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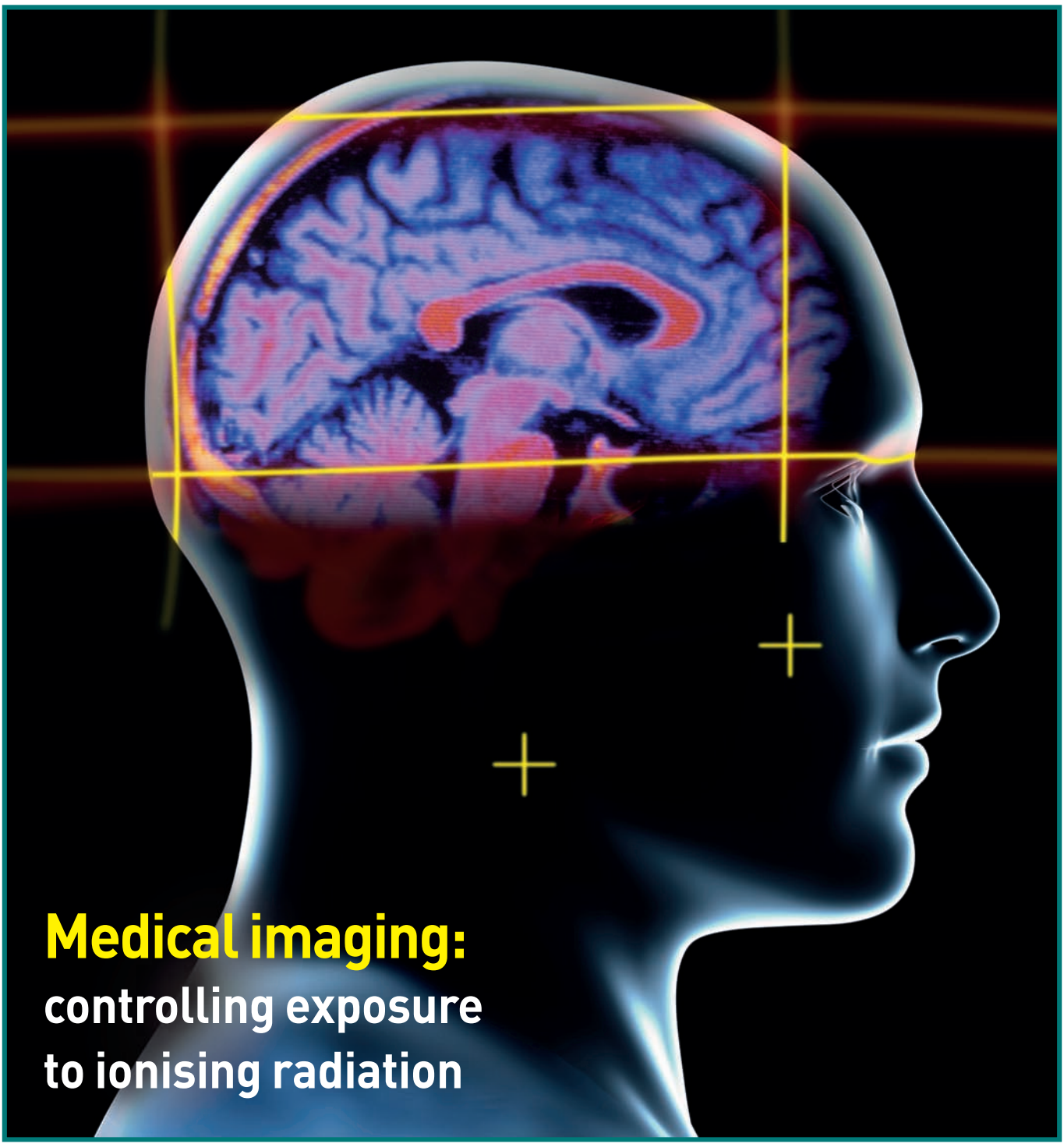

Medical imaging: controlling exposure to ionising radiation

The French Nuclear Safety Authority (ASN) website,

All the latest news on nuclear safety and radiation protection

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Foreword

by Jean-Christophe NIEL
ASN Director-General

ASN has been regulating medical applications of ionising radiation for nearly 10 years. After implementing an entirely new set of regulations for radiation protection of patients (2000-2005), it focused its inspection programme in 2007 on the safety of radiotherapy care and then, as of 2008, began to look at interventional radiology and the various medical procedures which are making increasing use of ionising radiation to guide the practitioner's hand (in surgery, cardiology and neurology for example). From now on, controlling the increasing exposure linked to computed tomography examinations is a new priority for ASN.

For the first time, Contrôle reviews the state of radiation protection in the medical field. It underlines the progress already achieved in enhancing the safety of radiotherapy procedures and spotlights the progress still needed in order to control exposure to ionising radiation in the medical imaging fields.

There is broad agreement on this need for progress, in the fields of computed tomography and interventional procedures, as highlighted by several articles in this issue of Contrôle from both professionals and health institutions. This issue is also illustrated by a number of articles showing the significant reductions in the doses delivered to patients that can be achieved when the professionals become proactive on this topic.

As was the case with radiotherapy, the mobilisation of institutions, professionals and manufacturers remains a precondition for any real application of the principles of justification of procedures and optimisation of the doses delivered to the patients by medical imaging, but also those received by the health professionals carrying out radiation guided procedures. Through the ties it has forged with these various stakeholders, ASN is focusing on implementing the various measures already identified, or having them implemented, in order to achieve real control of medical exposure. Appropriate involvement of "informed consumers" of radiology examinations, potential patients, is now an objective in its own right for ASN. ■

Medical imaging: controlling exposure to ionising radiation

TECHNICAL OVERVIEWS: INTERVENTIONAL RADIOLOGY

TECHNICAL OVERVIEWS: NUCLEAR MEDICINE

INTERNATIONAL INITIATIVES

NATIONAL INITIATIVES

Current status of radiation protection in the medical field: the French Nuclear Safety Authority's point of view

by Jean-Luc Godet, Director of ionising radiation and health – Nuclear Safety Authority (ASN)

Medical applications of ionising radiation occupy an important position in healthcare:
– radiotherapy is an essential method for treating cancer, used on about 50% of cancer patients with a cure rate of 80%;
– the use of increasingly sophisticated medical imaging, and computed tomography (CT) in particular, improves the quality of diagnosis and allows better targeting of therapeutic strategies and evaluation of treatment effectiveness;
– in interventional procedures, imaging enables high-precision actions to be accomplished (in surgery for example).

In this article, ASN gives its appraisal of the inspections carried out in radiotherapy and interventional radiology and the conclusions of its September 2010 seminar on the increase in doses delivered to patients in medical imaging. On the basis of this work, ASN reviews radiation protection in the medical field and sets forth its recommendations to improve it, particularly in medical imaging.

The results of the radiotherapy inspections performed in 2009 revealed progress in the management of treatment safety and quality, a trend that was confirmed in 2010.

The ASN inspections carried out in the 178 radiotherapy centres in 2009 confirmed the increase in human resources in medical physics, which began in 2008. This trend was confirmed in 2010. According to the national radiotherapy observatory[1], the number of medical physicists[2] dedicated to radiotherapy increased from 340 at the end of 2006 to 450 in 2009, and is hoped to reach 600 by the end of 2011. The number of dosimetry technicians has grown significantly, despite the lack of a regulatory framework specifying the conditions of exercise of the profession.

ASN did not provisionally suspend activities in any of the centres in 2010, compared with five suspensions in 2009.

1. Investigation report: situation at end of 2009, INCa, November 2010.
2. Medical physicist or person specialised in medical radiation physics.

ASN's appraisal is based on published documents available on *www.asn.fr:*

- National roundup of radiation protection in nuclear medicine further to the inspections performed in 2008 *(published in 2009).*
- Roundup of radiation protection of patients in external radiotherapy departments further to the inspections performed in 2009 *(published en 2011).*
- Results of the radiation protection inspections in interventional radiology performed in 2009 *(published in 2011).*
- Conclusions of the national seminar on the increase in doses in medical imaging *(ASN, Paris, September 2010).*
- Opinion of the Advisory Committee of Experts in Medical Radiation Protection (GPMED), meeting of 23 November 2010 on radiation protection in interventional radiology.

Nevertheless, as in 2009, ASN observed that the organisation of medical physics remained fragile in several centres at the end of 2010, particularly those with too few medical physicists on their staff (in September 2010, six centres had only one medical physicist).

The inspections also confirmed improvements in the management of radiotherapy treatment safety and quality. The results bear witness to a genuine mobilisation of the health professionals under the national radiotherapy plan coordinated by INCa, the National Cancer Institute. ASN nevertheless notes that progress varies substantially from one centre to another, as do the levels of involvement of management.

