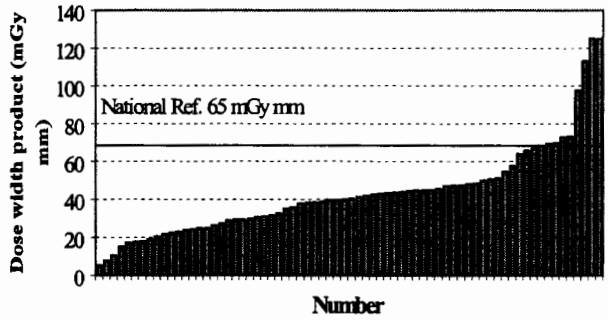


Figure 3
Dental Panoramic doses (mGy mm)



Discussion and Conclusions

In the UK reference doses for radiography and fluoroscopy, based on dose measurements in the late 1980's and very early 1990's, were published in 1992 as part of the national dose protocol [3] and have remained unchanged. The first round of local dose measurements for radiography confirmed, not unexpectedly regarding the increase in film speed and other dose reduction features introduced since the 1980's, that examinations at all hospitals were generally well within national reference doses. Typically the mean doses for each examination were about 50% of the reference dose. Since the national reference dose no longer impacted on the optimisation process, local reference doses, based on the 75th percentile of the dose distribution from the first round of measurements, were adopted. As shown in table I, the second round of measurements showed slight reductions in mean doses for most examinations.

A similar picture emerges for the fluoroscopy dose surveys where the measured dose area products for barium enemas and meals were again at about 50% of the national reference dose. Local reference doses were adopted in the same manner for these and ten other examinations.

In CT no formal reference doses have been published in the UK and instead the doses for examinations have been compared to mean dose values published by the NRPB [8] following a survey of CT practice. In a number of cases, by demonstrating that doses at some hospitals exceeded national means, radiologists were persuaded to review examination protocols and optimise exposure factors and technique.

In mammography, the use of a reference dose based on a 'standard breast' has enabled identification of systems where patient dose has not been optimised, or imaging materials and X-ray equipment have been poorly matched. Also, identification of incorrectly adjusted film processors or AEC systems has been possible.

In dental radiography, reference doses have only recently been recommended [7]. As illustrated in figures 2 and 3, small but significant numbers of clinics exceeded the reference doses. Dose reduction strategies were then targeted at these clinics.

Overall, the use of reference doses in all areas of radiology is demonstrated to be beneficial to the optimisation process and even where no formal national figures exist comparison can be drawn with relevant local dose measurements. Small but significant dose reductions have occurred and the use of local reference dose levels, where the user relates naturally to other local hospitals, has been found to be of particular merit.

References

[1] Council Directive on Health Protection of Individuals against dangers of Ionising Radiation in relation to Medical Exposures. 97/43/EURATOM L180 Vol 40 (1997).

[2] Her Majesty's Stationary Office (HMSO) The Ionising Radiation (Medical Exposure) Regulations 2000, Statutory Instrument 2000 No.1059, (HMSO, London) (2000).

[3] IPSM, NRPB AND COLLEGE OF RADIOGRAPHERS, National Protocol for Patient Dose Measurements in Diagnostic Radiology (NRPB, Chilton) (1992).
[4] JONES DG and SHRIMPTON PC Survey of CT Practice in the UK, Part3: Normalised organ doses for X-ray CT calculated using Monte Carlo techniques. NRPB SR250 (NRPB, Chilton) (1991).
[5] European guidelines on Quality Criteria for CT EUR 16262 (Luxembourg) (2000).
[6] INSTITUTE OF PHYSICAL SCIENCES IN MEDICINE The Commissioning and Routine Testing of Mammographic X-ray Systems Report No.59 2nd ed (IPEM York) (1994).
[7] ADVISORY GROUP ON IONISING RADIATION Guidelines on patient dose to promote the optimisation of protection for diagnostic exposures Documents of the NRPB Vol10 No 1 (Chilton NRPB) (1999)
[8] SHRIMPTON PC et al. Survey of CT Practice in the UK Part 2: Dosimetric Aspects. NRPB SR249 (NRPB, Chilton) (1991)

CYTOKINESIS BLOCK MICRONUCLEUS IN HUMAN LYMPHOCYTES: EFFECT OF LOW DOSE RADIATION IN VASCULAR RADIOLOGY.

[1]ALCARAZ, M.; [1]ROSA, B; [1]NAVARRO, J.L.; [1]DATO, M.J, [1]ACEVEDO, C. and [2]CANTERAS, M.

[1]Radiology and Physical Medicine Department and [2]Biostatistical Department. Faculty of Medicine, University of Murcia, 30100 Espinardo, Murcia, Spain.

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ABSTRACT

This paper studies the frequency of occurrence of micronuclei (MN) in irradiated patients' lymphocytes during medical radiodiagnostic examinations by cytogenetic block (CB) technique.

Firstly, dose-response curves have been obtained in order to determine MN occurrence in peripheral blood lymphocytes in nine healthy patients in connection with the radiation doses administered. Subsequently, total blood samples of 25 patients having undergone any complex radiological procedure have been analysed. Four different blood samples have been collected from those patients as follows: : **1)** prior to irradiation, corresponding to a non-irradiated control sample; **2)** prior to irradiation, to which the radiological contrast was added at a concentration of 5%; **3)** sample obtained at the beginning of the examination but remaining *in vitro*, exposed to the primary irradiation beam throughout the radiological exploration; **4)** sample obtained from the patient at the end of the radiological procedure.

Results show that MN frequency in lymphocytes with cytogenetic block and the ionizing radiation dose administered are interdependent. A significant increase of MN in patients' samples obtained after radiological examinations (irradiated samples) compared to those obtained before examinations (control samples) ($p<0,01$) has been observed. The radiological contrast medium has not produced significant changes in MN induction to the concentration used in this study.

The micronucleus assay (CB) is simple and could be applied in situations where physical dosimetry is not possible. It could be used to assess individual sensitivity to radiation and to determine exposures to low doses of irradiation if a previous comparative pattern were available for the exposed worker or patient.

INTRODUCTION

The cytokinesis blocking method in lymphocytes, described by Fenech and Morley (1985) [1] and based on earlier observations by Carter [2], is now considered to be the best for the micronucleus assay for dosimetry purposes.

In the present work the "in vitro" dose response for X-irradiation, gamma-radiation (Cs-137) and "in vivo" response in patients irradiated during medical radiodiagnostic exploration has been studied.

MATERIAL AND METHODS

The appearance of micronuclei (MN) in the lymphocytes of patients irradiated during medical radiodiagnostic explorations was studied to establish the existence of a dose-response relationship between irradiation with low doses of X-rays and the frequency of micronucleus appearance and to determine the importance of the Cytogenetic Block test to reveal these exposures.

$$D = \alpha + \beta \cdot y$$
$$D\ (mGy) = -53.66 + 11.26 \cdot$$

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RESULTS

Results show that MN frequency in lymphocytes with cytogenetic block and the ionizing radiation dose administered are interdependent (Fig.1,2). The results show a dependency relationship between micronucleus frequency and patient age ($r = 0.9237$; $p<0.01$).

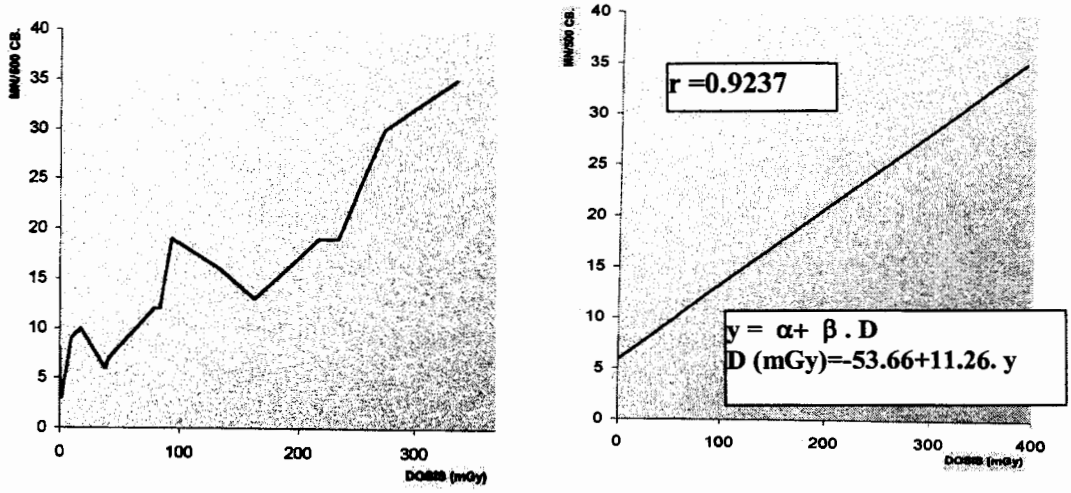


Fig. 1: Dose-effect curves for X-ray induced micronuclei (MN/500 CB) (0-335 mGy).

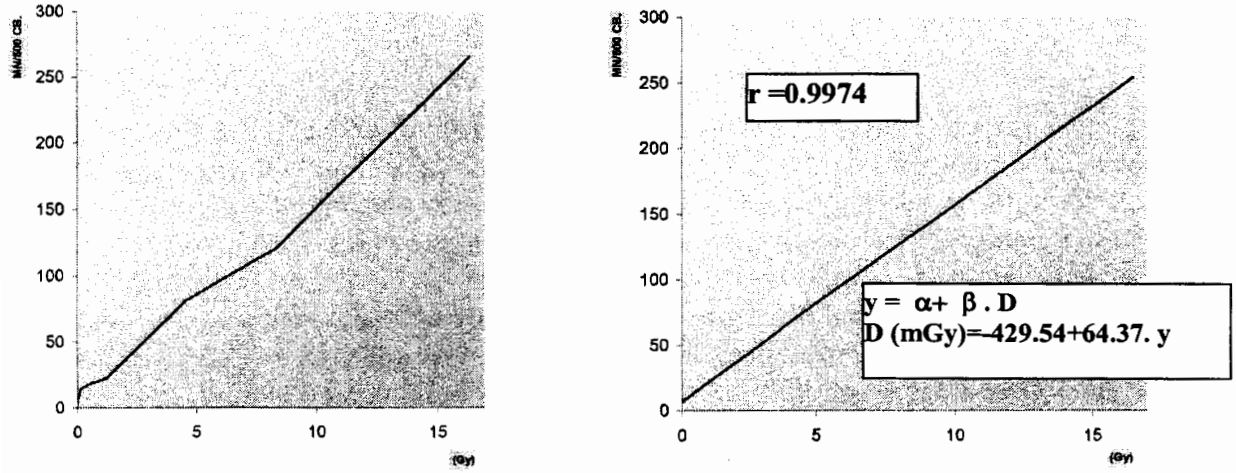


Fig. 2: Dose-effect curves for gamma-irradiation induced micronuclei (MN/500 CB) (0-16'362 Gy).

Likewise, a significant increase of MN in patients' samples obtained after radiological examinations (irradiated samples) compared to those obtained before examinations (control samples) ($p<0,01$) has been observed. The radiological contrast medium has not produced significant changes in MN induction to the concentration used in this study

			PREIRRADIATION				POSTIRRADIATION				
Code	Age (years)	EXPLORATION	Cells (CB) scored	Cells without a MN	Cells with MN	Σ MN	Cells (CB) scored	Cells without a MN	Cells with MN	Σ MN	Dose (mGy)
1	21	Arteriography of membrum.	500	497	3	3	500	497	3	3	0.58
2	26	Arteriography of membrum .	500	497	3	3	500	496	4	5	0.38
3	41	Coronary angiography.	500	496	4	4	500	489	11	14	17.32
4	42	Aortography.	500	496	4	4	500	497	3	3	4.24
5	46	Coronary angiography.	500	497	3	3	500	496	4	4	6.45
6	48	Aortography.	500	498	2	2	500	498	2	2	4.77
7	50	Coronary angiography.	500	496	4	4	500	495	5	5	4.28
8	50	Aortoiliac angiography.	500	497	3	3	500	496	4	4	1.21
9	50	Coronary angiography.	500	496	4	4	500	494	6	7	9.45
10	53	Arteriography of membrum	500	495	5	5	500	496	4	9	0.53
11	54	Arteriography of membrum.	500	496	4	4	500	493	7	8	1.51
12	54	Percutaneous cholangiogr..	500	491	9	11	500	493	7	9	4.19
13	54	Coronary angiography.	500	498	2	2	500	495	5	6	4.66
14	60	Coronary angiography.	500	497	3	3	500	493	7	9	4.53
15	60	Coronary angiography.	500	484	6	7	500	490	10	15	3.73
16	62	Coronary angiography.	500	489	11	11	500	491	9	9	2.10
17	64	Excretory urography.	500	489	11	12	500	486	14	20	0.32
18	64	Excretory urography.	500	493	7	7	500	492	8	10	0.25
19	66	Cholangiography transkerh.	500	492	8	10	500	490	10	10	1.97
20	67	Coronary angiography.	500	479	21	23	500	485	15	16	1.88
21	68	Coronary angiography.	500	488	12	12	500	484	16	18	4.07
22	72	Esophagoplasty.	500	490	10	10	500	490	10	13	2.20
23	77	Angioplasty.	500	492	8	10	500	490	10	10	4.10
24	82	Renal arteriography.	500	493	7	7	500	495	5	5	0.71
25	84	Aortography.	500	487	13	13	500	495	5	6	1.072

Fig. 3: Number of micronuclei (MN) in binucleated cells (BN) and distribution of BN presenting one o more micronuclei in the patients irradiated during medical radiodiagnostic exploration (Pre-irradiation: sample I; Post-irradiation: sample IV) .

CONCLUSION

The micronucleus assay is simple and could be applied in situations where physical dosimetry is not possible. It could be used to assess individual sensitivity to radiation and to determine exposures to low doses of irradiation if a previous comparative pattern were available for the exposed worker or patient.

REFERENCES

FENECH, M, MORLEY, A A, Mesurement of micronuclei in lymphocytes. Mutation Research 147 (1985) 29-36.

FENECH, M, MORLEY, A,A, Cytokinesis block micronucleus method in human lymphocytes: effect of in vivo ageing and low dose X-irradiation. Mutation Research 161 (1986) 193-298.

CARTER, S B, Effects of cytochalasins on mammalian cells, Nature 213 (1967) 261-264.

CONTROL DE CALIDAD Y PROTECCIÓN RADIOLÓGICA EN ODONTOLOGÍA: I. RADIOLOGÍA INTRAORAL

[1]MARTINEZ-BENEYTO, Y.; [1]ALCARAZ, M.; [1]JÓDAR-PÓRLAN, S.; [1]SAURA-INIESTA, A.M. y [2]VELASCO-HIDALGO, E.

[1]Area de Radiología y Medicina Física. Facultad de Medicina y Odontología. Universidad de Murcia. 30100--Espinardo. [2]Unidad Técnica de Protección Radiológica ASIGMA, S.A. 30202-CARTAGENA .

ABSTRACT.

This paper studies 2524 official reports on quality assurance in dental radiography, made in the context of the three first revisions of these dental clinics as a result of the entry into force of the regulations establishing the duties for this type of facilities. In the results section we present a quantitative analysis of the facilities equipped with an intraoral device, making a especial reference to the brands they have available, as well as their physical features (KV, mAs, filtration, length of cone) and the deviations detected in their operation. Some of the features in the process of obtaining radiological images at those facilities (Film control, development time, liquid renewal) are determined, and the average dose of ionizing radiation used in order to obtain the radiological image of the same tooth is presented.

This paper shows, in a quantitative way, the characteristic features of intraoral dental radiology in our medium. The study is intented to be continues during the next years, what would allow the assessment of the prospective improvement in dental radiological performances as a result of the newly established regulations.

INTRODUCCIÓN

La radiología dental es la exploración de diagnóstico radiológico más frecuente del mundo industrializado y representa casi el 25% de todos los exámenes radiológicos realizados en la Unión Europea.

En 1996 se instauró una nueva normativa en la que, con carácter de norma básica sanitaria, se establecen los criterios de calidad en radiodiagnóstico para mejorar el acto radiológico médico y evitar exposiciones inadecuadas o excesivas. Como consecuencia de su entrada en vigor, las clínicas odontológicas que utilizan este tipo de aparataje radiológico dental, se han ido sumando al proceso de control de calidad realizado por unidades técnicas, instituciones u organismos previamente homologados por el Consejo de Seguridad Nuclear.

En este trabajo se presenta el primer análisis cuantitativo de los parámetros controlados en estos informes preceptivos de control de calidad y supone una revisión del proceso de obtención de imagen radiológica en estas clínicas odontológicas. Esto podría representar la situación actual de la radiología dental intraoral en nuestro país.

MATERIAL Y MÉTODO

Se estudian 2524 informes oficiales de control de calidad en radiodiagnóstico de clínicas odontológicas en las dos primeras revisiones de la instalación radiológica como consecuencia de la entrada en vigor del Real Decreto 2071/1995, por el que se establecen los criterios de calidad en radiodiagnóstico. Los informes se han realizado desde la segunda mitad del año 1996 hasta diciembre de 1998, por la U:T:P:R Asigma S:A., y corresponden fundamentalmente a instalaciones de carácter privado. Todas las clínicas habían sido previamente verificadas por diversas Unidades Técnicas de Protección Radiológica homologadas por el Consejo de Seguridad Nuclear. Todas las clínicas se encontraban legalmente autorizadas como instalaciones de rayos X con fines de diagnóstico dental en el momento de la realización de los informes.

RESULTADOS

Las clínicas estudiadas poseen algún tipo de aparatos de radiodiagnóstico para radiografía intraoral y se encuentran ubicadas en territorio español, fundamentalmente en tres comunidades autónomas españolas: Andalucía (1105/2524), Murcia (383/2524) y Comunidad Valenciana (361/2524).

Los resultados obtenidos contabilizan 52 modelos de aparatos de rayos X para radiografía intraoral, correspondientes a 22 fabricantes diferentes, y en donde estaca la casa Trophy con cerca del 59.74% (1524/2551) de todos los aparatos intraorales descritos. Estos aparatos funcionan con valores de kilovoltaje que oscilan entre los 50 kV y los 70 kV como valores mínimo y máximo respectivamente, funcionando el 71.36% (1563/2190) de los equipos con valores de 70 kV; la filtración del haz primario de radiación ha variado entre los 0.4 mm y los 3.4 mm de Al como valores extremos, observándose que el 98.85 % (2495/2524) de los equipos incorpora valores de filtración superior a 1.5 mm de Al, valor recomendado actualmente por la Unión Europea para la utilización de aparatos que funcionen a menos de 70 kV. Los equipos incorporan valores de miliamperaje que oscilan entre los 7-11 mA, siendo el 75.78% (1912/2523) de estos aparatos los que funcionan con 8 mA. La longitud del colimador que se utiliza para establecer la distancia recomendada entre el foco y la piel del paciente ha variado desde la inexistencia del mismo en algún caso hasta los 40 cms, según modelos descritos; el 87.47% de los equipos utiliza colimadores de 20 cm de longitud.

Los parámetros obtenidos sobre el funcionamiento del aparato estudiado en cada una de las clínicas dentales han puesto de manifiesto que el 10.61 % (268/2524) de los aparatos presentaban alteraciones superiores al 20 % en alcanzar el kV que venía descrito por el fabricante del aparato, un 7.05% (178/2524) de los equipos presentaban alteraciones en el tiempo de exposición marcado por el cronómetro del aparato y un 9.23% (223/2524) de las instalaciones presentaban desviaciones superiores al 20% en el rendimiento del tubo de rayos X (dosis de radiación por unidad de tiempo, mAs). Otras alteraciones importantes se han detectado con una frecuencia mucho menor; desviaciones en la reproducibilidad de la linealidad (no hay aumento de la dosis proporcional al tiempo de exposición) en un 4.36%, pero durante las dos primeras revisiones se observó además desviaciones en la reproducibilidad de la dosis (una misma técnica de exposición produce diferente dosis de radiación)(3/1370) y reproducibilidad del tiempo (una misma técnica de exposición se realiza con diferente tiempo de exposición) (3/1370).

Sólo el 16.14% (388/2404) de las instalaciones dispone de un disparador fijo instalado fuera de la sala de exploración, aunque un 82.53% (1984/2404) de las instalaciones dispone de un cable alargador de una longitud mayor de 2 metros. Se ha puesto de manifiesto que durante la segunda revisión se produce un aumento significativo de las instalaciones las que ubicaron disparadores fijos situados fuera de la sala de exposición (5.54% anual). Además se ha constatado la utilización de cables disparadores de menos de 1 metro de longitud, e incluso la instalación de un dispositivo de exposición fijo dentro de la sala de exploración. Respecto a la señal acústica-luminosa de exposición a la radiación cabe reseñar que en el 4.86 % (122/2508) de los informes revisados esta señal no funciona.

Las películas radiográficas intraorales más utilizadas en la clínica diaria dental ha sido la fabricada por la casa Kodak, siendo el modelo Ultraspeed, de sensibilidad D, la utilizada por el 75.77% (1561/2060) de las clínicas; observándose un aumento significativo del 10.94% en la utilización de este tipo de película durante la segunda revisión (1998) con respecto de la primera (1996-1997). Solamente el 16.31% (336/2060) de las instalaciones utiliza películas de sensibilidad E , tipo Ektaspeed de Kodak, películas que disminuyen un 50% la dosis de

radiación a la que se expone el paciente. El sistema digital de obtención de imagen, se utiliza en cerca del 5.3% (115/2166) de las instalaciones revisadas, aumentando esta cifra en un 2.55% durante la segunda revisión efectuada en el año 1998. Las películas radiográficas intraorales se almacenan dentro de la sala de exploración en el 38.67% (741/1916) de las salas dentales, mostrándose una disminución significativa (23.66%) de las instalaciones que seguían almacenándolas dentro de la sala durante la segunda revisión. Generalmente se controla la fecha de caducidad de las películas (96.9%:1814/1872) por el personal que trabaja en la instalación.

El revelado radiográfico mayoritariamente es un revelado manual (88.20% (1824/2066), que suele realizarse a temperatura ambiente en el 99.9% de las instalaciones en donde se realiza de esta forma. Una parte importante de las instalaciones estudiadas (77.25% (1389/1798)) admite no mantener un tiempo de revelado o procesado radiográfico fijo, la renovación de los líquidos es semanal en el 73.42% (1293/1761) de las instalaciones.

La dosis de radiación estimada en dichas instalaciones odontológicas para la exposición de un molar superior en las condiciones habituales de cada sala ha puesto de manifiesto que una dosis inferior a 5 mGy es la empleada en el 83.35% (2083/2499) de las instalaciones odontológicas, que alcanzaría hasta el 98.2% (2454/2499) si se establece en 10 mGy la dosis máxima empleada para obtener dicha imagen radiológica. La dosis media empleada en dicha exploración atendiendo a todos los informes que recogen este dato es el 4.14 mGy, observándose una disminución de un 30 % en la dosis media de radiación empleada durante el años 1998 con respecto a los años 1996-1997. El 93.5% de las instalaciones cumpliría con las recomendaciones oficiales actuales de utilizar dosis de radiación inferiores a 7 mGy en esta exposición. En la actualidad se esta llevando a cabo el estudio de los informes correspondientes a la tercera revisión (1999), y se han obtenido datos de dosis medias para dicha exploración de 3.18 mGy , que supone una dosis inferiores a la empleada en la primera revisión (1996-19979) de 4.87 mGy, y a los 3.41 mGy empleados durante la segunda revisión efectuada en 1998.

DISCUSIÓN

En términos generales, los equipos para radiología intraoral que se han encontrado en las clínicas odontológicas son de características físicas habituales en el entorno del medio de desarrollo en el que nos encontramos [1,2]. Si las alteraciones de los parámetros físicos se hubiesen producido siempre en aparatos diferentes, podría decirse que aproximadamente un tercio de los equipos revisados (28%) pueden presentar alteraciones significativas (kV, mA, filtración, señal acústica, disparador) en el momento de las revisiones de control de calidad.

Las actuales recomendaciones oficiales de utilizar un aparato que funcione a 70 kV, 8 mA, 20 cms de distancia foco-piel y una filtración del haz superior a 1.5 mm de Al se cumplirían como máximo en el 71.36% de las instalaciones radiológicas dentales revisadas (2524). Gracias a este procedimiento obligatorio de control de calidad que deben cumplir todas las clínicas odontológicas con aparatos de radiología intraoral, se ha podido aumentar en casi un 14.5% el número de clínicas que durante la segunda revisión cumplirían con las recomendaciones oficiales de la Unión Europea con respecto a los años anteriores.

Se ha observado una ausencia completa en la utilización de un colimador rectangular adaptado al tamaño de la película radiológica en los informes (2524) de las clínicas estudiadas, frente al 5-7.33% con el que se emplea en Estados Unidos [3,4], o frente al 29-36% que se describe en instalaciones con aparatos intraorales en Suecia [6,7].

Por otro lado, otros parámetros fundamentales han quedado excluidos de los requisitos controlables en los informes de garantía y/o control de calidad y que pueden ser las causas del incremento considerable de las dosis de radiación administradas en las exploraciones

radiológicas: el revelado de la película fotográfica [7]. En este sentido, destaca que el 88.20% del revelado de la película radiográfica en nuestro medio es manual y sólo un 6´3% de las instalaciones realiza un procesado radiográfico automático. Estos resultados son significativamente inferiores al 50% de procesado automático en Dinamarca [1,2], el 88% en Suecia [5], o el 93% en Canadá [8].

La dosis de radiación de calidad suficiente de un molar superior en nuestro estudio es inferior a 7 mGy en el 93.5 % de los casos, en donde se ha puesto de manifiesto una dosis media de 4.14 mGy, disminuyendo este valor a 3.18 mGy durante la tercera revisión correspondiente a 1999.

En general, numerosos autores ponen de manifiesto un grado significativo de insatisfacción en incumplimiento de las recomendaciones oficiales para la reducción de la dosis de radiación en las instalaciones radiológicas odontológicas tanto en Europa [2,5], como en Estados Unidos [9]. Los resultados obtenidos del presente estudio han puesto de manifiesto, que en España y tras la instauración obligatoria de la normativa mediante la cual todas las clínicas odontológicas con aparatos de radiología intraoral deben de someterse a estudios de control de calidad efectuados por empresas externas homologadas, se ha reducido las dosis de radiación en un 30% y se ha conseguido aumentar en un 14.5% el número de instalaciones que cumpliría las Recomendaciones Oficiales de Protección Radiológica; todo ello en sólo dos años de evolución tras el citado requisito legal.

Se pretende continuar con este estudio durante los próximos años, lo que permitiría evaluar una posible mejoría en las actuaciones radiológicas dentales de nuestros profesionales y personal auxiliar como consecuencia de la nueva normativa instaurada.

BIBLIOGRAFÍA

[1].ALCARAZ, M., MARTÍNEZ-BENEYTO, Y., and VELASCO, E., Control de calidad en instalaciones de radiodiagnóstico dental, Revista Europea de Odontoestomatología. 11 (1999) 265-274.

[2].HINTZE,H., Radiographic screening examination: frequency, equipment, and film in general dental practice in Denmark, Scand.J.Dent.Res, 101 (1993) 52-56.

[3].PLATIN,E.; JANHOM,A., and TYNDALL,D., A quantitative analysis of dental radiography quality assurance practices among North Caroline dentists. Oral Sur, Oral Med. Pathol. Oral Radiol. Endod. 86 (1998) 115-120.

[4].HORNER,K., and HIRSCHMANN,P.N., Dose reduction in dental radiography, J.Dent. 18 (1990) 171-184.

[5].SVENSON,B., and PETERSSON,A., Questionnaire survey on the use of dental X-rays film and equipment among general practitioners in the Swedish Public Dental Health Service, Acta Odontol. Scand. 53 (1995) 230-235.

[6].SVENSON, B.; SEDERFELDT, B., and GRONDAHL, H.G., Attitudes of Swedish dentists to the choice of dental x-ray film and collimator for oral radiology, Dentomaxillofac. Radiol. 25 (1996) 157-161.

[7].HAVUKAINEN, R., Survey of dental radiographic equipment and radiation doses in Finland. Acta Radiol. 29 (1988) 481-485.

[8].NAKFOOR, C.A., and BROOKS, S.L., Compliance of Michigan dentists with radiographic safety recommendations, Oral Surg. Oral Med. Oral Pathol. 73 (1992) 510-513.

CONTROL DE CALIDAD Y PROTECCIÓN RADIOLÓGICA EN ODONTOLOGÍA: II LA RADIOLOGÍA PANORAMICA.

[1]JÓDAR-PÓRLAN, S.; [1]ALCARAZ, M.; [1]MARTINEZ-BENEYTO, Y.; [1]SAURA-INIESTA, A.M. y [2]VELASCO-HIDALGO, E.
[1]Area de Radiología y Medicina Física. Facultad de Medicina y Odontología. Universidad de Murcia. 30100--Espinardo. [2]Unidad Técnica de Protección Radiológica ASIGMA, S.A.

ABSTRACT

This paper studies 278 official reports on quality assurance in dental radiology in the context of the first revision of these dental clinics, as a result of the entry into force of the regulations establishisng the duties for this type of facilities. In the results section we present a quantitative analysis of the facilities equipped with an panoramic radiology apparatus, making a special reference to the brands they have available, as well as their physical features (kV, mA, filtration) and the desviations detected in their operation. Some of their features in the process of obtaining radiological images at those facilities (film control, development time, liquid renewal) are determined, an the average dose of ionising radiation used in order to obtain the same tooth radiological image is presented. This paper shows, in a quantitative way, the characteristic features of panoramic radiology in our medium. The study is intended to be continued during the next years, what would allow the assessment of the prospective improvement in dental radiological performances as a result of the newly established regulations.

INTRODUCCIÓN

La exploración radiológica en Odontología representa aproximadamente el 25% de todas las exploraciones radiológicas con fines de diagnostico medico que se realizan anualmente en al Unión Europea [1,2]. La radiología intraoral constituye casi el 90% de todas las exploraciones realizadas en odontología [1] , campo en donde la radiología panorámica constituye también un elemento esencial en la radiología oral actual, constituyendo la segunda exploración odontológica por su número de exploraciones realizas [3]

Sin embargo, recientes estudios ponen de manifiesto, tanto en Europa como en Estados Unidos, que muchas exploraciones radiológicas son de escasa calidad o representan imágenes sin calidad diagnóstica, bien porque se ha realizado una mala técnica radiológica o bien porque se ha realizado un inadecuado procesamiento de la película radiográfica [1,4]. En este trabajo se presenta el primer análisis cuantitativo de los parámetros controlados en los informes oficiales de control de calidad y supone una revisión del proceso de obtención de la imagen radiológica en las clínicas odontológicas que realizan radiografías panorámicas. Por ello, podría ayudar a reflejar la situación de desarrollo en la que se encuentra la radiología dental de nuestro país.

MATERIAL Y MÉTODO

Se estudian 278 informes oficiales de control de calidad en radiodiagnóstico de clínicas odontológicas que emplean radiología panorámica, generalmente desde la primera revisión de la instalación radiológica y hasta la tercera revisión, como consecuencia de la entrada en vigor del Real Decreto 2071/1995 de 22/12/95, en el que se establecen los criterios de control de calidad en radiodiagnóstico. Los informes se han realizado desde la segunda mitad del año 1996 hasta final de 1999, por la U.T.P.R. Asigma S.A.L. y corresponden fundamentalmente a instalaciones de carácter privado. Todas las clínicas han sido previamente verificadas por diversas Unidades Técnicas de Protección Radiológica homologadas por el Consejo de Seguridad Nuclear. En el momento de la primera revisión, todas las clínicas

odontológicas analizadas ya se encontraban legalmente autorizadas como Instalaciones de Rayos X con fines de diagnostico dental.

RESULTADOS

Los informes de control de calidad estudiados corresponden a clínicas odontológicas que poseen algún tipo de aparato de radiodiagnóstico para la realización de radiografía panorámica/ortopantomografia y se encuentran ubicadas en territorio español, fundamentalmente en tres comunidades autónomas: Murcia (82/278), Andalucía (79/278) y Comunidad Valenciana (63/278).

Los resultados obtenidos contabilizan más de 49 modelos de aparatos de rayos X para radiografía panorámica, correspondientes a 19 fabricantes diferentes, y en donde destaca la casa Trophy con cerca del 32% (90/278) de todos los equipos de radiología descritos. Estos aparatos funcionan con kilovoltajes variables que oscilan entre los 50 kV y los 130 kV como valores mínimo y máximo respectivamente, miliamperaje entre los 5 y los 400 mA, y una filtración del haz primario de radiación que ha variado entre los 2 mm y los 3.2 mm de Al como valores extremos, utilizando siempre filtración de Aluminio.

Los parámetros obtenidos sobre el funcionamiento del aparato estudiado en cada una de las clínicas dentales han puesto de manifiesto que el 4.18% (10/259) de los aparatos presentaban alteraciones superiores al 10% en alcanzar el kV que venia descrito por el fabricante del aparato y que por ello se han considerado fuera de tolerancia; un 2.1% de los equipos (5/237) han presentado alteraciones respecto al tiempo de exposición marcado por el cronómetro del aparato y un 4.8% (8/173) presentaban desviaciones superiores al 20% en el rendimiento del tubo de rayos X (dosis de radiación por unidad de tiempo).

El revelado radiográfico de la radiografía panorámica se realiza en procesadora automática mayoritariamente (63.92%:163/255), y en donde la renovación de los líquidos de revelado se hace mensualmente en el 61.5% (147/239) de las clínicas odontológicas analizadas en las que se ha recogido este dato.

El tipo de película más frecuentemente utilizada para la realización de la radiología panorámica es la Kodak T-MAT en sus diferentes modalidades con el 53.78% (142/264) de todas las instalaciones dentales verificadas en el control de calidad, en donde destaca la utilización de las pantallas de refuerzo Kodak Lanex en sus diferentes modalidades en el 89.71% (192/214) de todas las instalaciones revisadas.

En los informes de Control de Calidad que se han analizado se han descrito otras irregularidades en algunos parámetros sometidos a estudio: a) se pone de manifiesto que en el 5.43% (13/239) se realiza un almacenamiento incorrecto de la película radiográfica, ya que se mantiene dentro de la sala de exposición, expuesta a la radiación dispersa producida durante la exploración, con el consiguiente aumento del velo por la radiación de la película radiográfica; b) en el 6.43% (11/171) se encuentran entradas de luz en el cuarto oscuro que aumentarían el velo por luz de las películas radiográficas durante su manipulación; y c) se describe una ausencia completa de control en el tiempo de revelado de la película radiográfica en el 75% (33/44) de las instalaciones dentales en las que se ha recogido este dato.

En el 11.87% de los informes (33/278) se reflejan recomendaciones de carácter imperativo que exigen una corrección inmediata: en 25 instalaciones se exige revisión/reparación de los equipos (8.99%: 25/278); en otras 2 se recomienda la revisión de la instalación eléctrica (0.71%:2/278) por alterar el funcionamiento del equipo; en otra (0.35%: 1/278) se recomienda el cambio del tipo de líquidos empleados por ser completamente inadecuados para el procesado de la película radiográfica empleada.

La dosis de radiación de radiación se ha determinado con un detector de semiconductor (PMX III) en la posición de telerradiografia del aparato de radiodiagnóstico

estudiado y en las condiciones habituales en al que se realizan en la exploración de cada sala. La determinación de la dosis de radiación ha puesto de manifiesto un descenso significativo de las dosis empleadas durante los últimos años. La dosis media de radiación ha disminuido desde 1.473 mGy en 1996, 1.16 mGy en 1997, 0.37 mGy en 1998, hasta 0.21 mGy en 1999. Ello pone de manifiesto que desde la entrada en vigor de la reglamentación de control de calidad las dosis empleadas se han reducido hasta casi 8 veces respecto de las empleadas en 1996. La dosis media empleada en el conjunto global de todos los años analizados es de 0.80 mGy, siendo como valores máximos extremos alguna instalación que llegaron a emplear 18 mGy (en 1996), 28 mGy (en 1997) , o 12.75 mGy (en 1998). En 1999 ninguna instalación ha superado 1 mGy como nivel máximo de radiación administrada para dicha exploración. La determinación de la dosis de radiación ha puesto de manifiesto un significativo descenso de las dosis empleadas durante los últimos años.

DISCUSIÓN

Recientemente se ha publicado que el 95% de las clínicas odontológicas en la Comunidad de Murcia utilizan habitualmente un aparato de radiología intraoral, y que, además, durante 1996 un 2.8% de las mismas dispone de un aparato para radiología intraoral [5]. Esta situación refleja la segunda plaza que ocupa la practica de la radiología panorámica en el diagnostico odontológico en nuestro medio. Según nuestros resultados al menos un 4.5% de las clínicas odontológicas poseen un aparato para radiología panorámica actualmente en esta misma comunidad; resultado todavía muy distante al descrito en otros países en donde casi el 22% de las clínicas odontológicas [6] disponía de un aparato de estas características.

Los equipos de radiología panorámica que se han encontrado en las clínicas odontológicas son de características físicas (kV, mA, filtración) habituales en el entorno del medio desarrollado en el que nos encontramos [3]. Si las alteraciones de los parámetros físicos se hubiesen producido siempre en aparatos diferentes, podría decirse que más del 16% de los equipos revisados pueden presentar alteraciones significativas en el momento de las revisiones de control de calidad, y de los casi el 13% ha debido necesariamente solucionar algún tipo de problema antes de volver a trabajar.

Cabe destacar que el 63.92% del revelado de la película de la radiografía panorámica en nuestro medio es automático, y solo un 30% de las instalaciones realizada un procesado manual.. Se asume que el procesado radiográfico automático permite administrar menos dosis de radiación aumentando la calidad de la imagen radiológica [7]; siempre que se realiza el revelado de forma manual, todos los autores describen resultados similares a los nuestros en cuanto a una gran variedad de tiempos de revelado, tiempos de cambio de líquidos y temperaturas empleadas, actuaciones que pueden suponer un incremento de la dosis de radiación administradas y del número de exploraciones innecesarias que se realizan [2,3].

Igualmente se admite que entre el 26 y el 33% de las radiografías panorámicas que se realizan son inaceptables y carecen de suficiente calidad para la interpretación diagnostica [1,8], atribuyéndose al inadecuado procesamiento y /o movimientos del paciente y al escaso contraste o ennegrecimiento los defectos más frecuentes que las producen [9]. Otros estudios han descrito que hasta el 40% de los equipos de rayos X para radiología dental sobrepasan los valores óptimos recomendados. Si a ello se suma que algunos autores han asociado las exposiciones múltiples en exámenes radiológicos dentales con mayor incidencia de cáncer de glándulas salivales y tumores cerebrales [1] parece evidente la necesidad de optimizar las dosis de radiación empleadas en Odontología.

A pesar de lo anterior, las dosis de radiación empleadas en la radiología panorámica han ido disminuyendo significativamente durante los años sometidos al estudio. La técnica empleada para la determinación de la dosis de radiación no es la más recomendable y se han

descrito en los informes las dificultades para obtener un valor de dosis aceptable en aparatos que no disponían de telerradiografía, por lo que algunos de los valores más altos pueden deberse a medidas realizadas en la posición de realización de la radiografía panorámica y que no se han eliminado hasta la última revisión realizada en el año 1999. Aunque existen instalaciones que han empleado 151 veces más dosis de radiación que la media obtenida para 1999 en la realización de una misma exploración radiológica, la dosis actual ha disminuido el 14% de la dosis de 1996. La dosis media en nuestro estudio es de 0.80 mGy y se encontraría en la misma línea de las descritas por otros autores para la misma exploración radiológica.

En general, numerosos autores ponen de manifiesto un grado significativo de insatisfacción en el cumplimiento de las recomendaciones oficiales para la reducción de dosis de radiación en las instalaciones odontológicas tanto en Europa [10,11] como en Estados Unidos [12]. Dado que en nuestro estudio alguno de los parámetros analizados se alejan significativamente de las recomendaciones generales de protección radiológica resulta comprensible que se pretenda aunar esfuerzos para disminuir o eludir algunos de los factores que más influyen en el incremento de la dosis de radiación administrada o en la perdida de la calidad diagnostica de la imagen radiológica. Pretendemos continuar este estudio durante los próximos años, lo que permitiría evaluar la posible mejoría que puede experimentar la practica de la radiología panorámica en nuestro país, como consecuencia de la normativa instaurada.

REFERENCES

[1]. HORNER, K., Review article: radiation protection in dental radiology, Br. J. Radiol. 67 (1994) 1041-1049.

[2]. VAN DEL STELT, P.F., Radiation protection and quality assurance in dental radiography. A treatise from the European Community, Rev. Belge Med. Dent. 51 (1996) 111-22.

[3]. MOLANDER, B., Panoramic Radiography in Dental Diagnostics, Swed. Dent. J. 119 (1998) 6-52.

[4]. (4) RUSHTON V.E., HORNER K., The use of panoramic radiology in dental practice. J. Dent. 1996; 24(3): 185-201.

[5]. PONCE, R.; and GÓMEZ, J., Centro de Odonto-Estomatología. Análisis de la situación actual. Región de Murcia 1996. Serie Registro de Establecimientos sanitarios nº1, Dirección General de Salud, Murcia , (1997) 106págs.

[6]. OSMAN, F., SCULLY, C., DOWELL, T.B., and DAVIES, R.M., Use of panoramic radiographs in general dental practice in England. Community Dent, Oral Epidemiol. 14 (1986) 8-9.

[7]. ERASO, F.E., LUDLOW, J.B., PLATIN, E., TYNDALL, D., and PHILLIPS, C., Clinical and in vitro film quality comparison of manual and automatic exposure control in panoramic radiography, Oral Surg. Oral Med. Oral Pathol. Oral Radio. Endod.; 8784 (1999) 518-23.

[8]. RUSHTON, V.E., HORNER, K., and WORTHINGTON, H.V., Aspects of panoramic radiography in general dental practice, Br. Dent. J. 10 (1999) 342-344.

[9]. RUSHTON, V.E., HORNER, K., and WORTHINGTON, H.V., The quality of panoramic radiographs in a sample of general dental practices, Br. Dent. J.186 (.1999) 630-3.

[10]. HINTZE, H, Radiographic screening examination: frequency, equipment, and film in general dental practice in Denmark. Scand. J. Dent. Res. 101 (1993) 52-56.

[11]. SVENSON, B., and PETERSSON, A., Questionnaire survey on the use of dental X-rays film and equipment among general practitioners in the Swedish Public Dental Health Service, Acta Odontol. Scand. 53 (1995) 230-235.

[12].NAKFOOR, C.A., and BROOKS, S.L., Compliance of Michigan dentists with radiographic safety recommendations, Oral Surg. Oral Med. Oral Pathol. 73 (1992) 510-513.

DIAGNOSTIC REFERENCE ACTIVITIES FOR NUCLEAR MEDICINE IN AUSTRALIA AND NEW ZEALAND

Jocelyn E. Towson* and Richard C Smart**

*Department of PET and Nuclear Medicine, Royal Prince Alfred Hospital, Camperdown, NSW 2050, Australia. <jtowson@nucmed.rpa.cs.nsw.gov.au>
**Department of Nuclear Medicine, St. George Hospital, Kogarah, NSW 2217, Australia

Nuclear medicine centres in Australia and New Zealand were surveyed in 1998 on behalf of the Australian and New Zealand Society of Nuclear Medicine (ANZSNM) and the Australasian Radiation Protection Society (ARPS) in order to establish diagnostic reference levels. A survey form was mailed to all centres, requesting information on the usual radiopharmaceutical activity administered to a standard adult patient and how the activity is calculated for children. The overall response rate was 89.5%. Data was obtained for 80 imaging procedures and 17 non-imaging tracer studies. For the 68 procedures for which data was available from 10 or more centres, the Most Common Activity and the Reference Activity were found from the mode and 75th percentile of the distribution of activities. A follow-up survey of the 8 hospital centres specialising in pediatric nuclear medicine in Australia was conducted in 1999-2000. Data on the maximum and minimum administered activities (A_{max} and A_{min}) was obtained for 43 pediatric imaging procedures. A_{max} values were significantly less than the Reference Activities determined for adults. The median values of A_{max} and A_{min} are recommended as Pediatric Reference Activities. The effective dose from the Reference Activities was calculated for adults (male and female) and children. The survey results are available on the ANZSNM and ARPS websites at http://www.anzsnm.org.au and http://www.arps.org.au .

1 INTRODUCTION

The ICRP introduced the term *diagnostic reference levels* (also known as guidance levels) in 1996. In the case of nuclear medicine the quantity of reference is generally taken to be the radiopharmaceutical activity administered to "a typical adult patient". Reference levels are usually set at the 75th percentile (3rd quartile) or within a specified range of the median (2nd quartile) of the values used in routine clinical practice, parameters which are independent of the shape of the distribution of values or the presence of outlying values. The ICRP recommends that reference levels should be established by the appropriate professional organisations.

ANZSNM and ARPS convened a Working Party to survey the radiopharmaceutical activities used routinely in Australia and New Zealand, and to derive diagnostic reference levels from the survey. [1] The initiative was supported by the Australian and New Zealand Association of Physicians in Nuclear Medicine and the Australasian College of Physical Scientists and Engineers in Medicine.

2 METHODS

In 1998 a survey form was sent to all nuclear medicine departments and private practices in Australia and New Zealand known to the Working Party, 172 in all. The survey form did not identify the centre (other than whether it was in Australia or New Zealand, and if in a capital city or a regional centre). Information was sought as to whether the centre was a public hospital, private hospital or private practice, and the proportions of inpatients and pediatric patients.

The survey form listed 70 different imaging procedures and 8 non-imaging procedures, with space for the centre to add any further studies. Myocardial perfusion imaging required eight entries on the form in order to cover all procedural variations (eg 2 day stress/rest with ^{99m}Tc agent, 1 day rest/stress, 1 day stress/rest, etc). For each procedure that it performed, the centre was asked to state the radiopharmaceutical form and activity that it would administer to a standard adult patient for both planar and SPECT studies. The centre was also asked how it determines the activity administered for

a lung ventilation study, whether it uses less activity when imaging with a multi-detector system, how it calculates the activity to administer to a pediatric patient and what would be the minimum activity administered to an infant.

Due to the poor quality data for pediatric procedures obtained in this survey, a follow-up survey of the eight specialist pediatric nuclear medicine centres in Australian hospitals was conducted in 1999-2000 to obtain better guidance for pediatric procedures. Each centre stated how it calculates the activity to administer to a pediatric patient, the usual activity it would administer to an adult-sized patient (A_{max}) and the minimum activity (A_{min}) it would administer to an infant.

3 RESULTS

A total of 96 completed survey forms were received from the original survey. It is common for private practices in Australia to be part of a multi-centre group. The 96 returned forms represented a total of 154 centres, an overall response rate of 89.5%. Two-thirds of the responses were from capital cities with the remaining one-third being from regional areas. Fifty seven percent of the responses were from private practices, 29% from public hospitals and the remaining 14% from private hospitals. The high proportion of private practices was also reflected in the proportion of outpatients studied - most centres performing at least 70% of their procedures on outpatients. Paediatric patients most commonly represented 10% or less of the practice workload. Centres do not reduce the administered activities for planar studies compared to SPECT or when using multi-head detectors.

An additional ten imaging procedures and nine non-imaging procedures were identified from the responses, giving a total of 80 imaging procedures and 17 non-imaging procedures. Bone scans are the most common nuclear medicine procedure in Australia and New Zealand, being performed in all centres who responded to the survey. There were wide variations in administered activities, eg. ^{99m}Tc phosphonates for bone scans ranged from 600 MBq to 1500 MBq, ^{99m}Tc-MAG3 for renal scans ranged from 100 MBq to 800 MBq. Five myocardial perfusion protocols were in common use: ^{201}Tl was used by 44% of centres; ^{99m}Tc agents, primarily sestamibi, were used by the remaining 56%. The one-day rest/stress ^{99m}Tc protocol was most commonly used, although it was far from universal. A few centres used a combined ^{201}Tl rest/ ^{99m}Tc stress protocol. Only two centres used ^{133}Xe gas in preference to ^{99m}Tc aerosol or ^{99m}Tc-Technegas. External monitoring of the count rate over the patient's chest during the inhalation procedure was the most common means of estimating when the activity in the patient's lungs was adequate for diagnostic imaging.

For each procedure a frequency distribution of the administered activity was generated. For those procedures with ten or more responses, 68 in all, the mode and the 75th percentile of the distribution were determined as the **Most Common Activity (MCA)** and the **Reference Activity** respectively. For lung ventilation scans, the 75th percentile of the count rate distribution was 2000 c/s, which was assumed to correspond to 40 MBq of ^{99m}Tc administered.

Not all of the imaging procedures in the original survey are applicable to pediatric nuclear medicine. In the follow-up survey of the eight pediatric centres, there were 43 imaging procedures for which information was provided by at least two of the centres. The most commonly performed pediatric procedures were said to be bone, renal (^{99m}Tc-MAG3, ^{99m}Tc-DTPA and ^{99m}Tc-DMSA) and tumor (^{67}Ga citrate, ^{201}Tl chloride and ^{123}I-mIBG), followed by hepatobiliary (^{99m}Tc-IDA derivatives). Data was provided for two pediatric myocardial perfusion protocols: six centres reported ^{201}Tl chloride stress and rest activities, four of the same centres also reported a 1-day rest/stress protocol using ^{99m}Tc-sestamibi. All centres used ^{99m}Tc -Technegas or ^{99m}Tc-DTPA aerosol for lung scans.

The median values of A_{max} and A_{min} were determined for each procedure with two or more responses, being considered a more useful guide than the mode or 75th percentile given the very small sample sizes and obvious 'outlier' values. The pediatric A_{max} median values are similar to the corresponding MCAs and significantly less than the Reference Activities for adults. The variability in A_{min} was less than in the original survey, even though it was more than 5-fold for 8 of the 43 procedures. The

median values of A_{max} and A_{min} are recommended as **Pediatric Reference Activities**, with A_{max} capped by the adult Reference Activity.

Three of the pediatric centres calculate the activity to be administered to an individual patient by scaling A_{max} by the ratio of the patient's body weight to 70kg. The other five centres use scaling factors which represent surface area as a function of body weight, obtained from look-up tables or the 'Gilday Chart' which has surface area scaling factors transposed to the x-axis and weight on the y-axis.[2] The surface area factors used are identical to those recommended by the EANM.[3]

Table I Comparison of survey Reference Activities (MBq) with recommendations from EANM [3] and IAEA Basic Safety Standards (BSS) Schedule 3, Table III-V (*indicates SPECT value)

Procedure	R'pharm	adults		children			
		survey Ref.Act	BSS	survey Amax	EANM Amax	survey Amin	EANM Amin
blood pool	^{99m}Tc rbc	1000	-	770	800	90	80
bone	^{99m}Tc MDP	900	800	750	500	70	40
bone marrow	^{99m}Tc n.colloid	400	400	400	300	80	20
brain	^{99m}Tc HMPAO	800	500	740	740	100	100
cardiac GHPS	^{99m}Tc rbc	1000	800	800	-	80	-
gastric reflux, GIT motility	^{99m}Tc colloid	40	12	40	40	25	10
hepatobiliary	^{99m}Tc HIDA	200	150	170	150	25	20
infection	^{99m}Tc wbc	740	400	400	500	100	40
infection	^{67}Ga citrate	200	-	150	80	20	10
liver/spleen	^{99m}Tc colloid	200	200 *	150	80	20	15
lung perfusion	^{99m}Tc MAA	200	200 *	150	80	20	10
myocard perf	^{99m}Tc mibi 1 d rest+stress	400 +1100	-	300 +1000	-	40 +110	-
myocard perf	^{201}Tl chloride	120	80	100	-	25	-
renal scan	^{99m}Tc DMSA	185	160	130	100	35	15
renal scan	^{99m}Tc DTPA	500	350	370	200	50	20
renal scan	^{99m}Tc MAG3	350	100	180	70	30	15
thyroid	^{99m}Tc pertech	200	80	120	80	20	10
tumor	^{123}I mIBG	370	400	250	200	70	70
tumor	^{131}I mIBG	40	20	40	80	20	35
tumor	^{201}Tl chloride	160	-	120	-	20	-
tumor	^{67}Ga citrate	400	300	300	80	30	10
tumor	^{99m}Tc mibi	800	-	720	-	100	-
met.Ca thyroid	^{131}I iodide	200	400	-	-	-	-

The effective doses from the Most Common Activity and the Reference Activity were calculated for each procedure, using 'standard man' dose coefficients preferably from ICRP 80 [4]. Effective dose values for females were calculated by scaling the 'standard man' value by the ratio of effective doses (female/male) given by Stabin. [5] For any radiopharmaceutical not listed by Stabin a ratio of 1.25 was used, being the average of all the ratios determined by Stabin.

Similarly, the effective dose for the 43 pediatric imaging procedures was calculated for the Pediatric Reference Activities and both scaling methods using effective dose coefficients, preferably from ICRP 80, for children aged 0, 1, 5, 10 and 15 years. [4] Scaling factors were applied for 'standard child' weights for these ages. The larger of the A_{min} Reference Activity and the scaled activity was used in the dose calculations. The survey provides a realistic picture of pediatric exposures from nuclear medicine in Australia. Procedures fall into three broad categories:

- high dose, of the order of tens of mSv, for ^{201}Tl-chloride and ^{67}Ga-citrate

- moderate dose, about 10 mSv, for ^{99m}Tc labelled HMPAO, red cells and sestamibi
- low dose, less than 5 mSv, for the remainder.

Data for all procedures, including the effective dose estimates for adults and children, are available on http://www.anzsnm.org.au and http://www.arps.org.au .

4 DISCUSSION

Little attention has been directed towards establishing reference levels for nuclear medicine. [6] The IAEA gives no indication as to how the values in the BSS were derived. Currently there are no reference activities recommended by regulatory bodies in Australia. New Zealand has published reference activities, however these were not derived from a survey of current practice. [7]

The Reference Activities from the survey are between a factor of 1.0 and 1.3 higher than those in New Zealand, and up to two times higher than the IAEA values in the BSS. The factor of 2 for the BSS comparison is for a perfusion lung scan, for which the BSS recommends 100 MBq for planar imaging. This activity would be appropriate following a ventilation scan using a gas such as ^{133}Xe or ^{81m}Kr. Following a ventilation scan using ^{99m}Tc-aerosol or Technegas, the larger perfusion activities found in this survey are necessary to mask the ventilation activity.

The effective dose estimates for the Reference Activities and Most Common Activities are for a 'standard' 70 kg man and 57 kg woman. In Australia, the average weights for males and females over 45 years of age are substantially higher. In heavy patients the administered activity is often increased so that the diagnostic information is not compromised. It is not usual practice to administer less activity to lighter adult patients to maintain a constant radiation exposure.

The practical difficulties of achieving adequate image quality in pediatric nuclear medicine are well known. The risk of a non-diagnostic image from too few counts or patient movement, paticularly with dynamic studies and SPECT, has to be weighed against the radiation exposure. The activities administered to adults have generally risen over time which would have a flow-on effect on exposure if used to calculate the activities administered to children. The pediatric centres adopt a conservative approach, eg. the ^{67}Ga-citrate A_{max} medians for infection and tumor imaging are 75% of the MCAs in adults, resulting in a worthwhile reduction in radiation dose.

Surface area scaling boosts the administered activity and hence the information density of images. It results in a fairly uniform variation of effective dose with body size. However the amount of activity administered to infants under 10 kg using surface area scaling is approximately double that with body weight scaling. Similarly, A_{min} values were introduced to compensate for low counts in infants. An unintended consequence of high A_{min} values and surface area scaling is a substantial increase in the effective dose to an infant, eg. brain imaging with ^{99m}Tc-HMPAO, infection imaging with ^{99m}Tc-white cells, lung perfusion imaging with ^{99m}Tc-MAA and renal imaging with ^{99m}Tc-DMSA. Caution is indicated for an A_{min} value exceeding 10% of the corresponding A_{max}, eg. the A_{min} for tumor imaging with ^{123}I-mIBG is considered to be justified.

^{201}Tl-chloride and ^{67}Ga-citrate are associated with a high radiation dose, particularly in the very young. In the context of an infant or child with malignancy who is to receive chemotherapy and possibly radiotherapy, it is justifiable to image with these agents as the information obtained may influence treatment. Of greater concern is the use of ^{201}Tl or ^{67}Ga in infants and children with non-malignant disease, which should only be considered when the radiation dose is justified on very strong clinical grounds. Alternative investigations should be considered.

REFERENCES

1. SMART R. C, TOWSON J. E., Diagnostic reference activities for nuclear medicine procedures in Australia and New Zealand, Rad. Prot. Aust. **17** (2000) 2-14.
2. NEW ZEALAND MINISTRY OF HEALTH, National Radiation Laboratory, Code of safe practice for the

use of unsealed radioactive materials in medical diagnosis, therapy and research. Rep. NRL-C3 (1994).
3. GOETZ W. A., HENDEE W. R., GILDAY D. L., In vivo diagnostic nuclear medicine: pediatric experience, Clin. Nucl. Med. **8** (1983) 434-439.
4. EUROPEAN ASSOCIATION OF NUCLEAR MEDICINE Paediatric Task Group, Radiopharmaceuticals schedule for imaging in pediatrics, Eur. J. Nucl. Med. **17** (1990) 127-129.
5. INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, ICRP Publication 80: Addendum to Publication 53 - Radiation dose to patients from radiopharmaceuticals. Ann. ICRP **28** 3 (1998).
6. STABIN M. G., Health concerns related to radiation exposure of the female nuclear medicine patient. Environ. Health Perspect. **105** Supplement 6 (1997) 1403-1409.
7. MATTSSON S., JACOBSON L., VESTERGREN E., The basic principles in assessment and selection of reference doses: considerations in nuclear medicine. Rad. Prot. Dosim. **80** (1998) 23-27.

DOSE PROFILE MEASUREMENTS IN COMPUTED TOMOGRAPHY USING THERMOLUMINESCENT DOSIMETERS

J.C. Azorín-Vega[1], C. Falcony[1,2] y J. Azorín-Nieto[1,3]

[1]Centro de Investigación en Ciencia Aplicada y Tecnología Avanzada-IPN, México, D.F.
[2]Centro de Investigación y Estudios Avanzados-IPN, México, D.F.
[3]Universidad Autónoma Metropolitana-Iztapalapa, México, D.F.

ABSTRACT

This paper presents the results of measurements of dose profile in two computed axial tomography systems. Thermoluminescent dosimeters (TLD) consisting in discs of LiF:Mg,Cu,P+PTFE, developed and made in Mexico, were used. Results showed that these dosimeters are suitable to make this type of studies

INTRODUCTION

Thirty years have passed since the first clinical use of a computed axial tomography (CAT) system. At the present time, the availability and usefulness of this diagnosis procedure is widely recognized due that the technological developments associated have been promptly incorporated. However, doses administered to the patients are higher than those received in conventional X-ray studies[1,2]. For this reason, it is important to quantify the dose properly in order to limit as possible the amount of radiation the patient receives. The most important dosimetric parameter in CAT is the dose measured directly on the patient; but this is not always possible to make. Then it is necessary to use the reference dose values for computed tomography[3] or computed tomography dose index (CTDI) in air as good methods to describe this dose. This parameter does not take into account the scattering properties of the body.
In the present work, the dose profile of two computed axial tomography systems (Somatom Plus, Siemens and Toshiba) were measured. Measurements were made in a PMMA cylindrical phantom 12 cm diameter and 30 cm high to simulate a human body thorax. Dose profile provided for the slices scanned was measured with LiF:Mg,Cu,P+PTFE TLDs. The TLDs consisting in pellets of 5mm diameter and 0.8 mm thickness were placed along the longitudinal axis of the phantom. The dose profile provides information about the direct and scattered dose, which affects the dose received by the patient. This method provides also the collimating efficiency of each one of the CAT systems.

The useful X-rays beams of the CAT systems are commonly well collimated. Then the dose distribution in the patient rapidly varies as a function of the distance from the irradiated plane.

Thermoluminescent dosimeters are very useful for these type of studies due that their little dimensions which allow to make almost point measurements, and due that their high sensitivity and stability and easy handling[4].

METHODOLOGY

Dose profiles for the two CAT systems, Somatom Plus, Siemens and Toshiba, inside the PMMA phantom were measured using LiF:Mg,Cu,P+PTFE TLDs made in Mexico[5]. Dosimeters were placed into the holes made in the center of the phantom perpendicular to the rotation axis of the x-ray generator separated 2 mm to cover 10 mm length.

It is known that scattered radiation and penumbra are not negligible. For this reason TLDs were placed along 30 cm separated 10 mm among them, as it is shown in figure 1. The spaces among the separations were filled with PMMA.

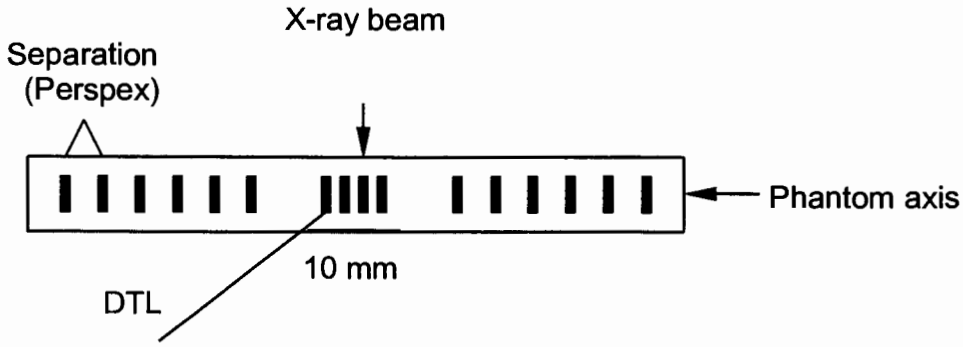


Fig. 1. Position of the DTL into the phantom

Irradiations were performed using the same parameters (kVp and mAs) in both systems, taking slices of: 1.5 mm, 5.0 mm and 10 mm that correspond to the irradiation parameters used in abdominal typical studies. Rotation angle of the X-ray tube was 360 ° in each case.

Readings of TLDs were made in a Harshaw 4000 TL Analyzer, integrating the signal from room temperature (~ 20°C) to 240°C at a heating rate of 10°C/s, in nitrogen atmosphere. Doses were evaluated by comparing the TL readings with a calibration equation previously obtained.

RESULTS

Figures 1 and 2 show the dose profiles obtained for the two CAT systems. These graphs show the distribution of the dose profile along the irradiation plane as a function of the distance from the center up to the edges.

CONCLUSIONS

Results showed that, due to the linearity of the dosimetric response, the use of these types of dosimeters is suitable for these kinds of studies. Analyzing the graphs, it is possible to appreciate that the system SOMATOM PLUS-Siemens provide higher dose to the patient that the Toshiba system. This is due to mistakes in the beam collimating and alignment in the former system.
From the results we can also conclude that this method of analysis is suitable for monitoring the performance of the CAT system. For this reason it is highly recommended to perform quality control tests in these systems.

REFERENCES

1.- Faulkner K and Moores B. M. Radiation Dose and Somatic Risk from Computed Tomography. Acta Radiol. **4** 483-488 (1987)

2.- Evens R. G. and Mettler F. National CT Use and Radiation Exposure: United States 1983. Am. J. Radiol. **144** 1007-1081 (1985).

3.- Spokas J. J. Dose Descriptors for Computed Tomography. Med. Phys. **9** 288-292 (1982).

4.- Azorín J. Luminescence Dosimetry. Theory and Applications. Ed. Tecnico-Científicas, México, D.F. (1990).

5.- Azorín J., Gutiérrez A., Niewiadomski T. and González P. Dosimetric Characteristics of LiF:Mg,Cu,P TL Phosphor Prepared at ININ, Mexico. Radiat. Prot. Dosim. **33**(1/4) 283-286 (1990).

DIMOND II: MEASURES FOR OPTIMISING RADIOLOGICAL INFORMATION CONTENT AND DOSE IN DIGITAL IMAGING

A. Dowling MSc, Prof. J. Malone, D. Marsh PhD.
Department of Medical Physics and Bioengineering, Garden Hill House, St. James's Hospital, Dublin 8, Ireland
Fax: +353-1-410 3478; e-mail: adowling@stjames.ie

ABSTRACT

The European Commission concerted action on 'Digital Imaging: Measures for Optimising Radiological Information Content and Dose', DIMOND II, was conducted by 12 European partners over the period January 1997 to June 1999.
The objective of the concerted action was to initiate a project in the area of digital medical imaging where practice was evolving without structured research in radiation protection, optimisation or justification. The main issues addressed were patient and staff dosimetry, image quality, quality criteria and technical issues. The scope included computed radiography (CR), image intensifier radiography and fluoroscopy, cardiology and interventional procedures.
The concerted action was based on the consolidation of work conducted in the partner's institutions together with elective new work. Protocols and approaches to dosimetry, radiological information content/image quality measurement and quality criteria were established and presented at an international workshop held in Dublin in June 1999. Details of the work conducted during the DIMOND II concerted action and a summary of the main findings and conclusions are presented in this contribution.

INTRODUCTION

The European Commission concerted action on 'Digital Imaging: Measures for Optimising Radiological Information Content and Dose', DIMOND II, was conducted by 12 European partners over the period January 1997 to June 1999.
The partners involved were as follows:

- Department of Medical Physics and Bioengineering, St. James's Hospital, Dublin.
- Regional Medical Physics Department, Newcastle General Hospital, UK.
- Department of Radiology, Krankenhaus der Barmherzigen Bruder, Trier, Germany.
- STUK, Helsinki, Finland.
- Department of Radiology, Leuven, Belgium.
- Department of Radiology, University of Innsbruck, Austria.
- Ministere de la Sante, Division de la Radio Protection, Luxembourg.
- Department of Radiology, Complutense University, Madrid, Spain.
- Medical Physics Department, Regional General Hospital of Athens, Greece.
- TNO Centre for Radiation Protection, Rijswijk, The Netherlands.
- Department of Radiology, Ospedale S. Maria Della Misericordia, Udine, Italy.
- Diakonissenkrankenhaus, Abt. Rontgendiagnostik, Karlsruhe, Germany.

The objective of the concerted action was to initiate project in area of digital medical imaging where practice was evolving without structured research in radiation protection, optimisation

or justification[1]. The main issues addressed were patient and staff dosimetry, image quality, quality criteria and technical issues. The scope included computed radiography (CR), image intensifier radiography and fluoroscopy, cardiology and other new interventional procedures[1].
In addition to the formal objective, there was also an informal objective of establishing a cohesive effective group with participants from a range of disciplines and from a wide range of European countries.
The structure of the concerted action consisted of many workpackages and deliverables and was based on the consolidation of work in partners' institutions and elective new work. In practice the work was organised into the following main tasks areas or groups:

- Dosimetry,
- Radiological information content,
- Quality criteria,
- Cardiology,
- Technical parameters and
- Project management,

with input from various other specialised subgroups

OBJECTIVES AND RESULTS

Dosimetry

The main objectives of the dosimetry group were to conduct a review of the wide diversity in approaches to patient, staff and equipment dosimetry for different examinations, to conduct a dosimetry intercomparison study between the project partners, to document calibration issues with respect to patient and staff dosimetry, to identify useful trends in published data for interventional and collective dose in Europe and elsewhere and to conduct cardiological patient and staff dosimetry studies[1].

Patient and staff dosimetry protocols have been produced[2,3]. The following approaches to patient dosimetry have been identified: i) patient dose may be established by monitoring the dose area product (DAP) for real or simulated patients, ii) entrance skin dose may be measured using an ionisation chamber for the technique factors used or iii) thermoluminiscent dosimeters (TLDs) may be placed on the patients skin at the centre of the radiation field[2,3]. Patient dose values may be used to develop reference values[3].
Patient examinations have been classified into the following categories: 'simple' (not involving more than four exposures, without the use of fluoroscopy or contrast media), 'complex conventional examinations' and 'interventional examinations'[3].

Staff dosimetry protocols have been established which cover two aspects: personal dosimetry and area dosimetry[2,3]. Area dosimetry involves the assessment of dose at various locations within the X-ray room which enables iso-contour maps to be deducted. Whole body dose should be assessed for all individuals monitored and for high risk individuals, shoulder (eye) and hand doses should also be assessed. A standard protocol has been written[2,3].

An intercomparison of TLD measurements was conducted between the participants as many patient and staff dose measurements utilise TLDs. The results demonstrated a high degree of variability and dispersion values of greater than 25% were found for some systems[3]. This survey demonstrates the importance of intercalibration work. A protocol for image intensifier dosimetry was compiled to be compared with reference values/protocols and to prompt further actions in quality assurance if required[2].

A review of published and partners data on interventional/collective doses has been conducted and the results were presented at the international workshop in Dublin[3]. This review data provides valuable baseline date from which comparisons can be made however factors such as lack of methodological standardisation between European scientists and lack of standardisation between radiographic devices, examinations and techniques contribute significantly to variations observed[3]. Cardiological dosimetry studies were documented for patients & staff [2,3].

Radiological Information Content

The objectives of the Radiological Information Content task group were to conduct a review of objective and semi-subjective methods of measurement of image quality, to review measured image quality and dose issues, to review methods of constancy checking and to relate visualisation criteria and objective / subjective measurements[1].

Methods and protocols were reviewed for quantitative and qualitative measurement of image quality for CR, angiography and digital subtraction angiography (DSA) and related to dose[2,3]. New investigations and reports on measured image quality and dose issues were published [4]. A report on psychophysical aspects of imaging/image quality was produced[3]. Constancy checking protocols have been established among partners and were presented at the international workshop[3]. These protocols highlight the advantages of constancy checking.

Quality Criteria

One of the objectives of the concerted action was to establish quality criteria guidelines for digital procedures. These guidelines are to be based on the quality criteria guidelines published by the European Commission for diagnostic radiology and CT[5,6] and will include recommendations on clinical and technical parameters, examples of good equipment performance, criteria for patient dose, definition of visualisation criteria and the meaning of linguistic descriptors. The objectives of the quality criteria task group were to select the procedures for the digital quality criteria study, to identify clinical visualisation criteria and technical parameters for these procedure and to conduct a pilot trial of the selected procedures among the partners[1].

The following procedures were identified: CR (chest, skeletal), Image intensifier (small bowel, ascending venography), DSA (pelvis, lower extremities, dilation of iliac arteries)[2]. Clinical visualisation criteria and technical parameters were established and the final draft of the quality criteria document is now in place[7]. An extensive trial of visualisation criteria and technical parameters has been conducted.

Cardiology

The need for a multi-centre group specialising in cardiology was identified at the start of the concerted action which lead to the establishment of the cardiology group. Quality criteria were established for angiographic images[2,3] and a scoring system was devised for image quality evaluation[2,3]. A proposal for a complexity index for PTCA procedures was made and radiation protection training objectives for staff were identified and addressed[2].

Technical Parameters

Prior to the commencement of the concerted action there was no generic specification for interventional radiology equipment for users or manufacturers, there were no international standards for interventional equipment, there were no technical parameters for digital quality criteria and visualisation studies and there was a lack of technically defined optimisation strategies. The main objectives of the technical parameters task group were to address these issues[1].

The group produced a draft generic specification for interventional radiological equipment for contribution to an IEC standard[8], provided technical parameters for the quality criteria guidelines[7] and identified approaches needed for a definitive study of optimisation strategies.

DISCUSSION AND CONCLUSIONS

Considerable progress was achieved in this concerted action in terms of scientific and clinical endeavor, co-ordination and cooperation. Many aspects of diagnostic and interventional radiology, dosimetry protocols, radiological information content and technical parameters were reviewed and have been used as a platform from which protocols, methodologies and quality criteria have been developed and clinical trials conducted. An international workshop was held in Dublin in 1999 and the proceedings are currently in press[3]. The participants of the project extend their thanks to the European Commission for their support in this work and to the co-ordinators of the working groups.

REFERENCES

[1] EUROPEAN COMMISSION, DIMOND II CA project objectives, F14P-CT96-0042 (DG12-WSMN), Brussels, (1997).
[2] EUROPEAN COMMISSION, DIMOND II CA final report, F14P-CT96-0042 (DG12-WSMN), 1999, Brussels, (1999).
[3] Dose and Image Quality in Digital Imaging and Interventional Radiology (proc. int. conf. Dublin, 1999), Radiation Protection Dosimetry, in press.
[4] MARSH, D., The optimisation of dose and image quality in subtraction angiography, PhD Thesis, Trinity College, Dublin (1999).
[5] EUROPEAN COMMISSION, European guidelines on Quality Criteria for Diagnostic radiographic images, EUR 16260EN, Luxembourg (1996)
[6] EUROPEAN COMMISSION, Quality Criteria for CT, EUR 16262EN, Luxembourg (1997)
[7] EUROPEAN COMMISSION, Diagnostic requirements for digital radiographic procedures, Luxembourg, in press.
[8] IEC, Requirements for dose display systems integrated in radiological equipment, draft standard, in press.

DOSIFICACION DE IODO 131 Y PACIENTES CON Ca INDIFERENCIADO DE TIROIDES

ASOSIACION NACIONAL DE TECNICOS RADIOLOGOS, RADIOTERAPEUTAS E IMAGENOLOGOS DEL SEGURO SOCIAL

NOMBRE Y APELLIDOS DE LOS AUTORES:
XOCHITL ALEJANDRA MERA CHAPA
GERARDO CARREON BAUTISTA
JOSE ALVAREZ GARCIA

DOSIFICACION DE I131 EN PACIENTES CON Ca INDIFERENCIADO DE TIROIDES.
The autors examined the association between the weight of thyroid gland obtainer in surgical act and the account number acquired in trace with Iodine 131, in restrospective study of 419 patients with thyroid cancer in the National Cancer Institute of Mexico. After six years of follow-up, 137 cases was recivied I 131 as therapeutical modality were observed 42 patients with three or more dose aplication of I131. The purpose is the adjust the dose in milie-curies from each patient, crosswise a mathematical constant, so that, consequently the radiology protection will be increase. In a second part of study, prospective, to attempt stimable to quantity of disperse radiation emanative as gas, at moment of medition the iodine 131, to found in major segurity from the thecnical personnal.

JUSTIFICACION: La acción terapéutica del I131 es efectiva pero limitada por diferentes factores cuando se habla de metástasis funcionantes de Cáncer Indiferenciado de tiroides. Es evidente que el propósito no es curativo, más bien se persigue impedir el crecimiento de las lesiones.
También es evidente que el crecimiento, la diferenciación y la funcionalidad del tejido tiroideo metastásico es actividad de la hormona estimulante del tiroides. Por tanto es necesaria la combinación de las dos acciones en forma racional, manteniendo el bloqueo en la producción de la hormona estimulante del tiroides a nivel hipofisiario mediante la administración sostenida por períodos prolongados de hormonas tiroideas a nivel supresivo, así como la aplicación **absolutamente dosificada de I131 para tejido residual postqirúrgico,** para lo cual el carácter propositivo de la presente investigación descriptiva retrospectiva, transversal y con análisis de regresión y correlación, en su primera fase, se basa en la dosificación obtenida a través de la resultante matemática de el peso de la glándula obtenida quirúrgicamente multiplicado por el factor constante del número de cuentas capturadas por imagen de medicina nuclear.
INTRODUCCION: Es la práctica usual administrar dosis terapéuticas de 100 m Ci de I oduro radioactivo en tiempo postqirúrgico, sin embargo, se puede establecer como uso común dosis de 50 u 80 m Ci; y esto es debido a que, difícilmente dadas las características de la glándula y del proceso tumoral el lograr la extirpación completa de la misma. Por lo que es natural que después de la cirugía existan zonas hiperfuncionantes, existe otro factor a considerar y que se presenta frecuentemente durante los días que siguen a la extirpación debido a la liberación excesiva de tiroxina hacía el torrente circulatorio durante el acto quirúrgico debido a que se logra una movilización y migración mayor de células - por lo que en la mayor parte de los casos la imagen de las metástasis cambia en relación a la imágen prequirúrgica de manera significativa al poco tiempo de la misma- en este caso el porcentaje de absorción del I oduro administrado en una sola dosis es del 80 al 90% tanto de la glándula residual como de las metástasis funcionantes, lo que aplica un factor de potencialización para esta funcionabilidad. Asimismo pareciera que en estos mismos pacientes cuando se

aplica una dosis mayor a los 90 m Ci se presentan psicósis exógenas de Von Hoeffer, debido alcanzar un hipotiroidismo esperado antes de la administración del I131.
La tiroglobulina contenida en los sacos o acinis es un material viscoso, "coloide", esta glicoproteina hecha en gran parte de residuos peptídicos que engloban a las hormonas tiroideas y a sus precursores. La síntesis de la tiroglobulina es realizada por los ribosomas del ergatoplasma de células foliculares y transportadas por las cisternas hasta la periferia de la célula, pero su Iodización, aparentemente no ocurre dentro de ella sino en la superficie de las microvellosidades, en la interfase que separa a los elementos celulares del coloide, con pesos moleculares diferentes, razón por la cual también las metástasis funcionantes de cáncer papilar, folicular o mixto tienen pesos moleculares diferentes. Cuando la fase de Iodización de la tiroglobulina ocurre, el peso molecular de esta permite un mayor grado de ionización, razón por la que la imágen de nódulos fríos o calientes es más evidente en los dínodos, no obstante el número de cuentas capturado por el tubo fotomultiplicador de la gammacámara suma ello con la cascada producida por el material dentro de los folículos, es decir el que es susceptible de ionización aún, caso que guardan también las metástasis funcionantes, razón por la cual, las dosis de I131 con fines terapéuticos ablativos dependerá de las cuentas obtenidas en pantalla y no de la intensidad y periodicidad de la imagen del rastreo en película 1

Debido a la friabilidad propia de la glándula es práctica común considerar un remanente de la misma post-quirúrgico de hasta el 30%, por ello es propuesto que sea cuantificada la glándula obtenida en gramos y considerar el número de cuentas obtenido en rastreo posterior a cirugía y previo a la ministración de I131, así como considerando la vida media de I131 y la actividad biológica de los folículos es indispensable fraccionar la dosis y considerar que no es una relación directa sino la resultante matemática de la constante en presentación típica de cada servicio, a fin de evitar las tormentas tiroideas y sus consecuencias.

Cuando el remanente es más grande, el fraccionamiento deberá ser hasta el doble de lo ideal, y entre uno y otro permitiendo el decaimiento del material a la mitad de su vida media y la misma actividad biológica, que en términos generales es muy irregular, pues depende de la provisión de fenilalanina y Iodo, pero que en aplicación terapéutica aumenta hasta un 100% de su producción en razón de la cantidad existente del otro sustrato, y que de manera genérica podemos valorarla entre 60 y 90 días, guardando así la máxima protección radiológica para el paciente y para el personal ocupacionalmente expuesto.

En una segunda fase de la presente investigación y de manera prospectiva, el Instituto Mexicano del Seguro Social está encargado de la cuantificaciòn y valoración dosimétrica de las emanaciones en forma de gas al momento de la medición del I131, siendo este proyecto calendarizado a un año a partir de la fecha, con el objetivo de proporcionar mayor seguridad radiológica al personal técnico que labora en área.
Se analiza en la primera parte de la presente investigación la experiencia del Instituto Nacional de cancerología en 419 casos de cáncer indiferenciado de tiroides en el período de 1992 a 1998.Página 2 de 5

Del total de casos 71 (16.9%) correspondieron a hombres y 348 (83.10%) a mujeres.
El promedio de edad fue de 51 años con intervalo de 16 a 93 años.
La estirpe tumoral de mayor frecuencia fue el papilar con el 74.4%, folicular 16% y el mixto del 8%. Para el cáncer medular hubo 16 casos y para el cáncer anaplásico 18 pacientes. Se realizaron un total de 1383 estudios de laboratorio y gabinete, siendo el promedio de examen por paciente de 3.3
El consumo de tiempo en los estudios tomó un promedio de 2.8 semanas por paciente antes de decidir su manejo terapéutico.

HIPOTESIS ALTERNA: Todos los pacientes que con diagnóstico de Cáncer Folicular o Mixto de Tiroides entre 1992-1998 y que siendo llevados a cirugía con estudio

histopatológico corroborado sea cuantificada en gramos el peso de la glándula obtenida, concomitantemente a ello el estudio previo de imagen por gammagrafía tiroidea será capturado en programa estadístico con fines de establecer una tabla de resultados para la media y la mediana en el número de cuentas obtenidos en estos pacientes a través de equipo Siemmens 200 de medicina nuclear, posterior a ello y con cálculo personalizado a través del cociente obtenido de número de cuentas entre el valor en miligramos menos uno se proporciona dosis terapéutica de I131 en forma fraccionada y cuantas veces sean suficientes para alcanzar el cálculo arrojado no debiendo exceder cinco aplicaciones y 100 m Ci por aplicación, con intervalos no menores a tres meses ni mayores a seis; al termino de esto nuevamente serán revisadas las imágenes de gammagrafía tiroidea y teleradiografía de tórax de cada uno de los pacientes.

Los resultados esperados deberán proporcionar una alternativa viable en calidad de vida a los pacientes con Ca de tiroides, así como el manejo de costos y equipo médico a utilizar. Así como alcanzar en el tiempo promedio de 36 meses posterior a cirugía la erradicación completa de metástasis y el total control con terapia hormonal sustitutiva. Tiempo en el cual clínicamente es esperable observar cambio en la imagen de metástasis.

Hipótesis estadística será la probatoria de la hipótesis alterna y cuya hipótesis científica guarda relación inversa a ella

Material y métodos:

De todos los expedientes clínicos correspondientes a los años 1992-1998 reportados por el servicio de cabeza y cuello de consulta externa para identificar a aquellos con codificación 8050/3 y 9990/3, según los criterios de la clasificación internacional de enfermedades, apartado oncología de 1975, fueron considerados para criterio de inclusión los que contaran con corroboración histopatológica por pieza quirúrgica y, o biopsia previa vírgenes a tratamiento y con seguimiento mayor a seis meses después de cirugía con respecto a resultados y; para consideraciones de descripción fueron tomados también los casos de códigos 8260/3, 8021/3 y 8140/3.

De la revisión de los expedientes se obtuvieron las siguientes variables: edad, sexo, órganos afectados, tiempo de evolución, antecedentes, procedencia, referencias, signos y síntomas, hábitos higiénico-dietéticos, karfnofsky, estudios de extensión, diagnóstico histológico, tipo de tratamiento, tiempo de tratamiento, respuesta a tratamiento y estado actual de los pacientes.

RESULTADOS: en el archivo clínico del Instituto Nacional de cancerología en el periodo de estudio se tienen registrados 419 casos como cáncer de tiroides, 407 casos tenían confirmación histológica de malignidad y en sólo 373 casos se obtuvo toda la información para realizar el presente trabajo.

65 pacientes correspondieron al sexo masculino (17%) y 308 (82%) al sexo femenino, las edades de presentación tuvieron un rango de 16 y 25 a 93 y 87 años con una media de 49 y 53 años; el tiempo de evolución varió de entre 0.5 y 24 meses con una mediana de once meses.

La referencia predominante fue de servicios generales de salud (primer nivel) 181 (48.5%) centros de salud 56 pacientes (15%), hospitales generales,136 (36%) y médicos particulares especialistas o no 22 casos.

Con respecto a la presentación en 48 pacientes (12.8%) se cursó con crecimiento anterior del cuellos de rápida evolución del orden de dos a seis semanas con una mediana de 3.5 y sin datos de mixedema; 325 (77.5%) casos tuvieron evolución lenta del orden de dos a 144 meses.

El síntoma de mayor presentación fue la disfagia progresiva, 96 casos del total del (25%), disnea de medianos y grandes esfuerzos 72 casos (19%) del total, perdida ponderal de peso 58 casos del total (15.5%), dolor localizado a hemicuello homolateral 39 (10.4%) ipsilateral 11 (2.9%), bilateral 7 (1.8%), en los pacientes con rango etaneo 22 a 29 años hubo referencia de perdida de la libido importante 47 casos.

En cuanto al karfnofsky la relación fue de 123 casos con un K-90 (33%), con un K-80 94 casos (25%) y por debajo de estos 89 casos (23%) en un solo caso se califico un K-50 y corresponde a cáncer anaplástico, el 18% de los casos 67 pacientes no hubo referencia de Karfnofsky. Solo de 105 los pacientes (28%) manifiesta en interrogatorio conocimiento de casos de cáncer familiar, en las dos líneas y/o niveles superiores, 31 pacientes desconocen el dato y 237 (63.5%) no hubo interrogatorio dirigido a la variable de interés.

El 47.9%, 179 casos provienen de distrito federal y área conurbada, perteneciendo esta al estado de México pero de características urbanas, para pacientes del Estado de México pero de área rural o semirural, los casos fueron 38 (10%), 53 (14%) casos del Estado de Veracruz, 27 Tlaxcala con 7.2%, Hidalgo 19, 3%, Guerrero 10-2.6%, Oaxaca 8-2% Estado de zona norte 14-3%, resto de los Estados 28-7.5%.

El 82% (305 casos) refieren diferentes hábitos alimenticios e ingesta normal de sal yodatada, 47 casos (12%) mantuvieron hábito tabaquico mayor a 10 cigarrillos diarios en los cinco años previos, y 29 (7.7%) un consumo de veinte o más cigarrillos al día también en los cinco años anteriores al estudio, de estos el 2% aun consumen tabaco.

Con relación al consumo de bebidas etílicas, destiladas o no en 84 casos (22%) la frecuencia es de embriaguez una vez por semana, 58 (15%) estado de embriaguez en un marco de treinta días naturales en promedio 26, 201 casos 53% del total no refieren en expediente datos al respecto de las tres ultimas variables.

Los estudios de gabinete se refieren a la toma de ultrasonido previo a cirugía en 5 3 casos (14%), tomografía anterior de cuello 13 casos (3.4%), ambas modalidade 2.14%, 08 casos teleradiografía de tórax para evidencia de mets, pulmonares 370 casos (99%).

El diagnostico histológico de la lesión se obtuvo en 36 casos (9.6%) por biopsia con aguja fina, en 175 casos (46.9%) en trans-operatorio o post-qx biopsia finc 156 casos (41.8%) a los cuales 150 fueron sometidos a revisión de laminillas 40.2%. En 344 casos el diagnóstico prenupcial corresponde al histopatológico, encontrando solo en 29 expedientes la información suficiente para el comparativo.

La técnica quirúrgica mayormente empleada en el Instituto Nacional de Cancerología fue la tiroidectomía total + DR ó DM con un número de 122 (53) 32.7% casos, 103 (27.6%) pacientes representan acto quirúrgico previo finc con predominio de hemitiroidectomia y sin disección, 89 casos (23%), TT+DMC 14 (3.7%) casos, de los pacientes con hemitiroidectomía a los que se les propone cirugía de extensión y que aceptan se reportan 71 casos (19%), es de señalar que el periodo se efectuaron dos cirugías de comando, y que corresponden a cáncer medular.

Respecto a el área de medicina nuclear en modalidad de diagnóstico obtuvimos 210 gammagrafías previas (56%), y 522 de control post TX (139%), con promedio de 1.4% por paciente. Cuando el paciente es referido urgente a tratamiento se realiza una primera imagen con Tc99, y posterior una con I131, en dosis de 5 microcuries.

Para la modalidad de terapéutica a 186 (50%) pacientes se proporcionaron entre una y dos dosis de 100 m Ci, a 42 (11%) pacientes tres o más dosis con promedio de 100 a 150 m Ci.

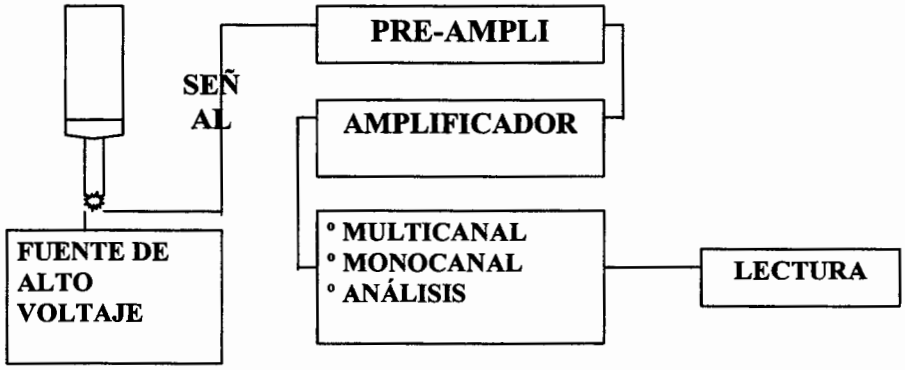
Con dos gammagrafías de control en promedio por paciente, con un lapso entre una y otra de 36 semanas.

En dos pacientes se presentaron cuadro de psicosis exógena durante su internamiento y en uno más depresión reactiva.

Los pacientes con evidencia de metástasis funcionantes para cáncer papilar, folicular o mixto tuvieron presentaciones solo en pulmón, otras variedades en rastreo se encontró desde la primera imagen evidencia de metástasis óseas.

La desaparición de las metástasis pulmonares en cáncer papilar, folicular o mixto fue evidencia en rango de doce a quince meses en 28 pacientes, del total (7.5%), para pacientes que después de este periodo resultaron son evidencia de disminución o incluso con incremento de las lesiones, se aplica terapéutica con I131 en una o dos

ocasiones más, de ellos tres pacientes abandonan y en 8 (2.14%) la evidencia a 24/30 meses seguía siendo casi la misma, es de señalar que la terapia sustitutiva hormonal no era homogénea en ninguno de los casos, ni para periodo fuera de rastreo ni para la aplicación de terapia de iodo, ni para el rastreo.
En todos los casos la medición de perfil de hormona tiroidea circulante previa a tratamiento es de hipotiroidismo, fluctuando la THS de manera importante entre los pacientes cuantificados y aún intrapacientes.



Conclusión: La práctica en la terapéutica en pacientes con Cáncer Indiferenciado de Tiroides requiere el máximo control en protección y seguridad radiológica en virtud de depender de fuente abierta y en muchos casos con dosis mayores a las realmente requeridas por cada paciente, la presente propuesta es accesible técnicamente.

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Patient doses and examination frequency for diagnostic radiology in Iceland 1993 - 1998

Gudlaugur Einarsson and Sigurdur M. Magnusson
Icelandic Radiation Protection Institute, Raudararstig 10, 150 Reykjavik, Iceland

Abstract: Presented are data on the frequency of x-ray examinations that have been gathered in two surways with a five year interval. There is a 17% increase in the number of x-ray examinations from 1993 - 1998. At the same time computed tomography examinations are nearly doubled. Patient dose data for the different types of examinations are also presented and an assessment is made of the contribution of these examinations to the Collective Effective Dose. The number of CT examinations has increased from 8,3% of all x-ray examinations in 1993 to 13,6% in 1998 and contributes more the 50% of the CED in 1998.

Introduction

The Icelandic Radiation Protection Institute (IRPI) performed two surveys on the frequency of diagnostic x-ray examinations in Iceland in 1993 and 1998. Earlier information are limited. Measurement of patient doses for over 4500 conventional x-ray examinations have been performed at 14 x-ray departments all over the country, in more than 28 x-ray rooms. These measurements were made with Dose Area Product meters (DAP). Dose evaluation for CT examination have been made for all the CT units in the country. Patients doses for breast examinations have also been evaluated.
This paper will present results of these efforts, revealing trends in the frequency of radiological examinations and patient doses and an assessment of the collective effective dose (CED)[1] contributed by diagnostic radiology examinations. Of particular interest are trends in patient doses and examination frequency in computed tomography and its contribution to the CED.

Material and Methods

Examination frequency

Data on examination frequency was collected by IRPI on two separate occasions, in 1994 (for examinations made in 1993) and again in 1999 (for examinations made in 1998). Earlier data collections have been made in Iceland, but not in the detail necessary for comparison with the this data. Data was collected from all x-ray departments in the country, covering more than 95% of the medical diagnostic imaging examinations done in Iceland in these years. About 80% of the data was detailed with information on examination types, age and sex of the patient.

Patient doses

In 1994 IRPI started a program to evaluate patient doses by using dose measurement systems consisting of DAP meters connected to PC-computers. A software was developed, that made it easy for the radiographers to collect data about all x-ray examinations made with the x-ray equipment. This includes information such as examination type, age, weight and sex of the patient, the high tension (kV) used, number of films used and the film-screen combination used. The software collected data from the DAP meters during the x-ray procedure and could separate DAP for fluoroscopy and radiographs. It could also calculate the fluoroscopy time. From this data the effective dose[1] for the different x-ray examinations could be calculated using appropriate conversion coefficients from the literature[2].

All Mammography examinations are performed at the Icelandic Cancer Societies Breast Screening Center in Reykjavik and with mobile equipment around the country. Patient doses for breast imaging is based on data collected by a computer program on the PC-computers which are connected to the x-ray equipment that are used in the screening program. This program collects information about exposure factors for each image made, such as kV, mA, exposuretime, thickness of the compressed breast and other information. The mean glandular tissue dose is calculated and stored for each exposure. The effective dose wase calculated be using the ICRP weight factor for breast[1], multiplyed with the mean glandular dose and the mean numer of projections used.

For CT examinations, patient doses were assessed by dose measurements in 4 of the 5 CT units used in Iceland. Free in air and phantom doses were measured with a pencil shaped ionization chamber connected to an electrometer (Radcal Corp. USA). The CTDIw[3] for each unit was calculated and with information from examination protocols at each location the DLP[3] for the most common examinations was calculated. The effective dose for CT examinations was calculated by using normalized values of effective dose per DLP for different body regions[3].

Table 1. Frequency of x-ray examinations 1993 and 1998

	1993	1998	Change %
Number of all x-ray examination (incl. CT and Mammography)	160.711	188.739	+17,4
Computed Tomography	13.368	25.841	+93,3
CT ex. as a fraction of all x-ray examinations	8,3%	13,6%	
Mammography	13.155	14.872	+13,1
Number of x-ray examinations per 1000 inhabitants	609	685	+12,5

Results

Examination frequency

The national survey in 1993 shows that 160.710 x-ray examinations were made that year and this number has increased to 188.740 in 1998 (+ 17,4%). The most striking increase is in CT examinations, which went from 13.370 to 25.760, which is an increase of 93%. The results are shown in table 1.

There are good data available about the number of CT examinations since they began in 1981. Today there are 5 CT-units in use in the country and the majority of the examinations are made with 4 of these units (1 is an old unit that only contributes less then 1% of the examinations). In figure 1, the examination frequency for CT examinations are shown, from 1981 and on the figure are indicators for the number of CT units

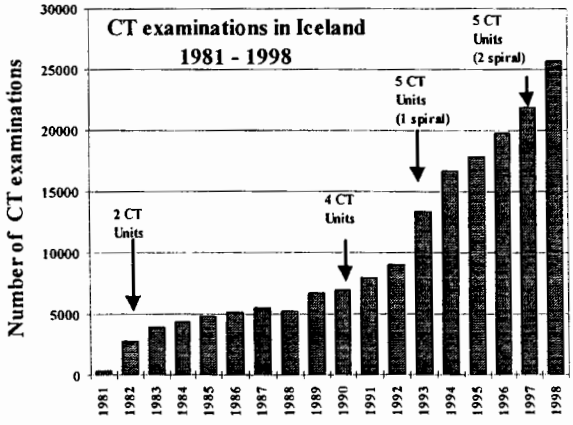

Figure 1. Frequency of CT examinations in Iceland 1981 - 1998

that are in use at each time. In 1993 the first spiral CT unit was introduced and today there are 2 spiral units and one multi-slice unit.

The increase in Mammography examination are mainly due to different coverage of the country in the screening program for these years. The average number of Mammography examinations per year from 1989 - 1998 is 14100.

Patient doses

Patient mean effective dose for the most common conventional x-ray examinations, based on DAP measurements are shown in table 2. The table also shows information on mean high tension (kV) used, the mean number of films, and mean DAP values (in $Gycm^2$) and measurement range. There is a very wide range in DAP measurements for most of these examinations.

Table 2. Mean effective doses for some common conventional x-ray examinations, with information about used kVp, number of films used, mean measured DAP and measurement range.

Examination type	Mean kVp	Mean number of films	Mean DAP $Gycm^2$	Range $Gycm^2$ Min	Range $Gycm^2$ Max	Mean effective dose mSv
Barium Enema	99	15,4	56,6	1,5	204,7	***11,9***
MUCG	74	11,0	34,5	2,3	51,9	***10,7***
ERCP	80	7,5	22,1	0,1	100,6	***4,4***
Urography	72	11,2	18,2	0,8	64,8	***3,5***
Lumbal Spine	73	4,6	12,9	0,2	97,6	***2,0***
Abdomen	76	3,2	6,1	0,2	40,1	***1,4***
Pelvis	74	1,4	3,4	0,1	24,6	***0,7***
Thoracal Spine	71	2,9	5,2	0,3	18,5	***0,7***
Cervical Spine	69	5,8	1,0	0,05	3,6	***0,2***
Lung	122	2,2	0,6	0,01	5,4	***0,1***
Skull	72	3,8	2,0	0,02	4,3	***0,05***

The mean effective dose for Mammography is 0,36 mSv and contribute 5,4 manSv to the CED. The method of data collection and dose measurements in CT, only gives average doses for the different examinations, with no indication of range. The mean effective dose for the most common CT examinations are shown in table 3 with assessment of their contribution to the CED. The contribution of the different x-ray examinations to the Collective Effective Dose are shown in figur 2.

Table 3. Number of CT examinations in 1998, mean effective dose and contribution to CED

Examination Type	*Number of examin. 1998*	*Mean Effective Dose mSv*	*Collective Effective Dose manSv*
Head	10.888	1,3	14,6
Lung/Chest	4.186	8,5	35,5
Neck	437	4,0	1,7
Spine	3.309	3,3	10,8
Kidneys	435	5,3	2,3
Abdomen	3.154	13,2	41,6
Liver/Spleen	2.046	5,8	11,9
Pelvis	775	6,1	4,7
Other	532	4,5	6,8
Total:	**25.762**		**129,9**

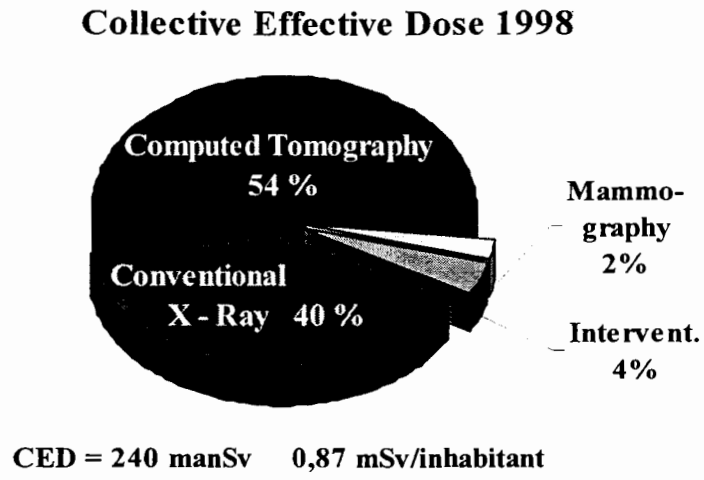

Figure 2. Collective effective dose for x -ray examinations in Iceland

Discussion and Conclusion

Examination frequency is increasing in Iceland but the number of examinations per thousand inhabitants is very similar in Iceland (689) as in the neighbouring countries, such as Norway (708), Sweden (568) and Finland (704)[4]. But lower then the average number for Level I countries according to the latest UNSCEAR report (920)[4]. The most pronounced trend in examination frequency is the increase in CT examinations which has nearly doubled.

CT examinations now contributes more than 50% of the total CED from all x-ray examinations, similar to trends in other countires[5]. The highest doses arise from CT examination of the abdomen, chest and pelvis. On average CT examinations are high dose examinations which have a great effect on CED. Patient dose measurements for conventional examinations show a wide range, which indicates a potential for optimization in performance. Advances in CT technology are opening new diagnostic possabilities for the benefit of the patient and CT examinations are becoming the examination of chocie for more and more indications. Even though new CT equipment can achieve examinations with lower patient doses compared to older CT units, changes in examination protocolls can include larger parts of the patient being irradiated and higher doses. The CED is increasing rapidly due to both higher number of CT examinations performed and increasing doses per examination. Efforts to reduce doses should inlude optimisation of both how CT examinations are performed and the criteria for requesting them.

References

1. ICRP. Annals of the ICRP, *Recommendations of the International Commission on Radiological Protection.* ICRP Publication 60, 1990
2. Hart, D., Jones, D.G., and Wall, B.F., *Estimation of effective dose in diagnostic radiology from entrance surface dose and dose-area product measurements.* Chilton, NRPB-R262 (1994), London HMSO.
3. EUR 16262 - Euorpean Guidelines on Quality Criteria for Computed Tomography. Luxembourg 2000, Office for Official Publications of the European Communitites.
4. UNSCEAR (2000). United Nations Scientific Committee on the Effects of Atomic Radiation. UNSCEAR 2000 Report to the General Assembly, Annex D: Medical Radiation Exposures. United Nations, New York NY.
5. RCR. *Making the Best Use of a Department of Radiology. Guidelines for Doctors*, 4th edition 1998. The Royal College of Radiologist, London, UK.