The increase in significant radiation protection events notified to ASN in 2010 is worth noting (total for 2010: 265 compared with 244 in 2009):

• The number of centres notifying events is increasing: today, 80% of the centres notified at least one significant radiation protection event (compared with 71% in 2009);

• Seven events were classified level 2 on the ASN-SFRO scale (8 in 2009);

• The majority of notified events are associated with organisational and human failings.

Other noteworthy happenings in 2011:

• The setting up of a joint events electronic filing portal between ASN and the French Health Product Safety Agency (AFSSAPS);

• Issuing of the first national bulletin on experience feedback (REX) from the events notified to ASN.

To be more precise, ASN has noted real progress in the control of the treatment preparation and delivery process, and in the "culture of risk", with widespread deployment of internal notifications of malfunctions and experience feedback analysis units (CREX). Further progress must nevertheless be made in developing the prospective risk analyses and analysing the causes in depth.

The results of the interventional radiology inspections performed in 2009 reveal shortcomings in the implementation of radiation protection for both patients and medical staff. These shortcomings are more prominent in surgery rooms in which radioguided procedures are performed (cardiology, neurology, surgery, etc.).

The first appraisal of ASN's inspections in interventional radiology, based on those carried out in 2009, reveals disparities in the implementation of radiation protection in healthcare establishments and in services practising radioguided interventions. It shows that radiation protection is better integrated in fixed, dedicated radiology facilities than in surgery rooms where mobile devices are used.

On the whole, where the radiation protection of patients is concerned, this appraisal reveals incomplete application of the optimisation principle for the radiological procedures, due firstly to insufficient operator training and secondly to a shortage of medical physicists and suitable equipment for this type of procedure. It also highlights deficiencies in the knowledge of the radiation doses delivered during the procedures and of the obligation to notify significant radiation protection events.

As far as medical personnel occupational exposure is concerned, the appraisal also reveals shortcomings in areas such as the dosimetric monitoring of workers (operational dosimetry, "extremities" dosimetry, etc.), the evaluation of risks associated with ionising radiation, the internal technical verifications of radiation protection, and the medical monitoring of practitioners.

These shortcomings are often due to insufficient allocation of resources by hospital or private establishment administrations to persons competent in radiation protection (PCR).

In surgery rooms where radioguided procedures are performed, such as in surgery, cardiology or orthopaedics, the inspections revealed:

– the use of devices by nurses instead of by radiological technicians, outside the legal framework;

– frequent absence of radiological protocols;

– insufficient training of personnel in worker and patient radiation protection.

With more particular regard to the radiation protection of workers in surgery rooms, the appraisal underlines a lack of rigour in the use of personal protective equipment and dosimeters, and a shortage of collective protective equipment. As for the radiation protection of patients, it must be pointed out that the radiological devices often do not have systems indicating the radiation doses delivered during the radioguided procedures.

Control of doses delivered to patients in medical imaging examinations is insufficient

Medical exposure to ionising radiation is increasing in the majority of countries (source UNSCEAR). In France, the average effective dose per person as a result of diagnostic radiological examinations increased from 0.83 to 1.3 millisievert (mSv) per year and per person between 2002 and 2007 (source IRSN/InVS, April 2010).

The seminar of 16 September 2010 organised by ASN on this subject showed that the health professionals (radiologists, medical physicists and radiographers) and the Health Authorities and Agencies present widely agree that the principles of justification and optimisation are not adequately applied in conventional radiology and computed tomography. Among the twelve recommendations figuring in the conclusions of the seminar, ASN underlines those aiming at:

ASN inspection of the nuclear medicine department in the North Saint-Denis Cardiology Centre – December 2010

1. encouraging access to magnetic resonance imaging (MRI), through regional planning initiatives and adopting a pricing system that acts as an incentive to use MRI;
2. encouraging the participation of the medical physicist in the optimisation of procedures, the monitoring and evaluation of delivered doses, and image quality;
3. developing training and decision aids for general practitioners and emergency physicians;
4. undertaking quality assurance in radiology and evaluating professional practices, particularly regarding aspects relating to justification;
5. informing patients of the benefits of medical imaging and of the associated risks, and encouraging them to have a proactive approach to their treatment.

Regarding the numbers of medical physicists, ASN considers that the training and recruitment efforts begun in 2008 to cover the urgent needs in radiotherapy must be continued for five years at least so that there are sufficient professionals to satisfy the needs of medical imaging, including in interventional radiology.

Measures must be taken to improve radiation protection in the medical field.

In the light of the results of the inspections carried out in radiotherapy, interventional radiology and nuclear medicine (results published in 2009), the conclusions of the seminar of 16 September 2010, and the recommendations of the GPMED meeting of 23 November 2010 on interventional radiology, ASN adopted two resolutions in June 2011, one concerning the control of doses in medical imaging, the other concerning radiation protection in interventional radiology.

Very generally, ASN considers that radiation protection is improving in radiotherapy thanks to the action stemming from the national plan coordinated by the INCa and the second cancer plan, but that it is essential to make further progress in interventional radiology and computed tomography. Action must therefore be taken to resolve the main weaknesses in radiation protection, which are particularly significant due to their generic nature:
– there are insufficient specialised human resources, with a shortage of medical physicists and persons competent in radiation protection (PCR);
– the training of health professionals is often incomplete, particularly when using new equipment or applying new practices, notably in interventional procedures;
– the organisation of departments in terms of procedural quality and safety is still in its infancy;
– the introduction of clinical audits to evaluate professional practices is very slow, at least as regards the justification and optimisation aspects.

Measures already in progress

In the framework of the national radiotherapy plan, ASN is closely monitoring the situation of the centres still considered vulnerable and is participating in the work to recognise the "dosimetry technician" qualification. It is also helping to prepare a Guide to good practices in medical radiation physics, coordinated by the French Society of Medical Physics (SFPM).

In medical imaging, ASN is also assisting with the updating of the Guide to good medical imaging examination practices (currently in progress with the French Society of Radiology - SFR, and the French National Authority for Health - HAS), the development of decision aids for choosing imaging examinations (on the initiative of SFR) and the development of tools for reducing the doses delivered during computed tomography image acquisition (action by the association HERCA[3] aimed at the manufacturers).

New measures to be implemented in medical imaging in 2011

ASN very recently put forward to the various administrations and professional organisations concerned[4], - with most of whom it has established collaboration framework agreements - the measures it considers necessary at national level to improve radiation protection. These measures are presented below.

3. HERCA : *Heads of European Radiological Protection Competent Authorities*, *www.herca.org*

4. The General Directorate for the Healthcare Offering (DGOS), the General Directorate for Health (DGS), the General Directorate for Labour (DGT), the High Authority for Health (HAS), the French Health Products Safety Agency (AFSSAPS), the National Cancer Institute (INCa) and the learned societes such as the French Society of Radiology (SFR), the French Society for Radiation Oncology SFRO), the French Society for Nuclear Medicine (SFMN), the French Society of Medical Physics(SFPM) and the French Association of Electroradiology Paramedical Staff (AFPPE).

New measures to take

Human resources

• Continue the medical physicist training and recruitment efforts deployed in radiotherapy to cover the medical imaging needs.
• Resolve the problem of insufficient presence of interventional radiology technicians in surgery rooms for radioguided procedures.
• Obtain true "recognition" of the persons competent in radiation protection (PCR) in healthcare establishments.

Equipments

• Develop the fleet of MRI equipment and establish a pricing system that encourages the use of magnetic resonance imaging.
• Render obligatory the installation of a system indicating the emitted dose of radiation (feasibility) on interventional radiology devices put into service before 2004.

Evaluation and quality of practices at national level

Evaluation and quality of practices at national level
• Launch a national initiative to audit the professional practices concerning justification and optimisation, in both radiotherapy and medical imaging.
• Develop the medical imaging quality "initiatives".

Informing the patient

• Continue the efforts to inform patients associations on the safety of radiotherapy treatments, based on the conclusions of the ASN conference in Versailles (December 2009).
• Inform patients of the benefits of medical imaging and of the associated risks, and encourage them to have a proactive approach to their treatment.

Training

• Develop the training of interventional radiology professionals in patient radiation protection.
• Develop technical training in the use of radiology devices, particularly for the acceptance testing of new equipment.
• Produce good practices guides for the most highly irradiating interventional procedures.

International evaluations and research

• Evaluate innovative imaging technologies, new practices and new equipment (radiotherapy) on the basis of user experience feedback.
• Develop a radiosensitivity test for patients, in the framework of a Research and Development project.

Among these measures, ASN emphasises those requiring decisions at national level to coordinate the health policy conducted locally by the Regional Health Agencies (ARS). With regard to human resources, this particularly concerns decisions to take to continue the efforts in the training and recruiting of medical physicists in order to cover the medical imaging needs, including in interventional radiology, but also to remedy the lack of interventional radiology technicians and in the surgery rooms in which radioguided interventions are performed.

Decisions must also be taken with respect to equipments, to ensure the development of the MRI equipment pool and set up a pricing structure that encourages the use of non-irradiating procedures when the justification pleads in their favour.

At European level, ASN actively participates in HERCA's work to optimise computed tomography (CT) doses, by supporting the initiative demanding CT scanner manufacturers to improve the aids for reducing patient exposure while at the same time ensuring diagnostic quality. ASN also recently took action with the European Commission - in agreement with the European Society of Radiology (ESR) - to support an initiative in favour of a European programme for updating the recommended good practices in medical imaging, published in 2004, and the development of electronic decision aids, especially for general practitioners who may have to request these examinations.

Lastly, ASN also pushed the benefits of carrying out an international evaluation of new equipment and practices in radiotherapy, at the IAEA[5]. It is participating in the development of an INES scale[6] for the radiation protection of patients, with the aim of sharing French experience acquired on the basis of the ASN-SFRO scale[7].

Conclusions

Medical applications of ionising radiation hold an important position in the treatment of cancer, in radiology, and in interventional procedures.

Progress in enhancing the safety of radiotherapy has been observed since 2008, but great vigilance remains necessary. Further progress is still necessary and possible in medical imaging to better control the doses delivered to patients in computed tomography and interventional radiology.

The recent efforts focused on patient radiation protection must however not overshadow the need to protect all the medical staff involved in procedures using ionising radiation, particularly in interventional radiology. ■

5. IAEA: International Atomic Energy Agency
6. INES scale: *International Nuclear Event Scale*
7. ASN-SFRO scale: this scale aims at communicating to the public, in clear and understandable terms, on radiation protection events leading to unexpected or unforeseeable effects on patients in the context of a medical radiotherapy procedure. The ASN-SFRO scale can be consulted on the ASN website.

Uses of ionising radiation in medical imaging

by Jean-Luc Godet, Director and **Dr. Thierry Kiffel,**
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Arguing for controlled use of ionising radiation in medicine

Medical applications of ionising radiation continue to develop, notably in imaging, in spite of the development of "competing" non-irradiating techniques. They remain indispensable in the current state of the science.

Given the potential risk of ionising radiation for humans, these techniques must be better controlled by the health professionals to ensure the radiation protection of the personnel and patients alike.

This control should be achievable through better justification and optimisation of the procedures, and the application of rules of good practices.

This article presents the different uses of ionising radiation in medical imaging, their implications in terms of radiation protection, and the applicable regulatory framework[1].

Medical imaging

Medical imaging comprises various techniques that enable the interior of the human body, the structure or function of the organs, to be viewed without directly intervening on them. Medical imaging is used to support a diagnosis or propose a treatment for numerous pathologies, particularly in oncology. Imaging also aids the performance of precise diagnostic and therapeutic actions during interventional procedures, in surgery, cardiology, rheumatology or neurology for example.

The contribution of medical imaging in healthcare from diagnosis through to treatment has become irreplaceable. Recourse to increasingly sophisticated medical imaging, and computed tomography (CT) in particular, improves the quality of diagnosis and allows better targeting of therapeutic strategies and evaluation of treatment effectiveness.

Some of the major scientific discoveries of the 20th century were rapidly applied to medicine.

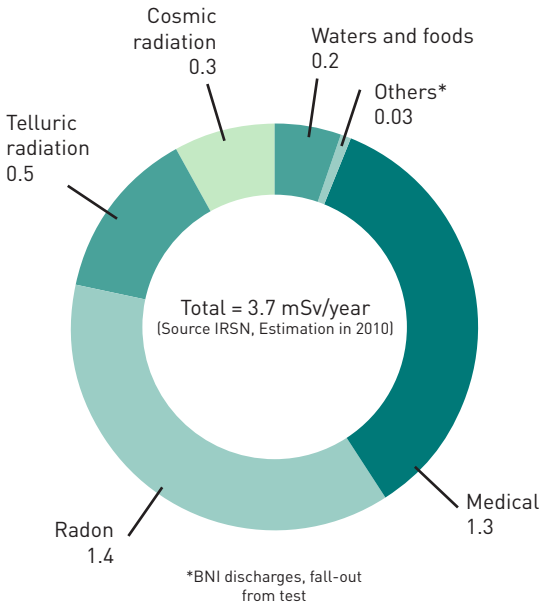
1. This article presents the various medical imaging techniques that use ionising radiation. It does not present the different techniques of using ionising radiation to treat cancers (radiotherapy), such as those used in external beam radiotherapy (particle accelerators), in brachytherapy (sealed internal radioactive sources) or internal vectorised (or targeted) radiotherapy (administration of iodine 131 in nuclear medicine).

Radiology, the oldest of the imaging techniques, was thus rapidly implemented after the discovery of X-rays by W.C. Röntgen in 1895, since the first radiography was produced just 6 weeks after radiation was evidenced. During the same period, the discovery of natural radioactivity by H. Becquerel and P. and M. Curie led to the development of the first therapeutic applications of ionising radiation. The computed tomography (CT) scanner, which also uses X-rays, was invented in the 1970's by A. Mc Cornack and G. N. Hounsfield.

The discovery of artificial radioactivity by I. and F. Joliot-Curie in the 1930's led to the development of nuclear medicine, which saw further advances at the end of the 1990's with the possibility of routinely using positron emitting elements (Positron Emitting Tomography, or PET). The discovery of ultrasound propagation in 1915 ultimately gave I. Edler the idea of the first ultrasound scans in the 1950's. The discovery of the resonance of atomic nuclei in 1945 by E. Purcell and F. Bloch led to the development of nuclear magnetic resonance imaging and spectrometry in the 1980's.

Some of these techniques use ionising radiation. This is the case with radiology - whether conventional, interventional, or using a scanner - and nuclear medicine.

The IRSN (French Institute of Radiation Protection and Nuclear Safety) report published in March 2010 based on data from 2007, describes exposure to ionising radiation of medical origin in France. Some 74.6 million diagnostic procedures were carried out in France in 2007. The average effective dose (AED) is 1.3 mSv per year per person, that is to say an increase of 57% with respect to the level of 2002 evaluated at 0.83 mSv. The increase in AED can be attributed to the higher frequency of procedures using computed tomography (10% of procedures but 58% of the AED) and nuclear medicine (1.6% of procedures and 10% of the AED). Comparison with the available international data shows that medical exposure in France is situated in the average for developed countries.



Dose distribution between the various sources of radiation

Replacing a technique involving exposure to ionising radiation (radiology, CT scanning, nuclear medicine) by one or more non-irradiating techniques (nuclear magnetic resonance imaging, ultrasound scan), though perhaps desirable, is not always possible, due either to the quality of the information obtained or the availability of the techniques in a given place.

Exposure to ionising radiation of medical origin constitutes the second source of population exposure after exposure to natural radiation, and the first source of artificial origin. Only the techniques involving exposure to ionising radiation are mentioned in this article.

Medical imaging practices using ionising radiation

X-rays: radiology, interventional radiology and X-ray computed tomography (CT)

X-rays are attenuated to varying extents by the human body structures they pass through, giving a projected structural image of the explored part of the body, which can be viewed by an analogue (e.g. photographic film) or digital receiver that allows image processing. Some structures (digestive tract, blood vessels) can be rendered opaque by injecting a contrast medium containing iodine to make them more visible.

The scanner uses the same radiation properties, but the image is acquired by combining rotation of the source around the patient with a longitudinal displacement, producing - after computerised reconstruction - human body imaging in cross-sections in the three planes of space or in volume.

Interventional radiology involves using ionising radiation to guide and monitor diagnostic or therapeutic medical procedures, including certain surgical procedures. The imaging, associated with the interventional practices, enables the therapeutic actions to be precisely monitored, to the benefit of the patient (e.g. placement of a stent in interventional cardiology, or the treatment of arteriovenous malformations in interventional neuroradiology). The source of radiation can sometimes be a scanner.

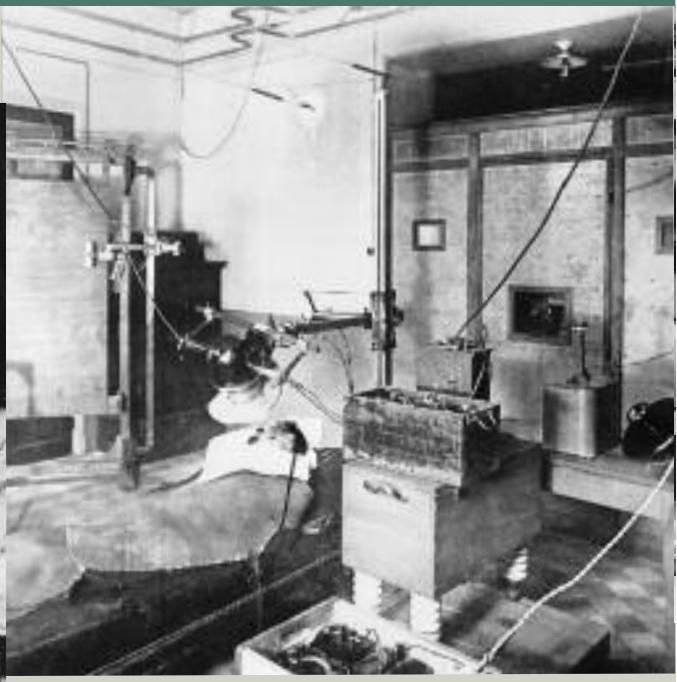
The principle of optimisation means reducing the dose while obtaining the same diagnostic information. It depends not only on improvements in the devices (beam collimation, filtration, improved image processing) but also in medical practices (adaptation according to the patient, mastery of device operation, use of specific acquisition protocols, etc.). Optimisation is of particular importance in interventional radiology, because ionising radiation can cause immediate or delayed deterministic effects (radio-dermatitis, etc.).