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RADIATION RISK FROM INTRACORONARY BRACHYTHERAPY

C Kirisits*, A Hefner†, D Georg*, R Pötter*
*Department of Radiotherapy and Radiobiology, Medical School, University of Vienna
†Austrian Research Centers Seibersdorf, Austria

Corresponding author:
ALFRED HEFNER
Austrian Research Centers Seibersdorf
Radiation Protection Division
A-2444 Seibersdorf, AUSTRIA
phone: ++43 2254 780 2509
E-mail: Alfred.Hefner@arcs.ac.at

ABSTRACT:
During the last years coronary endovascular brachytherapy has been extensively explored as a new treatment to prevent restenosis after percutaneous coronary interventions. While clinical and physical aspects of such treatments are addressed in literature, there is little information available on radiation protection and radiation safety aspects. In this paper we estimate the radiation risk for the patient using analytical methods and Monte Carlo calculations for three delivering systems currently used in clinics. Additionally, radiation risk to personnel involved in such treatments is investigated. For gamma emitting sources the radiation exposure to patients is in the order of magnitude of the exposure due to diagnostic angiography. Doses to organs at risk when applying beta emitting sources are significantly lower. Measured doses for the intervention personnel are consistent with the estimated whole body dose. They are smaller than 7,5 μSv per intervention, which is a dose much less than 0,1% of the annual radiation worker`s Maximum Permissible Dose (MPD) recommended by EC regulations, and less than 1% of the general public`s MPD.

1. INTRODUCTION

Ischemic heart disease due to narrowing is a significant cause of morbidity and mortality in the Western world. Restenosis is severely limiting the clinical outcome of percutaneous vascular interventions. Clinical studies have shown the possibility to apply endovascular irradiation for the prevention of restenosis [1-5]. Depending on trial protocol and source design, respectively, prescribed doses are between 7 and 20 Gy. The dose specification point, however, differs. For example, a point at 2 mm distance from the source axis has been used in some studies while others used a specified depths (e.g. 1 mm) into the vessel wall.

Detailed knowledge about the dose-distribution around endovascular brachytherapy sources is essential for retrospective analysis of dose-response relationship, to perform accurate treatment planning and to estimate the possible impact on radiation protection for the treated patients. However, since endovascular brachytherapy is a new field in brachytherapy, little information is available on dose distributions for treatment planning and estimations of the dose to organs at risk.

Additionally, detailed knowledge about the magnitude of the whole body dose received by the interventional staff (radiation oncologist, physicist, interventionalist) involved in coronary endovascular brachytherapy is needed in order to limit the dose to staff members according to the ALARA principle.

2. METHODS

We studied three different sources designs currently applied for intracoronary brachytherapy treatments: (1) a seed ribbon consisting of six ^{192}Ir seed sources, each 3 mm length, (2) a ^{32}P wire source of 40 mm length, and (3) a ^{90}Sr/^{90}Y seed train of 40 mm total length.

Precision dosimetric studies have been performed for these different source geometries and nuclides using Monte Carlo calculations with EGSnrc [6] code. Beta and gamma emitting sources were simulated in a plane-cylinder geometry model, using accurate energy emission spectra. We calculated the relative dose at various radial distances from the source center.

For distances beyond 1 cm from a ^{192}Ir source center line it is also possible to calculate the dose following the formalism described in the AAPM TG43 protocol [7]. Using the air kerma rate constant for a Ir-192 seed (0.109 μGy m^2 / MBq / h) and the dose rate constant (1.12 cGy / h / U) the dose rate at 1 cm from the source center can be calculated based on a given activity.

The quantity *Total Reference Air Kerma* can be used to specify brachytherapy applications [8]. It is the sum of the products of the *Reference Air Kerma Rate* and the irradiation time for each source, expressed in Gy (or convenient multiples). The TRAK is fast and easy to calculate and should be used in endovascular brachytherapy for the following reasons, (i) doses to all organs and thus to the integral dose to the patient are directly proportional to the TRAK, and (ii) the TRAK provides an estimation of the kerma (dose) rate at one meter from the source which can be useful for radiation protection purposes, and (iii) the inverse square law allows to estimate the dose delivered during the treatment to the organs at a distance from the source(s) down to 10-20cm.

The dose rate distribution in the standard cardiac catheterization laboratory is measured using suitable dosimeters and survey meters. In order to obtain the dose to individuals the measured dose rate is multiplied by the treatment time, for each relevant location in the catheterization laboratory. The doses to individuals are estimated by applying the inverse square law and taking into account shielding by the human body. Additionally, area monitoring inside and outside the cardiac catheterization laboratory is performed using dosimeters and survey meters [9]

3. RESULTS

Figure 1 presents Relative dose variation in radial direction from the source axis for the three different source design investigated.

In order to further compare the different nuclides concerning radiation exposure a dose prescription of 20Gy is presumed at 2 mm distance from to source axis. Table 1 summarizes the respective dose values at 1cm distance.

Based on a calculation using the TG 43 calculation formalism the dose rate at 1 cm distance from the source is 11.28 Gy/h for a 9250 MBq (250 mCi) ^{192}Ir source. For a typical treatment time of 18 min the resulting dose is 338 cGy at 1cm distance. This value confirms the Monte Carlo result presented in table 1.

Relevant organs, such as bones, lung tissue, spinal cord, thyroid, breast (women) are located at in distances from the source of 10cm and more. Therefore, the doses to these organs at risk can be estimated using the inverse square law and neglecting absorption or scatter. Following this theory, for beta emitting sources the dose to relevant organs at risk at 10cm distance is lower than 0.01cGy, for gamma sources it is lower than 4cGy, respectively.

Figure 1: Relative dose variation in radial direction from the source axis for the three different source design investigated.

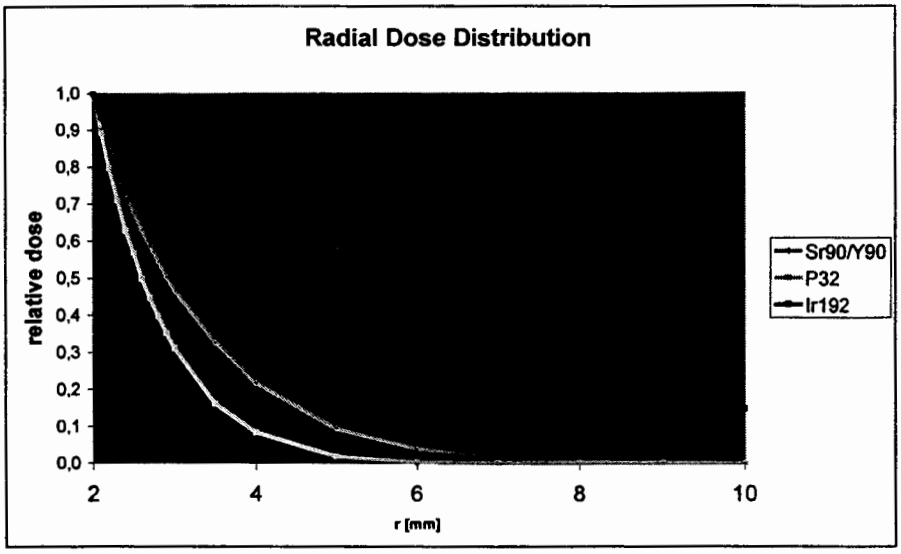

Table 1: Dose at 1 cm distance from the source axis (dose of 20 Gy at 2 mm) for the three sources types.

	Factor	Dose
Ir-192	0,16	320 cGy
Sr-90/Y-90	0,0003	0.6 cGy
P-32	0,0001	0.2 cGy

The Total Reference Air Kerma (TRAK) for the Ir-192 source specified above is 302μGy. Air Kerma Rate for beta sources are only due to Bremsstrahlung and cannot be defined precisely.

The doses measured for the intervention personnel are less than 7,5 μSv per treatment which is a dose less than 0,1% of the annual radiation worker's Maximum Permissible Dose (MPD) recommended in EC regulations. The measured dose for a single individual of the general public outside is the cardiac catheterization laboratory is less than 1‰ of the general public's MPD.

4. DISCUSSION AND CONCLUSION

Pattee et al. [9] estimated the organ dose during an 'average' coronary angioplasty procedure, which are 2.29 cGy for Bone, 9.35 cGy for lung, 0.99 cGy for thyroid and 4.89 cGy for breast (women). According to the results presented above the additional organ doses resulting from endovascular brachytherapy applications are far below this values when using beta emitting sources and in the same order of magnitude for for gamma emitting sources.

The dose at larger distance resulting from a beta emitting nuclei is due to Bremsstrahlung production. Therefore doses to organs at risk are much lower when applying beta emitting sources as compared to gamma sources.

The TRAK value presented for the Ir-192 source applied in intravascular brachytherapy is about one order of magnitude lower than the values reported for 'conventional' brachytherapy applications.

It has been shown in several clinical trials that restenosis can be avoided by intracoronary brachytherapy. The possible re-narrowing without brachytherapy have to be treated by another coronary intervention including further angiography exposure. Although there is an additional radiation exposure to patients and personnel by this single treatment the values are much smaller than those caused by a second angiography (ALARA principle).

The personal dose measurements and calculations showed that all principles of ALARA are fulfilled within the clinical trials. Safety and effectiveness is demonstrated for localized radiation therapy with endovascular brachytherapy sources during cardiovascular interventions for the treatment of patients with in-stent restenotic lesions.

5. ACKNOWLEDGEMENT

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6. REFERENCES

[1] TEIRSTEIN, P.S., MASSULLO, V., JANI, S. et al. Catheter-based radiotherapy to inhibit restenosis after coronary stenting. N Engl J Med **336** (1997) 1697-1703.

[2] VERIN, V., URBAN, P., POPOWSKI, Y. et al. Feasibility of intracoronary beta-irradiation to reduce restenosis after balloon angioplasty. A clinical pilot study. Circulation **95** (1997) 1138-44.

[3] WAKSMAN R, WHITE RL, CHAN RC ET AL. Intracoronary gamma-radiation therapy after angioplasty inhibits recurrence in patients with in-stent restenosis. Circulation **101** (2000) 2165-2171.

[4] WAKSMAN R, BHARGAVA B, WHITE L ET AL. Intracoronary beta-radiation therapy inhibits recurrence of in-stent restenosis. Circulation. **25** (2000) 1895-1898.

[5] POKRAJAC B, PÖTTER R, MACA T ET AL. Intraarterial ^{192}Ir HDR brachytherapy for prophylaxis of restenosis after femoropopliteal percutaneous transluminal angioplasty: the prospective randomised Vienna-2 trial. Int. J. Radiat. Oncol. Biol. Phys. 2000 (In press).

[6] KAWRAKOW, I., ROGERS, D.W.O., The EGSnrc Code System: Monte Carlo Simulation of Electron and Photon Transport, NRCC Report PIRS-701, Ottawa, Canada (2000).

[7] NATH, R., ANDERSON, L., LUXTON, G. et al. Dosimetry of interstitial brachytherapy sources, Recommendations of the AAPM Radiation Therapy Committee Task Group Nr. 43. Med. Phys. **22** (1995) 209-234.

[8] ICRU, International Commission on Radiation Units and Measurements, Dose and volume specification for reporting interstitial therapy, ICRU Report 58, 7910 Woodmont Avenue, Bethesda, Maryland 20814, USA, 1997.

[9] HEFNER, A., internal papers.

[10] PATTEE, P.L., JOHNS, P.C., CHAMBER, R.J., Radiation Risk to Patients from Percutaneous Transluminal Coronary Angioplasty, J Am Coll Cardiol **22** (1993) 1044-51.

RADIATION MORBIDITY IN RADIOTHERAPY – DEVLOPMENT OF A CLINICAL AUDIT TOOL

On behalf of the ESTRO-EU MORQA Networks

Radiotherapy treatments are evaluated by two main outcomes, rates of cure or local tumour control and normal tissue complication rates. Many excellent schemes have been devised for recording the late effects of radiotherapy treatments including the RTOG and LENT SOMA Scales. These have proved invaluable in documenting the outcome of clinical trials, but have proved too complex and time consuming for routine daily use in busy departments.

A group in Eindhoven led by Professor Lybeert undertook a pilot study of a potential way of auditing late radiation complications. Using a simplified form derived from the LENT SOMA scales, they collected data on grade 3 and 4 complications in a total of 675 patients and were able to correlate a number of particular complications with specific protocols, ICD codes and physician practice. Further review of the case records made it possible to identify specific factors which may have led to toxicity and could be taken into account to modify treatment protocols.

From September 1999 clinicians in participating centres undertaking normal follow-up procedures were asked to identify patients who showed evidence of grade 3 or 4 toxicity as defined in the pro-forma. Date of radiotherapy was recorded so that a temporal correlation of complication with treatment could be made, but this study did not attempt to assess the incidence of complications, but to provide a cross-sectional study of prevalence. Centres participating in the study have been Eindhoven, Köln, Gent, Brussels, Glasgow, Mount Vernon, Genova and Lyon.

In Eindhoven 651 reports were collected between January 1995 and December 1999. 89 reports had to be discarded because complications were not validated by the reviewing radiotherapists. Dr Lybeert noticed that individual radiotherapists appeared to have different thresholds for reporting specific complications. 13 patients deaths appeared to be related to radiation problems. An overall level of detection of morbidity was approximately 9%. It was possible to link morbidity with specific protocols. Some of these employed large doses per fraction and in some cases these were given in combination with chemotherapy.

In the second phase of the study, patients undergoing routine follow-up at the Beatson Oncology Centre were also studied. Forms were completed by the reviewing oncologist and checked and analysed separately by two other radiotherapists. So far a total of 7645 forms have been placed. Of these 4372 have been completed and at routine follow-up 8.9% of these have recorded grade 3 or 4 toxicity. Preliminary analysis of the data suggests again a correlation of large dose per fraction or concomitant chemotherapy with radiotherapy related problems.

It is hoped that this study will be completed by December 2000. Comparison of data from different centres will be made. Data from Lyon and Mount Vernon have been extracted from existing databases. It is hoped that there may be some consistency in results which may provide a benchmark for a useful audit tool. This approach will be discussed in relation to the need to develop a simple prospective recording of late morbidity.

Education for radiological protection in Radiotherapy

ESTRO Recommendations for EU EURATOM guidelines
European Society for Therapeutic Radiology and Oncology, Av.E. Mounierlaan 83, 1200 Brussels. Info@estro.be

"Outline of specific training objectives for Radiotherapy

The practice of radiation oncology (radiotherapy) encompasses the clinical care of patients as well as the technical aspects of radiotherapy. Benefits to patients accruing from radiotherapy depend upon the accurate delivery of high doses to the tumour with doses to normal tissues being kept to a minimum. In addition to these patient-centred aspects of radiation protection in radiotherapy, appropriate measures must also be taken to reduce the amount of radiation to staff and the general public to as low a level as is reasonably achievable.

In order to achieve these aims, a broad basic training is required in all of the disciplines involved in the delivery of ionising radiation. ESTRO has recommendations for core curricula for the disciplines involved, but this annex lists the elements from these curricula which relate specifically to radiation protection.

It is important to reiterate that the extent of training required will depend upon the existing levels of knowlege and training of different groups of professionals in physics, radiobiology etc, and this may vary from state to state

specific training objectives for radiation protection in Radiotherapy will cover following subjects:
Radiotherapy equipment - safety and accuracy
Dosimetric and geometric quantities for accuracy in radiotherapy
Radiobiology and radiation risks
Radiation treatment planning for optimising delivery of radiation dose
Optimal and safe use of radionuclides in radiotherapy
Radiation hazards in radiotherapy facilities

Keywords: radiotherapy, education, training, continuous professional development in

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Outline of specific training objectives

Radiotherapy equipment - safety and accuracy

- To show that the principles of operation and details of construction of therapy X-ray generators, including treatment head, are designed for safe and accurate delivery of radiation to the target volume with minimal collateral radiation dose.
- To discuss how filtration and factors affecting output of KV X-ray units determine the radiation dose to skin and target volume.
- To discuss how the construction of cobalt-60 units and methods of safety control minimise the risk of radiation accidents.
- To describe the production of MV X-rays in a linear accelerator, and the arrangements for limiting X-ray head leakage.
- To describe KV X-ray applicators, electron applicators, conventional linear accelerator collimators, multi-leaf collimators, the effect of collimators on penumbra size, shielding materials and dose under shielding materials, and the relevance in restricting radiation dose to the target volume.
- To describe equipment controls and interlocks, and select/confirm systems, and their role in hazard control.
- To explain the role of commissioning measurements and quality control checks in determining the accuracy of radiation dose delivered to the patient.
- To discuss the merits of equipment and limitations of use with respect to the optimal and safe delivery of radiation to the patient.
- To discuss the merits of verification in respect of the information needed to ensure accurate and safe delivery of radiation to the treatment volume.
- Dosimetric and geometric quanitities for accuracy in radiotherapy
- To discuss the use of percentage depth dose curves, backscatter and peakscatter factors, tissue phantom ratios, tissue standard factors and equivalent squares in determining the radiation dose delivered to a patient.
- To discuss the role of beam geometry, magnification and beam penumbra in determining the extent of the radiation field which treats a patient.
- To explain the definition of field size and its use in ensuring correct coverage of the target volume.
- To explain the variation of depth-dose characteristics with energy and to relate these to the optimum choice of energy in delivering radiation to a patient.
- To explain the general features of isodose charts and their dependence upon FSD and energy with regard to ensuring the adequate and homogeneous irradiation of the target volume.

- To describe the acquisition and use of beam data for radiotherapy treatment planning and to analyse the limitations of the algorithms used.
- To explain calibration protocols and the uncertainties in the calibration process and to relate these to the overall uncertainty of patient radiation dosage.

Radiobiology and radiation risks

- To discuss the justification and use of radiotherapy in malignant and benign disease
- To contrast the use of external beam therapy and brachytherapy in the treatment of disease and to discuss the relative benefits of both modalities to the patient.
- To relate the response to radiation at the molecular and cellular level, including cellular injury and cell survival curves to the macroscopic response of tissue to radiation.
- To discuss the response of tumours and normal tissue to therapeutic levels of radiation including dependence on fractionation, dose rate, radiosensitisation, reoxygenation.
- To consider radiation reactions - early and late.
- To discuss the role of radiobiological modelling including linear-quadratic model in explaining the effects of radiation injury to tissues.
- To discuss therapeutic ratio and its role in optimising dose delivered to patients.
- To discuss the effects of radiation on the embryo and foetus, leukaemogenesis and carcinogenesis, genetic and somatic hazards for exposed individuals and populations.
- To explain the assessment of the efficacy of radiotherapy and its role in the justification of radiation treatment.

Radiation treatment planning for optimising delivery of radiation dose

- To describe the delineation of target volumes including ICRU50 and ICRU62. and its role in optimising radiation treatment.
- To contrast fixed-SSD and isocentric radiotherapy, and to discuss the relative benefits of the two methods.
- To describe beam modification including oblique incidence, inhomogeneities, wedges, compensators and interface effects in the context of achieving accurate, homogeneous irradiation of the target volume.
- To discuss the combination of fields to produce homogeneous irradiation of the target volume.
- To discuss how 3-D treatment planning and optimisation can be used to limit the radiation exposure of normal tissues.To discuss how the use of conformal radiotherapy can optimise the irradiation of the target volume with respect to normal tissue.
- To explain how treatment verification and in-vivo dosimetry can enhance the accuracy of the dosage and targeting of the radiation field.
- To explain how Intensity Modulated Radiotherapy (IMRT) can be used to limit the radiation dose delivered to vulnerable organs.
- To explain how stereotactic radiotherapy can limit collateral radiation damage.

- To explain the role of Monte Carlo treatment planning in enhancing the accuracy of dose estimation.
- To discuss the role of different imaging modalities in radiotherapy including CT and MRI in enhancing the accuracy of target volume delineation.
- To describe methods of patient alignment and immobilisation and their role in enhancing the geometric accuracy of dose delivery to the patient.
- To discuss the risks and benefits of special techniques: total-body Irradiation (TBI), intra-operative radiotherapy (IORT) and total-skin electron irradiation (TSEI).

Optimal and safe use of radionuclides in radiotherapy

- To discuss the types of sources used in radiotherapy and their construction, with regard to their efficacy in irradiating target volumes.
- To relate the specification of source strength to the radiation dose delivered to patients.
- To discuss the hazards of specific sources.
- To discuss the principles of clinical use and the associated radiation hazards.
- To discuss the control and testing of sealed sources in relation to the radiation hazard.
- To discuss afterloading including benefits and hazards.
- To discuss the use of unsealed radionuclides for radiotherapy and radiation protection requirements.

Radiation hazards in radiotherapy facilities

- To discuss current national legislation.
- To discuss the design of treatment rooms, including primary and secondary barriers and the effects of leakage and scatter radiation.
- To discuss the design of sealed source storage and dispensing facilities.
- To discuss the measurement of radiation around treatment rooms.

Radiotherapy equipment - safety and accuracy

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IMPLANTACIÓN DE UN PROTOCOLO DE CONTROL DE CALIDAD PARA DETERMINAR SITUACIÓN DE LA MEDICINA NUCLEAR EN VENEZUELA. 1999-2000

CARRIZALES LILA, GÁMEZ LEANDRO.
Instituto Venezolano de Investigaciones Científicas. Unidad de Tecnología Nuclear. Laboratorio Secundario de Calibración Dosimétrica. Caracas. República Bolivariana de Venezuela.
Fax. 58-2-504.1546 e-mail: lcarriza@pion.ivic.ve

1. Abstract.
This paper present preliminaries results and the methodology followed for the implementation of a Protocol that included -Radiological Protection and -Quality Control at SPECT Systems in two important public hospitals at República Bolivariana de Venezuela.
We found in these inspections that the main problems were the lack of medical physicist capacity in nuclear medicine that implemented programs of quality assurance as well as radiation protection in these departments.

2. Introducción.

La República Bolivariana de Venezuela recientemente adoptó como Norma el Informe de Colección de Seguridad 115 del OIEA, el cual recomienda que cada país implante Programas de Garantía de Calidad a fin de optimizar la Práctica de la imaginología en general. Dado lo ambicioso, extenso y costoso de esta empresa y que, por otro lado, Venezuela carece de Físicos Médicos especializados en el área de la Medicina Nuclear que impulsen Programas de Control de Calidad para verificar el funcionamiento de los sistemas de imagen, así como también, de la optimización de los procesos de Protección Radiológica en la manipulación de fuentes radiactivas abiertas. Nos hemos dado a la tarea de desarrollar un protocolo de inspección de Seguridad Radiológica y un Protocolo de Control de Calidad de las unidades de medicina nuclear, basados en protocolos y recomendaciones internacionales pero adaptados a nuestra realidad, para poder estimar mediante su aplicación y análisis de los resultados obtenidos, la situación actual de dichas instalaciones en nuestra Nación.
Como primera etapa de este proyecto hemos aplicado dichos protocolos a dos importantes instituciones públicas, como comienzo para que los titulares responsables de las mismas tomen conciencia de la abrumadora necesidad de implantar Programas de Garantía de Calidad en dichos servicios en un futuro inmediato el cual incluya aspectos tales como una capacitación más profunda y rigurosa en lo que a la Práctica con fuentes radiactivas abiertas de actividades bajas y medias se refiere.

3. Metodología.

Durante aproximadamente cinco meses se llevó a cabo una exhaustiva revisión bibliográfica la cual involucró la selección de las pruebas que consideramos determinantes para verificar la situación desde el punto de vista de protección radiológica así como para determinar el funcionamiento de las unidades SPECT. Previa la implantación de dichos protocolos se realizaron múltiples ensayos para verificar la exactitud y objetividad de los mismos.

4. Resultados.

Tabla I. Aplicación del Protocolo para la Inspección de Seguridad Radiológica. [1-10]

PROTOCOLO DE SEGURIDAD RADIOLÓGICA		
Prueba	**INSTITUCIÓN A**	**INSTITUCIÓN B**
Existencia de detectores de radiación	No cuentan con detectores de contaminación superficial, ni con monitores de radiación. (CI)	No cuentan con detectores de contaminación superficial, monitores de radiación, ni activímetro. (CI).
Activímetro	Aceptable, aún cuando NO se pudo realizar la prueba de linealidad ya que parte del personal del servicio argumentó que el control de calidad no podía ser oneroso.	NA

Sala de espera	No hay un baño exclusivo para los pacientes inyectados con radiofármacos. Utilizan el baño común de la sala de espera (CI) Todos los pacientes y familiares permanecen juntos en la sala de espera, período que puede extenderse hasta dos horas. (CI)	No hay un baño exclusivo para los pacientes inyectados con radiofármacos. Utilizan el baño común de la sala de espera (CI) Todos los pacientes y familiares permanecen juntos en la sala de espera, período que puede extenderse hasta dos horas. (CI)
Radiofármacos Utilizados	^{99M}Tc (10 MBq, administración oral e intravenosa. ^{131}I (20 MBq, administración intravenosa y 200 MBq, por vía oral), ^{67}Ga, ^{153}Sm. Están debidamente identificados y su almacenamiento se realiza en el cuarto caliente pero no hay bitácora de recepción. (CI)	^{99M}Tc (10 MBq, administración oral e intravenosa. ^{131}I (20 MBq, administración intravenosa y 200 MBq, por vía oral), ^{67}Ga, ^{153}Sm. Están debidamente identificados y su almacenamiento se realiza en el cuarto caliente pero no hay bitácora de recepción. (CI)
Inspección general	Se informa al paciente sobre su tratamiento pero los cuidados que debe tener en casa no se le suministran por escrito. (CI)) Llevan registro de las actividades de los radiofármacos utilizados. (C) Están delimitadas y señalizadas las zonas de permanencia para el POE y pacientes. (C) No se admiten embarazadas en el servicio. (C) No hay cuarto habilitado para descontaminación del POE. (CI) No hay lámparas de emergencia, ni extintores de incendio(. (CI) No hay procedimientos de emergencia para contaminación, ni para siniestros (incendios, inundaciones, o terremotos, etc. (CI) No llevan un registro de desechos. Sin embargo, los mismos se almacenan en el cuarto caliente, bajo la campana extractora, clasificándolos según el tipo de radiofármaco, y esperan hasta siete vidas ½ antes de su disposición en la basura común. (A) No se pudo comprobar la integridad de los filtros de la campana. En las áreas de manipulación de material radiactivo no se ingieren alimentos, líquidos, ni se fuma. (C) La Institución no cuenta con tanques de triple decantación para los desechos líquidos producidos en el servicio, ni para las excretas de los pacientes hospitalizados por administración de radiofármacos. (CI)	Se informa al paciente sobre su tratamiento pero los cuidados que debe tener en casa no se le suministran por escrito. (CI)) El registro de las actividades de los radiofármacos utilizados comenzó en Agosto del 2000. (C). Están delimitadas y señalizadas las zonas de permanencia para el POE y pacientes. (C) No se admiten embarazadas en el servicio. (C) No hay cuarto habilitado para descontaminación del POE. (CI) No hay lámparas de emergencia, extintores de incendio, extractor, ni campanas. (CI) No hay procedimientos de emergencia para contaminación, ni para siniestros (incendios, inundaciones, o terremotos, etc. (CI) No llevan un registro de desechos. Tampoco tienen una gestión para los mismos, ya que son dispuestos directamente a la basura común después de cada jornada de trabajo. (CI) En las áreas de manipulación de material radiactivo se ingieren alimentos y líquidos. Se constató la presencia de frutas en el refrigerador del cuarto caliente donde también se almacena ^{131}I. (C) La Institución no cuenta con tanques de triple decantación para los desechos líquidos producidos en el servicio, ni para las excretas de los pacientes hospitalizados por administración de radiofármacos. (CI)

Cuarto caliente	Iluminación aceptable. No tienen lámpara de emergencia. (CI) Paredes pintadas con pintura soluble en agua. (CI) Piso de linóleo, pero sin bordes redondeados, ni sumideros. (CI) Techos de cielo raso. (CI). Sin extractor, pero con campana. (C) Puertas de madera. (CI) Mesón de fórmica, sin bordes redondeados, en su superficie está el generador en uso, y la L plomada de 50 mm de espesor, a menos de medio metro de distancia de éste se encuentra el Activímetro. (CI) Tienen lavamanos de seguridad. (C) Durante la Práctica no siempre usan papel absorbente para cubrir las superficies del mesón y L plomada. (CI) No trabajan con jeringas plomadas ni pipetas automáticas. (CI) Además de la campana extractora tienen una caja de guantes para manipulación de radioisótopos. (C) No hay refrigeradores, ni otros implementos ajenos a la Práctica. (C) No usan jabón de PH neutro. Pero usan sustancias para descontaminar, aunque para el momento de la inspección el personal no estaba al tanto. (CI)	Iluminación aceptable. No tienen lámpara de emergencia. (CI) Paredes pintadas con pintura soluble en agua. (CI) Piso de granito, sin bordes redondeados, ni sumideros. (CI) Techos de cielo raso y sin extractor. (CI) Puertas de madera. (CI) Mesón de cerámica, sin bordes redondeados, en su superficie está el radiofármaco utilizado dentro del castillete plomado, y la L plomada de 50 mm de espesor. (CI) El lavamanos no es de seguridad. (C) Durante la Práctica usan papel absorbente para cubrir las superficies del mesón y L plomada. (CI) Usan jeringas plomadas, algunas estaban contaminadas para el momento de la inspección. No usan pipetas automáticas (CI). Hay múltiples utensilios ajenos a la Práctica tal como una cafetera, la cual se sacó de inmediato de dicho recinto. (CI) Hay un refrigerador dentro del cual se encontraron alimentos, y se almacenaba ^{131}I. (CI) No usan jabón de PH neutro, ni sustancias para descontaminar. (CI)
Metodología de descontaminación de áreas	No tienen ningún manual de procedimientos en caso de contaminación. Para el momento de la inspección se le derramó a una paciente ^{131}I y la única medida que se tomó fue colocar un papel absorbente sobre la contaminación.	No tienen ningún manual de procedimientos en caso de contaminación. Para el momento de la inspección se le derramó a un paciente ^{131}I que contaminó la bata del Dr. Que realizó la administración, y en los frotis tomados en áreas de 10 cm^2, se encontró por ejemplo una contaminación removible de 75875 Bq.
Pacientes hospitalizados	Cuarto señalizado y visitas prohibidas. (A) No hay monitoreo de ropa de cama ni la del paciente, no hay procedimientos de manipulación de excretas. (CI) Dependiendo de la actividad administrada se le da de alta, p ejem si se le administra 200 MBq permanece de 4 a 7 días. (C)	Cuarto señalizado y visitas prohibidas. (A) No hay monitoreo de ropa de cama ni la del paciente, no hay procedimientos de manipulación de excretas. (CI) Dependiendo de la actividad administrada se le da de alta, p ejem. si se le administra 200 MBq permanece de 4 a 7 días. (C)
Personal Ocupacionalmente expuesto	No cuentan con dosimetría personal. (CI) No todos usan guantes durante la manipulación del material radiactivo pues hay alérgicos, y no todos usan batas. (CI)	No cuentan con dosimetría personal. (CI) Todos usan guantes y batas durante la manipulación del material radiactivo. (C)
Control de contaminación radiactiva	Se realizaron múltiples frotis de 10 cm^2 de área con papel de filtro en diversas áreas del cuarto caliente y del Servicio en general, así como también en la ropa del POE. Dichos frotis se analizaron con un espectrómetro de (Na-Tl) al cual se le estableció un límite de detección de 5 Bq, se encontró contaminación radiactiva removible en: -Interior de la L plomada (41 Bq), -Manos y lentes de la Dra (5,8 Bq), -Superficie del mesón (7 Bq). Vale la pena resaltar que estos frotis no fueron tomados el día que ocurrió el derrame de ^{131}I.	El día que ocurrió la contaminación de ^{131}I, se realizaron múltiples frotis de 10 cm^2 de área con papel de filtro en diversas áreas del cuarto caliente y del Servicio en general, así como también en la ropa del POE. Dichos frotis se analizaron con un espectrómetro de (Na-Tl) al cual se le estableció un límite de detección de 5 Bq, se encontró contaminación radiactiva removible en: -Bata del Dr (541 Bq), -Piso y puerta del cuarto caliente (75875 Bq y 6 Bq) respectivamente, -L plomada (31905 Bq), -Navaja (316 Bq), -Asa del refrigerador (11 Bq), -Zapatos del personal que estuvo involucrado (6 y 42 Bq)

Leyenda: (A) Aceptable; (C) Correcto; (CI) Condición Insegura; (POE) Personal Ocupacionalmente Expuesto; (NA) No Aplica

Tabla II. Aplicación del Protocolo para la Inspección de Control de Calidad. [1-10]

PROTOCOLO PARA LA INSPECCIÓN DE CONTROL DE CALIDAD EN DOS SISTEMAS SPECT		
Prueba	**SISTEMA SPECT A**	**SISTEMA SPECT B**
Inspección mecánica	La salida del aire acondicionado está ubicado sobre la gammacámara. (CI)	La salida del aire acondicionado está ubicado sobre la gammacámara. (CI) El Gantry está desnivelado desde el momento de la instalación. (CI)

Inspección eléctrica	Correcto		El sistema de rotación de la Gammacámara tiene un micro interruptor invertido que paraliza la máquina en el sentido anti-horario. (CI)	
Inspección colimadores	Desde su instalación la empresa de mantenimiento tiene en su poder el dispositivo que permite operar la máquina sin colimadores, sin ello no se pueden realizar las pruebas intrínsecas del sistema. (CI)		Correcto	
Inspección software	Aleatoriamente las imágenes adquiridas presentan líneas en los ejes X y Y		Correcto	
Sistema de rotación	Valor medio de las desviaciones del centro de rotación: 1,1 cm. (CI) Desviación del centro de rotación estimada en el centro y en el borde del campo de visión: 1,3 cm. (CI) Se corrigió durante la inspección por software		Levemente fuera de tolerancia debido al desnivel de la base de la gammacámara.	
Tolerancia	El valor medio de las desviaciones del centro de rotación deben ser menores de 2 mm La desviación del centro de rotación estimada en el centro y en los bordes del campo de visión no deben diferir entre sí en más de 2 mm			
Uniformidad intrínseca	CTVU	CCVU	CTVU	CCVU
	27.69 % (FT)	9,31 % (FT)	7,55 % (C)	5,57 % (FT)
	21.54 % (FT)	7, 31 % (FT)	4,41 % (C)	2,87 % (C)
Tolerancia	Las uniformidades para el CTVU no deben exceder el 20 % y para el CCVU el 5% intrínseca no debe superar el 5%			
Uniformidad extrínseca	CTVU	CCVU	CTVU	CCVU
	9.96 % (C)	9,83 %	NR	NR
	8.07 % (C)	8,07 %	NR	NR
Tolerancia	La uniformidad extrínseca no debe superar el 5 %			
Tasa Máxima de Conteo	35 kCuentas/s No existen valores de referencia		225 kCuentas/s No existen valores de referencia	
Tolerancia	No permitir una variación máxima de un 10 % respecto a los valores de referencia			
Resolución Temporal	Correcto No existen valores de referencia		Correcto No existen valores de referencia	
Tolerancia	No permitir una variación máxima de un 10 % respecto a los valores de referencia			
Resolución Espacial	Para el momento de la inspección no se pudo acceder al software para el análisis de la imagen obtenida		Correcto No existen valores de referencia	
Tolerancia	Iniciar acciones correctivas cuando el valor de FWMH sea mayor de 20% o más, respecto al valor de referencia			
Linealidad Espacial	Se realizó la prueba y se obtuvieron valores que sugieren comportamientos aceptables pero No existen valores de referencia para hacer la comparación		Se realizó la prueba y se obtuvieron valores que sugieren comportamientos aceptables pero No existen valores de referencia para hacer la comparación	
Tolerancia	Analizar visualmente la imagen obtenida, las mismas deben comparase con las de referencia para determinar si existen desviaciones importantes en las direcciones X y Y.			
Prueba de funcionamiento del SPECT con maniquí JACKSACK	En general en las imágenes obtenidas se observó una buena resolución en los bordes de las esferas. Además, se visualizó claramente la falta de uniformidad del sistema. No existen valores de referencia para hacer la comparación		En las imágenes obtenidas se observó el efecto del desnivel de la base de la Gammacámara que no permite resolver apropiadamente los bordes de las esferas. Por otra parte fue imposible visualizar los objetos pequeños. No existen valores de referencia para hacer la comparación	
Tolerancia	Analizar artefactos circulares que indique problemas de uniformidad, si el sistema presenta problemas de centrado o problemas con la ventana de energía. Las imágenes obtenidas rutinariamente deben compararse con los valores de referencia.			

Leyenda: (A) Aceptable; (C) Correcto; (FT) Fuera de Tolerancia. (NR) No realizado

5. Conclusiones

Si bien hasta los momentos solo se han realizado dos inspecciones completas de las seis que nos tenemos planteadas, los resultados obtenidos de la aplicación de los mencionados Protocolos, en las instituciones inspeccionadas demuestran de una manera clara y contundente la necesidad de establecer Programas rutinarios de control de calidad tanto en el aspecto de protección radiológica como del equipamiento empleado en los Departamentos de medicina nuclear. Además, demuestran que los mismos representan una

fase primordial dentro de un Programa de Garantía de calidad tanto para el paciente como para el personal ocupacionalmente expuesto y permitirán demostrar a las autoridades competentes la urgente necesidad de implantar dichos Programas en el ámbito nacional.

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A Todos mil gracias por creer en nosotros y ayudarnos en colocar este granito de arena que poco a poco irá transformando en realidad el sueño que tanto añoramos: ***"La optimización de nuestros servicios de imaginología mediante Programas de Garantía de Calidad".***

6. Referencias

[1] BAIRI B, SINGH B, RATHOD N, NARURKAR P. Handbook of Nuclear Medical Instruments Tata McGraw-Hill Publishing Co. Ltd, 1994.
[2] BORRAS C. Organización, Desarrollo, Garantía de Calidad y Radioprotección en los Servicios de Radiología, Imaginología y Radioterapia. Washington; OPS/OMS, (1997).
[3] BUSEMAN E. Quality Assurance in Nuclear Medicine Imaging: Hardware and Software Aspects. Amsterdam, (1992).
[4] CABREJAS, M. et., al., Tomografía en Medicina Nuclear. Comité de Instrumentación y Garantía de Calidad del ALASBIMN. (1999).
[5] Control de Calidad de los Instrumentos de Medicina Nuclear, IAEA. TECDOC-602/S. 1991 .Ed en español , (1996).
[6] KING M ZIMMERMAN R, LINKS J. Imaging Hardware and Software for Nuclear Medicine. AAPM Proceedings No 6. (1998).
[7] PALMER E, SCOFF J, STRAUSS H. Practical Nuclear Medicine. W. B. Saunders Co., Philadelphia, (1992)
[8] Performance Measurements of Scintillation Cameras. NEMA Standards Publication NU 1-1994.
[9]. RAABE, O. Internal Radiation Dosimetry. Health Physics Society. Medical Physics Publishing, Madison, Wiscosin, (1994).
[10] TÉLLEZ. M. et., al., Protocolo Nacional de Control de calidad en la Instrumentación en Medicina Nuclear. SEFM. (1999).

IAEA RADIATION EVENTS DATABASE (RADEV)

J. Wheatley & P. Ortiz-Lopez
International Atomic Energy Agency (IAEA) Vienna

Abstract

Whilst the use of ionizing radiation continues to bring benefits to many people throughout the world there is increasing concern at the number of reported accidents involving radiation. Such accidents have had an impact on the lives of patients, workers and members of the public, the consequences of which have ranged from trivial health effects to fatalities.

In order to reduce the number of accidents and to mitigate their consequences it is, therefore, necessary to raise awareness of the causes of accidents and to note the lessons that can be learned. The IAEA's database on unusual radiation events (RADEV) is intended to provide a world-wide focal point for such information.

Introduction

The use of radiation sources and radioactive material is well established throughout the world and brings substantial benefits to society when used in a safe and controlled manner. The IAEA, in addition to facilitating the transference of technology that utilizes the constructive properties of ionizing radiation, has a statutory function to establish international standards of safety and to provide for their application. The International Basic Safety Standards [1], which were jointly sponsored by FAO, IAEA, ILO, OECD/NEA, PAHO and WHO, establish requirements for protection against the risks associated with exposure to ionizing radiation and include a substantial appendix on Medical Exposure.

Even though many governments have adopted these international standards into their national arrangements, the large number of radiological accidents that have been reported worldwide implies that numerous radiation sources are not managed or regulated appropriately. Indeed, IAEA has, with the cooperation of Member States, already published a number of reports of accidents with significant consequences in order to provide feedback and identify lessons to be learned [2, 3].

Global awareness of the magnitude and seriousness of the problem was raised in September 1998 at the first international conference on the 'Safety of Radiation Sources and the Security of Radioactive Material' held in Dijon, France.

The conclusions of this conference were drawn to the attention of the IAEA Board of Governors at the General Conference. Subsequently, the IAEA Secretariat was requested to prepare and implement an *Action Plan* on the 'Safety of Radiation Sources and the Security of Radioactive Material'. The *Action Plan*, which was endorsed by the Board of Governors and the General Conference in 1999 covers the following seven areas: regulatory infrastructures; management of disused sources; categorization of sources; response to abnormal events; information exchange; education and training; and international undertakings. One of the actions under 'Information Exchange' is for the IAEA secretariat to fully develop and maintain an international database on unusual radiation events (RADEV) and to make it available to Member States.

BSS requirements for accidental Medical Exposures

As mentioned above, the BSS [1] includes requirements for Medical Exposures, amongst which are specific requirements relating to accidental medical exposures (as given below). RADEV has been designed to capture the details and lessons to be learned from such accidents.

The following is an extract from Appendix II (Medical Exposures) of the BSS:

II.29. Registrants and licensees shall promptly investigate any of the following incidents:

(a) any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute secondary effects;
(b) any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and
(c) any equipment failure, accident error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

II.30. Registrants and licensees shall, with respect to any investigation required under para. II.29:

(a) calculate or estimate the doses received and their distribution within the patient;
(b) indicate the corrective measures required to prevent recurrence of such an incident;
(c) implement all the corrective measures that are under their own responsibility;
(d) submit to the Regulatory Authority, as soon as possible after the investigation or as otherwise specified by the Regulatory Authority, a written report which states the cause of the incident and includes the information specified in (a) to (c), as relevant, and any other information required by the Regulatory Authority; and
(e) inform the patient and his or her doctor about the incident.

Overall Objectives of RADEV

Capturing information about accidental medical exposures is only part of RADEV's remit. On a broader scale, RADEV includes many different types of events that have occurred outside the nuclear power programme. The overall objectives of RADEV are to:

(a) disseminate information on radiation events and feedback lessons that may help to prevent future accidents, or mitigate their consequences should they occur, and
(b) provide a tool to help Member States, the IAEA and other organizations to identify priorities in their radiation safety programme to facilitate the efficient allocation of resources.

In order to achieve these general objectives a centralized RADEV database is being established at IAEA's headquarters in Vienna to:

(a) provide a repository of information on accidents, near-misses and any other unusual events involving radiation sources not directly involved in the production of nuclear power or its fuel cycle;
(b) categorize events in a standardized manner to facilitate the search for events fitting particular profiles, the identification of causes and the lessons to be learned;
(c) provide a means to analyze trends in radiation events; and
(d) provide summary descriptions of events that can be used directly as training material.

RADEV is designed to capture lessons to be learned from radiation events and is not meant to be a real-time on-line database. A separate IAEA initiative is concerned with developing a 24-hour reporting system for missing and found orphan sources.

Events to be included

General Events

— events or potential events involving patients, workers or members of the public;
— events involving radiation sources which have been lost, found, stolen, or subject to unauthorized and inadvertent transfer/sale; and
— events that occurred during the transportation of sources that result or could have resulted in the loss or degradation of control of radiation sources.

Events Involving Patients

Many types of radiation events involving patients have been reported, including:

— Wrong patient exposed
— Wrong tissue exposed (correct patient)
— Wrong radio-pharmaceutical administered
— Wrong activity administered
— Wrong beam settings
— Delivered dose different from intended

The consequences of such events include: ineffective treatment, ineffective diagnosis, severe radiation burns, severe degradation in quality of life and, in some cases death directly attributable to high radiation exposure. Many of these events were caused by deficiencies in, or a lack of: design, testing and calibration of equipment; education, training and qualification of personnel; procedures; defense in depth; quality assurance. In some cases, events involving patients have also resulted in exposures of hospital workers, lost sources and exposures of members of the public.

Management and Operation

The database has been designed to operate on a personal computer using Microsoft Access 97 or above. Copies of the RADEV software will be provided to selected organizations within Member States for their own use and users will be requested to provide data to IAEA on a regular basis. IAEA will be manage and operate the international RADEV

database and will act as the central focal point for all users. IAEA will publish regular summary reports from RADEV and will provide electronic updates of the data to participating organizations. Confidentiality will be maintained by IAEA at all times and details such as names of individuals, hospitals and factories will not be divulged.

Implementation

The RADEV project is being implemented in 3 phases:

Phase 1: Establishment of the database. IAEA will collect currently available details of radiation accidents and test the software.

Phase 2 : Limited international trials. IAEA will provide a working version of RADEV to several international and national organizations (including professional organizations in the medical field) for testing and evaluation. Feedback from the trials will be reviewed by IAEA and any necessary changes made to the software.

Phase 3: Distribution of RADEV. IAEA will collect data from participating organizations, compile international statistics and produce summary reports. Electronic copies of the summary reports and the updated database will be available to participating organizations.

The current status at time of the Malaga Conference is that Phase 1 has been successfully completed and international trials are taking place.

References

[1] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANISATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Lessons Learned from Accidents in Radiotherapy, Safety Report No. 17, IAEA, Vienna (1998).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Accidental Overexposure of Radiotherapy Patients in San José , Costa Rica, IAEA, Vienna (1998).

DEVELOPMENT OF AN INTERNATIONAL CODE OF PRACTICE FOR DOSIMETRY IN X-RAY DIAGNOSTIC RADIOLOGY

F. Pernicka, IAEA, Vienna, Austria, e-mail: f.pernicka@iaea.org
G. Alm Carlsson, University of Linköping, Linköping, Sweden
D. R. Dance, The Royal Marsden NHS Trust, London, UK
L. A. DeWerd, University of Wisconsin, Madison, Wisconsin, USA
H.-M. Kramer, PTB, Braunschweig, Germany
K.-H. Ng, University of Malaya, Kuala Lumpur, Malaysia

Abstract

Medical x-ray examinations contribute greatly to the population dose from man-made radiation sources. There is a need to control this dose and therefore to optimise the design and use of x-ray imaging systems. A key stage in this process is the standardisation of the procedures for dose measurement in the clinic. The Dosimetry and Medical Radiation Physics section of the IAEA has a number of activities to further advance the standards for x-ray diagnostics. One of these activities is the coordination of a working group to develop a code of practice, which will facilitate the IAEA calibration activities, TLD intercomparisons and audits, educational activities, and a technical assistance to Member States. The code of practice will aid in the standardisation of various dosimetric techniques in x-ray diagnostic radiology. The CoP working group has had an initial meeting to review the current status of dosimetry for conventional radiology, fluoroscopy, mammography, computed tomography and dental radiology. The CoP will include the establishment of standards and calibrations at the SSDLs, phantom and patient measurements and procedures for dosimetry in the clinic.

1. INTRODUCTION

A key stage in controlling x-ray irradiation of patients is the standardisation of the procedures for dose measurement in the clinic. In many situations, it is of interest to make measurements directly on the patient. However, for the control of technical parameters, for the comparison of different systems and for optimisation of the systems, it is preferable to make measurements using a standard phantom to simulate the patient. With the exception of mammography, there is hardly any international advice available for the performance of such measurements or the selection of phantoms for use in different situations.

Approximately 40% of Secondary Standard Dosimetry Laboratories (SSDLs) are currently involved with calibration of diagnostic ionization chambers. At present, the manner in which calibrations at diagnostic radiation qualities are performed at SSDLs is not co-ordinated. Many use different radiation qualities and standards, some of which may be unsuitable. Quality control can only work satisfactorily if correct measurements are made. A large number of SSDLs are requesting guidance on establishing calibration facilities.

The objective of the Dosimetry and Medical Radiation Physics (DMRP) section of the IAEA is to enhance the capacity of Member States to achieve and maintain a high level of quality in dosimetry and medical radiation physics, to improve the implementation of traceable standards at the national level and to ensure control of radiation dose in the Member States. This goal has as its precedent the prior work in radiation therapy. A series of recommendations for dosimetry have been published with the latest dosimetry protocol "Absorbed Dose Determination in External Beam Radiotherapy: An International Code of Practice for Dosimetry based on Standards of Absorbed Dose to Water", published in 2000 [1]. The increased need to standardize dosimetric measurements in x-ray diagnostic

radiology led the DMRP to establish a working group with the aim of preparing the new Code of Practice (CoP) that will review the current status of dosimetric measurements in conventional radiology[1], fluoroscopy, mammography, computerized tomography and dental radiology and give recommendations on selection of the instruments, their calibration and procedures for clinical dosimetry.

2. BACKGROUND OF X-RAY DIAGNOSTIC DOSIMETRY

In developed countries about 90% of medical radiation dose is due to x-ray diagnostics and 10% to nuclear medicine [2]. Since the risk for stochastic effects (induction of cancer and genetic disorders) is believed to be without a threshold, the detriment to the population increases with increasing population dose. An increasing part of this dose from diagnostic x-rays is due to the use of procedures such as fluoroscopy in interventional radiology and computed tomography (CT). Patient dose measurements are therefore becoming increasingly important. For example, in the International Basic Safety Standards [3] it is stated that representative dose values shall be determined in radiological examinations. The European Union has adopted a directive towards "health protection of individuals against the dangers of ionising radiation in relation to medical exposures" which requires extensive dose measurements [4]. This translates into a need to optimise the design and use of x-ray imaging systems. It is generally recognized that even a 10% reduction in patient dose is a worthwhile objective for optimisation. In this context it is important to note that the image quality should always be sufficient for the clinical need.

Due to the increased need for quality assurance in diagnostic radiology, it has become important to provide traceability of measurements in this field. The Standing Advisory Committee "SSDL Scientific Committee" recommended in 1996 that the experience of the IAEA in the field of standardization at radiotherapy and radiation protection levels for the IAEA/WHO Network of SSDLs be extended to the field of x-ray diagnostics. This recommendation has led DMRP to start the development of the necessary facilities and procedures for the calibration of ionization chambers [5].

Various examination techniques are used in x-ray diagnostics. They include conventional radiography, fluoroscopy and other interventional radiological procedures, mammography, CT and dental. In some cases specialised dosimeters are required, whose design and performance must be matched to the needs of the clinical measurement. The use of such dosimeters and/or the interpretation of the results obtained may require specialised techniques and knowledge. In addition there are special requirements for the calibration of such instruments at the SSDLs. Methods to perform such calibrations are not yet completely developed. The most common type of radiation detector for diagnostic radiological dose measurement is a parallel plate ionization chamber. There may be special requirements for the calibration and use of each type of chamber. All ionization chambers should have a sufficiently flat energy response over the range of the relevant radiation qualities. Mammographic ionization chambers generally require a thin entrance window and a construction using low atomic number materials, e.g. air equivalent or plastic materials. A CT-chamber, often called a pencil chamber, has an active volume in the form of a thin cylinder about 100 mm in length. Its response should be uniform along its entire axial length. In fluoroscopy there is a need to measure the input air kerma rate to the image intensifier and the patient dose. The chambers used for each aspect need to be of adequate design and size. Air Kerma Area Product (KAP) meters are also used in fluoroscopy. They are mounted on the x-ray housing and their sensitive area extends over the entire cross-section of the beam. The signal from a KAP meter is proportional to the product of air-kerma and field size at any plane perpendicular to the beam axis. For the measurement of panoramic dental examinations, ionisation chambers need to be cylindrical.