Particular attention must be paid to dose optimisation in paediatrics, because the radiosensitivity of children and their longer life expectancy increase the theoretical risk of radio-induced tumours.

Some techniques that are potentially more highly irradiating are in full development (this is the case with coronary CT angiography and CT colonography for example). If their indications are clearly specified and their application is

The German physicist Wilhelm Conrad Roentgen (1845-1923)

Pierre and Marie Curie in their laboratory (between 1890/1906)



X-ray treatment of a cancer patient (1928)

mastered, these techniques can provide the required information just as well as conventional invasive techniques (coronarography or colonoscopy).

In the case of radiology, the radiation protection implications are above all patient-oriented, save in interventional radiology where a double issue must be considered, namely the exposure of the medical personnel (physicians, radiographers, nurses, etc.) and the patient.

Nuclear medicine

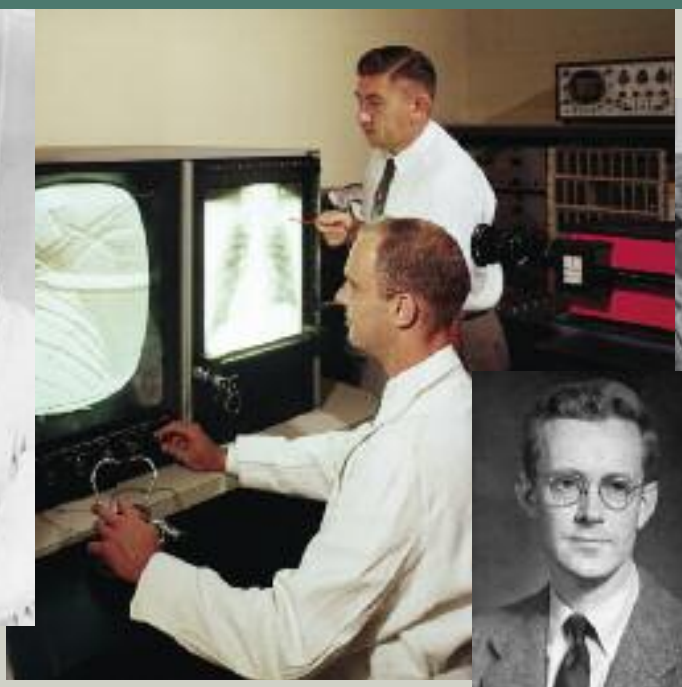
Nuclear medicine uses the administration of radiopharmaceuticals to view the functioning of an organ (heart, lungs, kidneys, bladder, digestive organs, skeleton, thyroid, etc.) or to trace a particular function (marking of white blood cells to detect an infection, for example). The examination is called a scintigraphy scan.

Table 1: Different levels of exposure from medical examinations using ionising radiation

Type of examination	Adult exposure value (effective dose in mSv)
Conventional radiology	
Thorax from front	0.02
Pelvis from front	0.7
Mammography	0.6
Computed tomography (CT scanner)	
Head	1.3
Thorax	9
Abdomen - Pelvic region	10
Heart (angiography by multidetector CT scanner)	8 to 30
Scintigraphy (diagnostic nuclear medicine)	
Skeleton	4
Thyroid (^{99m}Tc)	0. 5
Lungs (ventilation and perfusion)	0.6 +1.1 i.e. 1.7
Cerebral (HMPAO)	3.6
Myocardium with molecules marked with ^{99m}Tc	8
Myocardium with ^{201}Tl	23
PET-Scan	10 to 20

Source IRSN, SFR, SFMN

Frédérick Joliot and Irène Joliot-Curie in their laboratory (1930)



Visualisation of X-rays on IBM 9X08 display (1963)

The doctor Edward Purcell (1952)

The doctor Felix Bloch in laboratory (1952)

Detection is ensured by dedicated instruments called gamma cameras.

The radiopharmaceuticals can be either radioactive nuclei (Iodine 123) or molecules marked with a radioisotope, usually Technetium 99m (99mTc).

These techniques allow the creation of cross-sections of the distribution of the radiopharmaceutical in the human body and a scintigraphic image to be superimposed on a structural image (essentially from a scanner at present) to situate it precisely. The recent development of the use of positron emitters (essentially 18F-deoxyglucose) has led to a large increase in procedures performed using these techniques in numerous applications, notably in oncology.

The radiation protection implications in nuclear medicine concern the patients, especially since procedures using 18F-deoxyglucose have been developed. The patients receive both internal exposure from the administration of a radiopharmaceutical and external exposure from the use of CT scanners. The radiation protection issue for the medical personnel is to minimise exposure of the hands during preparation and administration of the radiopharmaceutical.

The fundamental principles of radiation protection: justification, optimisation and limitation

The European directives[2] transposed into French law (Public Health Code and Labour Code) have set forth the three fundamental principles of radiation protection, notably in the medical field. The principle of dose limitation applies to medical workers, not to patients (article L.1333-1 of the Public Health Code).

Justification

"A nuclear activity or a medical procedure can only be undertaken or carried out if its health, social, economic or scientific benefits outweigh the risks inherent to the human exposure to ionising radiation that it is likely to entail".

Although the use of ionising radiation in medicine is not questioned, it is absolutely necessary for each technique to be justified through precise indications and for application to be individually justified for each patient. The individual justification is based more specifically on application of the guides to appropriate procedures, knowledge of the different medical imaging techniques, and a benefit-risk assessment. In the medical field it is essential for the justification to be traceable, through written correspondence between the referring physician (referral letter requesting the examination and specifying its purpose) and the physician performing the procedure (drawing up a medical report).

Optimisation (ALARA)[3]

"Human exposure to ionising radiation as a result of a nuclear activity or medical procedure must be kept as low as reasonably achievable, given current technology, economic and social factors and, where applicable, the intended medical purpose."

The diagnostic examination must answer the questions posed by the physician requesting the procedure, using the smallest quantity of radiation reasonably possible. The resulting image must be of sufficient quality to permit a diagnosis without necessarily seeking the "top quality image" that would involve exposing the patient to higher levels of radiation.

Optimisation, which also has a strong impact on the radiation protection of both patients and personnel (particularly in interventional radiology), depends on the quality of the examination protocols, monitoring of delivered doses, and training of the staff involved in the examinations.

2. The Council Directive 96/29 Euratom of 13 May 1996 laying down basic safety standards for the protection of health of workers and the general public against the dangers arising from ionising radiation, and Council Directive 97/43 Euratom 97/43 of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure.

3. As Low As Reasonably Achievable

Limitation

"Exposure of an individual to ionising radiation as a result of a nuclear activity may not increase the sum of the doses received beyond the limits set by regulations, except when the individual is exposed for medical or biomedical research purposes."

Medical professionals benefit from the social security protection defined by the labour code for workers likely to be exposed to ionising radiation. On this account they are monitored by the occupational medicine services, and above all their exposure must be below the regulatory limits for workers (for whole body and extremity doses).

Although it is rare for the regulatory limits to be exceeded in conventional radiology and computed tomography, operators working in interventional radiology can approach and sometimes exceed these limits, justifying tightened monitoring, particularly in dosimetry of the extremities.

Some particular points

The installation and facility registration or licensing system

Computed tomography and nuclear medicine are activities subject to licensing by ASN. The other activities are subject to registration (articles R.1333-19, R.1333-23 and R.1333-34 of the Public Health Code). The registration and licence applications are transmitted to ASN.

Worker occupational exposure

a. Regulatory limits

(See table 2)

b. Role of the person competent in radiation protection

The person competent in radiation protection (PCR) is designated by the employer of persons exposed to ionising radiation in their work context. Reporting to the employer, the PCR helps produce the registration or license application file, assesses the nature and extent of the risks to which the workers are exposed, and helps organise the radiation protection (participation in workstation analyses, in defining dose objectives, in delimiting controlled access areas, verifying the appropriateness of the protective measures applied, etc.). The PCR carries out the internal checks on radiation protection and tracks the performance of external checks of radiation protection by an approved organisation. The PCR monitors worker occupational exposure (setting up and monitoring a dose measurement system adapted to the exposure of workers as prescribed by the occupational medicine service). The PCR also helps define and implement training in worker safety with regard to occupational exposure, and participates in the management of cases where worker exposure limits are exceeded.

The PCR reports to the employer, but works in collaboration with the Committee for Health, Safety and Work Conditions (CHSCT), the occupational physician, the approved organisations, the IRSN and the Authorities.

The training of PCRs is regulated by the order of 26 October 2005 amended by the order of 21 October 2007, in application of the labour code. Updating is currently in progress on the basis of the recommendations of the Advisory Committee for radiation protection in industry and research (GPRAD) meeting of 14 April 2010.

c. Worker classification and dose monitoring

In order to determine worker radiological and medical monitoring conditions, the employer - after consulting the occupational medicine service - defines each worker's category. This classification is based on the workstation analysis, which aims at assessing worker exposure levels. The categories (A and B) correspond to the dose levels likely to be received. Pregnant women, students and apprentices aged under 18 are prohibited from carrying out work classified in category A.

Any person working in a controlled access area is subject to personal and nominative dose monitoring corresponding to the risks entailed by the job. Nuclear medicine workers can be subject to internal contamination measurement (whole-body radiation measurement and/or radiotoxicological urine analyses).

Whenever work is carried out in particular areas called "controlled access areas", the passive dosimetry is supplemented by active (operational) dosimetry using dosimeters with alarm thresholds, allowing the received doses to be integrated and read in real time.

Table 2: Regulatory dose limits for ionising radiation

	Whole-body effective dose	Equivalent dose limit at extremities (hands, forearms, etc.)	Equivalent dose limit at lens of eye	Equivalent dose limit on skin (1 cm^2)
General public	1 mSv/year			
Workers	20 mSv/year	500 mSv/year	150 mSv/year	500 mSv/year
Pregnant woman	Less than 1 mSv equivalent dose to the foetus between confirmation of pregnancy and childbirth			

These dose limits do not apply to exposure resulting from medical examinations.

When performing an activity that exposes the extremities (fingers), the employer must implement appropriate additional means of dose measurement (dosimeter rings for example).

All the dosimetric data are recorded in SISERI, a national database managed by the IRSN.

Each worker classified in category A or B must hold a personal medical monitoring card delivered by the person's occupational physician.

d. Personnel training

In compliance with the Labour Code, workers likely to be exposed must receive training in the specific risk associated with the use of ionisation radiation.

Patient radiation protection

a. Diagnostic Reference Levels

Diagnostic reference levels (DRLs) represent one of the tools for optimising doses delivered to patients. Provided for in article R.1333-68 of the Public Health Code, the DRLs were defined by the order of 12 February 2004. In radiology the DRLs are dose values, whereas in nuclear medicine they are administered activities, which are established for the most common examinations or those involving the highest dose levels. Periodic measurements or recordings - depending on the type of examination - are taken in each radiology and nuclear medicine department and centralised at the IRSN, so that these reference levels can be updated. The DRLs published in the appendix to the order of 12 February 2004 are currently being updated.

b. Medical physicist

Optimising the doses delivered to patients through medical imaging procedures requires particular skills in medical physics. The obligation to have a medical physicist present, as was already the case in radiotherapy and nuclear medicine, has been extended to radiology.

The duties of medical physicists have been clarified and extended (amended order of 19 November 2004). The medical physicist must thus ensure that the equipment, the data and the calculation procedures used to determine and deliver the doses and activities administered to the patient in any procedure involving exposure to ionising radiation are appropriate. In radiotherapy more particularly, the medical physicist guarantees that the radiation dose received by the exposed tissues corresponds to that prescribed by the referring physician. The medical physicist also estimates the dose received by the patient during the diagnostic procedures and contributes to quality assurance, including quality control of medical devices. Lastly, the medical physicist takes part in the teaching and training of medical and paramedical staff in medical radiation physics.

Since 2005, heads of establishments must draw up a medical radiation physics plan defining the means to implement, notably in terms of staff numbers, taking account of the medical procedures performed, the actual or potential number of patient entries, the existing dosimetry skills, and the applied means of quality assurance and control. In 2011, ASN published a review of the content of medical physics organisation plans.

c. Staff training

In application of the Public Health Code, personnel involved in the medical exposure of patients to ionising radiation must receive training in patient radiation protection with 10-year validity (order of 18 May 2004 amended by the order of 22 September 2006).

Notification of significant events to ASN

Pursuant to articles L.1333-1 and L.1333-3 of the public health code, the persons responsible for a "nuclear activity" are under the obligation to notify ASN and the State representative in the administrative region of "any radiation protection incident or accident that could harm the health of individuals through exposure to ionising radiation".

Furthermore, Act 2009-879 of 21 July 2009 on hospital reforms and relating to patients, health and the regions, specifies that "health professionals participating in the treatment or monitoring of patients exposed to ionising radiation for medical purposes, who are aware of an incident or accident associated with this exposure, shall notify ASN and the general director of the Regional Health Agency of the event without delay". ■

NATIONAL INITIATIVES

Ministry of Health and regional health agencies measures for medical imaging

by Annie Podeur, General Director of the General Directorate of Health Care, Ministry of Labour, Employment and Health

Medical imaging raises major issues given its key position in determining the therapeutic strategy (diagnosis, adaptation of treatments and interventional procedures), the technological advances in the field and the costs that the examinations represent.

Societal expectations and technological trends have a direct influence on the medical imaging demand, with growing needs linked in particular to population ageing, with a predominance of neuro-degenerative, bone and cardiavascular diseases, and cancers. The development of diagnostic and therapeutic treatments using medical imaging, the obligation to guarantee good practices and correct usage of equipment, the need for alternative procedures, as well as the complementary nature of the techniques, implies tailoring the supply more closely to the demand.

The major issues in medical imaging are:

- improved access to slice imaging, and to magnetic resonance imaging (MRI) in priority. In France, outpatient waiting times for MRI appointments are still too long (median time of 21 days - source: French national agency for supporting medical institution performance (ANAP) benchmark) and there are large geographical disparities that represent a potential loss of opportunity for patients;

- availability of facilities that meets the needs associated with the major public health problems (cancer, cerebrovascular accident (stroke), neurology). Excessive variations in the geographical distribution of facilities and between the public hospital and private sectors in terms of equipment and medical and paramedical personnel resources, make it impossible to provide a totally equitable response to public health issues;

- appropriate and efficient examinations (cost/results ratio), in line with the recommendations of the French National Authority for Health (HAS), notably by reducing the number of unjustified examinations and making fair use of medical imaging platforms(device volume and utilisation time);

- a reduction in patient exposure to ionising radiation, failing sufficient replacement by alternative non-irradiating techniques (excessive use of conventional radiology and increase in doses from computed tomography scanning). This reduction in exposure applies in priority to children and pregnant women;

- a major issue of regional structuring of the health care offer: defining a grading for the technical platforms helps structure the health care activities, and vice versa (example in the field of oncology). The strategy governing the location of the imaging equipment is determinant in terms of regulation and efficiency. It implies cooperative measures favouring the sharing of facilities and equipment (private unit-hospital and public-private networking).

The development of efficient medical imaging is a national priority fostered by the Ministry of Labour, Employment and Health, and by Health Insurance, and is one of the priority risk management programmes for the period 2010-2013 intended to optimise public expenditure. The measures taken aim at speeding up the replacement of irradiating techniques (conventional radiology and computed tomography) and improving accessibility of MRI examinations for patients throughout France.

Medical imaging efficiency at an affordable cost depends jointly on the appropriateness of the indication, the organisational effectiveness of the available service (choice and distribution of equipment, organisation of teams, collaborations, out-of-hours (OOH) care, use of telemedicine, etc.), and the accessibility and quality/safety of the examination. As indicated by the Cour des Comptes (Government Court of Auditors), controlling the development of the availability of medical imaging resources relies on a necessary overall consistency between the various regulation levers and the performance of the care providers in strict compliance with the national health insurance expenditure objectives. Optimising the activities of the imaging platforms justifies the mutualisation of medical resources.

In 2011, 683 MRI licenses are expected when the 3rd regional health organisation scheme (SROS3) reaches term, which represents a 45% increase in licenses between 2006 and 2011 (CT scanners increased by 35% over the same period). On 31 December 2009, of the 619 MRI devices licensed in France, 531 were installed, that is to say 86% of the licenses delivered by the end of 2009.

Under the SROS-PRS (regional health organisation scheme - regional health project), the Regional Health Agencies (ARS) are required to continue this development and mobilise all necessary means to meet the national objectives of improving access to slice imaging (giving priority to the development of MRI in compliance with the good practices and radiation protection recommendations), reducing inequalities in access and efficiency of care providers in the field of imaging. The regional health agencies are responsible for defining the regional networking, with imaging platform grading identifying the means necessary - particularly in terms of cooperation - to better satisfy the needs and ensure OOH services.