[1] In this document the term conventional radiology is used to cover all x-ray imaging modalities other than dental radiography, fluoroscopy, mammography and CT.

Although ionization chambers are the main devices used for dosimetric measurements, other devices with special properties are frequently used. Important examples are semiconductor diodes and thermoluminescent dosimeters (TLDs). Because of the inherent problems involved in the use of these two devices, they should not be used for calibrations at SSDLs. They are used for quality control and in clinical dosimetry.

The contrast in a radiographic image is mainly determined by the x-ray tube voltage. It is standard practice, therefore, to measure this voltage as part of quality control. Non-invasive instruments are mostly used for this purpose. Such instruments require special calibration consideration [6].

It is obvious, that standardisation of procedures for measurements in the clinic and the SSDLs is of great importance. The CoP will address both of these areas to bring coordination to them.

3. PRESENT STATUS OF THE CODE OF PRACTICE

The working group established to prepare the CoP has met in November 2000 to review the current status of dosimetry in diagnostic radiology and prepare an initial draft of the document. Its basic concepts are briefly outlined below.

3.1. Requirements for calibrations at SSDLs

The chamber and electrometer (or charge-measuring device) both need to be calibrated at an SSDL, either separately or as a system. The quality for which the calibration was performed must be stated, since past work has indicated a significant energy dependence of response of some chambers. For this reason, the SSDLs need to establish radiation qualities suitable for each application. Radiation qualities as given in IEC 61267 [7] provide some guidance but these are in the process of revision. Where such radiation qualities do not exist, appropriate beams must be identified. Each SSDL must have chambers calibrated at the reference radiation qualities. For a chamber with sufficiently flat energy dependence, interpolation can be done for any intermediate point. Sufficiently flat energy response depends on the application, e.g. for conventional x-rays this is a maximum variation within +3% across the energy range. An application of this response is in the measurements of HVL with ionization chambers. These measurements can be affected by the energy dependence of response [8], and by the beam diameter used.

When choosing an instrument for dosimetry in diagnostic radiology, it is important to match the instrument to the task. This will include the size and sensitivity of the instrument and its response to different radiation qualities. The use of an appropriate instrument is essential. In some cases, the commercially available instrumentation marketed for general or particular applications does not meet these requirements [9] and there may be no internationally agreed specification. This can create difficulties, particularly where there is no local expertise available. Specific devices are designed for use in the clinic. For example, the KAP meter is a very useful instrument for dosimetry in diagnostic radiology as 'kerma-area product' is more directly related to radiation risk than dose itself. Opinion is divided about the calibration of KAP meters, whether they should be calibrated at the SSDL or in situ. Examples of calibration procedures are given by IPEM [10] and by Larsson et al. [11]. Semi-conductor devices can be as small as TLDs and have the advantage that they allow real time measurement. A problem is that the inherent response of semi-conductor devices is not sufficiently flat. This problem is sometimes compensated for by the software corrections in the instrument.

3.2. Clinical measurements

Many times it is preferable to make dose measurements using a phantom to simulate the patient. When a phantom is used, the measured dose will depend upon the phantom shape and size and it is essential that the phantom is standardised so that such variations are avoided. Ideally, standard phantoms should be designed to offer the same primary attenuation and scatter production as a representative patient. The phantom only needs to be representative of average or mean values of a typical patient. It is not the intention that the result of dose measurements with phantoms should equal

that from measurements with patients. When a phantom is used to simulate the patient, the x-ray equipment should be set up in the same way as for the real examination. Dose measurements made at the surface of the phantom include backscatter whereas those made free in-air do not. It is desirable to standardise the dose specification to avoid ambiguity. In this regard, standardized worksheets will be provided for each application. These worksheets will facilitate the international intercomparison of results. Two applications are discussed below as representative of the needs suggested by the CoP.

3.2.1. Mammography

During the past few decades there have been significant advances in the equipment used for mammography. Even when the latest equipment is used, there is considerable variation from centre-to-centre in the choice of imaging parameters and techniques. Thus, there may be quite large differences in breast dose. A review of the development and current status of dosimetry for mammography is given in Dance et al. [12].

The most practical dose measurement for mammography is an estimate of the incident air kerma at the surface of the breast (with or without backscatter). Since a low energy x-ray spectrum is used for the examination, the dose decreases rapidly with increasing depth in the breast. More appropriate quantities for specifying breast dose have therefore been suggested. The use of the mean dose to the glandular tissues within the breast (MGD) has been generally adopted. Direct measurement of MGD is not possible. Instead, use is made of conversion factors that relate measurements of entrance air kerma to MGD. Several countries have introduced protocols for dosimetry in mammography but there is wide variation in the methodology suggested.

3.2.2. CT

CT examinations constitute about 4% of all radiographic examinations but can contribute 40% of collective dose [13]. It is therefore of considerable importance to monitor the dose for such examinations. In conventional CT scanning, the patient dose is built up from that received from each individual CT slice. In-phantom measurements are more representative of the patient dose. Standard phantoms are available for both body and head examinations [14] and are in common use. Within the last decade helical CT scanning has been introduced. Care must be taken to ensure that the guidance is appropriate for this imaging technique.

4. CONCLUSION

The need for standardization of dosimetry measurements in diagnostic radiology and for calibrations of the measurement equipment is obvious. A limited international guidance is available for the performance of measurements in the hospital. A few SSDL laboratories offer a calibration service for diagnostic radiology instruments but a greater uniformity amongst the SSDLs is needed. Methods to perform such calibrations are not yet completely developed. The CoP should identify separately the requirements for conventional radiology, fluoroscopy, mammography, CT and dental radiography. It is expected that the document will be published in the beginning of 2003.

5. REFERENCES

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Absorbed Dose Determination in External Beam Radiotherapy: An International Code of Practice for Dosimetry based on Standards of Absorbed Dose to Water", Technical Report Series 398, in print

[2] UNITED NATIONS SCIENTIFIC COMMITTEE ON THE EFFECTS OF ATOMIC RADIATION, UNSCEAR 2000 Report to the General Assembly with Scientific Annexes, United Nations Sales Publication E.00.IX.3, New York (2000).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources: A Safety Standard, Safety Series No.115 [Jointly sponsored by FAO, IAEA, ILO, OECD/NEA, PAHO, WHO], IAEA, Vienna (1991).

[4] THE COUNCIL OF THE EUROPEAN UNION, Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom. Official Journal of the European Communities L180 **40** (1997) 22-27.

[5] PERNICKA, F., ANDREO, P., MEGHZIFENE, A., CZAP, L., GIRZIKOWSKI, R., Standards for Radiation Protection and Diagnostic Radiology at the IAEA Dosimetry Laboratory, SSDL Newsletter **41** (1999)12-23.

[6] KRAMER, H.-M., SELBACH, H.-J., ILES, W. J., The practical Peak Voltage of Diagnostic X-Ray Generators, British Journal of Radiology **71** (1998) 200-209.

[7] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical electrical equipment - Dosimeters with ionization chambers and/or semi-conductor detectors as used in x-ray diagnostic imaging, IEC 61267, IEC, Geneva (1997).

[8] WAGNER, L. K., FONTENLA, D. P., KIMME-SMITH, C., ROTHENBERG, L. N., SHEPARD, J., BOONE, J. M., Recommendations on the Performance Characteristics of Diagnostic Exposure Meters, Report of AAPM Diagnostic X-Ray Imaging Task Group No. 6, Med. Phys. **19** 1 (1992) 231-241.

[9] DeWERD, L.A., WAGNER, L.K., Characteristics of radiation detectors for diagnostic radiology, Applied Radiation and Isotopes **50** (1999) 125-136.

[10] NATIONAL RADIOLOGICAL PROTECTION BOARD, National protocol for patient dosimetry measurements in diagnostic radiology, Didcot (1992).

[11] LARSSON, J.P., ALM CARLSSON, G., PERSLIDEN, J., SANDBORG, M., Transmission ionization chambers for measurements of air collision kerma integrated over beam area. Factors limiting the accuracy of calibrations, Phys Med Biol.**41** (1996) 2381.

[12] DANCE, D.R., SKINNER, C.L, ALM CARLSSON, G., Breast dosimetry. Applied Radiation and Isotopes **50** (1999) 185-203.

[13] JESSEN, K.A., SHRIMPTON, P.C., GELEIJNS, J., PANZER, W., TOSI, G., Dosimetry for optimisation of patient protection in computed tomography. Applied Radiation and Isotopes **50** (1999) 165-172.

[14] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Standardized methods for measuring diagnostic x-ray exposures. AAPM Report 31, AAPM, New York (1990).

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PROYECTO PARA EL DESARROLLO E IMPLEMENTACION DEL PROGRAMA DE GARANTÍA DE CALIDAD EN RADIOTERAPIA

AUTORES: F. Mata (*) J. Pardo (**) , J. Serra (***) y S. Bertrán (****). Hospital Universitario Son Dureta. Palma de Mallorca. España

(*) Coordinador de Política de Calidad (**) Jefe del Servicio de Oncología Radioterápica, (***) Subdirector Médico y Presidente de la Comisión de Garantía y Control de Calidad en Radioterapia, (****) Director Gerente.

SUMMARY:

The Son Dureta University Hospital development and implementation project of the quality control program in radiotherapy is presented here. This project arises as a consequence of the R.D. 1566/98 focused on Quality Control in Radiotherapy.

RESUMEN:

Aquí se presenta el proyecto para el desarrollo e implementación del programa de garantía de calidad en Radioterapia del Hospital Universitario Son Dureta. Este proyecto surge como consecuencia de la publicación del R.D. 1566/98 sobre Control de Calidad en Radioterapia.

ANTECEDENTES Y OBJETIV0S

El Programa de Calidad que forma parte del Contrato de Gestión de los hospitales del INSALUD contempla la elaboración e implantación de los Programas de Garantía de Calidad cuyo reglamento se especifique mediante Reales Decretos. Concretamente, el Real Decreto 1556/1998, de 17 de julio, indica los criterios de calidad en Radioterapia, y a su vez incorpora al ordenamiento jurídico español la Directiva 84/466/ EURATOM, de 3 de septiembre sobre protección radiológica del paciente.

Por otra parte, el Hospital Universitario Son Dureta, como consecuencia del desarrollo de su Plan Estratégico, incluye en uno de sus apartados la elaboración de un Plan de Calidad Total.

El objetivo del presente trabajo es la de presentar todas las actividades y acciones que se están llevando a cabo en nuestro centro hospitalario para la elaboración e implantación en el Servicio de radioterapia de un Programa de Calidad que contemple los apartados del mencionado real Decreto. El fin último es articular el programa en base a la gestión de los procesos claves de la prestaciones asistenciales y la mejora continua.

MISIÓN DEL HOSPITAL UNIVERSITARIO SON DURETA

" El Hospital Universitario Son Dureta es un hospital público, universitario y de referencia para la Comunidad Autónoma de las Illes Balears, orientado al paciente en un entorno de calidad, en permanente evolución de mejoras asistenciales y organizativas que le permita una eficiencia acorde con la efectividad de sus prestaciones".

POLÍTICA DE CALIDAD DEL HOSPITAL UNIVERSITARIO SON DURETA

"El Hospital Son Dureta considera la Calidad como un elemento estratégico, siendo responsable de ella la Alta Dirección que marcará los objetivos para su implantación. La Calidad debe de ser explicada a toda la organización como un valor competitivo, en el que participaran todos los estamentos y profesionales del Centro con objetivos que aproximen y orienten la Organización hacia los criterios esenciales de la Misión.

La Política de Calidad estará fundamentada en el desarrollo y fortalezimiento de los criterios de Calidad Total, buscará un enfoque educativo, tratará de contribuir a un cambio cultural y fomentará la participación, el compromiso y la motivación de todos los profesionales.

La Política de Calidad tratará de orientar el Hospital hacia las necesidades de los pacientes a los que identifica como clientes del mismo y considerará a sus profesionales como clientes internos del sistema.

La Política de Calidad utilizará la información y comunicación como una herramienta básica, no solamente en la divulgación de sus contenidos hacia el interior de la Organización, sino también para transmitir a la Sociedad una imagen externa sólida y de prestigio.

Para ello el Hospital se marca los siguientes objetivos claves:

A.- Orientar los procesos y servicios prestados a las demandas y necesidades de nuestros pacientes y usuarios

B.- Analizar las oportunidades de mejora conjuntamente con los profesionales, creando las mejores condiciones para la mejora continua

C.- Promover la gestión y revisión de los procesos claves del hospital, con mayor énfasis en aquellos con repercusión directa en la atención a nuestros pacientes y usuarios

D.- Fomentar la autoevaluación por los profesionales y las auditorías internas

E.- Incidir en la formación de los profesionales en las áreas de Gestión de la Calidad y sus herramientas

F.- Integrar los indicadores de calidad a los sistemas y estrategias de información del hospital

ORGANIZACIÓN DEL PROYECTO

El hospital considera los criterios especificados en el Real Decreto 1566/1998 como un marco mas adecuado para iniciar todas aquellas acciones encaminadas a la elaboración de un Programa de Garantía de Calidad en el servicio de radioterapia. Partiendo de la constitución de una Comisión de Garantía y Control de Calidad en la que participan profesionales de todas las áreas relevantes, así como miembros del equipo directivo del hospital, se iniciaron los trabajos para la elaboración del índice del programa y las responsabilidades para su elaboración

Las fases inicialmente previstas fueron las siguientes:

1) Consensuar los apartados que forman parte del Programa de Garantía de Calidad
2) Distribución de las responsabilidades para la elaboración de los procedimientos y protocolos que constituyen el Programa
3) Debate y puesta en común de los distintos documentos
4) Remisión del documento a la Autoridad sanitaria competente
5) Identificación de las responsabilidades para las distintas actividades relacionados con los procedimientos llevados a cabo en el Servicio de Radioterapia
6) Diseño del plan de implantación
7) Establecimiento de la agenda para las auditorías internas
8) Desarrollo de un cuadro de mandos con los indicadores más relevantes para la evaluación de la implantación.

APARTADOS DEL PROGRAMA DE GARANTÍA DE CALIDAD

El Programa se articula por la definición y descripción de los siguientes apartados:

A.- Generales

A.1. Identificación de los recursos humanos y materiales
A.2. Norma de constitución y funcionamiento de la Comisión de Garantía y Control de Calidad

B.- Procedimientos y Procesos

B.1. Identificación de la cartera de servicio para el Servicio de Radioterapia y establecimiento de los criterios para su revisión y actualización
B.2. Establecimiento de los procesos necesarios para el desarrollo de las etapas asistenciales
B.3. Identificación de los responsables y los requerimientos de competencia técnica de los profesionales
B.4. Elaboración del protocolo para la comunicación de reacciones adversas, la investigación de las mismas y las acciones correctoras implantadas.
B.5. Elaboración de las hojas de registro, y muy especialmente el diseño de la hoja de tratamiento que permita el análisis de la trazabilidad

C.- Información al paciente

C.1. Plan de implantación del Consentimiento Informado y elaboración de las hojas específicas de información según las recomendaciones del Ministerio de Sanidad y Consumo aprobadas por el Consejo Interterritorial. Este apartado se extenderá a tratamientos en fase de investigación clínica
C.2. Plan de información a mujeres embarazadas
C.3. Plan de acogida e información general del Servicio de Radioterapia

D.- Equipamiento

D.1. Criterios para la aceptación del equipamiento (equipos de irradiación, localización, verificación, etc)
D.2. Protocolo para asegurar por parte de los proveedores el cumplimiento de los requisitos técnicos del equipamiento

D.3. Definición de los valores de referencia inicial del equipamiento

E.- Control de Calidad

E.1. Elaboración del protocolo de control de calidad para las distintas etapas clínicas. Establecimiento del plan de evaluación

E.2. Elaboración del protocolo de control de calidad de los equipamientos. Establecimiento del plan de evaluación

F.- Mantenimiento

F.1. Establecer el plan de mantenimiento, tanto preventivo como correctivo, por parte del proveedor o empresa autorizada

G.- Informes

G.1. Descripción del tipo de informes que debe generar cualquier actividad de evaluación

H.- Auditoría

H.1. Elaboración de un protocolo para las auditorías internas necesarias para comprobar con una frecuencia establecida el cumplimiento de lo especificado en el programa de Garantía de Calidad

I.- Responsabilidades

I.1. Definición de las responsabilidades del jefe de la unidad asistencial y del especialista de radiofísica hospitalaria

I.2. Definición de las responsabilidades para las diferentes etapas clínicas, control y evaluación del equipamiento, dosimetría clínica, información a los pacientes, elaboración de informes descriptivos, elaboración de informes para la toma de decisiones, etc.

GUIA PARA LA ELABORACION DEL REGLAMENTO DE FUNCIONAMIENTO DE LA COMISION DE GARANTIA Y CONTROL DE CALIDAD EN RADIOTERAPIA

AUTORES: Pardo J [1,4] , Galmés MªA [2], Font J [3], Caro J [2], Biete A [4], Carceller JA [4], Escó R [4], Palacios A [4], Veiras C 4, Vazquez MG [4]

Servicios de Oncología Radioterápica **(1)** , Asesoría Jurídica **(2)** y Radioprotección y Física Médica. Hospital Universitario Son Dureta. Palma de Mallorca. España **(4)** Asociación Española de Radioterapia y Oncología

SUMMARY: The guidelines for the design of the working rules of the quality assurance in radiotherapy commission are presented. They have been done by consensus in Son Dureta University Hospital and afterwards sent to all Radiation Oncology Departments by the Spanish Society for Radiotherapy and Oncology.

INTRODUCCIÓN:

La publicación en el Boletín Oficial del Estado, el 28 de Agosto de 1988, del Real Decreto 1566/1988 de 17 de Julio, por le que se establecen los criterios de calidad en Radioterapia, inició un proceso de reflexión interna en los Servicios de Oncología Radioterápica de toda España debido, entre otras razones, a que implica la realización de protocolos de todas las etapas asistenciales del paciente que va a recibir radioterapia, incluidas las revisiones y controles posteriores al tratamiento

Lo anterior no afecta solamente a los Servicios de Oncología radioterápica sino que involucra también a los Servicios de Protección radiológica y Física Médica y a las Direcciones y Gerencias de los Centros Asistenciales

Como uno de los primeros pasos para poder iniciar unos procedimientos y planes de trabajo eficientes y efectivos, se contempla en el Real Decreto 1566/1988 la obligatoriedad que tiene el titular del centro sanitario en cuanto a la creación de una Comisión de Garantía y Control de Calidad en Radioterapia.

Esta Comisión debe dotarse obligatoriamente de un reglamento de funcionamiento de acuerdo con lo previsto en el Capítulo II, sobre Organos Colegiados, de la Ley 30/1992 del 26 de Noviembre del Régimen Jurídico de las Administraciones Públicas.

El reglamento que a continuación se expone es fruto de una labor de consenso y se ajusta a las normativas legales vigentes en el Estado Español anteriormente mencionadas. Fue aprobado por la Comisión de Garantía y Control de Calidad en Radioterapia del Hospital Universitario Son Dureta en las Sesiones celebradas los días 03/02/99 y 17/06/99.

Posteriormente fue distribuido por la Asociación Española de Radioterapia y Oncología a todos los Servicios de Radioterapia

REGLAMENTO DE FUNCIONAMIENTO DE LA COMISION DE GARANTIA Y CONTROL DE CALIDAD EN RADIOTERAPIA

INTRODUCCIÓN: La Comisión de Garantía y Control de Calidad en Radioterapia se crea en base al Artículo 3, Apartado 1 a, del Real Decreto 1566/1998 de 17 de Julio por el que se

establecen los criterios de calidad en Radioterapia. Su composición se establece en base al Artículo 4. Apartado 1 del antedicho Real Decreto.

El presente Reglamento se establece de acuerdo con el Capítulo II (artículos 22 al 27) de la Ley 30/1992 del 26 de Diciembre del Régimen Jurídico de las Administraciones Públicas.

1.-VIGENCIA Y AMBITO DE APLICACIÓN: El presente reglamento entrará en vigor a partir del día de su aprobación por los componentes de la Comisión de Garantía y Control de Calidad en Radioterapia y será de aplicación en el Hospital _____ .

2.- COMPOSICION DE LA COMISION

2.1. Clases de Miembros: En principio la Comisión estará compuesta por los siguientes:

- **Miembros Permanentes**, aquellos que forman parte de la misma en función del cargo que ocupan:
  . Representante/s de la Administración del Centro.
  . Responsable de la Unidad Asistencial de Radioterapia.
  . Responsable de la Unidad de Radiofísica.
  . Responsable de Enfermería de Radioterapia y Radiofísica.

- **Miembros no Permanentes**, aquellos que forman parte de la misma a propuesta de los Responsables de las Unidades Asistenciales a las que pertenecen:

  . Un médico especialista en Oncología Radioterápica.
  . Un Radiofísico hospitalario.

Si por necesidades de funcionamiento o ampliación de funciones de la Comisión de Garantía y Control de Calidad en Radioterapia es necesario ampliar la representación de los componentes de esta, será necesaria la aprobación de estos por mayoría absoluta de los miembros de la Comisión.

2.2. Designación de los Miembros

El nombramiento de todos los miembros de la Comisión corresponde al Titular del Centro Sanitario (Gerente). En el caso de los miembros no permanentes, el nombramiento se efectuará a propuesta del responsable de la Unidad Asistencial correspondiente.

2.3. Renovación de los Miembros

- Permanentes: Si dejan de desempeñar el Cargo que motiva su designación.
- No permanentes: Deberá efectuarse una renovación anual, pudiendo ser reelegidos. Dejarán de ser miembros:
  . Si cesan en su relación laboral con la Unidad Asistencial.
  . A petición propia.
  . A petición del responsable de su Unidad Asistencial.

2.4. Derechos de los Miembros

- Recibirán, con una antelación mínima de 48 horas, la convocatoria para las Sesiones conteniendo el Orden del Día.
- Participarán en los debates y las votaciones de las Sesiones.
- Podrán formular ruegos, preguntas y su voto particular.
- Podrán obtener información precisa para cumplir las funciones que se les asignen.

- No podrán atribuirse las funciones de la representación de la Comisión que corresponden al Presidente de la misma a no ser que se les haya otorgado por acuerdo.
- Si se realizan votaciones, no podrán abstenerse en las mismas aquellos miembros que formen parte de la Comisión debido al cargo que ocupen.

2.5. Obligaciones de los Miembros

- A asistir a las reuniones de la Comisión a las que sea convocado, salvo por motivos o circunstancias de fuerza mayor.
- A respetar la confidencialidad de la información personal que conozca por su condición de componente de la Comisión, aún con posterioridad a su cese en la misma.

3.- PRESIDENTE

3.1. Elección del Presidente

- Se elegirá entre los miembros permanentes de la Comisión.
- Se elegirá preferentemente por acuerdo o por votación si fuera preciso.
- En caso de votación, todos los votos de los miembros tendrán el mismo valor.

3.2. Renovación del Presidente

- Deberá efectuarse una renovación cada dos años, pudiendo ser reelegido.
- Además, deberá elegirse un nuevo Presidente cuando el actual:

. Cese en el desempeño del cargo que conlleva ser miembro permanente.
. Solicite ser relevado de la presidencia.

3.3. Funciones del Presidente

- Ostentar la representación del órgano.
- Acordar la convocatoria de las Sesiones y fijación del Orden del Día.
- Presidir las Sesiones, moderar los debates y suspenderlos por causas justificadas.
- Dirimir con su voto los empates.
- Asegurar el cumplimiento de las Leyes y lo dispuesto en el presente Reglamento.
- Visar las Actas y certificaciones de los acuerdos de la Comisión.
- Ejercer el resto de funciones que sean inherentes a su condición de Presidente.
- Si la Comisión así lo decidiera, en caso de ausencia o enfermedad, sería sustituido por otro miembro de la misma.
- Responder a las solicitudes o sugerencias realizadas a la Comisión, tras consultar con los componentes de ésta.

4.- SECRETARIO

4.1. Elección del Secretario

- Se elegirá preferentemente entre los miembros de la Comisión.
- Se elegirá preferentemente por acuerdo o por votación si fuera preciso

4.2. Renovación del Secretario

- Deberá efectuarse una renovación cada dos años, pudiendo ser reelegido.
- Además, deberá elegirse un nuevo Secretario si los miembros de la Comisión así lo decidieran por mayoría, o si el actual:

. Deja de formar parte de la Comisión.
. Solicita ser relevado del cargo.

4.3. Funciones del Secretario

- Efectuar la convocatorio de las Sesiones por orden del Presidente.
- Recibirá los actos de comunicación de sus miembros.
- Redactará y autorizará las Actas de las sesiones que deberán ser firmadas por los asistentes a las mismas.
- Si no es miembro de la Comisión asistirá a las reuniones con voz y sin voto.

5.-FUNCIONES DE LA COMISION

Las funciones de la Comisión de Garantía y Control de Calidad en Radioterapia son las previstas a desarrollar conforme a lo dispuesto en el art. 2 "Programa de Garantía de Calidad", art. 4 "Comisión de Garantía y Control de calidad en Radioterapia" y art. 5 "Procedimientos en Radioterapia" del Real Decreto 1566/1998, de 17 de Julio.

6.-CONVOCATORIAS Y SESIONES

6.1. La Comisión de garantía y Control de Calidad en Radioterapia se reunirá con carácter ordinario, al menos una vez al trimestre, y con carácter extraordinario siempre que lo solicite alguno de sus miembros.

6.2. Los acuerdos se tomarán preferentemente por consenso. En el caso no deseable que hubiera que recurrir a la votación, el acuerdo será tomado por mayoría de votos. En caso de empate el Presidente de la Comisión tendrá voto de calidad.

6.3. No podrá ser objeto de deliberación o acuerdo ningún tema que no está en el Orden del Día a no ser por acuerdo de la mayoría de asistentes se decida la urgencia del mismo.

6.4. La Comisión podrá convocar a una o varias sesiones, como asesores, a los profesionales que acuerde previamente, en función de su especial conocimiento o dedicación a los temas a tratar.

6.5. De cada Sesión que celebre la Comisión se levantará Acta por el Secretario en la que se especificará los asistentes, el orden del día, los puntos principales de las deliberaciones y el contenido de los acuerdos adoptados.

6.6. Se podrá formular voto particular por escrito en el plazo de 48 horas que se incorporará al texto del Acta.

6.7. En la siguiente reunión que se realice será aprobada o modificada, según proceda, el Acta de la anterior reunión, siendo ello incluido siempre como primer punto del orden del día. El Secretario podrá emitir certificación sobre los acuerdos que se hayan adoptado sin perjuicio de la aprobación posterior del Acta, debiendo hacerse constar en este caso específicamente en la misma.

7.- NORMA FINAL

El presente Reglamento estará supeditado a la normativa que, en su caso, se vaya dictando en materia de Control de Calidad en Radioterapia.

PROGRAMA DE CALIDAD DEL PROCEDIMIENTO RADIOTERAPEUTICO: ELABORACIÓN DE UN DOCUMENTO-GUÍA POR LA ASOCIACIÓN ESPAÑOLA DE RADIOTERAPIA Y ONCOLOGÍA

Palacios A (1), Pardo J (2), Valls A (3), Petschen I (4), Castell A (5), Villar A (6), Pedro Olivé A (7), Muñoz V (8), Fernández J. (9), Rodríguez R (10), Otón C. (11)

Hospitales: Reina Sofía. Cordoba (1), Son Dureta. Palma de Mallorca (2), Ntra. Sra. de la Esperança. Barcelona (3), La Fe. Valencia (4), Germans Trias i Pujol. Badalona (5), Virgen de la Candelaria. Tenerife (6), Platón. Barcelona (7), Meixoeiro. Vigo (8), Virgen de la Arrixaca. Murcia (9), General de Asturias (10), Clinico de La Laguna. Tenerife (11).

Summary:

The Guidelines established by the Quality Control Program of Radiation Oncology Procedures Commission of the Spanish Society of Radiotherapy and Oncology are presented

Introducción:

El Real Decreto 1132/1990, de 14 de septiembre, por el que se establecen medidas fundamentales de protección radiológica de las personas sometidas a exámenes y tratamientos médicos, incorporó al ordenamiento jurídico español la Directiva 84/466/EURATOM, de 3 de septiembre, sobre protección radiológica del paciente.

El objeto de este Real Decreto es establecer los criterios de calidad en radioterapia para asegurar la optimización del tratamiento radioterápico y la protección radiológica del paciente.

En esta norma, se exige la implantación de un programa de garantía de calidad en las unidades asistenciales de radioterapia, que constará por escrito y estará siempre a disposición de la autoridad competente, a efectos tanto de auditoria como de vigilancia. Proponiendo si preciso, medidas correctoras para mejorar las características defectuosas o inadecuadas de las practicas clínicas o del equipamiento.

El programa de garantía de calidad, implica de forma directa a diversos profesionales sanitarios, fundamentalmente especialistas en Oncología Radioterápica, Radiofísicos hospitalarios y personal sanitario que administra los tratamientos radioterápicos.

Objetivo:

La AERO, a efectos de colaborar, coordinar y asesorar a sus miembros, nombró un grupo de trabajo, con el fin de crear un documento base, que sirviera de guión para que cada unidad asistencial de radioterapia, elaborara su propio programa de control de calidad del procedimiento radioterapeútico, abarcando todas sus etapas clínicas. Igualmente, elaborara un índice general de los apartados recomendados para formar parte del documento en su globalidad.

No se pretendió consensuar otros apartados que deben formar parte del programa de garantía en radioterapia tal como el programa de calidad del equipamiento y programa de mantenimiento, por corresponder fundamentalmente a profesionales representados por otras sociedades científicas.

Material y Método:

Se creó un grupo de trabajo constituido por 12 miembros, representantes de todas las autonomías, 11 especialistas en Oncología radioterápica y 1 radiofisico hospitalario. Todos ellos conocedores del estado del arte de la especialidad.

Un miembro ejercía de coordinador y otro de secretario. Se llevaron a cabo 2 reuniones de presencia física, consensuando el resto de opiniones a través de una lista de correo electrónico, mantenida por el secretario de la comisión.

Sirvieron de apoyo básico los siguientes documentos:

- Real decreto 1566/1998, de 17 de julio, por el que se establecen los criterios de calidad en radioterapia.
- Practical guidelines for the implementation of a quality system in radiotherapy. A project of the ESTRO Quality Assurance Committee sponsored by "Europe against Cáncer".
- Normas editadas por el Comité de Expertos en Radioterapia de la "Academia de Ciencias Medicas de Catalunya i Balears".

Resultados:

En diciembre de 1999, quedo concluido un documento, de 15 paginas, básico y genérico, de forma que pudiese ser guión de todas las unidades asistenciales españolas. Fue remitido por correo a todos los responsables de Servicios de Radioterapia y se encuentra a disposición de la comunidad científica en la secretaria de AERO.

Este documento consta de un *"índice"*, recomendado como guión del programa de garantía y control de calidad en radioterapia en su globalidad y el *"control de calidad de las etapas clínicas"*.

Índice:

- Introducción.
- Objetivos Generales.
- Disponibilidades:
  - Descripción del Servicio
  - Personal
  - Organización Jerárquica
  - Utillaje de Radioterapia
  - Utillaje de Radiofísica
- Funcionamiento Asistencial
  - Introducción
  - Descripción del circuito asistencial
  - Carga Asistencial.
- Control de Calidad Radiofisico
  - Aceptación de las Unidades
  - Estado de Referencia
  - Control de Calidad Periódico
- Control de Calidad Clínico

Control de Calidad de las Etapas clínicas:
Quedaron definidas todas ellas, así como su objetivo y el responsable o responsables de cada nivel de actuación. Igualmente aunque sobrepasa el ámbito de esta comunicación, quedaron explicitados los procedimientos a utilizar, los recursos mínimos humanos y materiales necesarios para realizarlos y los programas de control asociados en cada etapa clínica.

ETAPA CLÍNICA Nº 1: EVALUACIÓN INICIAL
Definición: valoración que realiza el médico especialista en Oncología Radioterápica del estado del paciente, tipo y extensión de la enfermedad y posibilidades terapéuticas aplicables.
Objetivo: obtener los datos que permitan ofrecer la mejor opción terapéutica.
Responsable: médico especialista en Oncología Radioterápica.

ETAPA CLÍNICA Nº 2: DECISIÓN TERAPÉUTICA
Definición: etapa clínica en la que el médico especialista en Oncología Radioterápica elige entre las modalidades de tratamiento posibles, aquella cuyos objetivos metodología y desarrollo se adaptan mejor a las necesidades y deseos del paciente.
Objetivo: obtener la opción terapéutica óptima para cada situación clínica y necesidades del paciente con relación a los medios disponibles.
Responsable: médico especialista en Oncología Radioterápica.

ETAPA CLÍNICA Nº 3: LOCALIZACIÓN
Definición: etapa clínico-técnica en la que el médico especialista en Oncología Radioterápica delimita los volúmenes blanco y los órganos críticos con sus márgenes correspondientes para la planificación del tratamiento.
Objetivo: definir y delimitar los volúmenes de tejido a irradiar y proteger.
Responsable: médico especialista en Oncología Radioterápica.

ETAPA CLÍNICA Nº 4: PLAN DE IRRADIACIÓN
Definición: Etapa clínico-técnica en la que se hace la propuesta terapéutica en base a la enfermedad, el estado del paciente, medios disponibles, experiencia y estado del arte de la especialidad. Consta de: Prescripción provisional, calculo, optimización y prescripción definitiva.
Objetivo: Obtener el plan de tratamiento óptimo.
Responsable: médico especialista en Oncología Radioterápica y radiofisico hospitalario.

ETAPA CLÍNICA Nº 5: SIMULACIÓN Y O VERIFICACION DEL TRATAMIENTO
Definición: reproducción fidedigna y documentada de las condiciones del tratamiento prescrito que se lleva a cabo antes de iniciarlo.
Objetivo: verificar que las características del tratamiento previsto se ajustan a las necesidades del paciente en cuanto a su enfermedad, anatomía y posición en la mesa de la unidad.
Responsable: médico especialista en Oncología Radioterápica.

ETAPA CLÍNICA Nº 6: APLICACIÓN DEL TRATAMIENTO
1. Irradiación externa o transcutánea o teleterapia
Definición: proceso mediante el cual se lleva a cabo la irradiación terapéutica, reproduciendo en la unidad de tratamiento los parámetros de irradiación y posición del paciente contenidos en el informe dosimétrico y ficha de tratamiento.
Objetivo: reproducir en cada sesión de tratamiento el plan terapéutico previsto y especificado en el informe dosimétrico y ficha de tratamiento.
Responsable: El personal sanitario que administra el tratamiento

ETAPA CLÍNICA Nº 6: APLICACIÓN DEL TRATAMIENTO

2. Braquiterapia.

Definición: Colocación del material radiactivo en el tejido tumoral (Braquiterapia intersticial), en su superficie externa (plesioterapia) o en una cavidad anatómica (endocavitaria), mediante carga inmediata o diferida (manual o mecanizada).

Objetivo: Situar el material radiactivo dentro o lo más cerca posible del tumor, para conseguir una distribución de dosis óptima en relación al tumor y tejidos sanos circundantes.

Responsable: Médico especialista en Oncología Radioterápica.

ETAPA CLÍNICA Nº 7: CONTROL DEL TRATAMIENTO

1. Radioterapia externa, transcutánea o teleterapia.

Definición: proceso en el que se controla la aplicación del tratamiento, sus características, así como la respuesta de la enfermedad y evolución del enfermo.

Objetivo: controlar la aplicación del tratamiento y la respuesta inmediata del paciente, así como verificar la constancia de los datos anatómicos, para modificar el plan de irradiación cuando se considere preciso.

Responsable: médico especialista en Oncología Radioterápica.

ETAPA CLÍNICA Nº 7: CONTROL DEL TRATAMIENTO

2. Braquiterapia.

Definición: proceso en el que se controla la aplicación del implante, su estabilidad y el correcto funcionamiento del equipo automatizado en cuanto a entrada y salida de las fuentes radiactivas, así como la evolución de la enfermedad y aparición de complicaciones. Al final de la aplicación se retiran las fuentes radiactivas, excepto en los implantes definitivos.

Objetivo: comprobar que el implante se mantiene estable, que no hay averías en los dispositivos de carga diferida que puedan modificar la dosis administrada, así como que no aparecen efectos tóxicos o complicaciones que aconsejen un cambio en la estrategia de tratamiento. Al final del tratamiento, comprobar que el paciente no es portador de fuentes radiactivas no previstas y éstas han sido almacenadas correctamente.

Responsable: Médico especialista en Oncología Radioterápica, Radiofísico hospitalario y operador.

ETAPA CLÍNICA Nº 8: EVALUACIÓN FINAL

Definición: Etapa clínico-técnica en la que se revisan las características de tratamiento administrado y sus efectos sobre la enfermedad, los tejidos sanos y el estado del paciente.

Objetivos: comprobar las eventuales variaciones entre el tratamiento prescrito y el administrado, su justificación, y valorar la respuesta al tratamiento y sus posibles toxicidades.

Responsable: médico especialista en oncología radioterápica.

ETAPA CLÍNICA Nº 9: SEGUIMIENTO DEL PACIENTE DESPUÉS DEL TRATAMIENTO

Definición: Etapa clínica en la que se valora la evolución de la enfermedad, y los posibles efectos tóxicos agudos, y la eventual aparición de efectos tóxicos tardíos.

Objetivos: Valorar la eficacia del tratamiento administrado.

Responsable: médico especialista en oncología radioterápica.

Este documento, cuyo resumen hemos expuesto, fue remitido a todos los responsables de Servicios de Oncología Radioterápica de la nación y se encuentra a disposición de la comunidad científica en la secretaria de AERO.

INFORME DE LA COMISIÓN DE INFRAESTRUCTURAS DE LA ASICIACION ESPAÑOLA DE RADIOTERAPIA Y ONCOLOGIA SOBRE ESTANDARES ASISTENCIALES RECOMENDABLES EN ONCOLOGÏA RADIOTERAPICA

AUTORES: Escó R (1), Pardo J (2), Palacios A (3), Biete A (4), Fernández J (5), Valls A (6), Herrazquin L (7), Román P (8), Magallón R (9).

Hospitales: Clínico Lozano Blesa. Zragoza (1), Son Dureta. Palma de Mallorca (2), Princesa Sofía. Córdoba (3). Clinic. Barcelona (4), Virgen de la Arrixaca. Murcia (5) Ntra. Sra. de la Esperança. Barcelona (6), Clínico Virgen Macarena. Sevilla (7), Puerta del Mar. Cádiz (8), Puerta de Hierro. Madrid (9).

SUMMARY: We present the final report of the Spanish Society of Radiotherapy and Oncology Infrastructures Commission about service standards recommendable in Radiation Oncology.

INTRODUCCIÓN

La publicación del R. D. 1566/1998 de 17 de julio, de Garantía y Control de Calidad en Radioterapia, obliga a la elaboración de unos procedimientos en radioterapia. Estos procedimientos deben contemplar necesariamente los recursos materiales y humanos precisos para la realización de una radioterapia práctica de calidad y ajustada a la legislación.

Para poder marcar unas normas respecto a recursos humanos y materiales es preciso que se establezcan antes unos estándares asistenciales que sirvan de marco referencial para la determinación de los citados recursos, necesarios para la realización de cada procedimiento. Por otra parte, la necesaria ordenación de recursos materiales y humanos que se debe producir en una correcta planificación asistencial obliga a la publicación de unas normas claras. En este sentido, las dos ediciones del "Libro Blanco de la Oncología en España", documento "GAT para la Radioterapia" y las normas editadas por el Comité de Expertos en Radioterapia de la "Academia de Ciencias Medicas de Catalunya i Balears" han supuesto avances importantes en el establecimiento de estos criterios para España.

La "Sociedad Española de Radioterapia y Oncología (AERO)", en un intento de facilitar, a todos sus asociados y a las autoridades sanitarias unos criterios de planificación y ordenación de recursos, sugiriendo cuales deben ser los límites de cargas de trabajo para desarrollar una radioterapia de calidad, ha solicitado al "Comité de Infraestructura de la AERO" la redacción de unas normas para la determinación de recursos en cada procedimiento en radioterapia, que sirvan de guía en la planificación de servicios de Oncología Radioterapia. Con estas normas se pretende que las cargas asistenciales queden limitadas de manera que la calidad no se vea mermada por la sobrecarga asistencial. Se pretende dar a los poderes públicos unas normas que les sirvan no sólo para la planificación, sino también para la auditoria de servicios, si lo consideraran pertinente.

OBJETIVO

Elaborar unas recomendaciones en cuanto a estándares básicos de capacidades de trabajo de unidades y de personal, que permitan ofrecer una actividad médica de calidad, así como, ofrecer unos criterios de planificación que sirvan para crear los necesarios servicios de Oncología Radioterapia, con la dotación adecuada, lo que redundará en la eliminación de las listas de espera en nuestra especialidad y en la ordenación racional de los recursos.

MÉTODO

Los miembros del "Comité de Infraestructura de la AERO", en sus reuniones de trabajo han aportado, además de su experiencia, las recomendaciones de organismos internacionales, datos publicados en la literatura internacional, así como, las prácticas habituales de los centros de trabajo en los que desarrollan su función.

De forma explícita, este Comisión no emite recomendaciones respecto a las cargas asistenciales de Físicos y Dosimetristas, por considerar que no son de su competencia.

Las recomendaciones que siguen se basan principalmente en la legislación vigente, en el tiempo que requiere todo el proceso asistencial en radioterapia, desde la primera visita hasta el final del seguimiento y fundamentalmente en el documento redactado por el "Comité de Expertos de la Academia de Ciencias Medicas de Catalunya i Balears", al representar un trabajo reciente y coincidente en los objetivos respecto al encargo de la AERO para todo el territorio nacional.

Al igual que en el documento mencionado, esta Comisión de Infraestructura, recomienda en primer lugar y como base de todo el proceso, un escrupuloso cumplimiento de la normativa existente, en cuanto a la garantía de la calidad recogida en la legislación publicada. Así mismo la Comisión hace un especial énfasis en la correcta información a los pacientes y en la indispensable obtención del consentimiento informado previamente al inicio de los tratamientos.

RECOMENDACIONES

Se recomienda que la responsabilidad de todas las unidades funcionales de radioterapia, recaigan sobre un Jefe de Servicio. En este sentido, se aconseja a las autoridades sanitarias la creación de jefaturas de servicio en todos los hospitales en que no exista este cargo.

Las etapas del tratamiento radioterápico, contempladas en el anexo 3, del Real Decreto 1966 son responsabilidad exclusiva del médico radioterapeuta. Estas etapas son: Evaluación inicial, decisión terapéutica, localización, plan de irradiación, simulación del tratamiento, aplicación del tratamiento, control del tratamiento, evaluación final y seguimiento del paciente.

UNIDADES DE TRATAMIENTO:

Tiempos estimados:

Los tiempos medios estimados para la realización de cálculos de cargas de trabajo son:

Para la realización de todas las etapas clínicas se calcula un tiempo de 9 a 10 horas por paciente. En este tiempo se computa la dedicación a labores puramente asistenciales, como puede ser la realización de la historia de primer día, el tiempo dedicado a la asistencia a comités para la toma de decisiones, etc. Creemos que es más razonable planificar en base a tiempos globales, pues la determinación de un tiempo para la realización de una historia, además de ser difícil de cuantificar, por depender de muchas variables individuales del paciente no contempla los tiempos dedicados a labores asistenciales, sin que el paciente esté físicamente presente, pero imprescindibles para una radioterapia de calidad. Por otro lado, el manejar una cifra global elimina la planificación basada en una medida de tiempos, como de sí una cadena de montaje se tratara, sin tener en consideración factores humanos y sociales, siempre presentes en las relaciones médico-enfermo.

Respecto a las unidades de tratamiento se calcula que su capacidad está en 4 pacientes por hora de tiempo efectivo de tratamiento. En este cálculo de tiempos se deben excluir todas las técnicas especiales, tales como radiocirugía, tratamientos esterotáxicos fraccionados, irradiaciones corporales totales e irradiaciones cutáneas totales, en las que no se pueden seguir estos criterios de tiempo, por ser técnicas mucho más laboriosas y requerir mas tiempo de máquina de tratamiento.

Idealmente una unidad de tratamiento debe funcionar entre 10 y 12 horas dedicada a tratar enfermos. Menos puede suponer una infrautilización de los recursos. Dedicar más tiempo supone un envejecimiento prematuro de la unidad con aumento de los tiempos de paradas por averías. A este tiempo de tratamiento siempre se debe añadir 2 horas adicionales para los necesarios controles diarios, pausas para descanso del personal, cambios de turnos y cierre de

unidades. Por ello, para 10 horas útiles de trabajo se precisan 12 de funcionamiento real y para 12 horas de tratamiento se precisan 14 de funcionamiento real.

Resultados para unidades de tratamiento:

En base a estas cifras, una unidad de tratamiento con un funcionamiento de 10 horas puede tratar a 40 pacientes diarios y con 12 horas a 48 pacientes.
Considerando que a los días útiles de trabajo se debe descontar el 10 % de tiempo útil por averías y revisiones y que la duración media de un tratamiento de radioterapia es de 22 días, una unidad puede realizar al año tratamientos entre 409 y 491 pacientes, dependiendo de que se siga el criterio de 10 o de 12 horas de trabajo.

Aplicando los datos de incidencia y prevalencia de cáncer, así como, los de porcentaje de pacientes que requieren radioterapia, perfectamente documentados tanto en el "Informe GAT" como en el "Libro Blanco de la Oncología en España", se calcula que debe de existir una unidad de tratamiento por cada 200 - 250.000 habitantes, debiéndose tender a alcanzar la ratio de una unidad por 200.000 habitantes.

Por otro lado, esta cifra debe depender de criterios geográficos, así en áreas de fuerte dispersión de la población podría ser adecuado disminuir el número de habitantes por máquina para no obligar a los pacientes a desplazamientos prolongados para alcanzar el recurso. No obstante, la "Comisión de Infraestructura de la AERO" considera que estas situaciones deben tratarse de manera individualizada, por depender no sólo de la distancia, sino también de las infraestructuras en comunicaciones y facilidades de acceso.

NECESIDADES DE PERSONAL:

Un servicio no puede dar adecuada calidad asistencial si tiene carencias de personal, lo que provoca sobrecargas asistenciales en los distintos colectivos implicados en los tratamientos, que siempre redundan en una disminución de la calidad asistencial.

Personal facultativo:

Para el cálculo de las necesidades de personal facultativo se debe considerar que el tiempo total dedicado a todo el proceso radioterápico es de 8 a 9 horas por paciente. Si consideramos que la jornada legal anual es de 1645 horas, cada facultativo puede realizar entre 165 a 185 pacientes completos por año.

Teniendo en cuenta que no todo el tiempo del facultativo puede dedicarse a labores asistenciales y que existe unos tiempos de dedicación a labores de gestión para cada estamento medico. Así se recomienda que a la carga asistencial de un facultativo especialista se debe descontar un 20 % que es el tiempo que debe dedicar a labores de gestión y calidad, para un jefe de sección se estima en un 40 % y para un jefe de servicio en un 80 %. De esta manera la capacidad de un facultativo especialista es de 132 a 148. Para un jefe de sección su capacidad será de 99 a 111 y para un jefe de servicio de 33 a 37 pacientes anuales. Si el servicio dispone de área propia de hospitalización se deba añadir un facultativo dedicado a la asistencia de los pacientes ingresados (igualmente no significa que un medico se dedique exclusivamente a la hospitalización, sin que el tiempo que cada facultativo dedica a este trabajo, se debe compensar con la disminución de la carga asistencial).

En los servicios en los que existan tratamientos de braquiterapia se debe añadir un médico por cada unidad de braquiterapia o lanzador de fuente, para los servicios que dispongan de unidades de carga diferida.

Personal no facultativo:

Respecto a personal no facultativo, esta Comisión hace las siguientes recomendaciones:

- 2 puestos de técnico superior en radioterapia (TERT) por unidad de tratamiento y turno de 7 horas de trabajo.
- 1 enfermero (DUE) por turno de trabajo, por cada 3 unidades de tratamiento radioterápico. Como minimo, independientemente de las unidades debe haber un DUE.
- 1 auxiliar de enfermería por cada 3 unidades de tratamiento. Como mínimo, independientemente de las unidades debe haber un auxiliar de enfermería.

- 1 TERT por cada unidad de simulación y turno.
- 1 TERT para el taller de radioterapia (moldes, bloques conformados, etc.).

Un Servicio de Física de las dimensiones adecuadas a la carga asistencial de radioterapia, que como exponíamos en la introducción debe ser definido por los profesionales responsables.

Para el área de consultas se precisa:

- 1 DUE para el área de consultas.
- 1 Auxiliar de enfermería en cada consulta.
- 1 Celador por turno, que debe atender tanto al área de consulta como al de unidades de tratamiento.
- 1 administrativo por cada 700 pacientes nuevos vistos en el servicio. Como mínimo, independientemente de la cantidad de pacientes vistos, de debe disponer de un administrativo.

Respecto a los criterios de reposición de unidades, la AERO recomienda que las unidades se repongan entre los 10 y 15 años de funcionamiento y que la reposición de las unidades de cobalto se haga por aceleradores multienergéticos. Respecto a la carga de las unidades de Cobalto, se recomienda que sea sustituida cuando la actividad se encuentre por debajo de los 3.000 Curios.

Se recomienda que todos los servicios dispongan de simulador virtual o acceso propio a tiempo de TAC y planificador 3D como herramientas fundamentales para poder brindar a los pacientes unos tratamientos con la calidad que estos merecen y de acuerdo al estado actual de la especialidad.

LEGISLACION SANITARIA EN MATERIA DE RADIOTERAPIA EN ESPAÑA. EL DILEMA LEGISLATIVO ENTRE PROTECCION RADIOLOGICA Y TRATAMIENTO DEL CANCER

AUTORES: Escó R (1), Biete A (2), Carceller JA (3), Veiras C (4), Vazquez MG (5), Palacios A (6), Pardo J (7).

Hospitales: Clínico Lozano Blesa. Zaragoza (1), Clinic. Barcelona (2), Arnau de Vilanova (3), Centro Oncológico de Galicia (4), 12 de Octubre. Madrid (5), Reina Sofía. Córdoba (6), Son Dureta. Palma de Mallorca (7)

SUMMARY: The authors make some reflections about health regulations about radiation oncology in Spain, pointing out that may occur a legislative dilemma between radiation protection and treatment of cancer.

El Real Decreto 1566/1998, de 17 de Julio, por el que se establecen los criterios de calidad en radioterapia, marca un hito importante en la visión legal de la radioterapia en nuestro país.

Este decreto esta basado en la normativa europea 84/466/EURATOM, sobre protección radiológica del paciente.

En él se marcan unas normas, que desde el punto de vista medico pueden ser incluidas en la buena praxis. La protección radiológica al paciente se entiende desde el punto de vista medico como indispensable para una radioterapia de calidad, de ahí que el titulo del Real Decreto sea el de "criterios de calidad en radioterapia".

Este decreto entró en vigor al día siguiente de su publicación y se estableció un plazo que expiró el 13 de mayo de 2000 para completar el establecimiento completo del programa de calidad en cada uno de los centros que contaran con unidades asistenciales de Radioterapia.

Un programa de calidad debe incluir una serie de capítulos entre los que se incluye la definición y objetivos del programa, la justificación y optimización de las exploraciones, el funcionamiento del servicio, control del funcionamiento del equipamiento radiológico, vigilancia de la protección radiológica del personal profesionalmente expuesto y del publico en general, formación del personal, auditorias y sistemas de control y procesos no conformes, acciones correctoras, preventivas y de mejora.

Este programa de calidad debe ser adaptado a cada centro y por tanto difícil de sistematizar, pero en la descripción del programa de calidad, por imperativo legal, deben estar contemplados los procedimientos médicos marcados en el anexo III del citado texto legislativo. Estos procedimientos que marcan las normas y pasos de buen hacer radioterápico, si que pueden adaptarse a criterios nacionales y por ello pueden ser redactados por un organismo nacional que dicte unos criterios mínimos de buen funcionamiento en cada una de las etapas clínicas.

Lo anterior, no obstante, además de mejorar la calidad de un servicio, marca una sistemática de trabajo muy bien definida y que no solo exige rigidez en el trabajo, sino también en los recursos que se manejan para cada procedimiento.

Por ejemplo, si no está regulado el equipamiento necesario para realizar una tarea, esta puede ser puesta en funcionamiento con unos recursos mínimos. Ahora bien, si está regulada, su incumplimiento es fácilmente detectable.

Por lo tanto nos encontramos con unas exigencias no solamente de buena calidad, sino también de adecuación de recursos humanos y materiales a cada tarea.

Lo anterior tal vez no hayan sido comprendido por la sociedad, con lo que se nos produce un primer conflicto al ser necesario cumplir una ley de calidad, pero debido a que en bastantes casos no se dispone de los medios adecuados, no es posible hacerlo.

Por otro lado, la Ley general de Sanidad de nuestro país, obliga a prestar atención sanitaria a los ciudadanos, y en el caso de que existan medios, pero no sean los adecuados para el nivel de calidad impuesto, ¿es licito no tratar a un paciente, teniendo los instrumentos para hacerlo, pero incumpliendo normas de calidad?.

A este respecto existen 2 comunicaciones a congresos de Radioterapia en la que se pone de manifiesto este problema. En 1993, Escó y cols. presentaron una comunicación al VII Congreso Nacional de Radioterapia titulado: La seguridad radiológica en un acelerador y los tratamientos ¿son compatibles?.

En esta comunicación los autores demostraron que al aumentar los controles técnicos y dosimétricos en un acelerador (al realizarse estos en horario de trabajo) se originan mayores interrupciones en los tratamientos, de manera que solo el 6'9 % de los pacientes, de una muestra de 318 terminan los tratamientos sin interrupciones, frente a un 34'1 % para una muestra de 401 pacientes en un periodo de tiempo en el que las revisiones no eran tan exhaustivas.

Hay que tener en cuenta que los alargamientos en los tiempos totales de tratamiento, es decir la interrupciones, producen una perdida de control de 1'5 a 1'7 % por cada día de tratamiento perdido. Por todo ello, los autores concluyeron que la seguridad radiológica puede comprometer seriamente la seguridad terapéutica de nuestros tratamientos, con lo que vuelva a plantearse el dilema de seguridad radiológica versus seguridad terapéutica como disyuntiva clave en la legislación.

Además en nuestro país la legislación sanitaria es compleja y no es el decreto de calidad el único que nos regula el trabajo. El Real Decreto 1836/99 sobre instalaciones nucleares y radiactivas de 3 de diciembre de 1999, marca los requisitos administrativos necesarios para la puesta en marcha de una instalación radiactiva, es decir de una instalación de radioterapia.

Estos requisitos legales, comprensibles para evitar daños a los profesionales, pacientes y publico en general, vuelven a presentar un dilema al retrasar la apertura de instalaciones para tratamiento de pacientes con tumores malignos.

En este sentido, en el X Congreso Nacional de Radioterapia, Esco y Col presentaron un trabajo en el que a partir de sus propios datos y de los publicados en la literatura, un acelerador lineal de electrones, es capaz de tratar cada año de funcionamiento unos 327 pacientes con intención curativa, de los que alrededor del 30 % se curaran, es decir, unos 98 pacientes anuales son curados gracias a la irradiación.

Por lo tanto, todo tramite que retrase la puesta en marcha de un acelerador de manera innecesaria tiene un coste social de 98 fallecimientos anuales, con lo que el dilema sanitario

vuelve a presentarse, protección radiológica si, pero meditando el coste social que puede suponer la excesiva burocratización y la lentitud en los trámites.

Actualmente existe un proyecto de Real Decreto sobre justificación del empleo de radiaciones ionizantes en el diagnostico y tratamiento de pacientes, con lo que se pretende reducir al máximo la irradiación de los pacientes y sobre todo eliminar la irradiación innecesaria.

De nuevo vuelve a presentarse el dilema, esta norma es necesaria, pero su aplicación excesiva puede llevar a la no irradiación de pacientes, pues aplicada a sus máximos extremos, ¿cómo podemos justificar una irradiación paliativa en un paciente con dolor si el tratamiento con radioterapia no es curativo y el tratamiento con mórficos, más tóxicos, no precisa justificación?.

Con este análisis de la legislación sanitaria mas importante que afecta a la radioterapia no queremos expresar su falta de acierto, únicamente llamar la atención sobre la necesidad de armonizar la protección radiológica del paciente con la posibilidad de tratar a los pacientes y sobre todo con la posibilidad de realizar un tratamiento que también sea efectivo y seguro desde el punto de vista de la curación del tumor o alivio de sus síntomas.

cw-276

Prevention of Thrombocytopenia and Neutropenia by rhIL-11 in Irradiated rhesus monkeys

HAO Jing, LUO Qingliang, XIONG Guolin, LIU Xiaolan, QIU Liling, CHEN Guozhi, HUANG Ying, GE Ping, GENG Yu, SUN Liansheng, DONG Bo, LI Yuanmin, CHEN Wangqiu, and SHEN Chun

Beijing Institute of Radiation Medicine, 27 Taiping Road, Beijing 100850, China

Abstract

The efficacy of rhIL-11 in treating thrombocytopenia and neutropenia in irradiated rhesus monkeys and the variation in curative effect due to difference in administration times were studied. Healthy rhesus monkeys were exposed to 3.0 Gy ^{60}Co total body irradiation (TBI) to result in pancytopenia for three weeks. Treatment with rhIL-11 (30, 60 or 120 μ g/kg/day) on early days (days 0-13 after TBI) could significantly improve the nadir of platelet count. Although the nadir of leukocyte count was not improved, the duration below 50% of its baseline value was shortened similarly to that of platelet. During the first two weeks after TBI, erythrocyte numbers of the animals treated with these doses of rhIL-11 were lower than those of the control group at first but they became higher beginning form the third week. Four monkeys were treated with rhIL-11 at 60 μ g/kg/day on days 13-26 after TBI. The numbers of their peripheral blood cells followed the similar decrease patterns as those of control group during the first three weeks, then they were improved rapidly. By semi-solid bone marrow cell culture it was demonstrated that rhIL-11 could stimulate bone marrow cells to form more CFU-MK, CFU-Mix, CFU-E, BFU-E and CFU-GM *in vitro*. Histopathological observation revealed that bone marrow of the control group was devoid of hematopoietic cells and bleeding, being contrary to that of the group treated with rhIL-11, in which the cells proliferated actively. The results suggest that rhIL-11 can accelerate hematopoietic recovery of irradiated monkeys.

CN-77

Radiological Assessment for the Build of a Positron Emission Tomograph (PET) Center

YANG G.S CAI F.G ZHOU H.M WANG S.J

Institute of Radiation Medicine, Beijing China

Abstract

Source term, types and tracks of ionizing radiation exposure for Positron Emission Tomograph (PET) and related cyclotron have been analyzed. The exposure level have been estimated by them. Based on these analysis and estimation the assessment of radiological protection and shield for the build of a PET center has been given.

Key wards PET Cyclotron Radiological protection Shield

FORM B
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in

- **Diagnostic and Interventional Radiology**
- **Nuclear Medicine and**
- **Radiotherapy**

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AUTHOR(S) INITIAL(S) AND FAMILY NAME(S)	SCIENTIFIC ESTABLISHMENT(S) IN WHICH THE WORK HAS BEEN CARRIED OUT	TOWN/COUNTRY
Dr. DONG A ZOK	Faculty of Medicine. University YAOUNDE I	YAOUNDE/CAMEROUN
2		
3		
4		
5		

AUTHOR WHO WILL PRESENT THE PAPER	Mailing Address: P.O. Box 5408 YAOUNDE CAMEROUN
Mr./Ms: Dr. DONG A ZOK	
Initial(s):	
Family Name: Dr. DONG A ZOK	Telefax No.: (237) 21 31 81
	E-Mail: dongazok@uycdc.Uninet.Cm Telex No

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EVALUACIÓN DE LA PROTECCIÓN RADIOLÓGICA EN VARIOS DEPARTAMENTOS DE MEDICINA NUCLEAR

Autores: Gladys López Bejerano, Luis Jova Sed
Centro de Protección e Higiene de las Radiaciones, Cuba
gladys@cphr.edu.cu; jova@cphr.edu.cu

Colaboradores: Marlenin Díaz Borroto, Leonel Torres Aroche, Adlin López Díaz, Felizardo Ponce Vicente, Vivian Freixas Lemus, Diosdado Castro Crespo, Aldo Barreras Caballero, Orlando Dranguet Palacios, Rafael Miller , Reinaldo Pérez , Heriberto Simón, Amilkar Failder.
Responsables de Protección Radiológica de las entidades encuestadas.

Summary

For the evaluation of the Radiation Protection in several departments of Nuclear Medicine was elaborated and it applied a survey that includes mainly: aspects of the licence and compliance with the requirements settled down in this, the program of individual radiological surveillance and their evaluation, functions that it completes the Service of Radiation Protection, training program and the personnel's training, equipment and means of Radiation Protection, radiological surveillance program of the work areas, characteristics of the installation, radioactive waste management, quality assurance program, relative aspects to the Radiation Protection in the procedures of diagnoses; as well as to pregnant patients and those related with the investigation of accidental medical exposures. The work makes a systematization and discussion of the state of compliance of the radiation protection requirements reflected in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) and the main recommendations are exposed to achieve in these departments the optimization of the Radiation Protection.

1. Introducción:

Con el propósito de evaluar la situación de la Protección Radiológica (PR) en la práctica nacional de Medicina Nuclear se aplicó una encuesta en 10 módulos de esta práctica en diferentes provincias del país, aportando la información que permite evaluar el grado de cumplimiento de los requisitos básicos, establecidos en las Normas Básicas Internacionales de Protección contra las Radiaciones Ionizantes y de Seguridad de las Fuentes de Radiación (NBIS) [1]. La encuesta consistía en 13 modelos, que recogen los diferentes aspectos relativos a la PR, agrupados de forma tal que facilitan la compilación y análisis posterior de la información. El análisis y conclusiones a que se arribó pueden ser considerados como representativos de la práctica nacional y las valoraciones presentadas en este trabajo, permitirán sentar las bases para realizar un análisis particular en cada entidad de los aspectos, que deben ser tenidos en cuenta para el correcto desempeño de los Servicios de Protección Radiológica (SPR), y como punto de partida para iniciar un proceso de optimización de la PR en ellas [2].

2. Resultados y discusión:

➢ Información general

Las instituciones estudiadas están licenciadas por el Centro Nacional de Seguridad Nuclear (CNSN), como Autoridad Reguladora se encuentran en período de renovación de dichas licencias y operan según las condiciones previstas en estas.

Desde el punto de vista organizativo, se encuentran nombrados el representante legal autorizado, el Responsable de Protección Radiológica (RPR) y el Facultativo principal; no así el Físico dedicado a Medicina Nuclear. No se cumple con la subordinación directa del RPR al Director de la entidad, aunque los aspectos de PR son tratados directamente con este y se les confiere determinada

autonomía para cumplir sus funciones. No se encuentra constituido el Comité de Protección Radiológica en la mayoría de las instituciones y en las que existe su funcionamiento es deficiente, por lo que la evaluación de los aspectos relativos a la seguridad radiológica no es sistemática, ni es vista desde un punto de vista integral.

- **Programa de Vigilancia Radiológica Individual y su evaluación**

Las entidades disponen de un programa de vigilancia radióloga individual, en el que se emplean diferentes métodos. El monitoreo individual de la irradiación externa comprende: cuerpo entero en el que se utilizan dosímetros fílmicos o TLD con una frecuencia trimestral y mensual respectivamente. Sólo cuatro entidades monitorean extremidades con dosímetros TLD con una frecuencia mensual. El monitoreo individual de la contaminación interna por método directo, para el ^{131}Iodo se realiza en dos entidades. Los métodos indirectos no son empleados.

Los resultados del control dosimétrico individual de cada uno de los servicios contratados son registrados, pero es deficiente su: actualización, la información a los TOE, la evaluación y su documentación. Se emplean niveles de registro e investigación, sin embargo la toma de medidas en caso de su superación no esta establecida en todos los servicios o no son documentadas.

Aspecto deficiente en el orden organizativo es la no-disponibilidad en todas las entidades de un lugar que garantice el adecuado almacenamiento de los dosímetros una vez concluido el trabajo y el uso inadecuado y no diario de los dosímetros por parte de algunos TOEs.

- **Funciones del Servicio de PR (SPR)**

La mayoría de las entidades tienen constituido el SPR por el RPR, lo que se adecua a sus características, pero no todos están certificados. En el aspecto organizativo se establecen las funciones y atribuciones del SPR, pero su cumplimiento y la elaboración de un sistema de registros adecuado de las mismas, con su actualización sistemática, presenta diferentes niveles de implementación. Las causas valoradas que inciden en ello, están dadas por: la ausencia de programas, equipamiento y conocimientos adecuados; así como aspectos propiamente de índole organizativos.

En cuanto a la evaluación por parte del SPR de la situación de la PR ésta se realiza con una frecuencia anual o posterior a las inspecciones realizadas por el CNSN, siendo documentada fundamentalmente para la presentación de la solicitud o renovación de la licencia.

- **Capacitación y entrenamiento del personal en materia de PR**

La capacitación y entrenamiento del personal en materia de PR aún son deficientes y no se realiza una evaluación periódica de sus resultados, lo cual está dado por la carencia de un programa concebido integralmente en el que se incluyan la capacitación diferenciada a los TOE y la realización de ejercicios prácticos.

El contar con procedimientos e instrucciones debidamente documentados en las entidades, que abarcan los estudios diagnósticos que se ejecutan y algunos aspectos de PR, resulta valioso para establecer el programa de capacitación y con su evaluación propiciar la revisión y modificación de dichos procedimientos, con el objetivo de ir dando pasos que lleven a optimizar la PR.

- **Equipos y medios de PR**

La disponibilidad de equipos de PR en los SPR para realizar el monitoreo de áreas presenta serias dificultades y en especial los equipos medidores de contaminación superficial, por su ausencia casi generalizada, o su empleo con un nivel de referencia preestablecido y la carencia de un servicio nacional para su calibración. Sin embargo un mayor número de entidades cuenta con equipos de

medición de tasa de dosis, que son regularmente calibrados. Los equipos que miden tasa de dosis o contaminación y cuentan con señalización de sobrepaso de umbral, no están disponibles en todas las entidades o su funcionamiento es defectuoso en parte de estas.

Se cuenta con medios para realizar la descontaminación radiactiva de áreas de trabajo y del personal; pero no siempre son ubicados en las áreas que lo requieren. De igual forma en todas las entidades se encuentran disponibles medios para la protección individual de los trabajadores y se conoce casos como usarlos.

Los aspectos tratados en este tema, requieren que las instituciones realicen inversiones; así como la implementación por parte del SPR de técnicas de medición alternativas que permitan realizar las evaluaciones requeridas.

- **Programa de monitoreo de las áreas de trabajo**

Las dificultades señaladas con el equipamiento, es la principal causa de que en las entidades exista un deficiente programa de monitoreo de áreas, unido a que no se ha concebido en muchas de ellas de forma integral. Como alternativa para cumplimentar el monitoreo de áreas, las entidades han contratado estos servicios; pero es necesario prestar atención en la necesidad de que este se diseñe respondiendo a las necesidades propias de la entidad y que incluya los diferentes tipos de monitoreo recomendados, estableciéndose niveles de investigación o intervención y procedimientos donde se recojan los pasos a seguir en el caso de su superación.

- **Características de los locales**

En todas las entidades existen las condiciones constructivas y de ventilación autorizadas en las licencias emitidas por el CNSN, aunque no siempre se cuenta con un registro donde se documenten modificaciones efectuadas.

Las diferentes áreas de trabajo poseen una clasificación adecuada y su disposición en el módulo permiten su correcta separación. Las señalizaciones disponibles en cada local, no reúnen todos los requisitos establecidos estando en algunos casos desactualizada, lo cual conlleva a la existencia de flujo y permanencia de público en áreas controladas.

Aspecto crítico, es la no-disponibilidad de áreas separadas para la permanencia de pacientes a los cuales se les ha suministrado el radionúclido, del resto de los pacientes y acompañantes, igual situación presenta los servicios sanitarios. Ello requiere en algunos casos de inversiones; pero en otros pueden ser tomadas medidas organizativas que posibiliten cumplir con lo establecido.

- **Gestión de desechos radiactivos**

La gestión de los desechos radiactivos en las entidades se realiza de forma general adecuadamente, aunque aún subsisten problemas organizativos y de sistematicidad. En ellas existe un local para el almacenamiento de los desechos radiactivos, que cumple con los requerimientos establecidos y que permite que estos se encuentren siempre dentro de las condiciones autorizadas. De forma general la segregación se realiza correctamente, no así la señalización de los bultos. Aún debe trabajarse en la optimización de los diferentes procedimientos relativos a la generación de desechos para lograr minimizar su volumen; así como en disponer de un registro que permita contar con un inventario de los desechos hasta su evacuación.

- **Programa de Garantía de Calidad (PGC)**

El establecimiento de un PGC en las entidades, es uno de los aspectos más novedosos dentro de las funciones del SPR. Las entidades han trabajado en la elaboración del Manual de Seguridad Radiológica, en el que se incluyen procedimientos de trabajo y establecen registros, también se cuenta

con procedimientos estándares nacionales e internacionales para la planificación de los estudios diagnósticos o tratamientos y selección del radiofármaco; pero deben ser considerados otros como: Programa de control de calidad (CC) para el equipamiento empleado en los estudios y de PR, a los radiofármacos y a la totalidad del proceso diagnóstico, definición de política, objetivos de calidad y responsabilidades en PR, registros, auditorías internas y externas.

- **Aspectos relativos a la PR en procedimientos de diagnóstico, terapia e investigación**

Como se ha señalado anteriormente, las entidades disponen de procedimientos para la ejecución de cada tipo de estudio, en los cuales se recomiendan las actividades a emplear en ellos [3], pero se tiene en cuenta adicionalmente las condiciones del equipamiento existente y sus posibilidades para la obtención de resultados con calidad diagnóstica, de ahí las variaciones encontradas. No obstante, debe trabajarse para realizar de forma regular un análisis de estos aspectos y su comparación con los niveles orientativos, con vista a lograr la optimización de la PR e ir incorporando otros aspectos, los cuales como se pudo constatar no son tenidos siempre en cuenta a la hora de realizar un estudio y su aplicabilidad resulta poco práctica, dentro de la organización del servicio de medicina nuclear.

En las entidades se disponen de criterios para la reducción de dosis a infantes y niños y de forma general se dan orientaciones para proteger a los familiares de personas estudiadas o tratadas, pero en este aspecto mucho se debe trabajar, por su implicación en la optimización de la PR.

- **Aspectos relativos a la PR de pacientes embarazadas:**

En las entidades se ha establecido que la realización de estudios a mujeres embarazadas, sólo serán realizados cuando el cuadro clínico así lo requiera y en estos casos se les orienta de forma oportuna. De la misma forma se procede con mujeres en etapa de lactancia materna.

Los SPR deben actuar de forma inmediata en la ubicación de señalizaciones adecuadas en los servicios, que alerten a las mujeres en edad de procreación, o que posean sospecha de un posible embarazo o ya lo estén, de la necesidad de informarle esto a su médico o a los especialistas y técnicos que realizan las investigaciones, para evitar situaciones de exposiciones no recomendadas o deseadas.

- **Investigaciones a exposiciones médicas accidentales:**

Es necesario trabajar en todas las entidades en la elaboración de procedimientos que establezcan las acciones a seguir en caso de que ocurran exposiciones médicas accidentales y la importancia que reviste desde el punto de vista de la PR, que una vez que estas sucedan sean documentadas y analizadas, lo cual permitirá la corrección de procedimientos y adecuación del programa de PR. Además debe recordarse que sobrepasar sistemáticamente los niveles de referencia es considerado una exposición medica accidental.

3. Conclusiones:

La aplicación de la encuesta diseñada, como base para la evaluación de la situación de la PR en la práctica de Medicina Nuclear, resultó adecuada para este fin, permitiendo que en cada entidad se iniciara de inmediato, la toma de medidas y acciones que posibiliten perfilar un programa más abarcador e integral y que permita cumplir con aquellos aspectos que aun no están establecidos de acuerdo a las recomendaciones de las NBIS.

Las consideraciones incluidas en este trabajo servirán de punto de partida y unidas al establecimiento de metodologías, permitirá realizar una optimización adecuada de la PR en la práctica nacional de Medicina Nuclear.

4. Referencias:

[1] International Atomic Energy Agency, International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, jointly sponsoud by FAO,IAEA,ILO,OECD/NEA, PAHO, WHO, Safety Series No. 115, IAEA, Vienna (1996).

[2] International Commission on Radiological Protection, Recommendations of the ICRP,Optimization and Decision Marking in Radiological Protection, ICRP Publication No. 55, Pergamon Press, Oxford and New York (1989).

[3] Manual de Normas y Procedimientos. Editado por el Grupo Nacional de Oncología del Ministerio de Salud Pública, 1989.

RESULTADOS PRELIMINARES DEL ANÁLISIS DE LAS ACTIVIDADES ADMINISTRADAS EN ESTUDIOS DIAGNÓSTICOS DE MEDICINA NUCLEAR

Autores: Gladys López Bejerano, Luis Jova Sed
Centro de Protección e Higiene de las Radiaciones, Cuba
gladys@cphr.edu.cu; jova@cphr.edu.cu

Colaboradores: Marlenin Díaz Borroto, Leonel Torres Aroche, Adlin López Díaz, Felizardo Ponce Vicente, Vivian Freixas Lemus, Diosdado Castro Crespo, Aldo Barreras Caballero, Orlando Dranguet Palacios, Rafael Miller , Reinaldo Pérez , Heriberto Simón, Amilkar Failder.
Responsables de Protección Radiológica de las entidades encuestadas.

Summary

The world wide use of the Nuclear Medicine diagnostic procedures and the tendency to its increment, infers an important exposure of the population to ionising radiation, it has motivated that the IAEA in the International Basic Safety Standards (BSS), emits recommendations for the establishment of guidance levels of activities administered to the patients in diagnostic procedures. Taking in account the above-mentioned and that in Cuba exist 20 departments of Nuclear Medicine, that possess in their majority equipment with more than 20 years of operation, that influences directly in the medical exposure, was designed and applied a survey in 10 of these departments. The survey evaluates the compliance with the BSS requirements, and in specific, the activities administered to the patients in Nuclear Medicine diagnostic procedures are analysed. In the present work are presented the obtained preliminary results of the statistical analysis carried out to the activity values used in Nuclear Medicine departments, and the comparison among them, making a proposal of guidance levels for the national practice, and they are compared with those recommended internationally.

1. Introducción:

Cada día se hace más amplio a nivel mundial el uso diagnóstico de las fuentes no selladas en diferentes ramas de la medicina, unido a un creciente desarrollo del equipamiento y los radiofármacos utilizados, infiriendo a la población una importante dosis de radiación y un potencial impacto medioambiental. Existen indicios de que la exposición de la población por esta vía seguirá incrementándose [1], lo que impone prestar atención a las recomendaciones de Protección Radiológicas emitidas por Organizaciones Internacionales, como es el caso del establecimiento de niveles orientativos para las actividades administradas a los pacientes en estudios diagnósticos de medicina nuclear [2], que sugieren el desarrollo de buenas prácticas y su empleo como herramienta de optimización de la Protección Radiológica a los pacientes.

En la actualidad Cuba cuenta, con unos 20 departamentos de Medicina Nuclear, donde se realiza un elevado número de estudios diagnósticos con el empleo, en su mayoría, de equipamiento con más de 20 años de explotación: captadores de iodo, renógrafos y gammatopógrafos, los cuales han sido desplazados en el mundo, por equipos más modernos y con los que se obtiene una mejor calidad de la imagen: Cámara Gamma, SPECT.

A pesar de que en el país están establecidos los procedimientos para la realización de los estudios, recomendando la actividad a emplear [3], se observa variaciones entre los diferentes departamentos, por lo que en el presente trabajo se hace un análisis de las actividades empleadas por estudio, a partir de las cuales se puede elaborar una propuesta de niveles orientativos, comparándolos con los establecidos internacionalmente.

2. Materiales y métodos:

Para conocer las actividades administradas a los pacientes en los principales estudios diagnósticos que se realizan en el país, se aplicó una encuesta en la que participaron 10 departamentos de Medicina Nuclear, de 6 provincias. Para lograr la representatividad de la muestra se seleccionaron los módulos de forma que se incluyera en el estudio todo los tipos de equipos con que se cuenta en el país.

Se tomó la actividad máxima empleada en cada módulo por examen, la que es representativa para estudios en pacientes adultos estándar. Para establecer la propuesta de los niveles orientativos, se realizó el tratamiento estadístico de estos valores, tomando el correspondiente al tercer cuartil [4].

3. Resultados y discusión:

Fueron evaluadas las actividades empleadas para los estudios más frecuentes y que en mayor número de entidades se realizan, observándose variaciones entre los valores reportados por éstas para un grupo de estudios. Dichas variaciones se muestran en la Figura 1.

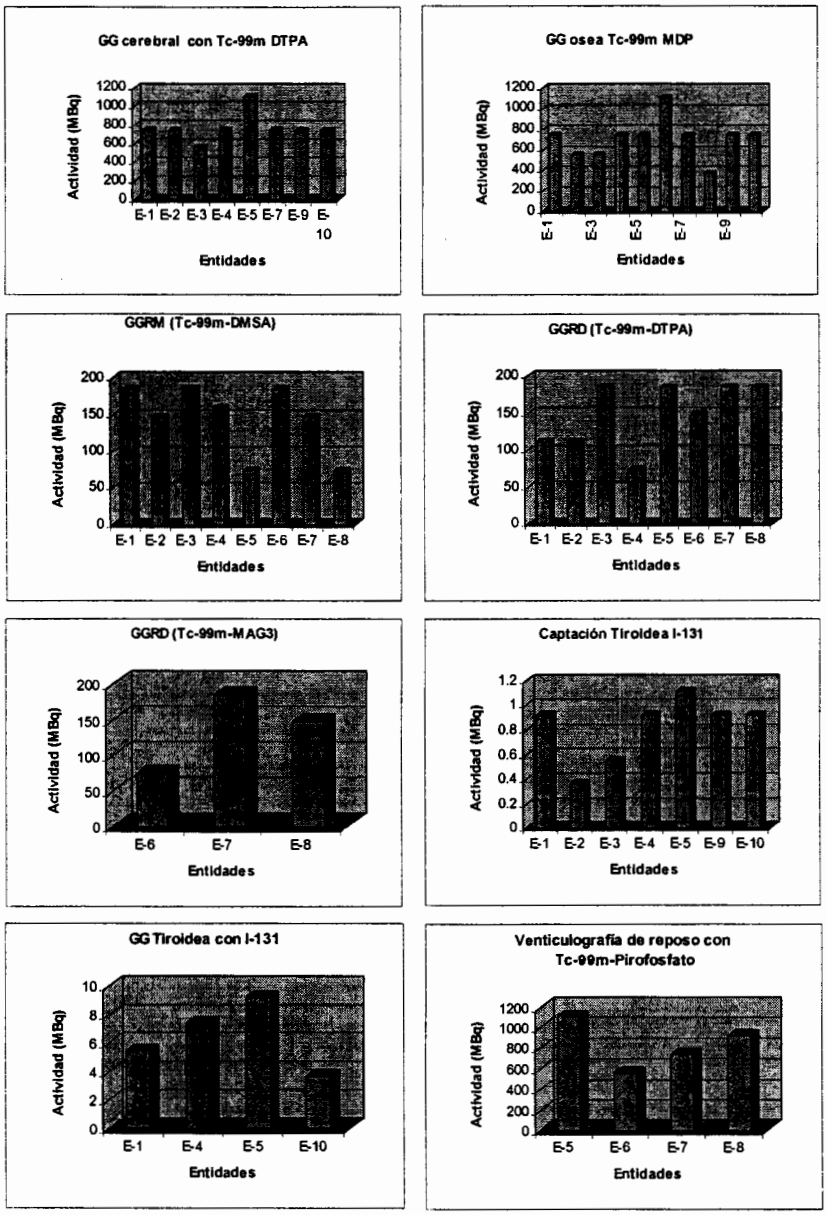


Figura 1. Valores de actividad por estudio en diferentes entidades.

En otros estudios como: GG Hepática con Fitato de Sodio, GG Tiroidea con Tc-99m y con I-131 para pacientes operados y en renogramas con Hipurán, no existen diferencias en la actividad suministrada, en cada departamento, a los pacientes, excepto en una de ellas.

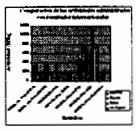
Las variaciones observadas en las actividades empleadas por las entidades están dadas por diferentes causas, entre las que pueden ser señaladas, las condiciones técnicas del equipamiento empleado, las diferentes tecnologías (desde detectores unidimensionales hasta SPECT), la capacitación, grado de asimilación y compromiso del personal, que interviene en la práctica, con las recomendaciones en materia de Protección Radiológica al paciente.

En la Tabla I se muestra un análisis estadístico de los valores de actividad empleada por estudio, en las diferentes entidades del país, observándose que en la mayoría de los casos el valor correspondiente a la media está próximo al del tercer cuartil. Esto puede ser debido a que los departamentos trabajan por protocolos nacionales establecidos donde se recomiendan los valores de actividad a administrar por exámen. Existen tres casos en los que la media supera el valor correspondiente al tercer cuartil, lo cual se debe a que una entidad emplea actividades altas en comparación con el resto, por lo que deben ser determinadas las causas específicas que provocan esta desviación, con relación a las recomendadas en protocolos nacionales.

Tabla 1- Evaluación de los resultados de la encuesta

Nombre del estudio	Organo de estudio	Radio-núclido	Fármaco	Análisis estadístico de los valores de actividad empleada en los estudios (MBq)				
				mínimo	3er Cuartil	Media	3er Cuartil	máximo
GG cerebral	Cerebro	Tc-99m	DTPA	555	740	763	740	1110
GG osea	Huesos	Tc-99m	MDP	370	601	703	740	1110
GG Hepática	Hígado	Tc-99m	Fitato de Sodio	148	185	179	185	185
GG Hepática	Hígado	Tc-99m	Coloides	185	185	185	185	185
GG Renal Morfológica	Riñones	Tc-99m	DMSA	74	130	145	185	185
GG Renal Dinámica	Riñones	Tc-99m	DTPA	74	111	148	185	185
GG Renal Dinámica	Riñones	Tc-99m	MAG3	74	111	136	167	185
Renograma	Riñón	I-131	Hipurán	0.74	0.74	0.79	0.79	0.93
GG Tiroidea	Tiroides	I-131	NaI	3.7	4.6	6.15	7.38	9.25
GG Tiroidea	Tiroides	Tc-99m	Pertecnectato	74	74	86	74	148
GG de cuello	Cuello	I-131	NaI	74	74	96	74	185
Captación Tiroidea	Tiroides	I-131	NaI	0.37	0.74	0.82	0.93	1.11
GG de paratiroides	Paratiroides	Tc-99m	MIBI	740	786	832	879	925
GG de mama	Mama	Tc-99m	MIBI	700	756	813	869	925
Venticulografía de reposo	Corazón	Tc-99m	Pirofosfato	555	694	833	971	1110

Los valores de actividad correspondientes al tercer cuartil, los cuales pueden ser propuestos como niveles orientativos en estudios diagnósticos de Medicina Nuclear, han sido comparados con los publicados internacionalmente, obteniéndose que en general los valores propuestos están por debajo de los recomendados. En los casos en que se superan, debe tenerse en cuenta el equipamiento con que son realizados los estudios y la posibilidad de obtener una imagen con calidad diagnóstica a niveles más bajos. No obstante en los estudios GGO(Tc-99m-MDP) y GGH(Tc-99m-Coloides) se deben investigar las causas específicas por las que se sobrepasan estos niveles.



Conclusiones:

Los valores de actividad propuestos como niveles orientativos para los diferentes estudios diagnósticos que se realizan en el país, están en el rango de los reportados internacionalmente. Se requiere a partir de estos resultados, realizar un análisis en cada entidad, que posibilite su implementación.

Las variaciones de la actividad administrada por estudios, en las entidades encuestadas, es un reflejo de las condiciones técnicas y diferencias tecnológicas del equipamiento empleado y la necesidad de

lograr elevar la preparación de todo el personal involucrado en los estudios en aspectos relativos a la Protección Radiológica.

Referencias:

[1] UNSCEAR, Sources and Effects of Ionizing Radiation. United Nation Scientific Commitee on the Effects of Atomic Radiation (1993)

[2] International Atomic Energy Agency, International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, jointly sponsoud by FAO,IAEA,ILO,OECD/NEA, PAHO, WHO, Safety Series No. 115, IAEA, Vienna (1996).

[3] Manual de Normas y Procedimientos. Editado por el Grupo Nacional de Oncología del Ministerio de Salud Pública, 1989.

[4] Dosimetry Working Party of the Institute of Physical Sciences in Medicine. National protocol for patient dose measurements in diagnostic radiology, National Radiological Protection Board, England, 1992.

CU-281

Resultados preliminares del estudio de las Dosis de Entrada en exámenes convencionales de radiodiagnóstico.

Autores principales: Alina Martínez*, Luis Jova *, Roxana de la Mora**, Carmen Guevara**
Colaboradores: Ileana Fleitas** Jorge Carrazana*, Efrén Díaz*

*Centro de Protección e Higiene de la Radiaciones
Email: alina@cphr.edu.cu
**Centro de Control Estatal de Equipos Médicos
Email: roxana@cceem.sld.cu

Abstracts

The wide diffusion of the X rays diagnostic together to the quick development and expansion that has come experiencing the technology in this practice, have motivated the emission of recommendations, in the Basic Safety Standards of the IAEA, for the establishment of guidance levels for different radiological examinations in each country that allow the optimization of the medical exposure. Considering the above-mentioned and the existence in Cuba of a great number of conventional X ray equipment, with an average over 10 years of use which influences directly on the patient dose, in 1999 began in the country an investigation on the patient exposure in this practice. This work shows the first results of measurements carried out in 9 major hospitals of several provinces of the country. The doses were evaluated in the examinations of lumbar spine AP, lumbar spine LAT, thorax PA, skull AP and skull LAT. The determination of the doses in these examinations was carried out by "in-vivo" measurements on the patients, placing in the center of the irradiation field TLD of LiF. The distributions obtained in the studies are compared with the guidance levels that is shown in the Basic Safety Standards of the IAEA.

Introducción

La radiología diagnóstica es la mayor contribuyente a la dosis colectiva de la población mundial entre todas las aplicaciones de las radiaciones ionizantes que el hombre utiliza [1]. Las variaciones en la exposición médica observadas en esta práctica, no solo entre países sino dentro de un mismo país; han motivado la emisión de recomendaciones internacionales, acerca del establecimiento de niveles orientativos de dosis para diferentes exámenes radiológicos, que permitan la optimización de la exposición médica.

Cuba cuenta en la actualidad con más de 1000 equipos de radiografía convencional instalados en el país y una tasa promedio de exámenes de radiodiagnóstico por habitantes comparables con la de los países desarrollados. Sin embargo la tecnología y los años de explotación de este equipamiento sobrepasan los 15 años, lo cual unido a dificultades en la formación en materia de protección radiológica del personal vinculado a esta práctica, hace que revista especial interés el conocimiento de los niveles de exposición recibidos por nuestra población en los exámenes de rayos X convencionales de mayor frecuencia.

El presente trabajo muestra los primeros resultados de un estudio llevado a cabo en el país para evaluar las dosis de entrada en paciente en hospitales cabeceras de diferentes provincias y la comparación de éstos con otros resultados obtenidos y/o recomendados por organizaciones internacionales.

Materiales y métodos

Los resultados que se presentan en este trabajo se obtuvieron de las mediciones realizadas en 9 hospitales cabeceras de 3 provincias del país y los equipos en los que se llevaron a cabo las mismas son representativos del 75 % del total de los instalados a nivel nacional. Las evaluaciones fueron realizadas para los estudios de tórax PA, columna lumbar LAT, columna lumbar AP, cráneo LAT y

cráneo PA teniendo en cuenta la alta frecuencia de ejecución de los mismos en los servicios radiológicos nacionales.

La metodología experimental adoptada, fue la medición "in vivo" de las Dosis de Entrada (DE), utilizando dosímetros termoluminiscentes (TLD) de fluoruro de Litio (JR1152C) de fabricación china, cuyo tratamiento y calibración se hicieron de acuerdo con lo descrito en la literatura [2]. Los dosímetros se ubicaron dentro de pequeñas bolsas de nylon para facilitar su manipulación y en grupos de tres a fin de obtener una lectura media de las exposiciones. De esta forma fueron colocados sobre la piel del paciente en el centro del campo de radiación.

Para cada equipo medido fue seleccionado un mínimo de 10 pacientes por estudio (altura y peso promedio de 1,65 m y 68 kg respectivamente), registrándose en cada caso los datos personales y aquellos relacionados con la exposición radiográfica.

A los valores obtenidos de dosis, por estudio, se les realizó tratamiento estadístico para determinar el tercer cuartil y compararlo con los niveles recomendados por las Organizaciones Internacionales.

Resultados y discusión

Los resultados obtenidos de dosis por estudio para cada equipo, se reflejan en la Figura 1. Las variaciones observadas entre los equipos son debidas a las inconsistencias en la selección de los parámetros de exposición para similares dimensiones de pacientes. Estas inconsistencias pueden estar relacionadas con el nivel de entrenamiento de los técnicos conjuntamente con las condiciones del equipamiento disponible y el procesamiento, que hacen necesaria la selección de parámetros disímiles para lograr una calidad de imagen aceptable.

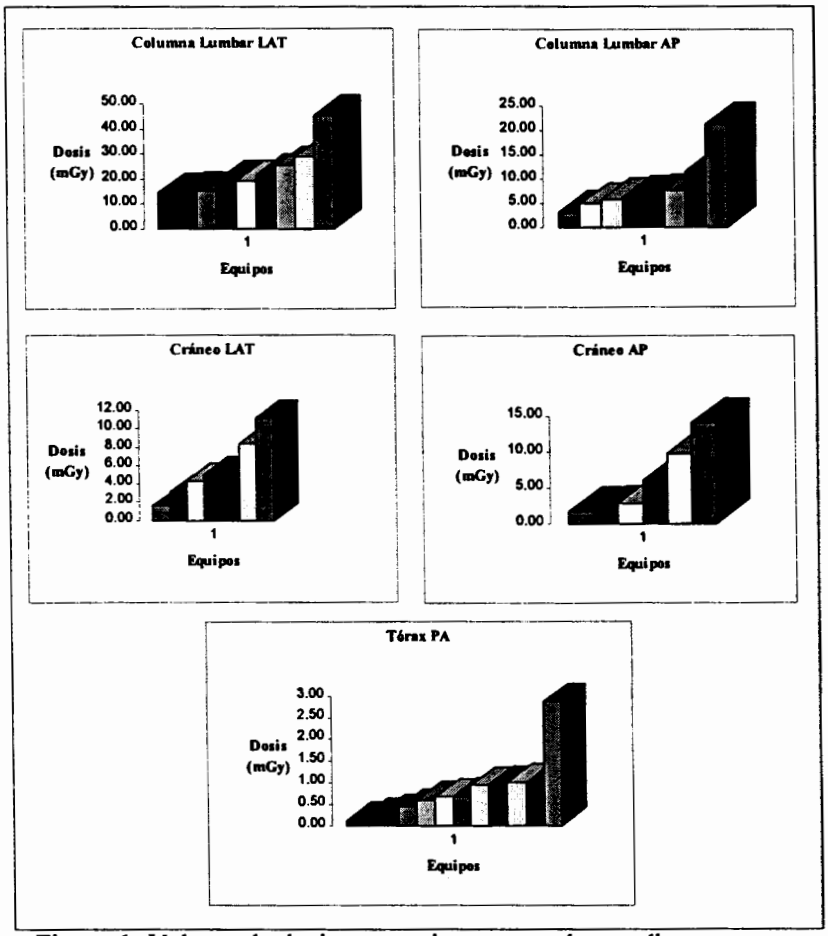


Figura 1. Valores de dosis por equipo para cada estudio.

La Tabla I muestra los valores de dosis obtenidos durante este trabajo conjuntamente con los publicados internacionalmente. Se puede apreciar que en el caso de los estudios de columna lumbar AP y columna lumbar LAT no existen grandes diferencias entre el tercer cuartil obtenido en el presente trabajo con los valores recomendados por las Normas Básicas de Seguridad y los publicados por la Comisión Europea. Sin embargo no ocurre lo mismo con los restantes estudios donde las diferencias son notables. Estas discrepancias pueden estar relacionadas, con las características propias del equipamiento de nuestro país (tecnología y años de explotación superiores a 15 años) y en el caso específico de los exámenes de tórax con la utilización, como promedio, de voltajes inferiores a 90 kV.

Tabla I. Comparación de las dosis obtenidas para cada examen con otros resultados internacionales.

Dosis de entrada (mGy)						
Examen	**1er cuartil**	**Media**	**3er cuartil**	**NBS**	**CE**	**EU(1)**
Tórax PA	0.5	1	1	0.4	0.3	0.2
CLS LAT	14	25	36	40	40	-
CLS AP	4	9	10	10	10	5
Cráneo AP	4	7	11	5	5	1.5
Cráneo LAT	3	6	9	3	-	-

*Leyenda:
NBS: Normas Básicas de Seguridad del OIEA
CE: Comisión Europea
EU: Estados Unidos

Los valores de DE correspondientes al tercer cuartil pueden ser analizados para su utilización en nuestro país como niveles orientativos. A su vez estos resultados demuestran que se requiere una investigación para precisar las causas de los valores de DE superiores a los recomendados internacionalmente en los estudios de tórax y cráneo. En todos los casos se aprecia la necesidad de aplicar técnicas de optimización entre ellas: el control de calidad periódico del equipamiento y elevar la preparación del personal que realiza los exámenes.

Una representación gráfica de la tabla anterior se muestra en la Figura 2.

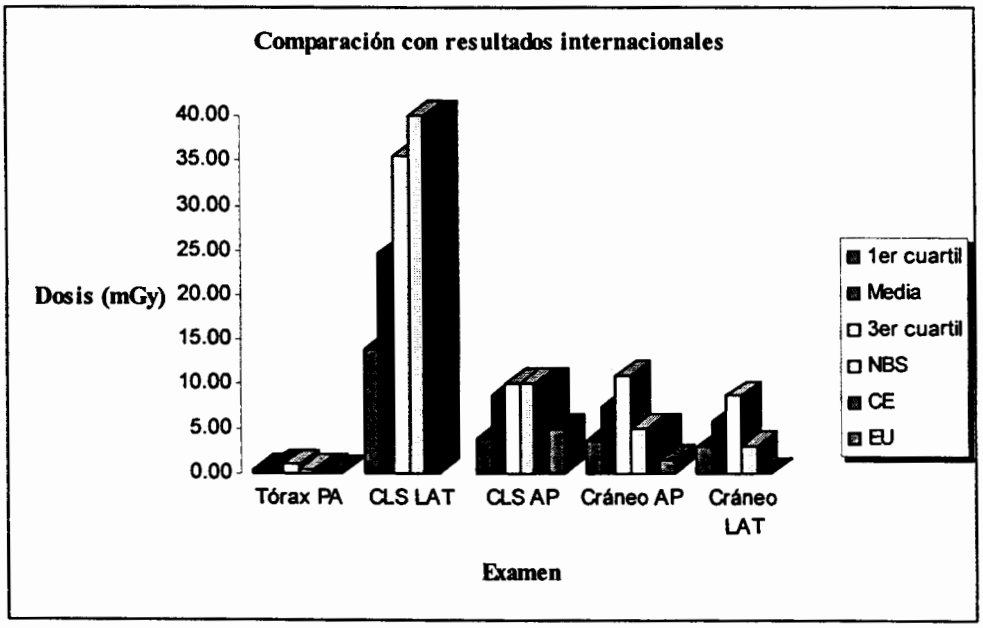


Figura 2. Comparación de las dosis obtenidas para cada examen con otros resultados internacionales.

* (1) Estos valores representan dosis promedios o límites y no incluyen la retrodispersión

Conclusiones

1. Los resultados muestran que en los estudios de columna lumbar las DE que reciben los pacientes se encuentran en correspondencia con las recomendadas internacionalmente.
2. En los estudios de tórax y cráneo se aprecian diferencias con los valores recomendados internacionalmente por lo que se impone la necesidad de establecer niveles de referencia nacionales que se adapten a las condiciones actuales del equipamiento y preparación del personal.
3. El análisis de los valores obtenidos demuestra la existencia de una considerable reserva para la reducción de las dosis que reciben los pacientes mediante la selección apropiada de los factores técnicos (kVp) y del adecuado procesamiento radiográfico.
4. Las variaciones de las dosis observadas entre equipos puso de manifiesto la necesidad de implantar programas nacionales de control de calidad en la práctica de radiodiagnóstico y la importancia de llevar a cabo mediciones periódicas de DE en cada institución.
5. Teniendo en cuenta los resultados se concluye además que es necesario elevar la preparación en protección radiológica del personal involucrado en la práctica, con especial énfasis en el personal técnico que realiza las exploraciones, como eslabón importante en la optimización de la exposición médica.

Referencias

[1] United Nations Scientific Committee on the Effects of Atomic Radiation, Report to the General Assembly with Scientific Annexes, UNSCEAR, United Nations, New York, 1993.

[2] Dosimetry Working Party of the Institute of Physical Sciences in Medicine, National protocol for patient dose measurements in diagnostic radiology, National Radiological Protection Board, England, 1992.

IAEA-CN-282

QUALITY ASSURANCE PROGRAMME FOR RADIOLOGICAL PROTECTION OF PATIENTS UNDERGOING RADIOTHERAPY

Mahajan MK, Singh O.A, Mohan P.A.K, Samual M, Kaur M,Singh V, Patil J, Sudan M and Jeyaraj P.
Department of Radiotherapy, Christian Medical College, Ludhiana - India.

INTRODUCTION:

In developing countries,the state of art facilites and infrastructures are lacking in most of the centres, especially in regard to the treatment planning,immobilization and quality assurance during execution of radiation treatment programme, which is mainly due to economic constraints.

A simple cost effective worksheet is used in our department so as to assure the complete treatment programme and thereby improve the patient compliance and quality of care.

MATERIAL AND METHODS:

After involving an individualistic treatment plan, a specified worksheet on the pattern of the enclosed format is drawn in addition to the treatment sheet.

The team of Radiographers comprising one male and another female staff member is made responsible for better communication skills and treatment delivery and also to bridge the communication gap between all levels of treatment team.

RESULTS:

The designed worksheet was used during the treatment of 281 patients from January 2000-October 2000. It was successful in enhancing patient care and reducing the morbidity of treatment as reactions were noted and dealt with at the earliest. It also helped in building up the patients' confidence and facilitated the treatment delivery programme

During this time period, only 5 patients left the treatment, for reasons other than medical ones. Treatment gaps due to medical reasons, especially in patients receiving Radiotherapy and concomitant Chemotherapy were seen in only 6 patients.

A better coordination between various levels of treatment team was the salient feature of this programme.

CN-282/616

QUALITY ASSURANCE IN CHEMO-RADIOTHERAPY PROGRAMME

Mahajan MK,Rai B,Shende S,Sood S,Patil J,Sudan M,Singh V and Jeyraj P
Department of Radiotherapy,Christian Medical College,Ludhiana-India.

Chemo-radiotherapy has emerged as a popular mode of management of solid tumours. In such combined modality programmes, the toxicity of the treatment is a result of complex biologic events due to different modes of action of various treatment modalities, adverse drug reactions and varied host responses

A retrospective analysis of patients revealed a significant number of complications. A Quality assurance programme was designed and the study during the last 18 months enrolled 88 patients.

The **aims** of the study were:
To improve patient compliance and quality of care,
Determine the cost effectiveness and
Reorganization of organizational structure

The **schema** included:
- Pre treatment evaluation of all patients
- Correction of pre existing anemia, electrolyte and fluid imbalance and control of infections
- Vigilant monitoring throughout the treatment course and
- Follow up

Material and Methods:
A total of 128 patients were included in the study out of which 40 were in the retrospective group i.e. group A and 88 patients were in the prospective group i.e. group B. All patients received concomitant chemo-radiotherapy. Chemotherapy consisted of Inj Cisplatin 50 mg/m2 on day 1,17 and 34 and Inj 5-fluorouracil 500mg twice weekly.
During the entire course of treatment, the patients were under close monitoring.
Close monitoring was kept on hematological levels, any development of gastrointestinal toxicity, cardiotoxicity and other treatment related complications. Maintenance of adequate intake and nutrition, orodental hygiene and adequate hydration was taken care of. Radiation reactions were graded according to RTOG scoring for chemoradiation.
A checklist was thus devised which consisted of evaluation of
- Nutritional status
- Water and electrolyte balance
- Cardiac stability
- Hematological monitoring
- Renal parameters
- Performance status

A significant reduction in incidence and severity of complications was possible.

CONCLUSIONS:
- Delivery of planned treatment achieved in all patients
- Programming of normal tissue reactions
- No Radiotherapy/Chemotherapy dose reductions required
- Hospitalization required only for Chemotherapy administration.