In terms of cooperation, the general director of the ARS already has tools in the framework of the "Hospital,

Conventional radiology examination

Patients, Health and Territories" (HPST) act, for optimising the regional organisation of the imaging platforms. Thus, article L.6133-1 of the Public Health Code provides for the setting up of health resource cooperation groups, the purpose of which is to facilitate, develop or improve the activity of its members, and notably for the joint management of equipment classified as "EML" (high-tech/high-cost equipment), to allow joint interventions of medical and non-medical professionals exercising in member health establishments or centres, and private professional members of the group.

In the methodological guide for the future regional healthcare organisation schemes 2011-2016, issued to the Regional Health Agencies on 24 February 2011, the General Directorate for Health Care defined the national orientations for medical imaging which more specifically target the equipment that is subject to authorisation (CT, MRI, and PET scanners) and regional installation objectives.

Improving access to care and reducing its inequalities:
- speed up the use of MRI in place of irradiating imaging techniques, for adults and above all children, in line with the good practice standards of the National Health Authority (HAS), with ASN's radiation protection recommendations, and with the MRI access improvement objectives of the national public health plans (cancer plan, stroke plan, Alzheimer plan);
- develop and diversify the MRI fleet (replacement of the existing fleet and new devices) under the following conditions:
• prioritise permanent access to MRI scanning for sites treating paediatric emergencies, strokes in the acute phase, and having (or scheduled to have) a neurovascular unit
• facilitate access to cancer diagnosis and surveillance by providing MRI with time slots or machines dedicated to oncology, allowing, for example, shared usage research programmes between university hospitals (CHU) and cancer treatment centres (CLCC);
• evaluate the need for additional devices on imaging platforms already equipped with an MRI that has reached its workload limit, notably the installation of machines dedicated to emergencies on sites with more than 30,000 to 40,000 accident and emergency (A&E) admittances per year.
- define an imaging platform grading system per health area to guide the installation choices : identify the needs in types and number of high-risk equipment per technical platform

level, taking into account the conditions of access (participation in OOH care, size of the team, level of specialisation);
- improve access to unscheduled imaging in relation with the emergencies network, the regional organisation of OOH care in health establishments, cooperative efforts using telemedicine among other things;
- encourage MRI access to all medical imaging professionals, or beyond this if necessary, through close private unit-hospital networking favouring resource mutualisation;
- guarantee the affordability of MRI and CT scan examinations per health area at sector1 tariffs ;
- identify the interventional therapeutic procedures using imaging equipment.

Improving health care quality and safety:
- diversify the categories of MRI machines according to the patient's topography and/or pathology, so that specific solutions can be proposed for osteoarticular diagnostic examinations and the treatment of certain population categories (children, pregnant women, obese persons, persons with handicaps and/or prostheses or implants);
- upgrade the fleet of CT and PET scanners to reduce patient exposure to ionising radiation and guarantee utilisation in accordance with the guide to good practices for imaging examinations;
- distribute the good practices guide for imaging examinations to the persons prescribing and performing them, to all the private unit-hospital healthcare professionals, and the general public through information campaigns.

Improving efficiency:
- balance and optimise machine productivity by increasing the mutualisation of available human resources (radiologists and radiographers) in order to extend the operational time slots and ensure permanent access for sites ensuring health care continuity;
- use the organisational tools of the ANAP (French national agency for supporting medical institution performance) to identify the major lines of improvement of the internal organisations of imaging technical platforms and regional cooperation with a view to optimising the examination procedures and management of the time of the imaging professionals;
- improve the access of hospitalised persons to imaging examinations in order to reduce the significant average dose;
- have a regional observatory to monitor and assess waiting times for consultation appointments.

Key points to study with the preventive care and socio-medical services:
- consider the specific imaging examination needs of the populations in socio-medical care (aged or disabled persons), where adaptation of access conditions is necessary;
- extend circulation of the Good practices guide for imaging examinations to all the health authority, hospital and socio-medical actors and to the general public.

The recommendations of the HAS (French National Authority for Health) expected in 2011 on the judicious use of imaging examinations, and MRI examinations in particular, will specify the needs and the development and diversification targets for the MRI equipment fleet.

It should be noted that MRI cannot fully substitute for computed tomography (CT) examinations, which are necessary for certain specific indications, in cardiology for example. Furthermore, the coupling of CT scanning and MRI is desirable in the gradation of the technical support centres, and notably for ensuring OOH services. In addition to this, technological developments in CT scanners enable radiation doses to be progressively reduced.

Innovations come particularly rapidly in medical imaging, and they must be promoted by seeking the benefit for patients and conducting medico-economic evaluations before they are disseminated. Imaging was thus selected as the first topic for the "Matinées de la Prospective" (roundtables for the future) organised by the DGOS (General Directorate for the Healthcare Offering) on 16 March 2011. Attended by manufacturers and professionals from the imaging field, it provided a forum for forward-looking discussions on the future of imaging in France five , ten and fifteen years hence, with a view to constantly adapting the offering. ■

NATIONAL INITIATIVES

CE marking of medical devices emitting ionising radiation

by Gérard Berthier, Assistant to the Director, and Jean-Claude Ghislain, Director of Medical Device Assessment – AFSSAPS (French Health and Product Safety Agency)

Releasing medical radiology devices to the market is governed by Directive 93/42/EEC, called the "New approach". This directive was revised by directive 2007/47/EC. The Directive 97/43/Euratom for its part concerns the utilisation of these devices. Reconciling these two regulations can lead to difficulties.

The "New approach"

In the 1980s, the European Commission was having difficulty in constituting the "Single market". Harmonisation of the technical standards existing in the member States, such as the approval of medical products and devices in France, was vital to eliminate the technical barriers to the exchange of goods within the community.

The Commission first started a harmonisation process applying what became known as the "Old approach", which consisted in defining in EC legislation all the detailed technical requirements per product category. It also used European and internationals standards, but mainly for the test methods. This avenue finally proved unfeasible, given the number and diversity of the product categories concerned and the difficulty in reconciling different technical systems.

Consequently, on 7 May 1985 the European Council adopted a resolution instituting a "New approach" in technical harmonisation and standardisation based on four principles:

- legislative harmonisation was limited to the adoption - through directives based on article 100 of the EEC treaty - of the essential safety requirements for marketed products, hence allowing them free circulation within the Community;

- the drafting of the technical specifications needed by the professionals in order to produce and market products that comply with the essential requirements set out in the directives, was entrusted to the competent industrial standards bodies;

- these technical specifications were voluntary standards and their application was in no way mandatory;

- but at the same however, the administrations were obliged to recognise - in the products manufactured in accordance with the harmonised standards - a presumption of conformity with the essential requirements set out by the directive. This also meant that producers were free not to manufacture in accordance with the standards, but in this case, they were responsible for proving the conformity of their products with the essential requirements of the directive.

Mammography examination

The EC marking applied to the product by the manufacturer certifies conformity with the essential requirements set by each of the directives of the "New approach". It is the passport necessary for the product to be put on the market in all the member states of the European Union. Today, many product sectors enter into the scope of the "New approach": toys, machines, pressure equipment, electrical, electronic and gas appliances, information and telecommunications technologies, air traffic, rail traffic, boats, metrology, explosives and pyrotechnical articles, materials used on the exterior of buildings, etc.

Medical devices stand apart in this extremely diverse list, as in the early 1990's some felt that the "New approach" was inappropriate for products relating directly to human health.

Directive 93/42/EEC

The medical field covers a huge variety of products, from condoms to magnetic resonance imaging (MRI) scanners. Defining essential health and safety requirements that are appropriate for all the possible technological and medical situations, therefore constitutes a seemingly impossible challenge, and is assuredly an exceptional intellectual feat, whose sole limit is the necessarily generic nature of the requirements adopted.

Medical radiology devices represent a particularly complex case: they often meet the definition of "machine" as given in Directive 2006/42/EC; they are active medical devices because they require an electrical power source to function, they integrate numerous electronic components and are therefore subject to rules of electromagnetic compatibility; their operation is also software-dependent, notably for the production of the images interpreted by the radiologists, and lastly and above all, they emit ionising radiation which places them under the scope of Directive 97/43/Euratom, for which it must be mentioned that paragraph 8 of article 1 of Directive 93/42/EEC specifies that the provisions of the medical devices directive are not an obstruction to application of Directive 97/43/Euratom.

Consequently, medical radiological devices are concerned by many essential health and safety requirements specified in appendix I of Directive 93/42/EEC. As an example, with regard to radiation protection, these devices must comply with requirements 11.1.1, 11.5.1 and 11.5.2:

11.1.1 - The devices shall be designed and manufactured in such a way that exposure of patients, users and other persons shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic or diagnostic purposes.