RADIOTHERAPY PRACTICE IN AN UNREGULATED ENVIRONMENT: CALL FOR JOINT ACTION

Shams Elegba
The Presidency
Energy Commission of Nigeria
Plot 701C, Central Area,
P.M. B. 358, Area 10, Garki, Abuja, FCT, Nigeria
Tel: ()-234-9-5234924 e-mail: ecn@hyperia.com

ABSTRACT

There are five radiotherapy centres and thousands of diagnostic x-ray units in Nigeria. There is a five-year old radiation protection decree, which is yet to be implemented. Consequently, radiotherapy and radio-diagnosis are practiced in the country without any form of regulatory guidelines backed by law. This paper is a call for the concerted effort of the WHO and the IAEA to persuade the Nigerian Government to establish the Nigerian Nuclear Regulatory Authority. This will ensure safe applications of atomic energy in the national heath delivery system.

Introduction

In the early 1960's, nuclear weapon tests were carried out in the Sahara Desert, which resulted in radiation being drifted into Nigeria with the northeasterly winds. In reaction to this development, the Federal Government in 1964 established the Federal Radiation Protection Service (FRPS) at the Physics Department of the University of Ibadan. The FRPS was established without an Act of Parliament and therefore lacked the powers to regulate and control the use of nuclear radiation. In 1971, a draft decree on Nuclear Safety and Radiation Protection was proposed by the FRPS and sent to the then Federal Military Government for consideration and promulgation. It never went beyond a draft

On the 24th August 1976, the Federal Military Government enacted Decree No. 46, whic established the Nigeria Atomic Energy Commission, (NAEC [1]. This became the very first by an government in the federation towards the orderly and safe use of nuclear energy. According to thi Decree, the Commission was entrusted with the responsibility for the development of atomic energ and all matters relating to its peaceful uses

The Nigerian Atomic Energy Commission Decree No. 46 (1976) was not intended to regulate the us of nuclear radiation but rather to promote and increase its use. The decree led to the establishmen of the two nuclear energy research centres at the Ahmadu Bello University, Zaria and at th Obafemi Awolowo University, Ile-Ife. Over the past 25 years, these two nuclear energy researc centres have trained about 250 scientists, engineers and technicians in the various peacefu applications of nuclear energy. Yet there is still no legally constituted body to regulate the activitie of these centres. During the same period, the two research centres acquired very sophisticated an powerful nuclear research equipment and machines, including a nuclear reactor, a particl accelerator and neutron generators. They are however not alone in this business of unregulated us of nuclear energy in the country. It is pertinent to know also that the NAEC, which led to th creation of the Research Centres does not exist, yet the decree establishing it has not bee repealed

A similar situation exists in the petroleum industry, which is the mainstay of the Nigerian economy. The petroleum industry is the largest importer and user of radioactive substances in the country. All these applications are neither regulated nor controlled, except for the radiation protection practices imposed by the home countries of the multinational companies. The industry was so concerned about the situation so much that the Department of Petroleum Resources in 1993 organised an International Workshop on Radiation Protection in the Nigerian Petroleum Industry. This was the first call by a user industry for legislation on radiation protection in Nigeria.

Since the establishment of the FRPS, the number of diagnostic x-ray units in operation nationwide has increased to about two thousand. Similarly, the number of radiotherapy centres in the country also increased from zero to five in the year 2000. By this development, thousands of patients are exposed to radiation annually at the radiotherapy centres in Ibadan, Lagos, Zaria and Abuja. There however, exists a law after all, but it is only not enforceable.

Nigeria and indeed the world do not need a "Koko" before action is taken. Indeed, a pleasant "Koko" incident actually did happen in the Nigerian nuclear energy industry before a regulatory decree was promulgated. Under the auspices of the Energy Commission of Nigeria and the active collaboration of the Ministry of Petroleum Resources and the Ministry of Foreign Affairs, the International Atomic Energy Agency (IAEA), Vienna approved to donate and install a nuclear research reactor in Nigeria. This was based on a Technical Cooperation Project proposal submitted by the Centre for Energy Research and Training, Zaria in 1993. The project commenced in January 1995. The IAEA gave the Nigerian Government some pre-conditions for the implementation of the project, which included promulgation of a decree to regulate the use of ionizing radiation and nuclear materials in Nigeria.

The road to the promulgation of the decree was long and difficult. It was towards this end that th Centre for Energy Research and Training, Zaria held a National Workshop on "Radiation Safety an the Nigerian Legal System" in June 1995 The Energy Commission of Nigeria (ECN) spearheaded the drive to persuade the then Federal Military Government to put in place a law that would regulate all peaceful applications of nuclear energy in the country. As earlier stated above, this struggle started in 1971! The effort this time around yielded the desired result. By August 1995, the Government promptly promulgated the Nuclear Safety and Radiation Protection Decree 19 of 1995[2]. This single act facilitated the supply of the nuclear reactor to Zaria. The installation of the reactor was completed during the first quarter of 1999. It is pertinent to add that the same Federal Government invested a lot of resources to provide the buildings and other infrastructure for the nuclear reactor. The nuclear reactor can however not be commissioned because there is no nuclear regulatory authority on ground. The Nuclear Safety and Radiation Protection Decree 19 of 1995 provides for the establishment of the **Nigerian Nuclear Regulatory Authority**, but none has been set up since 1995. The situation is however different in the case of the radiotherapy facilities. They are being used but in an unregulated manner.

Radiotherapy Centres

There are five radiotherapy centres in the country. These are located at the:

i. National Hospital, Abuja
ii. Ahmadu Bello University Teaching Hospital, Zaria
iii. University College Hospital, Ibadan
iv. Lagos University Teaching Hospital, Lagos and
v. EKO Hospitals, Lagos

They all have facilities for external beam radiotherapy and for brachytherapy. The radiotherapy centre at the National Hospital Abuja was fully established and equipped by the Federal Government of Nigeria without any foreign assistance. It is the "flagship of the medical institutions in Nigeria". Its facilities include a linear accelerator, X-ray generator and Cesium-137 radioactive sources. There is however only one Medical Physicist, who also doubles as the Radiation Protection Officer for the hospital. The radiotherapy centres at the three university teaching hospitals are to a very large extent equipped and trained under Technical Cooperation programmes with the IAEA. The facilities include Cobalt-60 and Cesium 137 radioactive sources. Here again, there are about 2-3 Medical Physicists. The reason for this is the non-establishment of the NNRA, which is the organ to regulate the number and quality of every cadre of workers in the radiotherapy centres and the procedures of their activities. The radiotherapy centre at the EKO Hospitals in Lagos is a private outfit. It has a Co-60 radioactive source and an X-ray generator. There is also one Medical Physicist. With the existing facilities, it is obvious that there

is a lot of room for improvement in terms of training and recruitment of personnel in the areas of radiation protection and dosimetry. The Draft IAEA Regulation Guidelines for Radiotherapy provides a useful resource base and will be very useful to the NNRA whenever it gets established.

Decree 19 of 1995

The Nuclear Safety and Radiation Protection Decree of 1995[2] provides for the establishment of the Nigerian Nuclear Regulatory Authority (NNRA).

It has a Governing Board with the Head of State as its chairman and six Federal ministers as members, amongst others. Under such a tremendous weight of its members, the Board may never be able to meet regularly and consequently render the NNRA weak and effective. This may also partially explain the reason for not constituting the NNRA five years after the law establishing it came into existence.

The NNRA has the responsibility for nuclear safety and radiological protection regulation in the country. The Authority has the powers, amongst others, to:

a. categorize and license all activities involving exposure to ionizing radiation;
b. establish appropriate register for each category of sources (or machines) and practices involving ionizing radiation;
c. license operators of practices;
d. issue codes of practice;
e. review and approve safety standards and documentation;
f. protect the health of all users, handlers and the general public from the harmful effects of ionizing radiation;
g. undertake investigations and research into ionizing radiation sources and practices

In carrying out its functions, the NNRA shall establish the National Institute of Radiation Protection and Research (NIRPR). This is to serve as the technical arm of Authority. Thus the decree can be seen to be broad and adequate in terms of its responsibilities, powers and functions. The structure of the Governing Board can not make the Authority operate effectively.

Five years have lapsed since the enactment of this decree. The national pride of "operating a nuclear reactor in Nigeria before the year 2000" was not a sufficient reason for its implementation! This is the historical task that the nuclear medicine and radiotherapy centres in the country are being faced with. It is noteworthy, that the Ministry of Health (**heath)**started 'the struggle' for the Radiation Safety Law in 1971, but the Energy Commission of Nigeria (**research)** succeeded in getting the decree enacted in 1995. For the implementation of the decree, the Energy Commission of Nigeria started the initiative in 1995 without a breakthrough. It may well now be the turn of **'health'** to get the NNRA established for the benefit of all. History may indeed repeat itself, *albeit* in a spiral. With the joint effort of the IAEA and the WHO, health considerations may provide the sufficient reason for the Nigerian Government to implement Decree 19 of 1995 so that medical applications of ionizing radiation, as well as other peaceful applications of nuclear energy may carried out safely. This will also enhance international confidence on such practices in Nigeria.

Draft IAEA TECDOC on Regulatory Guidance for Radiation safety in Radiotherapy
According to this draft IAEA TECDOC [3], the objective is to assist regulatory authorities in preparing regulatory guidance for radiotherapy practice. The document is applicable to all established uses of ionizing radioactive sources and machines radiation-emitting machines employed in radiotherapy practice. It covers occupational, public, medical, potential and emergency exposure situations. The document provides for authorization of practice, procedure and personnel and their cadres. In fact the document is particularization of the BSS[1]. Of all the various cadres listed in the document that are vital to the safe practice of radiotherapy, this paper will dwell on the medical physics and radiation protection cadres. This is in view of the BSS requirement for radiation protection, which demands for justification of the practice, dose limitation and optimization of protection, and dose constraints.

It is conceivable to start a radiotherapy practice with just the Radiation Oncology but without a Medical Physicist and without a Radiation Protection Officer. In fact this is what happened in the case of Nigeria, where five Radiotherapy Centres got established without a regulatory authority. Consequently, there are only about three Medical Physicists superintending the dose limitation and dose constraints in the five hospitals located in four different cities! At other times, these same Medical Physicists perform the duties of the Radiation Protection Officers. The situation is like driving a car without a break. It is just a question of time before the 'unexpected' happens. All these are happening principally because there is no regulatory authority. This is not to say that the Radiotherapy Centres have not been prudent, but that when one person does the work of three, then safety could be compromised. This draft TECDOC, along with others for different specific practices constitute veritable regulatory guidance for the Nigerian Nuclear Regulatory Authority.

Recommendations
(a) IAEA and WHO
IAEA should tie future assistance to Nigeria to the establishment of the NNRA. The IAEA has done this before to get the decree implemented, in the first instance. This time around, the IAEA and the WHO should make a joint presentation to the Nigerian Government on the need to establish the NNRA.

(b) ECN and Federal Ministry of Health
Pending the establishment of the NNRA, the ECN should in consultation with the National health Council of Nigeria setup an ad hoc committee to carry out some of the regulatory functions of the NNRA. This should be done with the support and understanding of such international bodies, such as the IAEA and WHO.

(c) Nigerian Government
The Government should establish the NNRA without further delay. The decree should thereafter b amended accordingly to facilitate the operations of the **NNR** by amending its composition an appointing somebody with less state responsibilities as its chairman

References

[1] Decree No. 46 Nigerian Atomic Energy Commission
Official Gazette of the Federal republic of Nigeria, (1976)

[2] Decree No. 19 Nuclear safety and Radiation Protection
Official Gazette of the Federal republic of Nigeria, Vol82, A547- A 569, (1995)

[3] *Draft* TECDOC on Regulatory Guidance for Radiation Safety in Radiotherapy
IAEA, Vienna, Austria (May 2000)

IAEA-CN-85-284

RADIATION PROTECTION PROBLEMS IN THE PRACTICE OF RADIOTHERAPY IN NIGERIA

BY

DR. K. K. KETIKU AND MR. O. T. OLADEJI

DEPARTMENT OF RADIATION BIOLOGY,
RADIOTHERAPY AND RADIODIAGNOSIS
COLLEGE OF MEDICINE OF THE UNIVERSITY OF LAGOS,
LAGOS, NIGERIA
E-mail: cmul cmul@rcl.nig.com
Fax: 01-5851432

ABSTRACT

Many radiation protection problems have been identified in the practice of radiotherapy in Nigeria.

Majority of these arise as a result of non-availability of essential equipment. Others are due to breakdown of equipment as a result of lack of spare parts and necessary expertise for maintenance.

Recommendations are made for tackling these problems and these include regional cooperation with exchange of human and material resources between institutions

1. INTRODUCTION

The radiation protection of patients receiving radiotherapy involves the accurate delivery of the prescribed radiation dose to the tumour while avoiding as much as possible the irradiation of healthy tissues [1].

In order to achieve these objectives, there must be proper guidelines with respect to the dosimeter, treatment planning, patient positioning, choice of equipment, equipment design and performance, radiation quality assurance and personnel training and experience.

For a period of 20-30 years there have been only two radiotherapy centres in the country (both with Cobalt 60 equipment) serving a population of 100 million people. They have largely operated with equipment installed at the time of establishment. The IAEA has over the last 10 years provided some technical assistance to the country for the improvement of radiotherapy services.

Two additional government centres will commence operation soon while a private centre was opened over a year ago.

2. DOSIMETRY ASPECT

Radiation delivery must involve accurate knowledge of radiation output characteristics from the therapy unit. Radiation output from the equipment must be calibrated regularly at least annually using a more recent international code of practice for absorbed dose determination and the results cross-checked by taking part in the IAEA/WHO Postal Dose Intercomparison using TLD capsules [2]. In addition, the reference or standard ionization chamber with the electrometer in use must be calibrated against a primary standard for various photon energies available in the centre. These dosimetry equipment should be re-calibrated once every two or three years in a standardizing laboratory for accuracy while a constancy check must be performed occasionally using a suitable radioactive source check.

It is also necessary to have a beam data acquisition system for producing isodose charts and evaluation of dose distribution for each treatment condition required in treatment planning procedures. It will be useful to have the beam data linked to a treatment-planning computer.

Presently, dosimetry equipment are not readily available for calibration of radiotherapy equipment and plotting radiation profiles and isodose curves. Radiation output determination from the Cobalt 60 equipment is based in most cases on decay factors from previous calibration and IAEA TLD intercomparison studies.

3. QUALITY ASSURANCE

Quality assurance is very essential to the safety and effective treatment of patients in radiotherapy. There should be periodic checks on beam symmetry, uniformity and flatness as recommended in the protocols used for the quality control programme [3] [4].

4. TREATMENT PLANNING

This involves a consideration of the beam quality, accurate dose delivery, beam directional and modification devices and patient's positioning. There should be a uniform dose distribution to the target volume within 5% [5] [6] variation while every effort must be made to limit radiation dose to surrounding tissues to the minimum levels using beam shaping devices and making allowance in dosimetry plans for tissues with different densities.

Patient's contour and internal structure information must be accurately determined. These can be achieved using a simulator and a CT scanner linked to a computerised treatment planning system. In centres where these are not available, some gadgets like solder and callipers, multi-pin device or pantograph will help limit errors in obtaining patient's outline compared with the use of lead strips.

Each Radiotherapy Department must have essential accessories and good mould room facilities to aid patient's planning, positioning and protection. These include beam directional and modification devices, like beam direction shells, wedges, lead shields. Mechanical and optical alignment devices should be essential parts of every therapy equipment.

The 2 old radiotherapy centres in Nigeria do not have many of these facilities. Radiation plannings are still manually done. There are very few wedges and isodose curves. Radiation planning is done based on clinical parameters only with the risk of some inaccuracy in the definition of the target organ and unnecessary irradiation of normal structures.

5. LIMITATIONS IN PROVISION & DESIGNS OF EQUIPMENT

(a) **Superficial Therapy**: There are no orthovoltage and Linear Accelerator for superficial therapy of skin cancers and especially Keloid lesions, which are very common in Nigerians. Therefore, in many cases Cobalt 60 machines are used with boluses to increase skin dose. This gives unnecessary irradiation to normal deep sealed organs.

(b) **Cobalt 60 Equipment**: The only working Cobalt 60 machine in Lagos has a solid couch thus precluding undercouch treatment and accurate replication of parallel A-P opposed fields. This may cause wrong areas to be radiated when patient turns.

(c) **Brachytherapy**: The department uses a curietron machine for the treatment of cervical cancer, which is the second most common female cancer in Nigeria. There are no rectal dose meters to assess correctly doses received during intracavitary insertion. Radiation doses and distribution are determined using plain radiographs to calculate doses to Points A & B. A computer planning system will give more accurate results.

6. RECOMMENDATIONS

a) Increased technical assistance to third world countries to help acquire essential equipment.

b) There should be standardization in the design of radiotherapy equipment to ensure good quality and safety compliance and performance.

c) Spare parts should be widely and readily available for equipment. This is a major problem in third world countries, which rely on importation of equipment from abroad and technical assistance from donor agencies.

d) There should be good training of local staff to make them self-reliant in the operation and maintenance of equipment.

e) There is a need to set up a secondary standard Dosimetry Laboratory in the country to calibrate dosimeter, equipment used for radiotherapy equipment.

f) Regional cooperation and exchange of facilities, equipment and experts between institutions is recommended.

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REFERENCES

1. DUTREIX A. : When and how can we improve precision in radiotherapy? Radiotherapy and Oncology 2 (1984) 275-292

2. SVENSSON, H. AND ZSDANSZKY : The Calibration Chain: Role of the IAEA/WHO Networks of SSDLs IAEA-TECDOC-734, February 1994.

3. SVENSSON, H. : Quality assurance in Radiation therapy: Physical aspects. Int. J. Radiat Oncol. Bwl. Phys. 10: 59-65, 1984.

4. RASSOW J. : Quality control of radiation therapy equipment Radiottier. Onc. 12, 1988, 45.

5. HERNUG, D. F. AND CAMPTON D. M. J. : The degree of precision required in the Radiation dose delivered in cancer therapy in: Computers in Radiotherapy (Glasgow, Scotland, Sept 1970).

6. INTERNATIONAL COMMISSION ON RADIATION UNITS AND MEASUREMENTS, Determination of absorbed dose in a patient irradiated by beams of X or gamma rays in radiotherapy procedures. ICRU Report 24, Woodmont Avenue 7910, Washington, DC (1976).

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CN-285

INTERNATIONAL CONFERENCE ON THE RADIOLOGICAL PROTECTION OF PATIENTS

in

- **Diagnostic and Interventional Radiology**
- **Nuclear Medicine and**
- **Radiotherapy**

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AUTHOR(S) INITIAL(S) AND FAMILY NAME(S)	SCIENTIFIC ESTABLISHMENT(S) IN WHICH THE WORK HAS BEEN CARRIED OUT	TOWN/COUNTRY
1. T.A. OLASINDE	AHMADU BELLO UNIVERSITY TEACHING HOSPITAL	ZARIA, NIGERIA.
2.		
3.		
4.		
5.		

AUTHOR WHO WILL PRESENT THE PAPER	Mailing Address:
Mr./Ms.	RADIOTHERAPY & ONCOLOGY CENTRE, A.B.U. TEACH-
Initial(s): T.A.	ING HOSPITAL, ZARIA, NIGERIA.
Family Name: OLASINDE	Telefax No.:
	E-Mail: cert@cyberspace.net.ng olasinde@abu.edu.ng Telex No.:

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1. C.A.MOLINA	HOSPITAL NACIONAL "EDGARDO REBAGLIATI MARTINS"	PERU
2. R.E.LUNA	"	"
3.		
4.		
5.		

AUTHOR WHO WILL PRESENT THE PAPER	Mailing Address:
Mr./Ms. C.A.MOLINA	CALLE STA.SOFIA 289 URB.STA.MAGDALENA SOFIA LA MOLINA LIMA 12-PERU
Initial(s): C.A.	
Family Name: MOLINA	Telefax No.. 4377105
	E-Mail César_Molina@latinmail.com
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CALCULO Y MEDICION DE DISTRIBUCION ESPECIALL DE DOSIS UTILIZANDO LA PELICULA DE TINTE RADIOCROMICO PARA APLICACIONES EN RADIOTERAPIA

Rolando Paucar (1), Paola Condori (2), Javier Paucar
Complejo Hospitalario San Pablo El Polo 780 - Surco
E-Mail: **ropaja@hotmail.com** Telefax: 51 1 437-2355

Las primeras aplicaciones de las películas de tinte radiocrómico como herramientas para el mapeo de las distribuciones de las dosis absorbidas con alta resolución se presenta en el área de la caracterización de fuentes de braquiterapia. Una de las aplicaciones que presenta mas demanda en términos de resolución espacial y gradiente de dosis absorbida es la utilizada en braquiterapia intravascular, aplicación destinada a la reducción de la incidencia de restenosis post-agioplastia.

En este trabajo se evalúan los resultados de la dosimetria realizada con película GafChromic (MR) MD-55 (Nuclear Associates) de fuentes lineales preparadas con 3, 4, y 5 semillas de iridio 192.

QUALITY CONTROL AND PATIENT DOSES FROM X-RAY EXAMINATIONS IN SOME HOSPITALS IN THAILAND

P. Plainoi, W. Diswath and N. Manatrakul
Div. of Radiation and Medical Devices, Dept. of Medical Sciences
Ministry of Public Health, Tiwanon Road, Nonthaburi 11000, Thailand

Abstract -- Quality control measurements on 203 diagnostic X-ray units were carried out in 126 hospitals in the central region of Thailand during 1998-2000. The measurements consisted of tube voltage, half-value layer (HVL), exposure time, radiation output, beam alignment, light beam diaphragm and entrance surface dose (ESD) in four common radiographic procedures namely adult chest PA, adult mass chest PA in mobile bus unit, abdomen AP and mammography (cephalo caudal view). ESD measurements of 320 examinations were performed using parallel plate ionization chamber and Keithley model 35050A Dosimeter on 192 X-ray units (conventional and mobile) and 11 mammography units.

The analysis of test results showed that:

(1) 92% had X-ray tube voltage within the tolerance limit of 10% and HVL 3.03 mmAl ± 0.55 SD at 80 kVp measured

(2) 90% had exposure time within tolerance limit of 10%

(3) 86% and 98% had acceptable beam alignment and light beam diaphragm

(4) 95% had radiation output > 25 μGy at 1 m. for true 80 KVp

(5) It was found that the ESD values were

adult chest (PA) varied from 0.18 mGy to 1.17 mGy (mean 0.2021 ± 0.2218 SD)

adult mass chest (PA) varied from 0.043 mGy to 1.03 mGy (mean 0.2935 ± 0.2195 SD)

abdomen (AP) varied from 0.302 mGy to 6.30 mGy (mean 2.177 ± 1.4818 SD)

mammography (cephalo caudal view) varied from 3.49 mGy to 12.21 mGy (mean 7.788 ± 2.9896 SD)

Further surveys are necessary and are being done to include measurements of image quality and for propagation of quality assurance activities in Thailand so as to reduce patient doses while maintaining the image quality.

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The Radiological Accident at Samut Prakram, Thailand

***Y. Kongthanarat M.D., **P. Sahachjesdakul M.Sc. (Medical Physics)**
Division of Radiation Oncology, Department of Radiology,
Rajavithi Hospital, Bangkok 10400, Thailand.

(*, ** A team who carried out a radiation survey at the junkyard)

Abstract

On January 24th, 2000 a scrap metal merchant stole a metal container enclosing a radiation source from a deserted private car park. He then tried to sell it to another merchant. The subsequent dismantling of the container resulted in a major radiation accident with 10 persons severely exposed to radiation. Three of the radiation victims died. Four patients were permanently crippled. One first trimester pregnant woman was exposed to 0.07 Gray of whole body radiation.

The Accident

On January 24th, 2000 a scrap metal merchant stole a very heavy metal container from a deserted private car park on the outskirts of Bangkok (the capital city of Thailand). As the container was made from different kinds of metal, it must be dismantled to separate the metals in order to get a high price. In a period of one week he and 3 relatives were able to partially dismantle the container. They decided to take the metal container to a scrap metal junkyard in Samut Prakarn Province (a satellite city of Bangkok) for further dismantling. Together with 3 other men at the junkyard they were able to break the metal container into pieces by using an oxyacetylene torch. However there were smoke and unpleasant smell during the final process of dismantling. They began to feel dizzy and nauseous. There was confusion and chaos at the place, what exactly happened was very difficult to determine. They suspected that 2 cylindrical metal pieces were the cause of their illness. So they discarded the two cylinders into a near by ditch. The small Co-60 source somehow fell (was thrown?) into a pile of scrap metal in the junkyard without being noticed. There were 3 more persons living in the junkyard, all of them are women. All the 10 people began to feel sick, the onset of signs and symptoms were different depending on how and how much they were exposed to radiation.

The first two patients were admitted to Samut Prakran Hospital on February 16th, 2000 with fever, weakness, nausea, vomiting, epilation and gangrenous hands. Further investigations revealed severe pancytopenia. On February 18th, 2000 the doctors suspected that the cause of their illness might be radiation exposure. The Office of Atomic Energy for Peace (OAEP) and the Ministry of Public Health were notified immediately. A team from OAEP found high radiation activity in the premise of the junkyard and the salvage operation that evening was unsuccessful. On February 19th, 2000 a radiation specialist team chaired by the permanent secretary of the Ministry of Public Health located the private car park from where the metal container was stolen. They also found two other decommissioned medical Co-60 sources there. At this moment it was known for certain that the radiation source at the junkyard was a decommissioned Co-60 source. With the cooperation and coordination of the local government agencies, a team of radiation oncologist*

and medical physicist** from Rajavithi Hospital carried out a radiation survey of the area up to 300 meters away from the junkyard. (Figure 1) As the radiation doses measured outside the junkyard were not very high, namely 200 μSv/hr at the nearest house, evacuation of the area was not recommended for the time being. The OAEP team was able to secure the Co-60 source at the junkyard in the early morning of the next day.

All the 10 people at the junkyard were admitted on different dates and all were subsequently transferred to Rajavithi Hospital for further treatment. From signs, symptoms and timing of the illness it was estimated that all victims received from 2 - 6 Gray of total body irradiation. Some of them received very high local radiation resulting in necrosis of hand and thigh. Three victims died from acute radiation exposure in the next few weeks. Four survived with permanent injuries, 3 with amputated hands or fingers, one with massive soft tissue necrosis of his right thigh. Only 3 persons survived this accident without detectable abnormality. A first trimester pregnant woman living most of her time in a beauty saloon next to the junkyard (about 12 m. - 15 m. from the source) received at calculated absorbed dose of about 0.07 Gray of total body irradiation (assuming 100 percent occupancy). A special committee chaired by the President of the Royal College of Radiologist composing of radiation oncologists, medical physicists and dosimetrists was appointed to consider the therapeutic abortion issue. Although the dose was slightly lower than the cutoff value of 0.1 Gray, a therapeutic abortion with the consent of the victim was recommended.

This accident is a major one. The causalities in this accident are the highest in the history of mankind from such a small sealed source. It happened because of mishandling of decommissioned radiation sources. A local company should not be authorized to deposit radioactive sources. It is obvious that a small private company cannot provide long-term surveillance.

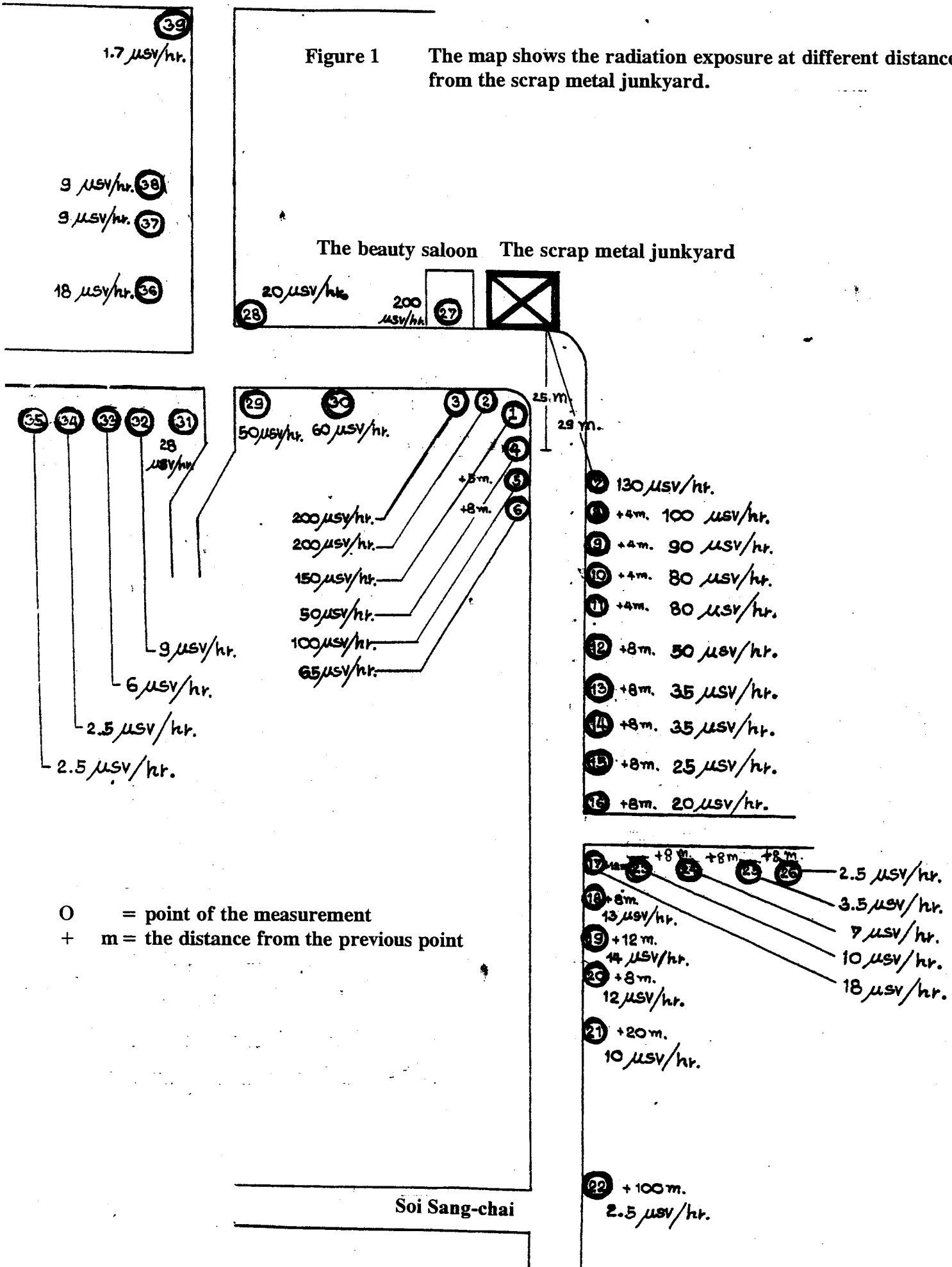
Conclusion

Deposition of decommissioned Co-60 teletherapy sources is always a problem in the country. In the past one hospital in Bangkok had to embed a decommissioned Co-60 source in a cement cube and buried it in the hospital compound. This method poses a serious problem in the distant future when we are all long gone. Two years ago Rajavithi Hospital almost had to do the same because the OAEP at first refused to deposit the source citing inadequacy of space as an excuse. Depository of decommissioned teletherapy Co-60 source requires very limited facilities as the source is already in a very safe container. The OAEP should take the depository problem seriously to avoid future accidents. Free deposition of decommissioned sources provided by the government might be the solution.

References:

- Hall E.J., Radiobiology for radiologist, Lippincott Raven, Philadelphia New York (1994) 453-464 pp.
- International Commission on Radiological Protection: Recommendation. Report No.60 Pergamon Press, New York (1991)
- The international basic safety standards for protection against ionizing radiation and for the safety of radiation sources, Safety Series No.115,IAEA, Vienna (1996)

Figure 1 The map shows the radiation exposure at different distances from the scrap metal junkyard.



IAEA-CN-290

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The fetal dose outside therapeutic radiation beam: Safety distance

Jongjin Pataramontree*
Wannapa Methapirak** Nuanpan Toin*

Pataramontree J, Methapirak W, Toin N. The fetal dose outside therapeutic radiation beam: Safety distance. Chula Med J 1999 Mar; 43(3): 159-68

Background : *The Radiation Oncology Section, Department of Radiology was presented with a young female patient, who was apt to later become pregnant. The fetal radiation dose was the question.*

Objective : *To measure the scattered dose level outside the x-ray beam at fetal in Rando phantom using thermoluminescent dosimeters. To determine the safety distance for a fetus.*

Setting : *Department of Radiology, King Chulalongkorn Memorial Hospital*

Design : *Experimental study*

Material : *A female phantom, thermoluminescent dosimeters and a linear accelerator (Clinac 1800).*

Methods : *Measuring the scattered dose from 6 and 10 MV x-rays, beam area 10 x 10 cm^2 and 20 x 20 cm^2 at fetal position which is 5-50 cm away from the primary beam. Calculate the average fetal doses and the standard deviation.*

Results : *The scattered at fetal position depends on the distance and the area of the primary beam rather than the energy. The threshold dose for fetus is 0.1 Gy. When the mother receives 60 Gy, beam area of 10 x 10 cm^2 and 20 x 20 cm^2, the safety distance for him is at least 22 cm and 28 cm away from beam edges respectively.*

* Department of Radiology, Faculty of Medicine, Chulalongkorn University.
**Department of Radiology, King Chulalongkorn Memorial Hospital

The Radiation Oncology Section of King Chulalongkorn Memorial Hospital was presented with a 22 year old female patient for treatment of Hodgkin's disease. It was decided to irradiate the lymphatic chains with the mantle field. The absorbed dose outside of the radiation field is clinically important, potentially affecting gonadal function. Fetal development might be abnormal if the patient become pregnant. This outside dose can also be responsible for radiation-induced carcinogenesis in other exposed tissue. Beir III[1] reported that single doses of 10 cGy can produce damage in a fetus and the threshold is 5 cGy. Radiogenic mental deficiency occurs during the gestational age of 8-15 weeks with a decreasing of 7-13 IQ points per Gy.[2] The increase in relative risk for breast cancer[3] in women exposed to ionizing radiation is about 0.5%/ cGy while the threshold is 100 cGy. Dose levels down to 200 cGy had been found to cause cataracts.[4] Sterility in males may be caused by single doses on the order of 300 cGy.[1] The dose level of clinical concern can thus vary from 5 cGy to 300 cGy or 0.08% to 5% relative to a total treatment dose of 60 Gy. A study dose down to a level of 0.1% of the ce dose is thus necessary.

Materials and Methods

This study of outside doses evaluate the level of the scattered dose it can also applied to other sensi Measurements were made in the positio in a Rando phantom along a line perpe beam axis for the 10 x10 cm^2 and 20 x areas. Measurements were done on a Va 10 MV linear accelerator (Clinac 18 phantom containing a female human ske in tissue-equivalent material (mass densit Z=7.3) was chosen for the outside do From the radiograph of the phantom thi in section number 31 as shown in Fig.1.a. to study the distribution of scattere section, which was 2.5 cm thick.

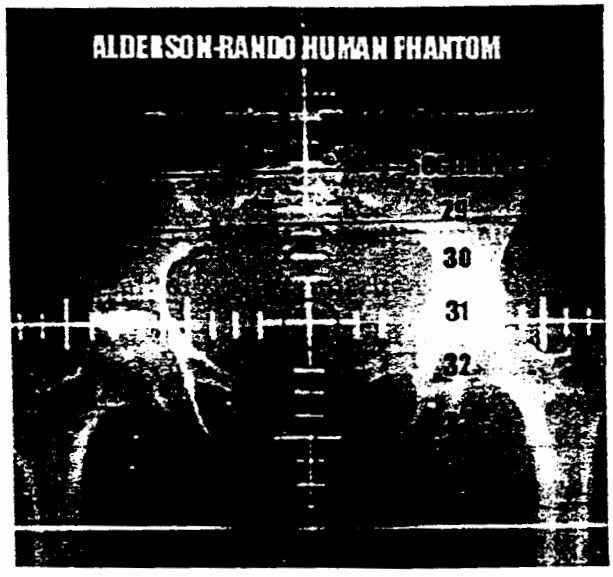

Figure 1a. Anterior-posterior view of the female Rando phantom estimated fetal pos

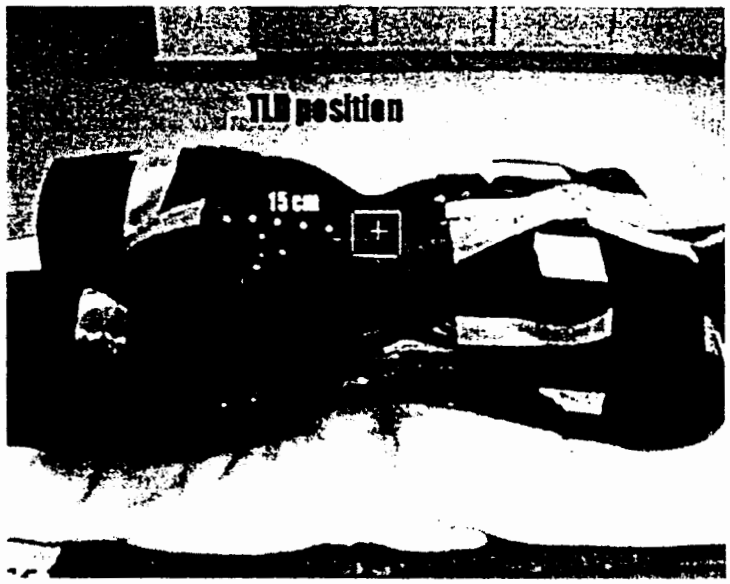

Figure 2. The female Rhando phantom was exposed to 100 cGy of 6 MV x-rays, 10 x 10 100 cm source tumor distance at 15 cm away from thermolumescent dosen in slab number 31.

Table 1. Average photon scattered doses at the fetal position in a Rando phantom (percent and s deviation of peak dose at central axis)

Energy	Field size	Distance from central axis of x-ray beam (cm)						
	$(cm)^2$	5	10	15	20	25	30	45
6 MV	10 x 10	50	1.4 ± 0.1	0.6 ± 0.03	(0.3)	0.2 ± 0.03	(0.13)	0.04 ± 0.01
	20 x 20	100	(50)	4.0 ± 0.18	1.2 ± 0.12	(6.2)	0.3 ± 0.04	(0.1)
10MV	10 x 10	100	1.4 ± 0.07	0.6 ± 0.03	(0.3)	0.2 ± 0.01	(0.13)	0.04 ± 0.01
	20 x 20	100	(50)	4.0 ± 0.14	1.0 ± 0.05	(6.2)	(0.34)	0.3 ± 0.02

N.B. Figures in brackets are interpolated from the profile curve in Fig.3.

In considering the results as a function of field size, the radiation levels outside the useful beams are plotted as a function of distance from the nominal beam axis in fig.3. It can be seen that for 6 MV and 10 MV x-rays, their beam profiles are very alike at distances of 10, 15, 20, 25, 30, and 40 cm from the axis of radiation.

This outside dose can induce or deterministic effects. Table 2 de threshold dose[5] for these effects and the from the beam edge which were calc exposure to 10x10 cm^2 and 20x20 cm^2 MV x-rays for 60 Gy.

Table 2. Threshold dose and safety distance from beam edges when exposure to 6000 cGy, 6-10 M Clinac 1800.

Effects	Dose (cGy)	Safety distance from beam ed area 10 x 10 cm	area 20
Sterility	300@	> 3 cm	>
Cataract	200 +	> 4 cm	>
Ca breast	100 ++	> 5 cm	> 8
Fetus			
Malforma.	10 *	> 22 cm	> 28
	5 **	> 33 cm	> 38
IQ (-7pt)	100 ***	> 5 cm	> 8

N.B. @ Figures are quoted from ref.1
\+ Figures are quoted from ref.4
++ Figures are quoted from ref.3
* Figures are quoted from ref.5
** Figures are quoted from ref.1
*** Figures are quoted from ref.2

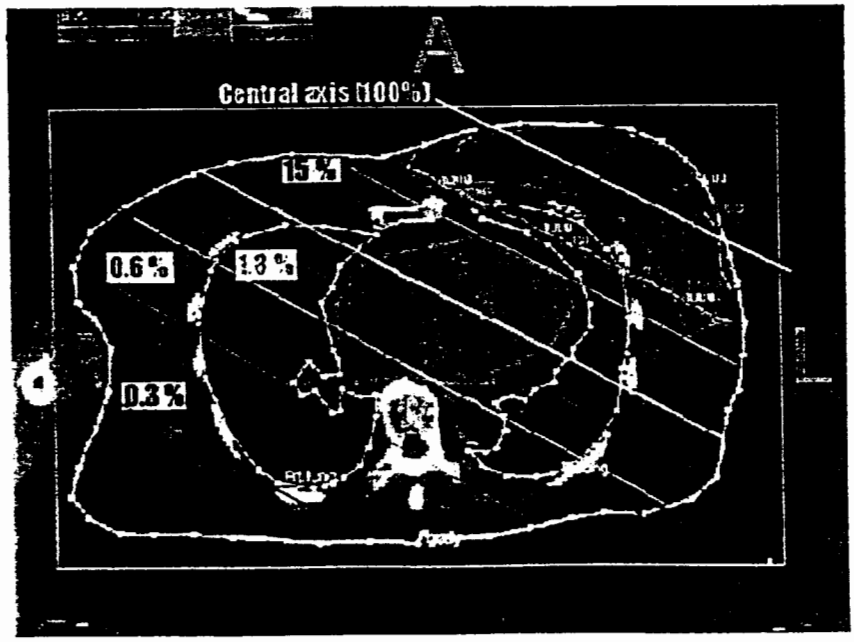

Figure 4. Isodose distribution of parallel opposed fields for treatment of carcinoma of breast. T levels perpedicular to been axes were shown. The contralateral breast doses vary fron of the treatment dose from medial to lateral aspect of the contra lateral breast.

3. Land CE. Low-dose radiation - a cause of breast cancer? Cancer 1980 Aug 15; 46(4 Suppl): 686-73

4. Merriam GR, Focht EF. A clinical study of radiation cataracts and the relationships to dose. Am J Roentgen 1957 May; 77(5): 759-85

5. ICRP Publication 60. Radiation Protection. Recommendation of the International Commission on Radiological Protection 1990: 103

6. Kelly CA, Wang XY, Chu JCH, Hartsell. WF. Dose to contralateral breast: a comparison of four primary breast irradiation techniques. Int J Radiat Oncol Biol Phys 1996 Feb 1; 34(3): 727-32

7. Fraass BA, Van de Geijn J. Peripheral dose from megavolt beams. Med Phys 1983 Nov - Dec; 10(6): 809-18

8. Nair RP, Nair TKM, EL- Akkad S. Evaluation of fetal dose from megavoltage irradiation of the knee and neonate follow up. Med Phys. 1983 Nov -Dec; 10(6): 862-5

9. Greene D, Chu GL, Thomas DW. Dose levels outside radiotherapy beams. Br J Radiol 1983 Aug; 56(668): 543-50

Estimation of the intrauterine fatal dose measurement in phantom during Neurointervention procedures including Angiogram and Embolization

[1] S Asavaphatiboon, MSc, [2] R Pirabul, MSc, [3] P Yongvithisatid, MSc

Abstract:

Neurointervention procedures including angiogram and embolization are useful methods in the surgical treatment of intracranial neurovascular disease such as arteriovenous malformations (AVMS) and aneurysm. The longer consuming time fluoroscopy causes higher radiation dose to the patient. The purpose of this study was to estimate the intrauterine fetal dose in the twenty weeks pregnant patient during treatment of AVMS. Absorbed doses at the fetal location were determined by ionization chamber and PTW- UNIDOS Universal Dosemeter type serial # 1002-20084 in a solid phantom. Measurements were performed by two conditions; with and without lead apron lying on the table underneath the phantom for the reduction of the fetal dose from PA fluoroscopy. From this experiment, the absorbed dose with and without lead apron was 2.089 and 2.464 cGy respectively. But in the real situation, there were lead aprons underneath and over the abdomen of the patient. Therefore the dose that the fetus received must be lower than the measurement dose performed in the phantom.

El objeto es la regulación y control de toda actividad que implique riesgo de exposición a las radiaciones ionizantes.

En el marco de la generalidad, debe ser lo más completa posible, para tener la preparación suficiente para hacer uso de las múltiples aplicaciones de la energía nuclear que la haga compatible con la protección de las personas, bienes y medio ambiente.

Lo específico debe quedar librado al ámbito reglamentario, más técnico. Se deberán usar definiciones de términos esenciales que serán la base de futuras legislaciones y que sean las utilizadas por convenciones o recomendaciones internacionales.

Sus fines esenciales son:

* establecer el marco legislativo dentro del cual se reglamentará el desarrollo sin riesgos de la energía nuclear y el empleo de ésta, atendiendo al interés nacional, teniendo presente los compromisos que al respecto haya contraído el Estado en virtud de convenios o tratados.

* fijar los principios fundamentales y las condiciones de su puesta en práctica, dejando a una reglamentación especifica la función de determinar las modalidades y procedimientos de aplicación en cada sector, según las necesidades.

* crear una estructura de reglamentación revestida de autoridad suficiente para poder controlar y vigilar de manera efectiva las actividades autorizadas.

* garantizar una protección financiera adecuada contra los daños derivados de un accidente nuclear o radiológico.

El contenido de la legislación , debe ser :

1. Establecimiento de la autoridad competente , con competencia para proponer y aplicar la legislación en materia de protección radiológica, la adopción o proposición de reglamentos, normas, guías y procedimientos para la autorización y control de materiales e instalaciones nucleares y coordinar con otras organizaciones públicas o privadas competentes en la materia, así como la autorización , control y supervisión de todas las actividades nucleares en el ámbito de aplicación de la legislación se le deberán conferir atribuciones suficientes de dictar los reglamentos necesarios. El organismo regulatorio deberá gozar de independencia, competencia y confiabilidad en el ejercicio de sus funciones y poderes. Es importante que esté asistido y trabaje coordinadamente con cuerpos técnicos consultivos, representativos de otros organismos competentes.

2. Establecimiento de un sistema de autorizaciones previamente para todas las actividades desarrolladas en aquellas instalaciones en las que exista riesgo de exposición a las radiaciones ionizantes. Definición de los principios y condiciones bajo las cuales el organismo reglamentario podrá autorizar las actividades nucleares que no conlleven riesgo inaceptable para la salud y la seguridad de los trabajadores y del público y para el medio ambiente, asegurando una protección física adecuada de los materiales e instalaciones nucleares. Se enunciará aquello que quedará librado al ámbito reglamentario, conforme a principios generales y objetivos especificados por la ley.

Los requisitos que se exigirán para solicitar la autorización , así como sus deberes y responsabilidades

IAEA-CN-85-292

CARACTERISTICAS DE LAS LEYES EN MATERIA DE PROTECCION RADIOLOGICA

PUIG, D.
Dirección Nacional de Tecnología Nuclear
Mercedes 1041
CP 11.100- Montevideo- URUGUAY

ABSTRACT :Legislation to protect workers exposed to ionizing radiation ,public and the environment has developed separately and in paralell with legislation in other topics such as labour , health, environment . The purpose of this legislation: to provide one comprehensive and integrated system of law concerning health and safety in order to contribute to the development of nuclear energy in the Country and to assure a reasonable safety that nuclear and radioactive facilities are constructed and operated without undue risk. Consultation with all interested parties during and after the develoment of legislation. Law: to regulate and control all activities that involve radiological risk exposition: Chapter of definitions. Establishment of the regulatory body. System of authorizations. Control. Radiation protection. Health and environmental protection. Inspections. Punishments. (It follows international recommendations)Modern legislation : a strong punishment (many years of prision) for the person who has not a licencee. Strong penalties : yes or not?

La naturaleza particular de la energía nuclear exige condiciones de seguridad y medidas de protección más rigurosas, lo que añade otras dimensiones a los sistemas tradicionales de reglamentación y, hace indispensable la existencia de una autoridad apropiada o de instituciones especializadas. Pueden existir leyes que regulen las actividades peligrosas, en lo que respecta, por ejemplo, a la seguridad en el trabajo, la protección de la salud o la del medio ambiente. Esta legislación también será aplicable, en la medida que corresponda a las actividades que entrañen el empleo de materiales radiactivos.

El objetivo de la legislación en esta materia es proveer un sistema legal integrado relativo a la salud y seguridad para :

* Contribuir al desarrollo de la energía nuclear en el pais.

* Proveer las bases reguladoras que aseguren una razonable seguridad de que las instalaciones nucleares y radiactivas sean construidas y operadas sin riesgo indebido.

Es muy importante obtener la cooperación de diferentes instituciones nacionales y organizaciones especializadas existentes en el país, tanto en el proceso de elaboración de las leyes como en la preparación y ejecución de las actividades de reglamentación. Esto permite que todos los interesados, poderes públicos y otras entidades, comprendan bien las cuestiones que hay que reglamentar y los principios y fines que la legislación y los reglamentos contemplan. Ello permitiría acelerar los trabajos preparatorios y posteriormente facilitar la aplicación de las leyes y reglamentos.

están establecidos en la ley, sin perjuicio de la remisión a la reglamentación. También se establece el organismo encargado de otorgarla, suspenderla, revocarla.

La ley deberá establecer que:

- la actividad debe ser compatible con los principios generales establecidos en la ley y los objetivos de seguridad.

- el solicitante debe estar capacitado del punto de vista técnico y financiero.

- la actividad no debe suponer ningún riesgo para la salud y seguridad de la población, para bienes ni para el medio ambiente y debe cumplir medidas adecuadas de protección física.

Se deberá prever la posibilidad de apelar una decisión en materia de autorización ante una autoridad superior.

3. La seguridad radiológica, la salud, la protección al medio ambiente.

Se establecen medidas para que la exposición sea lo más segura posible, con medidas como distancia, tiempo de exposición , dosis máxima admisible.

La dosis limite para la exposición interna o externa deberá estar acorde con las recomendaciones internacionales, las cuales deberán tener fuerza legal ya sea porque la legislación se remita a ellas sin incorporarlas o porque las incorpora , previa adaptación a su sistema legal. Se deberá contemplar la protección al paciente expuesto a las radiaciones por razones médicas , previendo la reducción de la exposición al mínimo compatible con la eficacia del tratamiento.

La atribución de responsabilidad en toda actividad que implica el uso de fuentes de radiación deberá especificarse claramente pudiendo delegarse en una o varias personas que tendrán a su cargo el cumplimiento de las medidas de seguridad.

En caso necesario se establecerán previsiones para los desechos radiactivos.

Las recomendaciones de la Comisión Internacional de Protección Radiológica , modelos nacionales e internacionales, dan los principios básicos de protección radiológica, dejando librado a los organismos nacionales el derecho la responsabilidad de introducir detalles técnicos, recomendaciones o códigos de práctica que mejor se adapten a las necesidades de cada país.

. Régimen de inspección

Se deberá prever un régimen de inspección otorgando las facultades necesarias a la autoridad competente para intervenir e imponer sus decisiones cuando surjan deficiencias en una instalación o las condiciones de trabajo no sean las adecuadas o en casos de urgencia.

Sanciones.

Se establecerá un régimen de sanciones para el caso que se infrinjan leyes o reglamentos y disposiciones complementarias, que variarán según la gravedad, entre multas, suspensión, revocación de una autorización u otras previstas en el derecho penal del país.