11.5.1 - Devices intended to emit ionising radiation must be designed and manufactured in such as way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can varied and controlled taking into account the intended use.

11.5.2 - Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.

These general requirements are clarified by a whole collection of harmonised European standards directly transposed by the CENELEC[1] from the international standards drafted by the IEC[2], and notably the collateral standard EN 601-1-1-3 "General rules for radiation protection in diagnostic X-ray equipment" and the vertical standards in the EN 60601-1-2 series devoted to the different types of medical radiology devices:

Partie 2.7 : Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators.

Part 2.28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis.

Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures.

Part 2.44: Particular requirements for the safety of X-ray equipment for computed tomography.

Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices.

Part 2.54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and fluoroscopy.

Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment.

Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment.

Conformity with the essential requirements is established by carrying out conformity certification procedures. These procedures have the same typology for all the "New approach" directives. The complexity of the procedure to prove conformity with the essential requirements depends on the potential hazards the equipment can represent.

- **Appendix II:** complete quality assurance system;
- **Point 4 of appendix II:** product design review;
- **Appendix III:** type review;
- **Appendix IV:** verification of manufactured medical device type conformity;
- **Appendix V:** production quality assurance;
- **Appendix VI:** product quality assurance;
- **Appendix VII:** EC declaration of conformity.

Medical radiology equipment falls into class IIb category of medical devices, in a scale of increasing risks from I to III. For this type of device the manufacturer can adopt either the procedure provided for in appendix II excluding point four, or that provided for in appendix III combined with those provided for in appendices IV or V or VI. If the manufacturer chooses the first procedure, which is the most frequent situation, there is no real device design review.

This is because in this case, the main task of the notified organisation responsible for assessing conformity with the essential requirements, is to certify the manufacturer's quality management system, which must cover the design,

1. European Committee for Electrotechnical Standardization.
2. International Electrotechnical Commission.

manufacture and final inspection of the products concerned, with the assessment focusing more particularly on the procedures implemented to inspect and verify product design.

Directive 2007/47/EC, which amends Directive 93/42/EEC, tightens the quality management system assessment requirements, among other things.

Directive 2007/47/EC

Directive 93/42/EEC - which was adopted in June 1993 and came definitively into force in 1998 - provided for its own amendment, which followed extensive consultation of the competent Authorities of the member States to assess its application. Directive 2007/47/EC, which amends the 1993 Directive, was adopted by the European Parliament and Council of the European Union in September 2007 and came definitively into force in March 2010.

Medical radiology devices are concerned by a number of advances, and notably:
- the change in the definition of medical devices, which now covers independent software that has a medical end-purpose, such as diagnostic software for radiological applications;
- conformity with the essential requirements of the "Machines" directive if they are more stringent that the requirements of the "MD" directive;
- the addition of an essential requirement concerning the requirement for the manufacturer to provide the information allowing the MD to be used correctly and completely safely, taking account of the training and knowledge of the potential users;
- extension of the need for the conformity with the essential requirements and the acceptability of the risk-benefit ratio to be based on clinical data;
- extension of the quality management system assessment to the documents, data and records resulting from the product design procedures put in place;
- extension of the manufacturer's surveillance after putting a product on the market to include the collection of clinical data.

Even if Directive 2007/47/EC does not institute a true evaluation of the design of devices whose manufacturers opted for appendix II excluding point 4, the tightening of the quality management system assessment requirements should allow a better evaluation of the design of medical radiology devices.

Directive 97/43/Euratom

Directive 97/43/Euratom institutes rules aiming to protect individuals against the dangers of ionising radiation in relation to medical exposure. This directive chiefly concerns the licensed operators of radiological installations and their users. It notably covers the acceptance of the equipment items and the verification of their performance throughout the life cycle.

Although based essentially on the principle of the justification of using X-rays for diagnostic and therapeutic procedures, and on the optimisation of the delivered dose when medical exposure of individuals is justified, Directive 97/43/Euratom nonetheless contains provisions that more particularly concern devices emitting ionising radiation:

Article 8 : Equipments

The measures that may be considered necessary to avoid unnecessary proliferation of radiological equipment must be taken.
All radiological equipment in service must be kept under strict surveillance regarding radiation protection.
An up-do-date inventory of the radiological equipment for each radiological installation must be available to the competent authorities.
Appropriate quality assurance programmes (quality control measures, patient dose or administered activity assessments) must be implemented by the holder of radiological installation.
Acceptance testing must be carried out before the first use of the equipment for clinical purposes, and performance testing on a regular basis and after any major maintenance procedure.
Fluoroscopic examinations without using image intensification or an equivalent technique are prohibited.
Fluoroscopic examinations without devices to control the dose rate shall limited to justified circumstances.
If new radiodiagnostic equipment is used, it shall, where practicable, have a device informing the practitioner of the quantity of radiation produced by the equipment during the radiological procedure.

Pursuant to Directive 97/47/Euratom, decree 2004-547 of 15 June 2004 makes it obligatory for radiology equipment to have a device that can inform the user of the quantity of ionising radiation produced by the equipment during the radiological procedure. This provision only concerns equipment put onto the market after publication of the decree, which raises the problem of the installed fleet.

Decree 2001-1154 of 5 December 2001 and the Order of 3 March 2003 institute the obligation to ensure maintenance and quality control of medical radiology equipment in France:

For the medical devices mentioned in Article R. 5212-26 of the Public Health Code, the licensee is obliged:

1. To have a regularly updated inventory of the devices it operates, indicating for each one the common and commercial designations, the name of the manufacturer and the supplier, the serial number, its location and the date of first entry into service;
2. To define and implement an organisation to ensure performance of the maintenance and the internal or external quality inspection of the devices, the conditions of which are specified and transcribed in a document. In the healthcare facilities and inter-hospital syndicates mentioned in article R. 5212-12, the organisation is adopted taking account of the opinion of the advisory medical authorities; in the healthcare cooperative groups

mentioned in article R. 5212-12, this organisation is defined in the group's founding agreement; this organisation is made known to the users; changes in this organisation entail document updating without delay;
3. To have information for assessing the measures adopted for the organisation of maintenance, of the internal or external quality control, and their conditions of performance;
4. To implement the quality control provided for in article R. 5212-27;
5. To keep an up-to-date register for each device, recording all the maintenance and internal or external quality control operations, and indicating in each case the identity of the person who performed them and, if applicable, the person's employer, the date the operations were performed and, if applicable, the date of stopping and restarting of operation in the event of nonconformity, the nature of these operations, the performance levels obtained, and the decision on the conformity of the medical device; this register is kept for five years after withdrawal of the device from service, save special provisions decided by the Director-General of the AFSSAPS (French Health and Products Safety Agency) for certain categories of devices;
6. To allow any person responsible for maintenance or quality control operations to have access to the medical devices and the information provided for in this article.

Between 2003 and 2008, the AFSSAPS thus gradually put in place the quality control reference standards covering the majority of the medical radiology devices used in France, and delivered some fifty accreditations to independent organisations responsible for external quality control.

The contractual discrepancy

Although the regulatory provisions for the quality control of medical radiology devices generally include an external quality control before they are used routinely, their acceptance and subsequent utilisation represents a discrepancy between the European directives concerning the marketing of medical devices and radiation protection.

Medical radiology devices are durable operating assets. After acceptance of the assets, ownership is transferred from the supplier to the operator. Generally speaking, the purchaser is protected against hidden defects for a one-year guarantee period. Once this guarantee period has expired, maintenance of the device is the responsibility of the licensed operator under the regulations stipulated above. The same goes for the use of the device, which usually requires specific training, and this is not governed by any specific regulations.

Article 2 of Directive 93/42/EEC specifies that *"Member States shall take all necessary steps to ensure that devices may be placed on the market and put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose",* which means that the manufacturer can only be held liable, if applicable, on this four-fold condition.

Acceptance, post-guarantee maintenance and user training must therefore necessarily be governed by the contract. The security of acceptance and subsequent operation of the device therefore depends on the quality of drafting of the contract and its performance.

Action of the European association HERCA towards computed tomography scanners

HERCA *(Head of European Radiological Protection Competent Authorities)* was created in 2007 on the initiative of ASN. One of the aims of this association is to try to harmonise radiation protection practices in Europe on the basis of a voluntary commitment of its members. HERCA deals with all questions concerning the radiation protection of individuals (public, workers and patients) and protection of the environment against the effects of ionising radiation.
HERCA currently has five working groups, one of which is dedicated to medical applications of ionising radiation.
This group is focusing more specifically on the problems associated with the radiation protection of patients in medical imaging. The group members are currently reflecting on ways of promoting the optimisation of the use of radiation in imaging. The increase in doses delivered by CT scanning at national and international level has led this working group to approach four CT scanner manufacturers (General Electric, Siemens, Toshiba and Philips) to incite them to take commitments to develop benchmarking tools to characterise and compare scanner performance in terms of dose and image quality, to continue to introduce aids to reduce the dose delivered during CT image acquisition, to give the users means of monitoring, recording and comparing the doses delivered, and to provide specific training for the users.
With this aim in view, representatives of the medical applications working group have had several meetings with representatives of the four manufacturers, who are also represented by COCIR *(European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry).* HERCA has moreover had contacts with the FDA *(Food and Drug Administration, USA)* and the NCRP *(National Council on Radiation protection and measurements, USA),* who have begun a similar reflection in the United States. ■

Viewpoint of the SNITEM (National Union of the Medical Technologies Industry) on interventional radiology

The problem concerns the possible appearance of immediate or latest deterministic effects on the skin for long procedures (peak skin dose > 1 Gray), which necessitates real-time dose management for the duration of the procedure.