Es de destacar que en el derecho comparado se observa una moderna tendencia a sancionar con graves penas de prisión la no tenencia de una licencia.

Esto se debe estudiar detenidamente pues ¿ mayor pena es sinónimo de mayor garantía de seguridad .? ¿Podemos establecer penas tan severas solamente por no poseer una licencia.? ¿ Se debe penar tan severamente el incumplimiento de este requisito por si solo ?

Aplicando la analogía entonces ¿ se debería establecer la misma pena a quien no posee una licencia en una industria petroquímica por ejemplo cuyos riesgos potenciales son también severísimos .?

Entiendo que no es conveniente establecer penas tan severas únicamente por el hecho de no poseer una licencia ya que aquí estaríamos entrando por un peligroso camino que podría llevar a desestimular esta actividad .

FORM B
IAEA-CN-85

CN-294
NEW
PAPER

INTERNATIONAL CONFERENCE ON THE RADIOLOGICAL PROTECTION OF PATIENTS

in

- **Diagnostic and Interventional Radiology**
- **Nuclear Medicine and**
- **Radiotherapy**

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The state–of–the-art of "in vivo dosimetry in radiotherapy in the Czech Republic

AUTHOR(S) INITIAL(S) AND FAMILY NAME(S)	SCIENTIFIC ESTABLISHMENT(S) IN WHICH THE WORK HAS BEEN CARRIED OUT	TOWN/COUNTRY
1.HELENA ÁKOVÁ	NATIONAL RADIATION PROTECTION INSTITUTE	PRAGUE
2.HANA STANKUŠOVÁ	FACULTY HSPITAL OF THE CHARLES UNIVERSITY IN MOTOL	PRAGUE
3.		
4.		
5.		

AUTHOR WHO WILL PRESENT THE PAPER	Mailing Address:
Ms.	NRPI , Šrobárova 48, 100 00 Praha 10, Czech Republic
Initial(s): HELENA	
Family Name: ÁKOVÁ	Telefax No.:+ 422 6731 14 10 E-Mail : hzackova @suro.cz Telex No.:+ 422 6708 2677

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RADIOLOGICAL PROTECTION OF PATIENT IN CZECH REPUBLIC

Name (s) Zuzana PaškováMarcela áková,

Address: State Office for Nuclear Safety, Regional Center of Prague

Senová né nám. 9, Praha 1, Postal Code 110 00, Czech Republic

Tel: +4202 21624262 Fax: +4202 21624760 e-mail: zuzana.paskova@sujb.cz

Oral Presentation: ❍ Poster Presentation: **X**

Equipment: 35 mm Projector ❍ Overhead Projector ❍ Other:

ABSTRACT (Less than 200 words)

The poster (paper) presents situation of radiation protection in Diagnostic and Interventional Radiology and in Nuclear Medicine. There are possibilities of protecting of patients by the way of using some kinds of protection things and also by the way of diagnostic reference levels for Diagnostic Radiology and Nuclear Medicine. The purpose is to inform about a method of the incorporation of diagnostic reference levels into radiation protection regulations in Czech Republic and about results of evaluation of the diagnostic reference levels.

The use of diagnostic reference levels as a component of a Quality Assurance Programme is shown in the poster (paper). The radiation protection of patient is supervised by State Office for Nuclear Safety in Czech Republic and Quality Assurance Programme appear to aid in the optimisation of protection for patients undergoing radiological procedures in Diagnostic Radiology and Nuclear Medicine.

PHENOMENA AND PARAMETERS IMPORTANT TO BURNUP CREDIT

C. V. PARKS, M. D. DEHART, J. C. WAGNER
Oak Ridge National Laboratory (ORNL),
Oak Ridge, Tennessee
USA

Abstract

Since the mid-1980s, a significant number of studies have been directed at understanding the phenomena and parameters important to implementation of burnup credit in out-of-reactor applications involving pressurized-water-reactor (PWR) spent fuel. The efforts directed at burnup credit involving boiling-water-reactor (BWR) spent fuel have been more limited. This paper reviews the knowledge and experience gained from work performed in the United States and other countries in the study of burnup credit. Relevant physics and analysis phenomenon are identified, and an assessment of their importance to burnup credit implementation for transport and dry cask storage is given.

1. INTRODUCTION

In contrast to criticality safety analyses that employ the fresh-fuel assumption, credit for fuel burnup necessitates careful consideration of the fuel operating history, additional validation of calculational methods (due to prediction and use of nuclide compositions for spent fuel), consideration of new conditions or configurations for the licensing basis, and additional measures to ensure proper cask loading. For pressurized-water-reactor (PWR) fuel, each of these four areas have been studied in some detail over the last decade and considerable progress has been made in understanding the issues and developing the information needed for an effective safety evaluation that applies burnup credit. More recently, studies to expand the understanding needed to use burnup credit with spent nuclear fuel (SNF) from boiling-water reactors (BWRs) have been performed in the United States. The purpose of this paper is to identify the characteristic parameters and physics phenomena that are important to understanding burnup credit and review the current knowledge as gleaned from the studies performed in the United States, in other countries, and within international organizations. The following sections discuss the parameters and physics associated with the nuclides important to burnup credit, depletion and decay phenomena, and modeling of a SNF cask.

2. NUCLIDES IMPORTANT TO BURNUP CREDIT

Spent nuclear fuel contains hundreds of unique nuclides. The actual reactivity worth of the fuel is a function of the net neutron production and absorption by all nuclides present. However, if criticality calculations are performed based on all fissile nuclides and a limited subset of absorbers, the calculated value of the effective neutron multiplication factor (k_{eff}) is conservative (i.e., k_{eff} is overestimated). To date, the approach proposed in the United States for burnup credit in storage and transport casks has involved the qualification of calculated isotopic predictions via validation against destructive assay measurements from SNF samples. Thus, utilization of nuclides in the safety analysis process has been limited based on the availability of measured assay data and chemical characteristics (e.g., volatility) that might cause the nuclide to escape the fuel matrix [1,2].

Several studies have been performed to identify the nuclides that have the most significant effect on the calculated value of k_{eff} as a function of burnup and cooling time [2,3]. Figures 1B3 provide the results of one study [3] which performed a relative ranking based on the fraction of total absorptions for each nuclide. The adequacy of this simple ranking approach has been confirmed with

Phenomena and Parameters Important to Burnup Credit

C. V. Parks, M. D. DeHart, and J. C. Wagner

Nuclear Engineering Applications Section
Oak Ridge National Laboratory
P. O. Box 2008
Oak Ridge, TN 37831-6370
865 (574-5280)
parkscv@ornll.gov

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Technical Committee Meeting
on the Evaluation and Review of the Implementation of
Burnup Credit in Spent Fuel Management Systems

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more rigorous approaches that obtained the actual change in k_{eff} for an infinite lattice of rods based on a change in each nuclide [2]. The relative worth of the nuclides will vary somewhat with fuel design, initial enrichment, and cooling time, but

FIG. 1. Fraction of Neutron Absorptions versus Cooling Time for 4.5-wt %-Enriched PWR Fuel Burned to 50 GWd/t

the important nuclides remain the same. A recent study for BWR spent fuel also indicates the ranking of
important nuclides changes only slightly in going from PWR to BWR operating conditions [4], and that the important nuclides are the same.

Figures 1B3 indicate that the majority of neutron absorption is caused by only a few actinide isotopes and, individually, the fission products contribute much less to neutron absorption. Within the cooling time range of interest to transport and dry cask storage (approximately 2 to 100 years), Figures 2B3 indicate that the relative importance of only a few nuclides change significantly. The buildup of ^{155}Gd and ^{147}Sm from the decay of other essentially non-absorbing fission products and the decay of ^{241}Pu (14.4 y-half-life) to ^{241}Am contribute to the decrease in k_{eff} as cooling time increases. The effect of the decay of ^{151}Sm appears to be compensated by the commensurate buildup of ^{151}Eu. Based on these and other studies, the nuclides listed in Table I are considered to be the prime candidates for inclusion in burnup credit analyses related to storage and transport casks. Obviously, ^{151}Sm (90-y half-life) and ^{151}Eu are a pair, and ^{151}Eu only needs to be considered if the absorption credit for ^{151}Sm must be maintained. Note, ^{135}Cs is a relatively minor absorber that has a negligible effect on cask reactivity; however, it has been included in many previous studies because measured isotopic data currently exist.

FIG. 2. Fraction of Neutron Absorbed by Major Actinides at Various Cooling Times for 4.5-wt %-Enriched PWR Fuel Burned to 50 GWd/t

As indicated earlier, validation of calculated isotopic predictions against experimental measurements is desirable for any nuclide upon which burnup credit criticality calculations are based. For BWR fuel, the number of nuclides for which there are measured data is significantly reduced and is limited primarily to the actinides of Table I [5]. For the most part, the fission product measurements available in the United States for PWR fuel is limited to 3B6 measurements, and prediction methods for these nuclides may not be considered to be fully validated [6]. This situation is a major reason that only partial or Aactinide-only@ burnup credit was considered in the U.S. Department of Energy (DOE) Topical Report on burnup credit [1] and the current U.S. regulatory guidance on burnup credit for transport and storage casks [7]. The fission product margin is still present, but since sufficient measured data for isotopic validation do not exist, credit for its negative worth has not been recommended for inclusion in safety analyses.

FIG. 3. Fraction of Neutrons Absorbed for Major Fission Products at Various Cooling Times for 4.5-wt %-Enriched PWR Fuel Burned to 50 GWd/t

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Issues for Effective Implementation of Burnup Credit

C. V. Parks and J. C. Wagner

Nuclear Engineering Applications Section
Oak Ridge National Laboratory*
P. O. Box 2008
Oak Ridge, TN 37831-6370
865 (574-5280)
parkscv@ornl.gov

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ISSUES FOR EFFECTIVE IMPLEMENTATION OF BURNUP CREDIT

C. V. PARKS, J. C. WAGNER
Oak Ridge National Laboratory (ORNL),
Oak Ridge, Tennessee,
USA

Abstract

In the United States, burnup credit has been used in the criticality safety evaluation for storage pools at pressurized water reactors (PWRs) and considerable work has been performed to lay the foundation for use of burnup credit in dry storage and transport cask applications and permanent disposal applications. Many of the technical issues related to the basic physics phenomena and parameters of importance are similar in each of these applications. However, the nuclear fuel cycle in the United States has never been fully integrated and the implementation of burnup credit to each of these applications is dependent somewhat on the specific safety bases developed over the history of each operational area. This paper will briefly review the implementation status of burnup credit for each application area and explore some of the remaining issues associated with effective implementation of burnup credit.

1. INTRODUCTION

Since the mid-1980s the domestic utility industry, the U.S. Department of Energy (DOE), and the U.S. Nuclear Regulatory Commission (NRC) have actively considered the incentives, benefits, and obstacles associated with implementing burnup credit in the criticality safety evaluation for storage, transport, and disposal of spent nuclear fuel (SNF). The incentives first emerged with spent fuel storage pools. Lack of off-site alternatives (i.e., reprocessing, permanent disposal, or interim storage) provided significant incentives for utilities to obtain optimum use of the fixed pool storage capacity currently in place. Exacerbating the demand to optimize pool storage space was the trend towards increased initial enrichments, a trend, which continues to the present. Thus the simple, yet conservative, assumption of using unirradiated Afresh fuel@ isotopics for the criticality safety analysis became a significant economic barrier to continued operation of reactor power plants.

By the end of the 1980s several utilities had begun to use burnup credit in the safety analysis for their storage pools at PWRs. Efforts were initiated to evaluate the incentives and seek resolution of technical issues associated with the use of burnup credit in SNF storage and transport casks. In contrast to many countries where burnup credit is desired primarily to increase the allowable enrichment within existing cask designs, the United States nuclear industry is seeking to develop a new fleet of storage and transport casks that are optimized for the anticipated SNF contents. The long cooling times, on the order of 5 years or more, provide considerable flexibility for capacity increase in comparison to the shorter cooling times used in countries that reprocess. Rail casks with capacities of 32 PWR assemblies are being designed—an ~30% increase over existing storage cask concepts. These increased cask capacities can enable a reduction in the number of casks and shipments, and thus have notable economic benefits while providing a risk-based approach to improving safety. Arguments for improvement in safety have noted that the fewer shipments required with burnup credit cask designs will reduce the radiation exposure to both workers and the public as well as reducing the potential for a transport accident involving a cask. Arguments have also been made that the increased capacity per cask increases the potential consequence from any hypothetical transport accident. In either case, from the perspective of criticality safety, it is clear that the use of burnup credit should enable an adequate margin of subcriticality to be maintained while increasing cask capacity.

Incentives for use of burnup credit in boiling water reactor (BWR) applications have not been as significant as for PWR applications. The reason for this reduced incentive is that BWR fuels have less reactivity than PWR fuels and increased use of neutron poisons in intervening regions between assemblies have proven effective for maximizing capacities and allowing fairly high initial enrichments [1]. Thus, the incentives are largely limited to reducing the cost of neutron poison plates and allowance for higher initial enrichment fuel (up to 5.0 wt% ^{235}U).

However, the incentives for implementing burnup credit have really not been a debated issue in the United States. Rather the debated issues have been associated with the ability to demonstrate the technical basis commensurate with the existing expectations of each application area. This paper will briefly review the implementation status of burnup credit for each application area and explore some of the remaining issues associated with effective implementation of burnup credit.

2. APPLICATION AREAS

2.1. Reactor Operations

Accurate prediction and understanding of the changing nuclide inventory as a function of burnup is a necessity to safe and efficient operation of a nuclear reactor. Major efforts have been expended by the nuclear industry to ensure that the changing isotopic compositions of fuel assemblies in an operating reactor are properly accounted for and that effective analysis methods are available to Afollow@ and predict operating conditions for the reactor. Of primary interest is the integral effect (i.e., neutron multiplication) of the changing SNF inventory. The analytic methods used in reactor operations have traditionally been based on geometric and physics approximations (primarily applicability of neutron diffusion theory) to the Boltzmann radiation transport equation, but have been made increasingly reliable with continuous feedback experience (i.e., integral validation) gleaned from a 40-year period of operating commercial light water reactors (LWRs) in a controlled facility. However, the analysis methods used for calculation of the effective neutron multiplication factor (k_{eff}) in commercial LWR operations are typically not applicable for out-of-reactor situations where their geometric and physics approximations are not valid. In addition, the nuclide inventory provided by the reactor core-following codes has historically not included many of the nuclides that are important to the prediction of k_{eff} in out-of-reactor operations because of the build-up of absorbers in the absence of a significant neutron fluence.

2.2. Pool Storage

Storage of spent fuel in underwater racks at reactors has been standard practice in the United States since the start of the nuclear industry. Spent fuel pools (SFPs) at reactors are licensed in the United States under 10 CFR 50 [2]. They represent controlled facilities operated in conjunction with the reactor operations. In lieu of credit for boron in the water, the NRC Office of Nuclear Reactor Regulation has licensed use of burnup credit for many years in borated SFPs at PWR plants. In establishing the safety basis, the general approach used in the United States involves blending the experience and reliability from the reactor core-following codes with the double contingency principle typically applied for out-of-reactor criticality safety. The SNF inventory subsequent to decay of the short-lived ^{135}Xe isotope is typically used within a storage pool geometry to determine a fresh fuel enrichment that provides the same reactivity as the SNF inventory. This Aequivalent@ fresh fuel enrichment is then used within a criticality safety analysis code to perform the actual safety analysis for the pool. Little or no validation of the isotopic inventory prediction via comparison with SNF chemical assays is performed; instead, the reliability of the analysis approach in performing

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Validation Issues for Depletion and Criticality Analysis in Burnup Credit

C. V. Parks, B. L. Broadhead, M. D. DeHart, and I. C. Gauld

Nuclear Engineering Applications Section,
Oak Ridge National Laboratory,*
P. O. Box 2008,
Oak Ridge, TN 37831-6370
(865) 574-5280
parkscv@ornl.gov

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VALIDATION ISSUES FOR DEPLETION AND CRITICALITY ANALYSIS IN BURNUP CREDIT*

C. V. PARKS, B. L. BROADHEAD, M. D. DEHART, I. C. GAULD
Oak Ridge National Laboratory (ORNL),
Oak Ridge, Tennessee
USA

Abstract

This paper reviews validation issues associated with implementation of burnup credit in transport, dry storage, and disposal. The issues discussed are ones that have been identified by one or more constituents of the United States technical community (national laboratories, licensees, and regulators) that have been exploring the use of burnup credit. There is not necessarily agreement on the importance of the various issues, which sometimes is what creates the issue. The broad issues relate to the paucity of available experimental data (radiochemical assays and critical experiments) covering the full range and characteristics of spent nuclear fuel in away-from-reactor systems. The paper will also introduce recent efforts initiated at Oak Ridge National Laboratory (ORNL) to provide technical information that can help better assess the value of different experiments. The focus of the paper is on experience with validation issues related to use of burnup credit for transport and dry storage applications.

1. INTRODUCTION

Requirements applied within the United States, for validation of codes and data used for criticality safety outside reactors, are provided by ANSI/ANS-8.1 [1]. This standard requires that the calculational method be validated by comparison with "the results of critical and exponential experiments." Such a comparison yields information on biases and uncertainties in the calculational methods and model. The area of applicability for the calculational method is established by the characteristics of the measured critical experiments that are considered in the validation. The standard gives no guidance on how to establish the area of applicability (e.g., which parameters, characteristics, etc., and how similar they should be to the application).

The process of performing criticality calculations for spent fuel in a burnup credit model for transport or dry cask storage requires two distinct sets of calculations — the first to estimate the isotopic contents of spent fuel based on depletion calculations; the second to perform a criticality calculation based on the predicted isotopic contents from the first set of calculations. Thus, application of ANSI/ANS-8.1 to burnup credit validation becomes somewhat complicated by (1) the need to consider both the depletion analysis methodology and the criticality analysis methodology and (2) the lack of spent fuel critical experiments.

The objective of a validation effort per ANSI/ANS-8.1 guidance is to establish a limit for the calculated neutron multiplication factor (k_{eff}) below which the system of concern would be considered subcritical. The "fresh fuel" assumption has provided a simple, bounding approach which allows less scrutiny of the validation needs relative to fuel composition. Under burnup credit,

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applicability of experiments are not as obvious and validation efforts may be more closely scrutinized to ensure adequate definition and understanding of the subcritical margin.

The nature of experimental data appropriate for use in validation of burnup credit analysis methodologies and the value and applicability of such data have been debated topics for over a decade. Available (albeit some are proprietary) experimental data include chemical assays of spent nuclear fuel (SNF) inventories, critical experiments performed with fresh fuel (unirradiated fissile material) in cask-like geometries, reactivity-worth measurements, subcritical experiments, and reactor critical configurations. The following subsections discuss each of these sources of measured information and their potential value to the validation process.

2. CHEMICAL ASSAY MEASUREMENTS

2.1. Review of Available Data

Radiochemical assay measurements in the United States have been made for select spent fuel nuclides, for both PWR [2 to 8] and BWR fuels [9,10]. In addition, Ref. [11] is a compilation of sources of radiochemical assay data from these and other sources. Reference [12] describes sources for additional isotopic assays and assesses the completeness of available data describing each set of measurements.

Within the United States, chemical assay data have historically focused on the major actinides within PWR spent fuel. The actinides of importance in burnup credit have been measured for approximately 50 PWR fuel samples that provide the basis for performing code validation. Of these 50 samples, only seven had burnable poison rods available during irradiation – an indication of the age of the fuel designs and the data. For most fission product nuclides important in burnup credit, very few assay measurements (typically three samples) have been made in the United States. The enrichment and burnup ranges of the PWR spent fuel samples readily available in the United States are shown in Fig. 1 as the "existing database." The majority of these measurements have been used to determine the biases and uncertainties of computational methods [13 to 15]. With the current trend towards higher enrichment and burnup values, the acquisition of additional assay data to support code validation in this regime is considered a high priority in the United States. Additional PWR and BWR spent fuel assays with the desired characteristics are currently being performed to support U.S. Department of Energy (DOE) programs, but will not be available until sometime in 2001. Other sources of chemical assay data currently exist and/or are planned, largely within programs organized by other countries and held proprietary by those who procured the data. The French program on burnup credit [16], the REBUS program organized by Belgonucleaire [17], the LWR-PROTEUS program organized in Switzerland [18], and referenced Japanese data [19] are all potential sources of additional chemical assay data for use in validation. Figure 1 highlights the characteristics of the known sources of assay data identified by ORNL for potential use in burnup credit validation.

2.2. Validation Approaches

The use of the chemical assays in the validation process involves a comparison of predicted nuclide concentrations to the measured concentrations. The depletion model is based on the known in-core history for the fuel sample that was characterized. Given a significant number of comparisons, it becomes possible to statistically estimate the bias and uncertainty in the calculated prediction of each individual nuclide concentration. The bias is obtained by finding the average difference between computed and measured concentrations for each individual nuclide; the

uncertainty characterizes in a statistical manner the variation of individual comparisons around the mean [20]. The total uncertainty should also include statistical uncertainty based on a limited sample size. Reference [20] describes an approach for calculating bias and uncertainties such that one has a reasonable confidence that one can conservatively predict the concentration of a nuclide. Conservatism is defined in terms of correcting a nuclide concentration in such a way that has the effect of maximizing k_{eff} for a system. A second statistical approach is presented in Ref. 21. In both of these procedures, total calculated biases and uncertainties include any biases and uncertainties inherent in the experimental measurements. Thus, there is potential for offsetting errors in the bias, and the uncertainty may not be properly characterized. However, this is a random process, and non-offsetting errors would also be present.

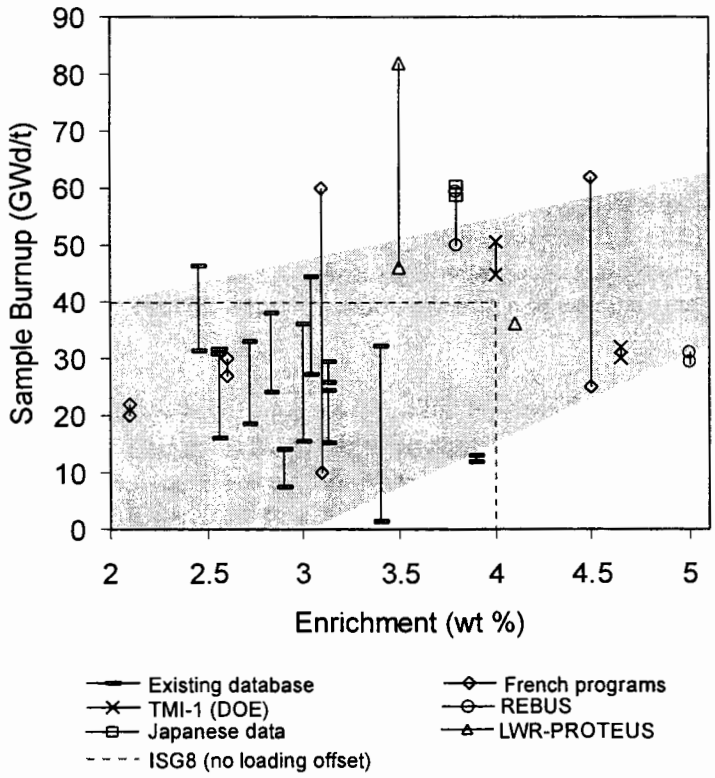

FIG. 1. Available and Potential PWR Chemical Assay Data Overlaid on a Shaded Range of High Applicability With Respect to the Enrichment and Burnup Regime of Existing Assay Data

Note that the procedure described above determines the calculational biases and uncertainties for each individual isotope evaluated. Simultaneous application of conservative corrections to individual nuclides within a predicted SNF inventory is a bounding, but unrealistic approach.

Another approach that could be used to obtain uncertainties in the SNF inventory would be to assess the integral effect on k_{eff} due to random variations to the SNF nuclide set within the characterized uncertainty bounds defined for each nuclide. This random variation of the inventory may provide a more realistic distribution of k_{eff} values for the application that can be directly tied to nuclide uncertainties and prevent simultaneous conservative correction of each nuclide. A conservative margin can be assigned based on the expected statistical distribution of k_{eff} values. Perceived advantages (better estimates of the impact of the uncertainty in the spent fuel inventory)

RADIOLOGICAL PROTECTION CONSIDERATIONS DURING THE TREATMENT OF GLIOBLASTOMA PATIENTS BY BORON NEUTRON CAPTURE THERAPY AT THE HIGH FLUX REACTOR IN PETTEN, THE NETHERLANDS

R.L.Moss[1], J.Rassow[2], E.Finke[2], F.Stecher-Rasmussen[3], W.Sauerwein[2]

[1] *HFR Unit, Joint Research Centre, European Commission, Petten, The Netherlands*
[2] *Universitätsklinikum, Essen, Germany*
[3] *Nuclear Research and consultancy Group, NRG Petten, The Netherlands*

ABSTRACT

A clinical trial of Boron Neutron Capture Therapy (BNCT) for glioblastoma patients has been in progress at the High Flux Reactor (HFR) at Petten since October 1997. The JRC (as licence holder of the HFR) must ensure that radiological protection measures are provided. The BNCT trial is a truly European trial, whereby the treatment takes place at a facility in the Netherlands under the responsibility of clinicians from Germany and patients are treated from several European countries. Consequently, radiological protection measures satisfy both German and Dutch laws. To respect both laws, a BNCT radioprotection committee was formed under the chairmanship of an independent radioprotection expert, with members representing all disciplines in the trial. A special nuance of BNCT is that the radiation is provided by a mixed neutron/gamma beam. The radiation dose to the patient is thus a complex mix due to neutrons, gammas and neutron capture in boron, nitrogen and hydrogen, which, amongst others, need to be correctly calculated in non-commercial and validated treatment planning codes. Furthermore, due to neutron activation, measurements on the patient are taken regularly after treatment. Further investigations along these lines, include, dose determination using TLDs and boron distribution measurements using on-line gamma ray spectroscopy.

1. INTRODUCTION

The European clinical trial (EORTC 11961) of BNCT for glioblastoma patients started at Petten in October 1997 [1]. The treatment of a patient and the potential exposure of personnel to ionising radiation require by the national Nuclear Energy Law that the JRC (as licence holder of the HFR) must ensure that radiological protection and monitoring of all personnel, including external staff, is provided and that the correct radiation protection measures are taken and followed.

Due to the structure of the European trial, where the treatment takes place at a facility in the Netherlands under the responsibility of clinicians from Germany, it had to be demonstrated that measures taken satisfy both German and Dutch radioprotection laws. To respect both laws, a BNCT radioprotection committee was formed under the chairmanship of an independent radioprotection expert, with members representing all disciplines in the trial. A contractual agreement had to be signed between the German institute (University of Essen) and JRC Petten to guarantee that procedures to be followed complied with German radioprotection regulations (Strahlenschutzordnung §20).

During BNCT, both the patient and the supporting treatment tools, such as mask and therapy table, become radioactive. As such, measurements of the patient and surrounds are taken at

regular intervals after treatment, checked and an appropriate form completed and reported to the BNCT Radioprotection Committee.

As at the HFR, BNCT worldwide is performed using mixed neutron/gamma beams at nuclear research reactors. The mixed beam must be thoroughly and regularly characterised, using dosimetry techniques in addition to those of conventional radiotherapy. Furthermore, the complex beam and subsequent dose distribution in the patient are modelled using treatment planning codes based on programs developed for nuclear applications, e.g. MCNP [2].

To improve radiological protection of the patient and staff, investigations are continuously in progress to fully characterise the beam (using activation foils, ionisation chambers, TLDs) and to determine the boron distribution in the patient using on-line prompt gamma ray spectroscopy.

2. RADIOPROTECTION COMMITTEE

To conform with the Dutch regulations on radio-protection, a Radio-Protection Committee for BNCT has been formed. The committee has the prime task to review and advise, on a half-yearly basis, the radio-protection methods used for BNCT. If need be, this advice is transmitted to any external authority. The Committee consists of members from each discipline in the BNCT group, and is chaired by an independent expert in radio-protection.

Due to the fact that German staff from Essen University Hospital need to work at Petten, German regulations on radio-protection, especially application of the radio-protection decree: §20 StrSchV (Strahlenschutzverordnung), which regulates the activities of German staff in foreign institutions, had to be contractually agreed. The decree defines regulations on supervision of the staff, personal dosimetry, rules of behaviour, etc.

Radio-protection includes the issuing of personal dosimeters (type: universal dosimeter) to all staff, finger or ring dosimeters to the radiotherapists, and pen dosimeters to participants classified as visitors, eg. nurse(s) and relatives of the patient, [3]. Furthermore it is necessary to measure and record all material in and out of the reactor and perform activation measurements on all material used in patient treatment. The patient is an exceptional case, of course, and it is not required that a personal dosimeter is issued to the patient. However, following treatment, the patient is monitored for radioactivity. So far, the reported radiation doses received by the staff are well below the allowable limits.

3. TREATMENT PLANNING FOR BNCT

For BNCT it is necessary to perform a full 3D calculation to predict the dose distributions in the patient's head. Calculations at Petten are performed with the INEEL treatment planning program 'bnct_rtpe/rtt_MC' [4]. This program is based on a Monte Carlo simulation of the particle tracks in a full 3D reconstruction of the head. As part of the overall treatment planning procedure, a quality assurance (QA) system is provided. As part of the QA system, a quality control procedure for the program involves calculations on two standard test cases, i.e. a standard patient and standard phantom, which are calculated to check for possible non-conformance. The cases are chosen in such a way that all the essential parts of the program are

used. A control procedure is followed and performed each time a new version of the program is installed.

For the patient plans, each treatment plan is calculated in Petten and presented, discussed and agreed at the radiotherapy department of Essen University during their daily audit on treatment planning.

4. PATIENT ACTIVATION MEASUREMENTS

3.1 Standard measurements [3]

BNCT of the patient results in neutron activation of a number of naturally occurring elements in the irradiated volume, i.e. the head. As a result, activation measurements of the patient's head are taken on 3 separate occasions using a standard portable dose ratemeter (Type: NE-PDR1). The first measurement is some 1-2 minutes directly following treatment, the second when the patient leaves the reactor building (5-10 minutes post-BNCT) and lastly, just prior to the patient leaving Petten to return to the hospital in Amsterdam (30-45 minutes post-BNCT). Measurements are taken both at contact and at 30cm distance from the head. The results have been compiled for all patients.

In summary, peak levels, i.e. at contact and directly after radiation, are of the order of 40-50 μSv/h, falling to less than 10 μSv/h some 30-50 minutes after treatment. The remaining activity is predominately due to ^{24}Na only (half-life = 15 h). Activity due to other elements have much shorter half-lives, hence do not contribute or are not additive to the final levels. Measurements, taken at 30cm from the patient's head are an order of magnitude lower. Hence, the dose received by medical staff and relative(s) accompanying the patient is well below recommended limits.

3.2 Activation measurements using a portable gamma analyser [3]

As one of the many research topics associated with BNCT, gamma-ray spectrometry measurements have been performed on 2 patients. The equipment or counting chain consists of an EG&G HPGe detector (relative efficiency and FWHM at 1.33 MeV of Co-60: 12.7% and 1.71 keV, type : 26N-1602C), an EG&G 459 high voltage power supply, an EG&G 572 amplifier, an ECN portable power supply and a Canberra Accuspec interface, mounted in a Toshiba 3200 SX laptop computer.

Shortly after the treatment, a patient was placed on a chair in the BNCT-Wing, where the portable spectrometer had been set-up. Prior to the arrival of the patient, background measurements were taken. The resulting spectra, with and without the patient, were analysed.

The predominate isotopes were, as expected, identified as ^{38}Cl, ^{49}Ca and ^{24}Na. However, in one patient, the isotopes ^{198}Au and ^{116m}In, were also present. It was concluded that the former isotope was due to (this) patient's gold filling and the latter isotope, assumably, due to the content of one of the drugs taken by the patient. It should be noted that only those radioisotopes which are gamma emitters have been measured.

5. BEAM CHARACTERISATION

Dosimetry guidelines, as followed in conventional treatment centres, apply to photon, electron or fast neutron facilities. For BNCT facilities, where an epithermal neutron beam is used, the beam (in air) includes fast neutrons (>10keV) and gamma rays. The latter comes from both the beam itself (reactor gammas) and from activation of the in-beam material. In human tissue, containing boron-10 compounds, the beam produces effectively four main dose components, all with different biological effectiveness: the boron neutron capture absorbed dose, the nitrogen neutron capture absorbed dose, the fast neutron absorbed dose and the gamma ray absorbed dose.

Furthermore, the neutron beam emanates from a reactor, which in the case of the HFR, has a strict operating schedule, running 24 hours per day for eleven cycles of 4 weeks each, per year. Hence due to burn-up of the reactor fuel, the intensity of the beam over the scheduled 4 weeks cycle reduces by some 4-5%. Also, the intensity of the beam at the start of each cycle may vary by some ±4% per cycle, due to experimental loading changes in the reactor. Hence, quality assurance of the beam during treatment must follow a strictly controlled procedure, which includes the following steps:

- free beam measurements on a monthly basis, using a multi-foil packet consisting of 12 activation foils,
- on the first day of the treatment week (each patient receives a fraction of radiation on four consecutive days), reference phantom measurements are performed using activation foils, twinned ionisation chambers and a pn-diode,
- the measurements are used to calibrate the on-line monitors (see next section),
- on succeeding days of treatment, the reference phantom measurements are repeated using the pn-diode, twinned ionisation chambers and the in-beam monitors, which are all normalised to the first day's measurements.

Following the QA system, as well as Good Clinical Practice (GCP) [5,6], all measurements are written down, controlled and countersigned by the responsible person, documented and later archived. Despite the complexity associated with BNCT dosimetry, QA procedures applied for BNCT infer less radiation and operational procedures than for conventional radiotherapy. Furthermore, reproducibility in BNCT is equivalent with medical accelerators, whilst all safety requirements and equipment functions, including against stray radiation are equivalent. The above philosophy is being developed, along with other European groups, to formulate a European Code of Practice on Dosimetry for BNCT [7].

Additional investigations are underway using thermoluminescence dosimeters (TLDs) which have become the current dosimetric tool in photon, electron and neutron radiation beams for dose determination in "in-vivo" dosimetry, as well as in phantoms simulating patients treatments. The epithermal neutron beam used in BNCT, has gamma and neutron components, which have different relative biological effectiveness (RBE). Hence, knowledge of the separate dose components is required for a safe patient treatment. For reliable and accurate TL dosimetry in BNCT, a study is in progress looking at the detector response to the mixed field in order to determine the sensitivity to each component [8]. The work investigates:-

- Comparative examinations for the selection of TLD's for further application
- Examination of surface properties of TLD 300

- Calibration of the TLD 300

As part of the study, in-vivo measurements have been performed on 4 BNCT patients using TLD 300s. Initial results are related alone to treatment parameters without any patient influence. Simultaneously, measurements were done inside the patient mask at the centre point of the beams on the patient entrance and exit surface for both beams. These results are dependent on treatment parameters of the BNCT facility as well as the patient related parameters.

6. PROMPT GAMMA RAY SPECTROSCOPY

Application of prompt gamma spectroscopy (PGS) may improve the safety and efficacy of BNCT [9]. PGS holds the potential of in-vivo boron concentration determination at the time of the treatment through the detection of gamma rays promptly emitted in the $^{10}B(n,á)^{7}Li$ and $^{1}H(n,ã)^{2}D$ reactions. A series of phantom measurements have been performed, where a tumour within a homogeneously boronated head phantom was simulated [10]. The results indicate that it is possible to determine a boron concentration of 5 ì g/g with an accuracy of ± 3 % in a homogeneous boron distribution. Subsequent measurements have been recently performed on patients. The results are pending. Nevertheless, the technique looks very promising and work continues.

7. ACKNOWLEDGEMENTS

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8. REFERENCES

1. Hideghéty K., Sauerwein W., De Vries M., Grochulla F., Goetz C., Haselsberger K., et al., "Post-operative Treatment of Glioblastoma with Boron Neutron Capture Therapy at the European High Flux Reactor Petten (EORTC protocol 11961)", Ann Oncol 9 (suppl 2) (1998): 129.
2. Briesmeister, J.F., "MCNP - A General Monte Carlo N-Particle Transport Code", Version 4B, LA-12625- M, Los Alamos National Laboratory, 1997.
3. Moss,R.L., Stecher-Rasmussen,F., Keverling-Buisman,A., Rassow,J., Sauerwein,W., "Radioprotection for patients and staff during BNCT at the HFR Petten", Proc. 8th International Symposium on Neutron Capture Therapy for Cancer, La Jolla California, September 1998, Plenum Press
4. Nigg,D.W., "Methods for radiation dose distribution analysis and treatment planning in boron neutron capture therapy", Int.J.Radiat. Oncol. Biol. Phys. 28; 1121-1134, 1994
5. Bohaychuk,W., Ball,G., "Good Clinical Research Practices, An indexed reference to international guidelines and regulations, with practical interpretation", GCRP Publications, January 1994
6. Good Clinical Practice for Trials on Medicinal Products in the European Community, Committee for Proprietary Medicinal Products [CPMP] EEC 111/3976/88-EN, July 1990

7. Stecher-Rasmussen,F., "Code of Practice for BNCT Dosimetry", IAEA Joint Technical Committee Meeting on "Current Issues Relating to Neutron Capture Therapy (F1-TCM-1095)", IAEA Headquarter Vienna, 14-18 June 1999
8. Finke, E., Hidegéty K., Kessler,C., Morrissey,J., Moss,R., Rassow,J., Sauerwein,W., "In-vivo measurements with TLD detectors for BNCT of glioblastoma patients at the High-Flux Research Petten/NL", Proc. 9th International Symposium on Neutron Capture Therapy for Cancer, Osaka, Japan, October 2000
9. Verbakel, W. and Stecher-Rasmussen, F., "ã-ray telescope for on-line measurements of low boron concentrations in a head phantom for BNCT," Nucl. lnstr. Meth. A 394,163-172 (1997).
10. Munck af Rosenschöld,P., Verbakel,W., Ceberg,C., Stecher-Rasmussen,F., Perrson,B., "Towards clinical application of prompt gamma spectroscopy for in-vivo monitoring of boron uptake in BNCT:, Proc. 9th International Symposium on Neutron Capture Therapy for Cancer, Osaka, Japan, October 2000

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in

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Radiation Protection measures in Nuclear Medicine Dept.

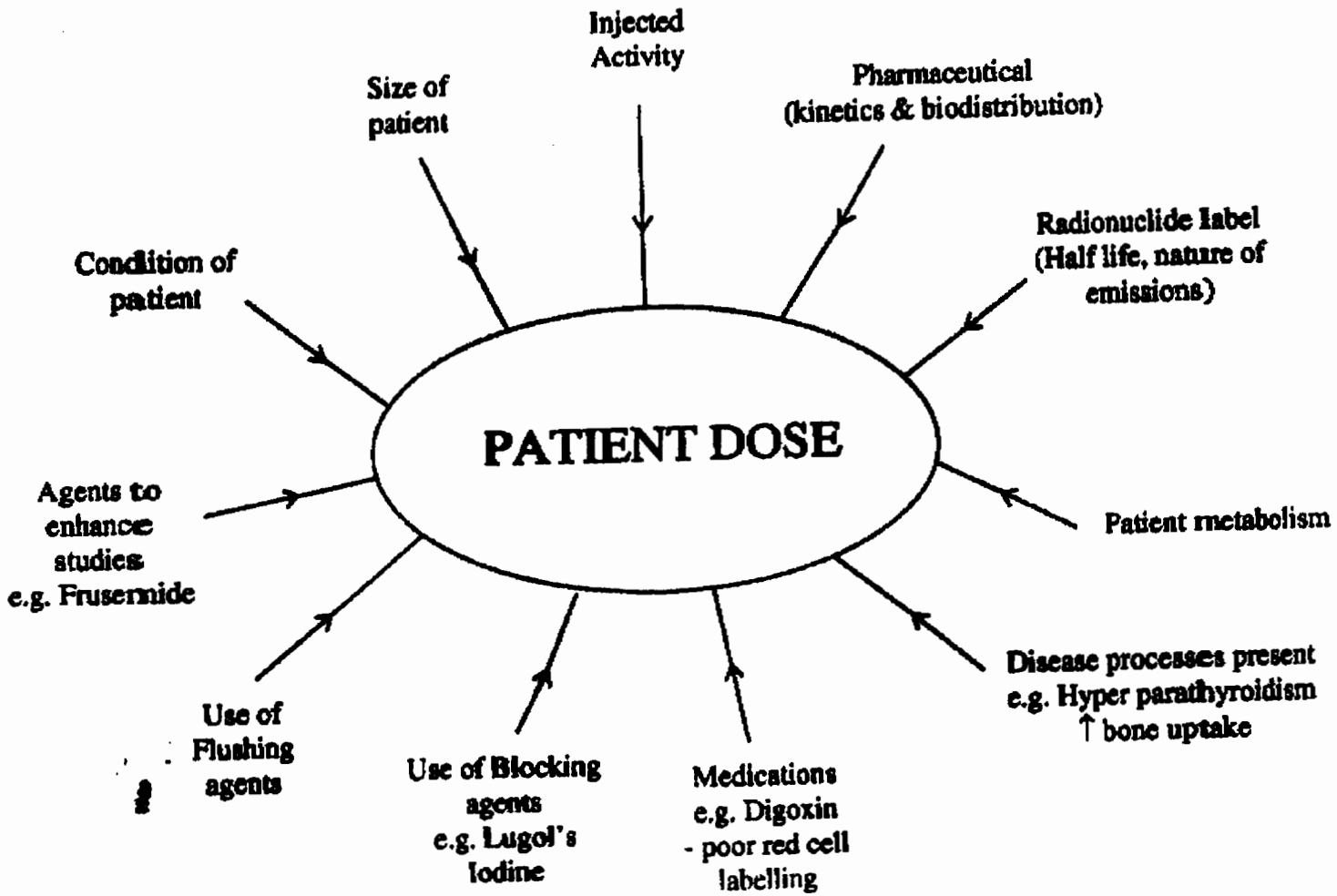
Legal and Administartive measures

1. Justify all tests first.
2. Results of prior test to be available.
3. Consider alternative non-ionising tests. Eg Ultrasound.
4. Adequate & accurate medical details included in request.
5. Consider possibility of pregnancy or breast feeding.
6. Correct identification of parient before injection.
7. Staff well trained in procedures and Radiation Safety.
8. Written protocols for procedures.
9. Equipment maintenance.
10. Quality assurance.

Members of staff who are nor radiation workers

1. Diagnostic tests are unlikely to be problem unless there is frequent close contact.
2. Therapeutic applications need special consideration.
3. Frequent close contact for diagnosis could be set at for example:
   3 hours at a distance of 30cm from a Bone scan patient every week for a year. If this level is approached then radiation badges should be issued for a test period to see if person needs to be classified.
4. People to be considered:
   Accompanying nurses

5. Practical measures for control:
   - Information and training.
   - Notification to go with patient.
   - Rules on wearing of gloves and plastic aprons when handling urine bags, urinals, bedpans, dirty linen.
   - Reduction of close contact with patients.
   - Reduction of close contact with pregnant staff.
   - Possible postponement of non-urgent studies or treatment requiring more than 30 mins close contact.



Protection of patient's family/friends/members of public

- It is very unlikely that 1mSv dose limit will be received by member of family if test is diagnostic rather than therapeutic.
- If the dose is likely to be significant then family member/ friend could be considered under the heading of:

  Individual helping in the comfort and support of a parient (other than as part of their work).

- For such a perdon the 1mSv dose limit does not apply if the person consents, knowingly and willingly to the dose.
- However, a dose constraint must be applied.
- Under new legislation patients undergoing diagnosis or treatment with radionuclides must be given written instructions about ALARA and information about risks.
- Information should cover:

  Conception
  Pregnancy
  Breast feeding
  Contact with small children
  Contact with pregnant women
  Contact with members of public as appropriate.

Practical Considerations

1. Before injecting patient ensure that all preparations have been made.
   Eg. Fasting, Cimetidine given, Lugol's iodine given, sedation given if necessary, patient able to return after set waiting time etc...
2. Select radiopharmaceuticals and activities which give minimum patient dose consistent with optimal diagnostic result.

Practical considerations (continues)

3. Careful Preparation of radiopharmaceuticals
   QC checks of quality
   Records of materials used and activities measured
   Labelling and segregation of made up vials and syringes for injection.
4. Immediately before injection make sure that there is no change in condition of

5.For patients with difficult veins reduce risk of extravasation by using "Butterfly" cannula.

NB. Some injections eg Thallium 201 can cause ulceration at injection site.

Note for staff safety: Use of a cannula can reduce dose to staff by factor of approx 2

6.In all studies where excretion is through the kidneys and bladder increase the patient fluid intake and ask them to empty bladder frequently.

This is also good for staff safety even if you are not imaging the pelvis.

7.Use blocking agents to prevent uptake in thyroid, salivary glands, stomach.

8.Enter patient's name, radiopharmaceutical & injected activity in Patient Log.

Special Considerations for Paediatric patients

Injected doses

There are conflicting requirements:

- Higher activity may be required because we need higher spatial resolution than for adults (high resolution collimator) and shorter imaging time to minimise patient movement.
- Lower activity required for lower rad dose as life expectancy is long and tissues are more sensitive.

Several methods for determining activity are available:

1.Body surface method:

Paed.Activity = BSA(in m^2)X Adult activity/ 1.73

2.Age method:

Paed.Activity = Age + 1 X Adult activity / Age + 7

(only useful if child is of average weight for age)

3.Weight method:

Paed. Activity = Weight (Kg) X Adult activity / 70

Height method:

Paed. Activity = Height (cm) X Adult activity / 174

1 and 2 are recommended for giving similar information density as for adults. Some groups use 1 for 'thin' organs and 3 for 'thick' organs. Method 4 is recommended for dynamic studies as imaging times cannot be increased.

Study on patient dose in diagnostic radiology in Japan: Investigation of entrance surface dose of patient using direct measurement by TLD

S.Iwanami[1] T.Ishiguchi[2] T.Ishigaki[2] S.Koga[3]

[1]Kitasato University School of Allied Health Sciences, 1-15-1 Kitasato, Sagamihara, kanagawa 228-8555, Japan [2]Nagoya University School of Medicine [3]Fujita Health University School of Medicine

Abstract

This study was conducted to research radiation exposures by routine X-ray examinations in the hospitals to establish the guidance level in Japan. So a multicenter study was carried out to evaluate radiation doses in routine radiographic examinations. In this study, we investigated entrance surface doses of patients using direct measurement by TLD for various 5 types of radiography; Chest PA, Abdomen AP, Lumber spine AP, Lumber spine LAT and Pelvis AP. From the results, we examines the (a) need for introducing the guidance level in Japan, (b) controversial points in the calculation method for patient dose evaluation, (c) evaluation accuracy required for introducing the guidance level, and (d) necessity for a standardized method for patient dose evaluation.

Introduction

X-ray examinations are commonly used in health care and become the largest man-made source of exposure for the population. The need for standardization of medical exposure has been suggested and the guidance levels has been proposed for various radiographic examinations by IAEA(1). Problems in introducing the guidance level should be researched before the appropriate guidance level is established(2). One of the problems is an evaluation of patient doses(3). To date, patient doses have been evaluated by calculations based on radiographic conditions, or model experiments using phantoms. The patient doses are then evaluated based on several assumptions. Direct measurement of patient dose is difficult to perform in many patients due to its time requirement, level of expertise required and difficulty in providing an explanation of the procedure to the patient. However, such direct measurement is essential since it incorporates all

aspects of radiography from the radiographic equipment used, to the actual conditions of each patient without assumption. In this study, we investigated entrance surface doses of patients using direct measurement by TLD for various types of radiography. From the results, we examines the (a) need for introducing the guidance level in Japan, (b) controversial points in the calculation method for patient dose evaluation, (c) evaluation accuracy required for introducing the guidance level, and (d) necessity for a standardized method for patient dose evaluation.

Materials and Methods

The research method matched the English protocol(4) as much as possible while considering differences at Japanese medical treatment sites. Five types of simple radiography were selected on the basis of their prevalence in the clinical practice; the posteroanterior (PA) chest, anteroposteterior (AP) abdomen, AP pelvis, and AP and lateral (LAT) lumber spine.

Direct measurement of the patient's entrance surface dose was performed using thermoluminesent dosimeters (MSO-TLD) for the 5 types of radiographic examination at 18 university hospitals. TLDs were mailed to the hospitals and each TLD was placed on the patient's skin at the center of the radiation field when the radiography was taken. Then the TLDs were returned by mail for read out. All preprocessing, calibration and reading of TLD were undergone by one of the authors to eliminate variations between measurement facilities.

Results

Figs.1 show distributions of entrance surface doses per radiograph for all adult patients at 13 institutions for 5 types of radiographies. Table 1 summarizes the results for 5 types of radiography. Fig.2 shows distribution of average entrance surface doses for 5 types of radiography at each institute. Fig.3 shows average entrance surface doses of each institution, in order to smallest to largest.

Results are compared with patient doses calculated by radiographic conditions such as a tube voltage, a tube current and an exposure time.

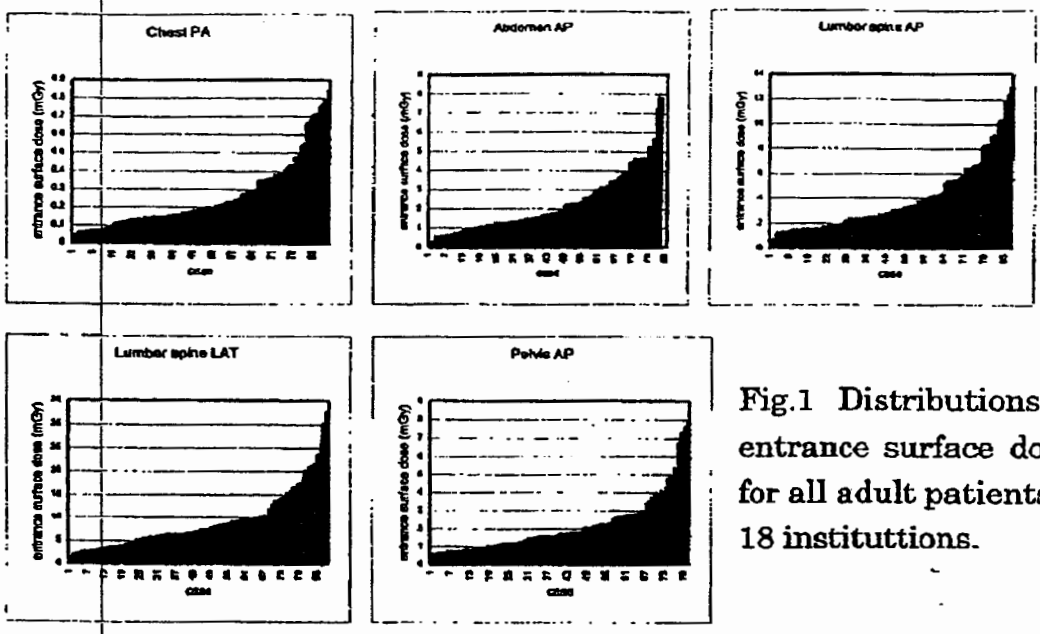


Fig.1 Distributions of entrance surface doses for all adult patients at 18 instituttions.

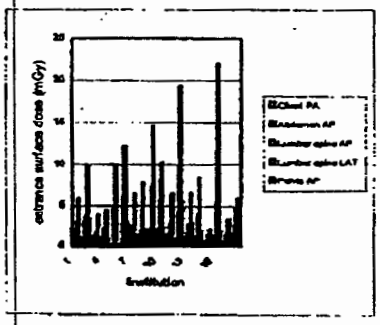


Fig.2 Distribution of average entrance doses for 5 types of radiograph at each institute.

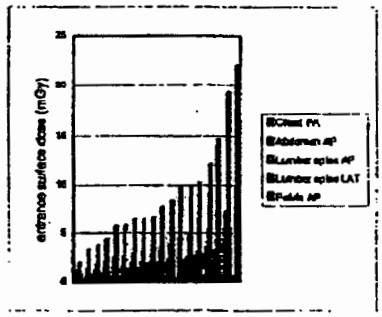


Fig.3 Average entrance surface doses of each institute , in order of smallest to largest.

Table 1 Minimum, median, mean and maximum values of entrance surface doses (mGy) for all adult patients at 18 institutions.

Radiograph	Minimum	Median	Mean	Third quartile	Maximum
Chest PA	0.04	0.19	0.26	0.35	0.84
Abdomen AP	0.2	1.6	2.2	3.1	7.8
Lumber spine AP	0.5	2.8	3.9	5.3	13
Lumber spine LAT	1.2	7.1	8.9	10	33
Pelvis AP	0.5	1.6	2.1	2.6	7.8

Discussions and Conclusions

Results are discussed according to the 4 points described in Introduction and the following 4 points are concluded.

(a) The guidance level is needed also in Japan. (b) Calculation methods are not effective for patient dose evaluation whenever the quality assurance (AC) is performed for X-ray equipments. (c) Evaluation accuracy in patient dose is required within 25% for introducing the guidance level. (d) A protocol on patient dose evaluation is necessity for introducing the guidance level also in Japan.

References

1. IAEA, International basic safety standards for protection against ionizing radiations and for safety of radiation sources. IAEA Safety Series No.115-1, IAEA, Vienna, 1994.
2. T.Ishiguchi, S.Iwanami, S.Kawatsu, T.Ishigaki and S.Koga, Radiation exposures by routine radiographic examinations: Multicenter study in Japan with thermoluminescence dosimetry and estimation from the radiographic data. Proceedings of the 10th International Congress of The International Radiation Protection Association, P-7-21, Hiroshima, 2000.
3. S.Iwanami, T.Ishiguchi, T.Ishigaki, S.Koga et al., Study on evaluation method of patient dose in diagnostic radiology required for introducing the guidance level: Investigation of entrance surface dose of patient using direct measurement by TLD. Nippon Acta Radiologica 60, 396-405, 2000.
4. The Institute of Physical Sciences in Medicine (IPSM), National Radiological Protection Board (NRPB) and College of Radiographers (CR), National protocol for patient dose measurement in diagnostic radiology. NRPB, Oxon, 1992.

Acknowledgement

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PROTECCION RADIOLOGICA EN PACIENTES CON BRAQUITERAPIA GINECOLOGICA DE MEDIA TASA DE DOSIS (MDR). UNICA EXPERIENCIA EN CHILE

Dra. Mariela Silva Munoz
Lic. T.M. Enrique Soto Vidal

INTRODUCCION

Despues de 38 años de efectuar Braquiterapia Ginecológica (BQT) con dispositivos cargados y sistema de carga diferida manual, el advenimiento de la BQT con carga diferida a control remoto, vino a solucionar un problema de Protección Radiológica del Operador.

Desde el punto de vista de la paciente, los tratamientos se han optimizado recurriendo a la obtención de mejores radiografías de Simulación y a la inclusión de Sistemas computarizados de cáculo de dosis.

En el Hospital Base de Valdivia (Valdivia-Chile). Desde 1998 , se cuenta con el único equipo de Media Tasa de Dosis (MDR) existente en el país. Se han tratado 190 pacientes (a sept-2000), se ha logrado bajar significativamente las dosis en los puntos críticos (**vejiga** y **recto**), permitiendo el control de la enfermedad, con la consiguiente disminución de las complicaciones. Esto es posible, recurriendo a la inmovilización de los aplicadores (Fletcher-Suit-Delclos), al uso de "packing"rectal y al uso de porta-chasis adaptados a la camilla de tratamiento (evitando al máximo el movimiento de la paciente desde que le es instalado el aplicador y que se aplica la dosis de radiación).

METODO

1.- Inmovilizacion de los aplicadores: se diseño un dispositivo que sirve de soporte al aplicador Fletcher, que permite mantener el fletcher paralelo a la superficie de la camilla. Consta de una barra "T" abrochada al aplicador y una columna ajustable, con contrapeso, que sostiene todo el dispositivo. (Ver foto1 y 2)

2.- Uso de "packing"rectal: Se utiliza una gasa impregnada con una solución de medio de contraste (iodado), empujando la pared posterior de la vagina y por vecindad alejando la mucosa rectal de las fuentes radiactivas instaladas en los colpostatos. Este "packing" iodado permite, además, la visualización de la pared posterior de la vagina, con lo cual se puede marcar en la Rx. lateral dicho punto y el punto rectal a 0,5 cm. del anterior. Se marca, además la vejiga, inyectando el "ballon" de la sonda vesical con 7 ml de una solución iodada. (Ver fotos 3 y 4)

3.- Porta chasis adaptado a camilla: Se diseñó una "caja porta chasis" para Rx. AP. que se instala a la altura de la pelvis, sobre la camilla de tratamiento de la paciente. Se diseñó, además, una "barra porta chasis" para Rx. Lateral que se instala al borde y perpendicular a la caja porta chasis. Se utilizan chasis radiográficos con parrilla antidifusora incorporada. (Ver fotos 5 a 9)

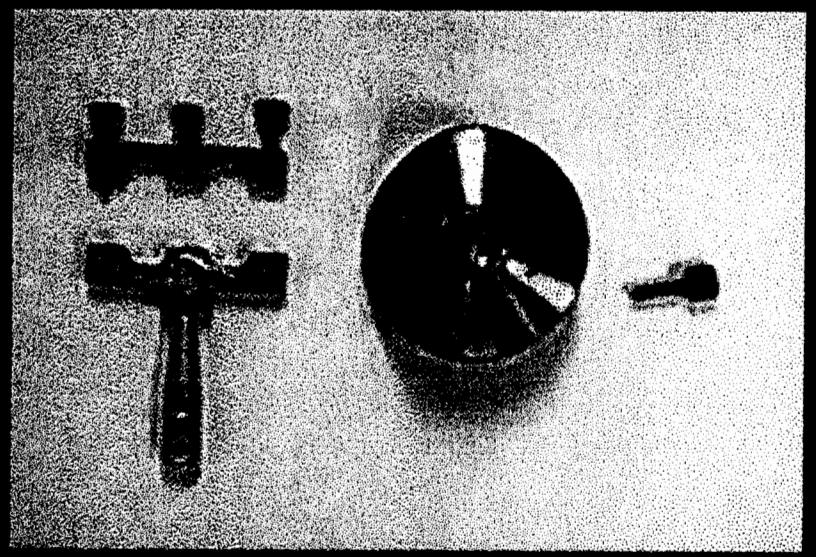
CONCLUSIONES

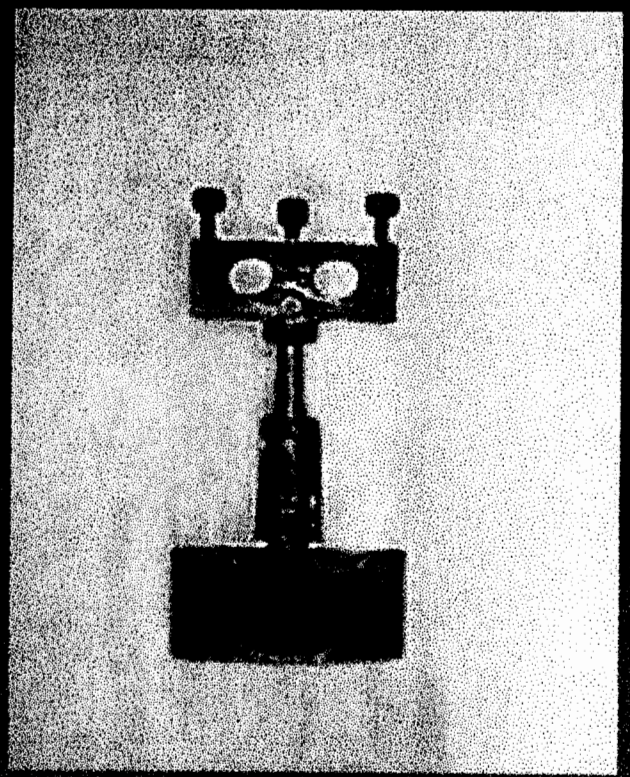
La incorporación de la dosimetría computarizada ha permitido efectuar cálculos precisos de dosis en puntos de interés y en los órganos críticos.

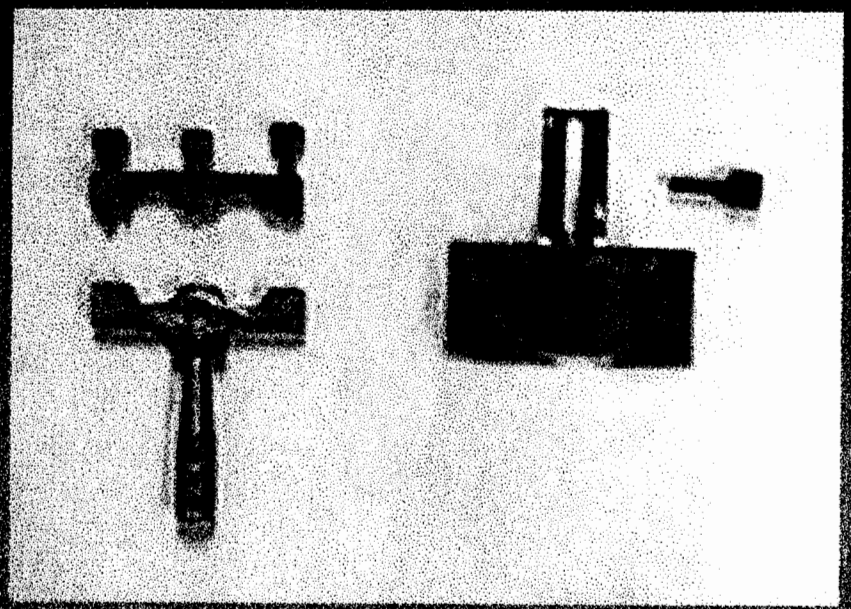
La incorporación de accesorios ha permitido mejorar el sistema de simulación y lograr mantener los dispositivos sin desplazarse luego de haber efectuado el cálculo dosimétrico y durante el tiempo que transcurre el tratamiento.

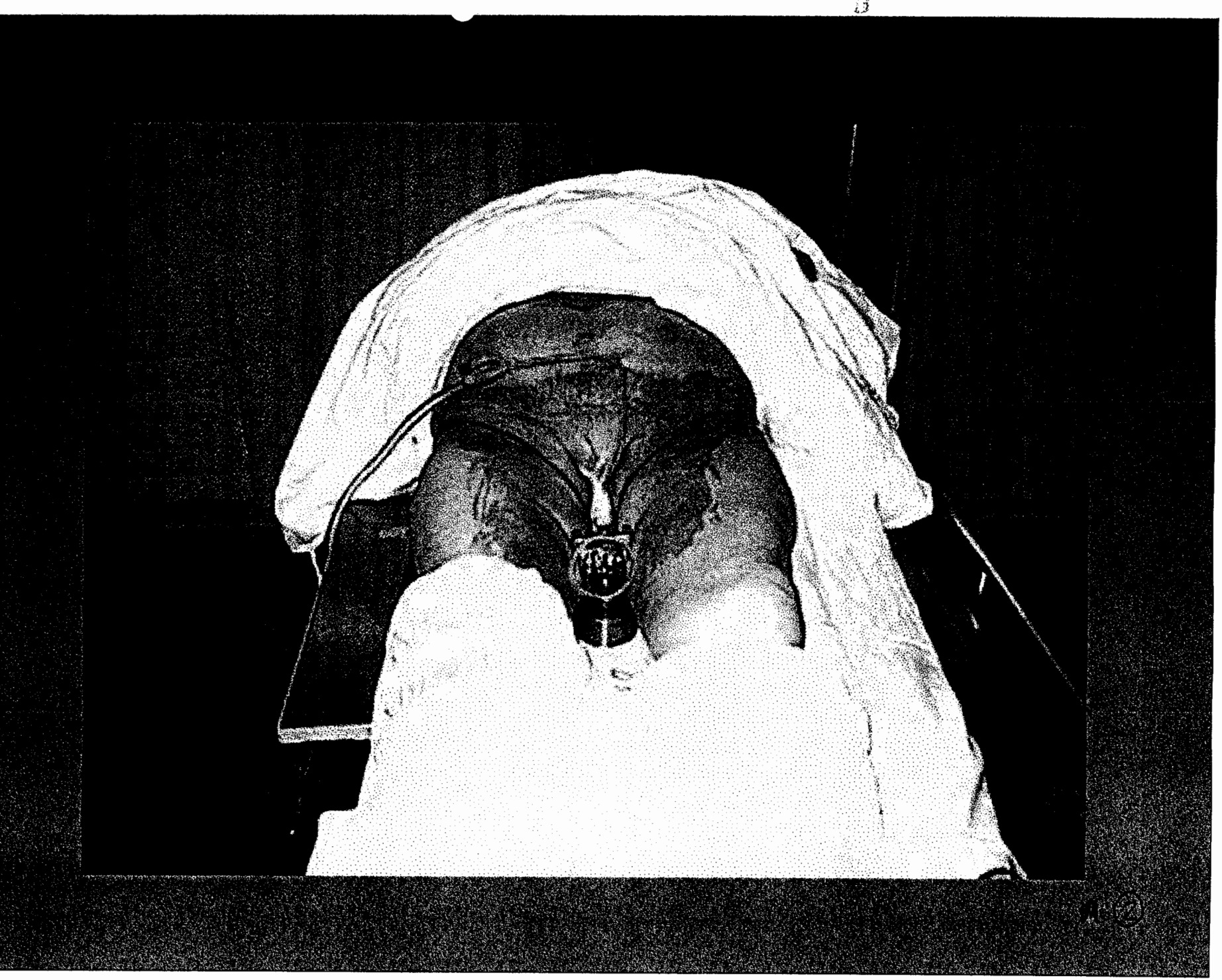
La protección del recto con el uso del packing ha sido efectiva ya que los porcentajes de dosis recividas por éste no ha sobrepasado del 75 % de la dosis prescrita en el sitio de interés .

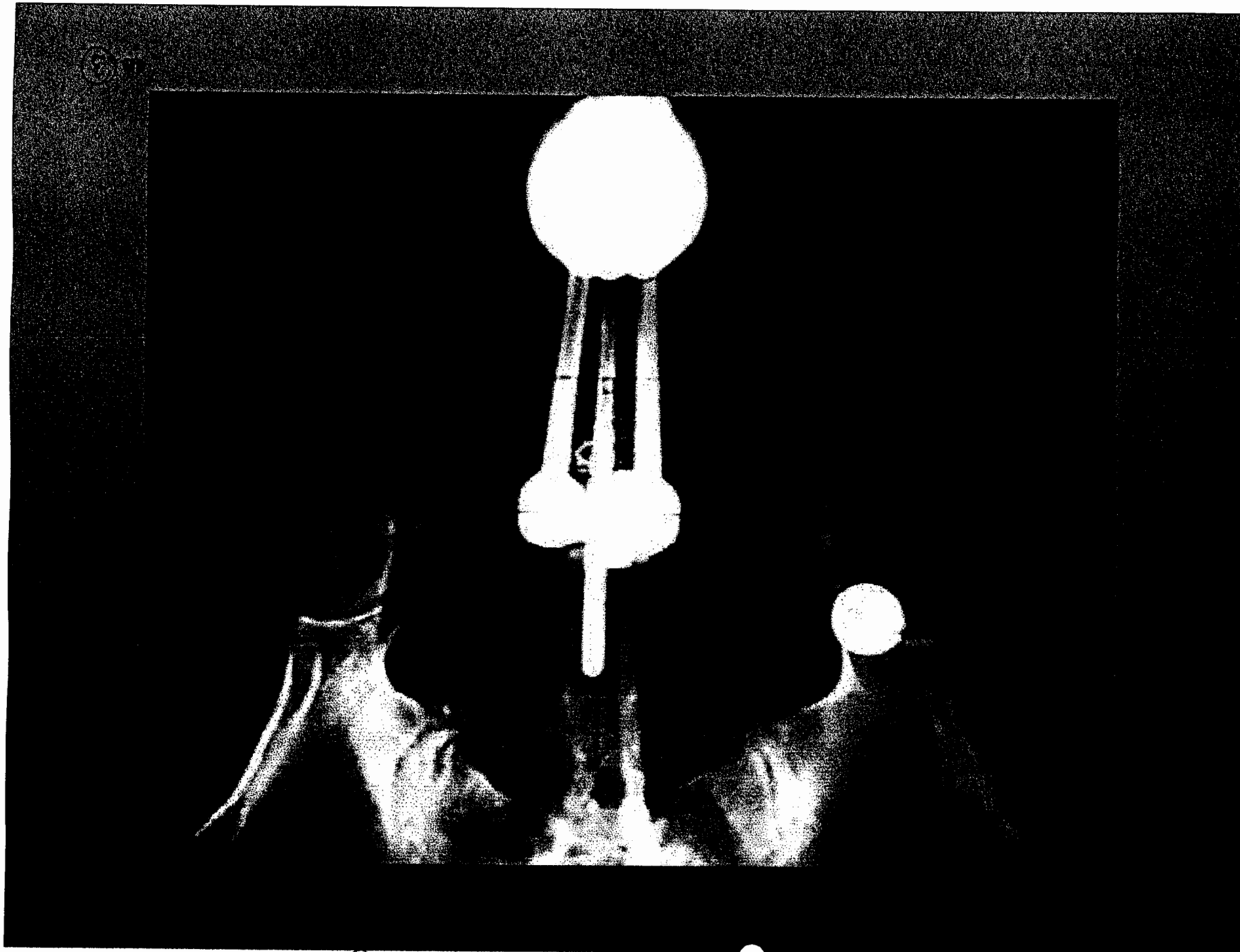
Ha habido una correlación positiva entre la protección radiológica del paciente y la expresión clínica de ésta ; ya que a pesar del uso de media tasa de dosis (12.5 Gy/h) la incidencia de complicaciones observada son menores o iguales a las que se presentan con baja tasa de dosis.

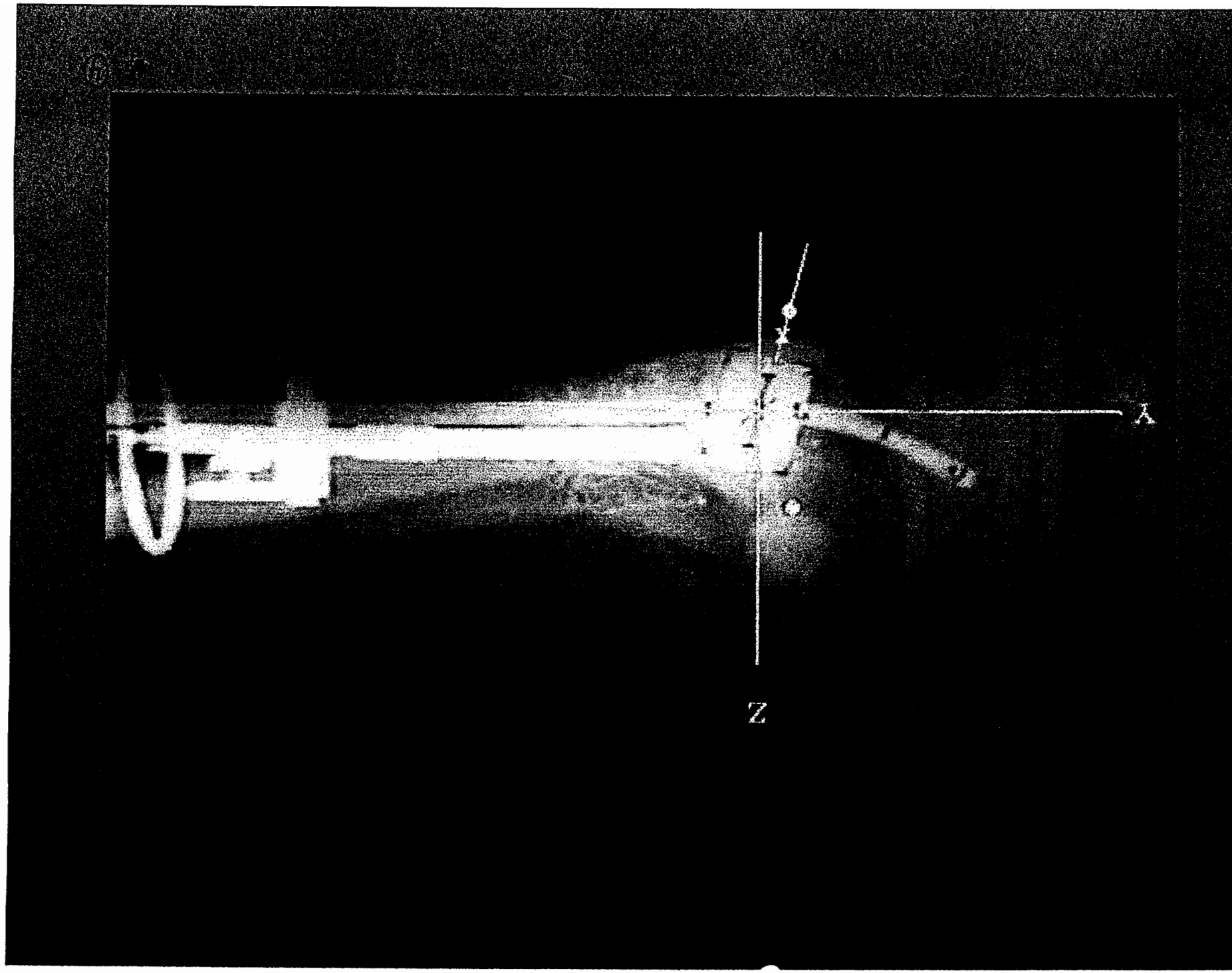








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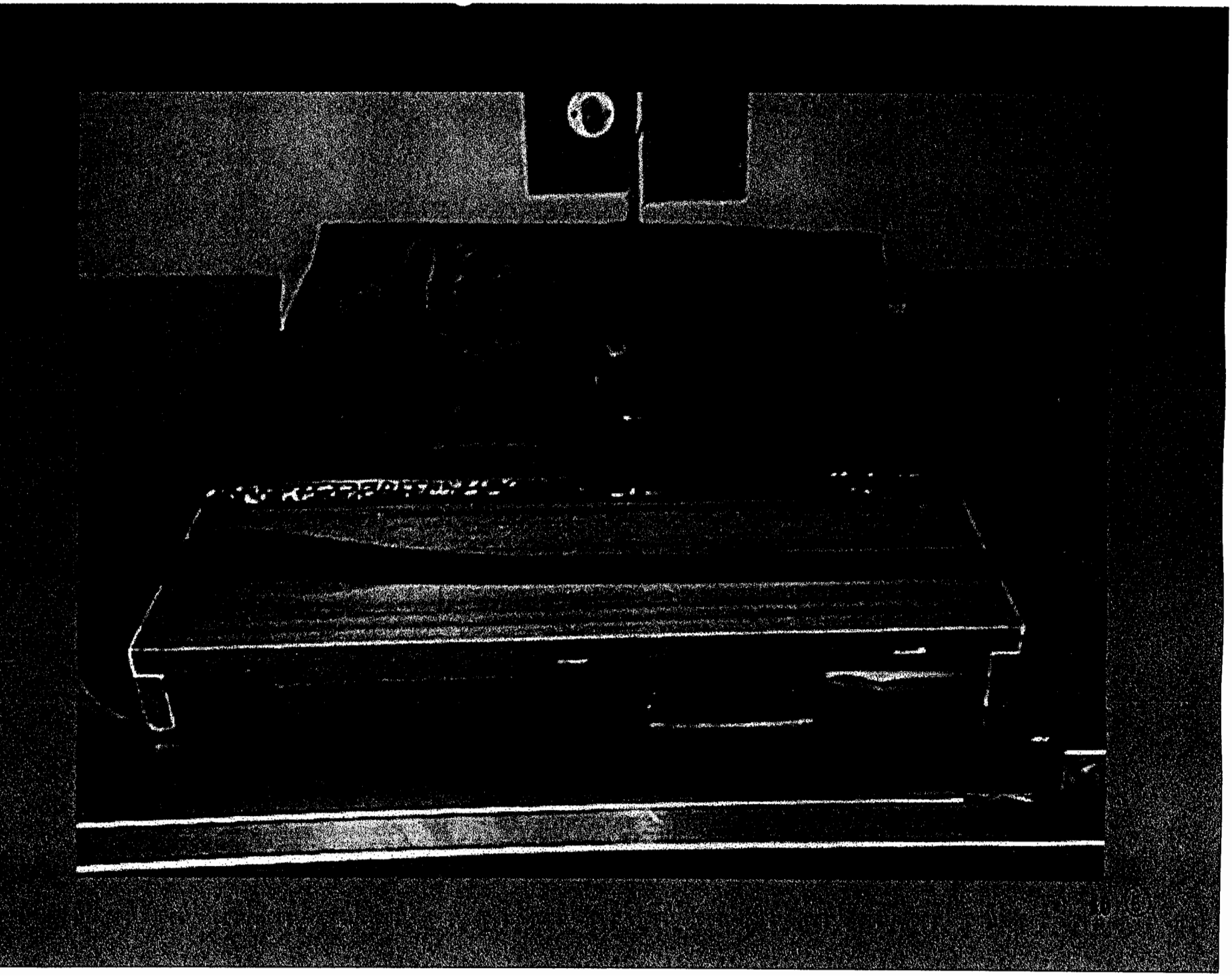

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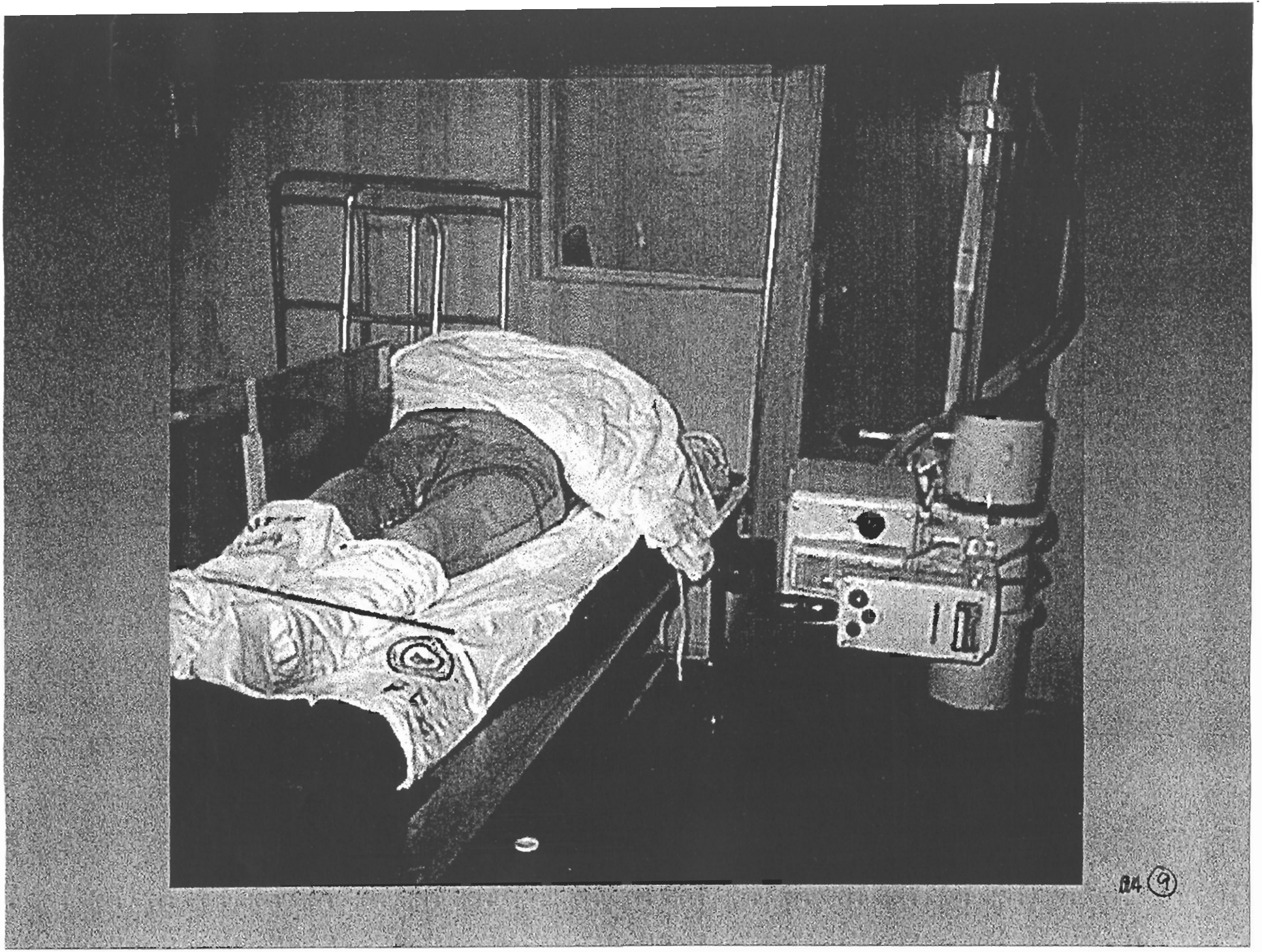
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COMPARTMENTAL ANALYSIS OF DRUG INTERACTIONS IN RADIOPHARMACOKINETICS

Antonio S Rezende Avila MD[a], Roberto José A. C. Bezerra PhD[a], Joyce L Lippestein PhD[a,b], Mario Bernardo-Filho PhD[a,c], Dayse M Mattos MSc[a]

[a]Universidade do Estado do Rio de Janeiro, Instituto de Biologia Roberto Alcântara Gomes, Departamento de Biofísica e Biometria, Av. 28 de setembro, 87 - Rio de Janeiro/RJ, Brasil - 20551-030
[b] Instituto de Radioproteção e Dosimetria, Comissão Nacional de Energia Nuclear, Rio de Janeiro/RJ, Brasil
[c] Ministério da Saúde, Instituto Nacional de Câncer, Centro de Pesquisa Básica, Rio de Janeiro/RJ, Brasil
E-mail: asra@uerj.br Fax : 55 21 254-3532

1. ABSTRACT

The radiation measurement is a essential branch of Nuclear Medicine. The knowledge of radiopharmaceuticals, their biodistribution as well as the factors to bring changes upon the regular radiopharmacokinetics are of special importance. Decreased or increased doses, in different compartments or organs (as gonads), induced by drug interactions with radiopharmaceuticals have theoretical and practical importance on internal dosimetry. The purpose of this study was to characterize some *in vitro* properties of the drug interaction. **Methods**: We evaluated the action of cyclophosphamide (CP) on the binding of the radiopharmaceutical sodium methylenediphosphonate (99mTc-MDP) on plasma and blood cells isolated from blood withdrawn from Wistar rats, using an in vitro model. The experimental measures were studied starting with the parameter estimation of regressive trendlines, analysis of variance and residuals. The hypothesis of a closed two compartment system and the CP effects were analyzed. **Results:** In the presence of CP, the curves crossed each other at 48 h, but diverged without the drug. The short-term components of the two-compartment system converged in 1 hour. **Discussion**: Since the CP solution is only stable for 48 h and may alter the permeability of the membranes of the blood cells, the two-compartment closed system might be suggested. **Conclusion**: The mathematical approach to analyze the drug interactions mechanism with the studied radiopharmaceutical is in agreement with the known biological phenomena. In spite of these results, it is necessary to consider new procedures to define the behaviors of drugs with radiopharmaceuticals.

2. INTRODUCTION

A radiotracer can be considered to be any radiolabeled substance that remains detectable by an observer when mixed with other substances (*1,2*). In general, the purpose of experiments carried out with radiotracer is to deduce properties of the system being studied from observations of the behavior of the tracer when introduced into the system. In particular, the distribution kinetics of the tracer provide a basis for determining the rates of transfer of substances among various compartments which may be hypothesized with the system (*1*). There may be input of the tracer from the environment into one or more compartments and outputs (excretion) from the system as well. Radiopharmacokinetics studies the time course distribution of specific radiotracers (radiopharmaceuticals) in various biologic environments and the use of mathematical relationships to analyze the data.

The interactions of different drugs with radiopharmaceuticals has not been well studied, and may in some cases have a significant effect on the system kinetics. The alteration of the protein binding of radiopharmaceuticals on blood elements (plasma proteins and blood cells constituents) may alter their biodistributions (*3,4*).

Since the data for study are experimental measurements of a biological system, with the possibility of several substances acting on each other, the inverse model was the first approach chosen The initial results became the initial conditions to try to identify a compartmental model (direct model) for description of the

action of a chemotherapeutic agent, cyclophosphamide (CP) on the distribution of the radiopharmaceutical 99mTc-MDP on the blood compartments (plasma and blood cells).

3. MATERIAL AND METHODS

As previously reported (*3*) CP was purchased from Abbott, Brazil. 99mTc, as sodium pertechnetate ($NaTcO_4$) was milked from a 99Mo/99mTc generator (Instituto de Pesquisas Energéticas e Nucleares, SP, Brazil), and was directly used into a kit (Laboratório de Radiofarmácia, INCa, Brazil) containing 1 mg of $SnCl_2.2H_2O$ and 5 mg of methylenediphosphonic acid to prepare the 99mTc-MDP. The 99mTc-MDP was diluted approximately 1,000 times with 0.9% NaCl solution to reach the desired activity. Briefly, in "in vitro" studies, vials with samples of heparinized blood (4 ml) withdrawn from Wistar rats were incubated with solutions (0.5 ml) of the radiopharmaceutical (37 kBq/ml). After 1, 2, 3, 4, 6 and 24 h the vials were centrifuged and samples (25 μl) of plasma (P) and blood cells (BC) were isolated. To study the effect of the presence of CP, blood samples were previously incubated with 0.5 ml of this drug (50 μg) 1 h before the MDP was added (in the control samples, the CP was substituted for 0.5 ml of 0.9% NaCl solution). The samples of P and BC were precipitated with 5% trichloroacetic acid and soluble (SF) and insoluble fractions (IF) were isolated and then counted in a well counter. The percentage of administered activity (% rad) was calculated and normalized to the total activity, respectively to P or BC in P + BC, and to SF or IF of P in SF-P + IF-P, and to SF or IF of BC in SF-BC + IF-BC.

To quantify the variations in the analysis, the direct method was partitioned into the following stages:

(a) hypothesis formulation (*5*),
  (i) model specification: a closed two compartment with constant coefficients was specified;
  (ii) parameter estimation: linear regression analysis was performed, with equations, determination coefficient (r square - r^2), adjusted r^2, standard error, residuals analysis and analysis of variance (ANOVA) assessed (*6*).

(b) analysis and model checking (*5*).

The hypothesis of a closed two-compartment was analyzed following a first order kinetics model. The curves for two ranges – short-term (0 to 4 hours) and long-term (4 to 24 hours) - were fitted and their values as initial conditions were entered into the BMDP program. This program uses numerical integration to solve the system of differential equations for specific values of parameters of proposed model , and then employs the results to evaluate the desired regression function.

4. RESULTS

The study of the distribution of the 99mTc-MDP reveals that, initially, the % ATI is concentrated in P. The curves appear to be converging with CP present, but appear to be diverging with CP absent. The forward forecasting curves (Figures 1a and 1b) confirm these observations. The polynomial curves crossed each other after approximately at 48 h, diverging afterwards

The analysis of variance parameters ([alpha] = 5%) for the initial regressions are summarized in Table I. The correlation coefficient (multiple r), determination coefficient (r^2) and standard error are also shown.

TABLE I :

Statistic Values for Fitted Curves

Curves	A	B	C	D	E
Polynomial(with CP)	0,6335	1,85648	0,79594	0,1343	3,452
Exponential(with CP)	0,4670	0,02190	0,68169	0,0917	4,340
Polynomial(without CP)	0,4432	1,69477	0,66574	0,3100	1,592
Exponential(without CP)	0,1202	0,02158	0,34678	0,4460	0,683

Values for r^2, multiple r and F-test for initial fitted curves, from 0 to 24 hours, using polynomial and exponential functions with and without CP presence. (A) – R square (B) - Std Error (C) - Multipl R (D) - Signif F (E) - F value

The estimated parameters for the short and long-term components of closed two-compartment system were calculated from the initial results. In order to study the behavior of short-term (with 5 experimental points) in the first hour, values of the concentrations in the plasma and in blood cells at 10 minutes were estimated. The calculated data converged in 1 hour when CP was present. The half-time and the exponential function corresponding to the system were obtained. Convergence was also observed at long times, but since only 3 data points are available, this may be misleading (*5*) .

The semi-log plots (fig. 2) show that the exponential curves, for short-term, may approximate the mean values of the observed data. The k_1 (P→ BC) is 0.77 and k_2 (BC→ P) is 10.21 (k represents the transfer rate values into two-compartments of the closed system, according to the arrows, as indicated – P and BC) .

5. DISCUSSION

In this study about the effect of cyclophosphamide on the distribution of the evaluated radiopharmaceutical in the blood comparments, although a significant F statistic (*1, 11*) was not obtained, the highest r^2 (ratio between explainable and unexplainable variance) was found in the polynomial fit. In the curves (Figure 2.a), the P and the BC in presence of CP, approach each other at about 48 h. Because the CP solution is only stable for 48 h, this result may be expected. Furthermore, the 3-dimensional graph gives evidence of distinct behaviors with and without CP. The results show a tendency for CP to alter some processes, perhaps inhibiting them, allowing a closed system of two compartments to describe the kinetics. As reported by the other investigators, CP is capable of binding to proteins (*7,8*) and the BC may compete for binding, probably altering the permeability of blood cell membranes. This may change the radiopharmaceutical distributions (*9*), producing behavior as in a two-compartment closed system. The convergence of data in 1 hour when CP was present and the trend to an exponential curve might explain the observed results in the short-term as fluctuations in data after the incubation of the blood with CP. Data without CP suggest that more complex models, perhaps non-stationary or probabilistic system, may be needed to describe the processes involving the distribution of radiopharmaceuticals on blood elements (*10*).

6. CONCLUSION

The first results indicate that compartmental models can be applied to study drug interactions in radiopharmacokinetics, in agreement with the biological characteristics of the evaluated substances and mathematical methods. However, it is necessary to employ simulation and modeling. Thus, more studies are needed to provide a more quantitative mathematical knowledge to understand the actions of drugs on the binding of the radiopharmaceuticals on blood elements. This is, perhaps, the first step to analyze the effects of drugs on internal dosimetry.

7. REFERENCES

[1] JACQUEZ JA. Compartmental Analysis in Biology and Medicine, John Wiley&Sons, Canada (1988)
[2] ROBERTSON JS. Compartmental Distribution of Radiotracers, CRC Press; Bocca Raton, Florida, USA (1983)
[3] RIPOLL-HAMER E, FREITAS LC, DE-PAULA EF, FONSECA LM , GUTFILEN B, BERNARDO-FILHO M. In Vitro effect of cyclophosphamide on the binding of radiopharmaceuticals (99mTcO4 - and 99mTc-MDP) to blood elements. Braz J Med Biol Res. **28** (1995) 236-260.
[4] SANTOS JS, DE-PAULA EF, CORREA TC, DE-FREITAS LC, DA-FONSECA LM, GUTFILEN B, BERNARDO-FILHO M. Effect of cyclophosphamide on the binding of 99mTcO4- and 99mTc-MDP to blood cells and plasma proteins . Braz J Med Biol Res. **28** (1995):131-135.
[5] RESCIGNO A. Radiopharmacokinetics: Methods and Prospect. J Nucl Med.;38(suppl):(1994)1-4: 3-14 pp

[6] DARHAM AA, GANDELMAN M, ZOGHBI SS, INNIS RB: Reproducibility of SPECT measurement of benzodiazepine receptors in human brain with Iodine-123-Iomazenil. J Nucl Med. **36** (1995) 167-175.
[7] PERRY CCP. The Chemotherapeutic Science Book., Williams and Wilkins; Tokio (1991)
[8] HOLLEB AL, FINK DJ, MURPHY GP. American cancer Society Textbook of Clinical Oncology. New York , NY: American Cancer Society (1991)
[9] AVILA ASR, Gutfilen B, BERNARDO-FILHO M. Drug interaction with radiopharmaceuticals: a study using a statistical analysis. British J Radiol.;70 (suppl) (1997) 97 pp.
[10] LEBRETOM JD, MILLIER C. Modèles dynamiques determinístes en biologie. Paris : Masson (1982)
[11] SAPOTA S. Probabilités Analyse des Donnés et Statistique, Editions Technip , Paris (1990)

PATIENT DOSIMETRY IN ^{18}F PET IMAGING

L. Gonzalez[1], C. A. Cordeiro[1], E. Vano[1], M. J. Perez Castejon[1,2], A. Jimenez[1,2], H. R. Montz[2], M. Domper[2] and J. L. Carreras[1,2]

(1) Radiology Department, Complutense University, 28040 Madrid, SPAIN.
(2) Instituto PET-Dr. Carreras, Clínica López Ibor, 28035 Madrid, SPAIN.

Abstract

PET imaging for diagnosis in Nuclear Medicine is being increasingly used, but experimental patient dose measurements and optimisation of this technique has not followed a parallel development. Patient protection standards in the European Union force the evaluation of patient doses as a part of the quality control programmes. Dosimetry at reliable locations of the patient's skin can provide data to establish dose values, as a way to audit the patient dose. In the present work, surface doses derived from the administration of ^{18}F-FDG for PET imaging have been measured in two PET facilities. The need for further experimental work to establish typical dose levels is stressed.

Introduction

Nuclear medicine imaging by positron emission tomography (PET) is being increasingly used. On the one hand, small cyclotrons dedicated to positron emission radioisotope production for Nuclear Medicine imaging are being installed in medical facilities. Also, PET diagnostic capabilities find increasing fields of application. In third place, camera manufacturers offer the possibility of adapting the dual head SPECT machines to work with positron emitters, making easier the implementation of this technique. Therefore, satellite centres from an installation with a dedicated cyclotron are becoming customary.

The Council of the European Union (EU) Directive 97/43/EURATOM [1], on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, introduces the concept of Diagnostic Reference Levels (DRL), and the European Guideline "Radiation Protection 109" [2] states that 'Member States shall promote the establishment and the use of DRL, as a strategy within optimisation. To this end, appropriate quality assurance programmes, including quality control measures and patient dose assessments should be implemented'. These considerations force the development of methods to achieve an easy experimental way to evaluate patient doses. Since the particular characteristics of each patient can produce changes in the radiopharmaceutical biokinetics, the knowledge of such surface doses can be a practical way to audit and derive doses in individual patients.

There is not yet much information available on dose to patient, based on experimental measurements. In fact, depending on the characteristics of their PET cameras now on the market, the manufacturers recommend different radioisotope activities for a given study. In the present work, surface doses derived from the administration of ^{18}F-FDG for PET imaging have been measured in two PET facilities. A comparison is made with data in literature.

Material and methods

Measurements were carried out in two facilities, one equipped with a baby cyclotron and one just receiving ^{18}FDG from an outside centre. The first one, described in a previous work [3], consists of a superconducting compact cyclotron which produces typically 35 GBq of ^{18}F (some 12 GBq of ^{18}FDG delivered by the chemistry module after synthesis), plus a Posicam HZL-R camera, from Positron Corporation (Houston, TX, USA), based on BGO technology. Usual activities injected in patients vary between 0.11 and 0.44 GBq, for whole body studies. The second centre is equipped with an ADAC C-PET model 250 system, from UGM Medical Systems Inc (USA), consisting of 6 INa(Tl) curved detectors. For whole body studies, typical activities injected are below 0.2 GBq.

Patient dosimetry was achieved by thermoluminiscent dosimetry (TLD). Three lithium fluoride TLD-100 chips, from Harshaw TLD/Bicron/NE-Technology (BICRON-NE, Solon, OH, USA) were used per patient in both centres, placing them before injection. One of them was located on the groin skin in males, and at some 5 cm over the pubis sinfisis, positioned some 10 cm to one side, to place it near ovary, for female patients, the other two near each breast, at the middle of the mammalian fold. Dosimeters were taken out after about two hours. The TLD reading system was a Harshaw model 4400. The patient sample were 41 and 88 adults in the first and second centres, respectively. The overall uncertainty in the dosimeter read-out process was estimated to be about 7%.

Results

From the first centre, a sample of adult patients injected with between 0.37 and 0.55 Gbq of ^{18}FDG for whole body studies, yields average results of 1.9 μGy/MBq on the skin of the left breast, 2.1 μGy/MBq for right breast and 1.6 μGy/MBq for gonads (averaged for both sexes).

The figure displays the dose values from breast skin patient dosimetry as a function of the injected activity, in the second centre. Here, the measured rates are about 2.5 μGy/MBq as skin dose near gonads, 2.6 μGy/MBq for the left breast and 2.7 μGy/MBq for the right breast.

Note that, as in the case of the first centre, dose values on the right hand side seem consistently higher than on the left hand side, contrary to what could be expected taking into account the location of the TL chips in relation to the heart. In both graphs, shifts in dosimeter location and staying time on the patient skin, patient body size and fluctuation in dosage are some sources of uncertainty. Globally, these move between 14 and over 50%, even more for gonads, because of a rather unreliable dosimeter location, apart from the sample size, lower than for breasts (as data in this case are handled irrespective of sex).

Discussion

Different sources [4 -8] supply values of organ absorbed doses per injected activity unit of ^{18}FDG. Among different authors, the respective values of effective dose equivalent range between 19 and 30 μSv/MBq. Two facts are apparent from inspection of such data: one, that, numerically, breast glandular doses are up to about 20 times greater than the values measured on patient surface in the present work. Though our result come only from a two

hour exposure time of the TLD chips, the discrepancy seems large, taking into account the photon energy. In second place, calculated dose values are the same for both breasts.

In our work, doses measured on the patient's skin exhibit quite a good correlation with the injected ^{18}FDG activities, though the values found are higher for the right breast than for the left one. The International Commission on Radiological Protection [4] remarks the evidence from investigations on dogs of concentrations in organs such as spleen, liver and kidneys, but significant uptake in these organs has not been observed in human studies. Since absorbed doses are calculated on the basis of uniform distribution of activity in the body tissues other than brain and heart, local uptakes above the average value derived from the residual activity not absorbed brain and heart may imply changes in organ doses and effective dose equivalent, compared to the values assessed in references [4 -8].

An excess of exposure to the right breast dosimeter assumed by proximity of the syringe during injection (usually applied on the right forearm) or a certain radiopharmaceutical vessel leakage after injection do not explain the higher dose values measured, since the corresponding increases are negligible versus the total measured values. Therefore, the glucose captured by the liver, though diffuse when compared with that observed in the heart, is the cause of the dose excess measured. Also, since near 30% of the circulating blood passes through the liver, doses to the neighbouring tissues will increase until the radiopharmaceutical is cleared from the circulation.

From the above, it seems necessary to improve the relationship between administered activity and organ doses in PET with ^{18}FDG. However, our results should be considered an early approach, until further evidence allow us to confirm data reliability.

For both breasts, a second order polynomial expansion produces the best fit of the data from the second centre and a very good fit is also obtained by plotting the dose versus the log of the activity, whereas a linear regression yields the worst results. This circumstance may explain the differences in mean dose per activity unit found between the centres monitored in the present work, not constant according to our results. In fact, the polynomial (or the log) expansions fitted from data of the second centre predict fairly accurately the values of dose per unit activity found in the first one.

The non-proportionality between the injected activity and the skin doses measured is not easy to explain, since cellular uptake of glucose is not made following a simple diffusion model or a first order kinetics, but by tissue-specific transport systems, partially dependent on insulin [9]. Qualitatively, it seems from our results that the radiopharmaceutical uptake rate would depend on the activity previously absorbed, thus the total activity uptaken would not be proportional to the bolus injected. The implications could be important, since the percent of activity actually contributing to the image production would seem to decrease gradually as injected activity increased. Conversely speaking, experimental results would reflect, for a given injected activity, organ doses below the expected values from literature. This point is not easy to confirm without further experimentation, so that uncertainties for individual doses become reduced.

Conclusions

Dose values measured on the patient skin exhibit correlation with the injected activities, though they do not seem proportional. Anyway, it is possible to relate skin doses with

injected activity values, based on these measurements, for patient dose audit purposes. At breast locations, skin dose values are consistently higher for the right breast than for the left one. Further experimental work will be promoted to provide more precise data, aiming to confirm our results and to improve data reliability in studies with ^{18}FDG.

References

1. European Union 1997. Council Directive 97/43 Euratom, on health protection of individuals against the dangers of ionising radiation in relation to medical exposure. Official Journal of the European Communities No L 180, 9th July 1997, 22-27.
2. European Commission. Guidance on diagnostic reference levels for medical exposures. Radiation Protection 109 (1999).
3. Gonzalez L, Vano E, Cordeiro CA and Carreras JL. Preliminary safety evaluation of a cyclotron facility for positron emission tomography imaging. Eur J Nucl Med 1999; 26:894-899.
4. Radiation dose to patients from radiopharmaceuticals. ICRP Publication 53. Pergamon Press, 1988.
5. Herzog H, Zilken H, Niederbremer A, Friedrich W and Müller-Gärtner HW. Calculation of residence times and radiation doses using the standard PC software Excel. Eur J Nucl Med 1997; 24:1514-1521.
6. International Commission on Radiological Protection. Radiation dose to patients from radiopharmaceuticals. ICRP Publication 80, Pergamon Press.
7. Stabin MG, Stubbs JB, Toohey RE. Radiation dose estimates for radiopharmaceuticals. Radiation Internal Dose Information Center, Oak Ridge Institute for Science and Education, Oak Ridge, TN, 1996.
8. Mejia AA, Nakamura T, Masatoshi I, Hatazawa J, Masaki M, Watanuki S. Estimation of absorbed dose in humans due to intravenous administration of fluorine-18-fluorodeoxyglucose in PET studies. J Nucl Med 1991; 32: 699-706.
9. Ruhlman J, Oehr P, Biersack HJ, editors. PET in oncology. Basics and clinical applications. Springer Verlag, New York (USA), 1999.