The dose received during a procedure depends partly on the technology but also on the operator, who must, for example, position the detector as close as possible to the patient.

There are several means of reducing the delivered doses:
- manual or virtual beam collimation;
- flexible image acquisition protocols that allow operators to adjust the dose delivered to the patient;
- system ergonomics (controls on the examination table, touch sensitive differentiator) reducing procedure times;
- operator alarms (dose at which predictable adverse effects can arise);
- display of last image acquired;
- automatic or manual beam filtering;
- for paediatrics, additional filtering and retraction of the anti-scatter grid;
- varying the imaging rate.

The DICOM SR standard now enables the information on the dose level of an examination, or even the total dose delivered to a patient during a stay, to be automated and rendered systematic. ■

Conclusion

Two serious incidents have occurred in succession in the external radiotherapy sector in France, leading the Authorities to implement a series of measures to enhance the safety of radiotherapy practices. The AFSSAPS has published recommendations with a view to improving the conditions of acceptance testing of equipment used in this field. More recently, on the recommendations of an ad hoc working group, ASN and the AFSSAPS have referred the discrepancy that exists between the Directives 93/42/EEC and 97/43/Euratom regarding medical devices used in external radiotherapy to the attention of the European Commission.

Other incidents in interventional radiology have also shown the need for better coordination between the marketing, the acceptance testing and the utilisation of medical radiology devices. The question of whether it is necessary to tighten the regulations in these fields is therefore raised. ■

INTERNATIONAL INITIATIVES

Actions of the French Society of Radiology (SFR) in the field of radiation protection

by le Prof. Hubert Ducou Le Pointe, Radiology Department, Armand-Trousseau Children's Hospital – Paris

The French Society of Radiology (SFR) is the learned society for radiology. It has created a "radiation protection" working group, with members from the different radiology sub-specialities. It reflects the unity of the profession and the common will to ensure progress in radiation protection.

Drafting and publishing guides and recommendations

The French Public Health Code (CSP), transposing the European Directive 97/43 Euratom, imposes a set of rules for the radiation protection of patients. The regulations make it obligatory for the practitioners prescribing or carrying out medical imaging examinations that use ionising radiation, to apply two principles of radiation protection, namely justification and optimisation. Justification of the procedures is the first principle of radiation protection: this is the operation that establishes the net benefit of an examination with respect to the potential harm from exposure to ionising radiation. Optimisation of practices is the second principle of radiation protection. When an examination that uses ionising radiation is justified (necessary), it must be optimised: this means obtaining the desired diagnostic information using the lowest possible exposure dose.

The Guide to good medical imaging examination practices is an essential tool for the practical implementation of the justification principle. It is intended for all health professionals who are authorised to prescribe or perform medical imaging examinations. Apart from the radiation protection aspects, this guide is designed to improve the streamlining of practices, interdisciplinary exchanges, and the organisation of clinical audits. It enables patient exposure to be reduced by eliminating unnecessary imaging examinations, by favouring the use of non-irradiating techniques (ultrasound imaging, magnetic resonance imaging). The first issue of this guide, which is currently being updated, was produced in 2005 in partnership with the SFBMN (French Society for Biophysics and Nuclear Medicine, with the collaboration of the HAS (French National Authority for Health) and the support of the former DGSNR (General Directorate for Nuclear Safety and Radiation Protection), now ASN.

Two guides cover the methods of optimisation in radiology provided for in article R. 1333.71 of the Public Health Code:

- the Guide to radiological procedures: criteria, quality and dose optimisation. It contains written procedures for the most common radiological examinations (127 protocols) in conventional radiology, computed tomography, interventional radiology and paediatric radiology, the particular precautions required in case of actual or possible pregnancy, the most common examination reference levels and recommendations for reducing irradiation doses. It is planned to update this guide;

- the Practical guide for radiologist to evaluate their professional practices, which proposes appropriate ways of performing and interpreting the most frequently practised imaging examinations. It contains 400 items for which there is a professional consensus established in accordance with the formal consensus of experts method defined by the HAS. This guide was published in 2009.

The SFR has supported the action of the SFNR (French Society of Neuroradiology) which published recommendations to optimise radiological procedures in vascular interventional radiology. Most of the pathologies treated using these techniques (vascular malformations of the brain or spinal cord, treatment of ischemic cerebrovascular accidents) are extremely severe and threaten the patient's life or functional prognosis. Though it does not seem possible to define standardised protocols for procedures in interventional neuroradiology, it is nevertheless essential to define recommendations to optimise them.

In 2011 the FRI (Federation of Interventional Radiology) and the SFR will publish a practical guide for interventional radiologists. This guide aims to set forth the general rules and principles, the constraints and the pre-requisites for the exercise of interventional radiology. It will propose technical sheets by broad category of intervention, which will be available on the SFR web site.

Organising continuous medical training and promoting research into it

The initial theory training for radiologists is the responsibility of the University and the French College of Radiology Teachers (CERF). In the field of radiation protection, the CERF wanted the future professionals to receive teaching of a high and uniform standard. It thus proposes a national course in radiation protection that is compulsory for interns and leads to a national exam.

Continuous professional medical training has always been an ethical obligation, and since 1996 it is also a legal obligation. This obligation was stepped up in 2004 with the evaluation of professional practices (EPP). The "Hospital, patient, health, territory" (HPST) Act of July 2009 supplemented these obligations by introducing the notion of continuous professional development (CPD), which is planned to be in place by January 2012.

The SFR and its regional delegations are also involved in continuous medical training in new technologies and their optimisation: creation of working groups (CT[1], MRI[2], radiation protection, etc.), organisation of scientific or continuous medical training evenings. Several regional delegations have taken the initiative to organise courses in radiation protection for the radiologists and clinical practitioners of their region.

The Annual Convention of the SFR, called "Les Journées françaises de radiologie", is the biggest annual event in terms of medical training and imaging research. The conventions of 2009 and 2010 were attended by more than 8600 radiologists and hosted 15 courses on radiation protection, practical workshops in dosimetry, and several scientific sessions. In 2009 a professional practices assessment path for radiation protection was put in place, while in 2010 there was a session on experience feedback in radiation protection and CPD. In 2011 a session will be dedicated to radiation protection in interventional radiology in partnership with the FRI, and practical workshops will address optimisation in conventional radiology and computed tomography. The SFR also offers an on-line electronic training aid that provides access to the courses given during the annual conventions, and to the electronic posters. The radiation protection courses are available on line.

Working in partnership with the CERF, the SFR promotes continuous medical training through the publication of "Cahier FMC" (CMT Journal). One issue in 2010 was devoted entirely to radiation protection.

The SFR helps radiologists meet their legal obligations in patient radiation protection by enabling them to obtain the patient radiation protection qualification training certificate. Pursuant to article R. 1333-74 of the Public Health Code, the order of 18 May 2004 sets the training programme for the radiation protection of patients exposed to ionising radiation. This programme is intended for medical professionals, whether already established or just starting out. Whatever the case, a refresher course must be followed every ten years at least. Over the last few years, more than 1000 people have sat the exam for the "Radiation protection" at the SFR's Annual Convention.

Radiologists working in public or private healthcare establishments are involved in the assessment of their professional practices by participating in the certification of the establishments and in their indicators of the improvement of healthcare quality and safety. In 2010 for example, the SFR approved the final version of the indicator concerning the request for imaging examinations. At present this indicator is optional and concerns the "MSO" (Medicine - Surgery - Obstetrics) establishments that have an imaging activity in at least one of the following areas: ultrasonography, computed tomography, or MRI. The conformity and quality of the imaging request is vital for the radiologists. It enables them to judge whether the imaging procedure is justified, and to propose an alternative method to the patient and the referring doctor if necessary. Replacing an examination that uses ionising radiation by one that does not (ultrasonography or magnetic resonance imaging) is an integral part of the radiologists job.

1. CT: Computed tomography.
2. MRI: Magnetic resonance imaging.

The profession has created the CEPPIM (Commission for evaluating professional practices in medical imaging), with the aim of developing the actions, methods and programmes for evaluating the professional practices, and carrying out the evaluations. Radiation protection is one of the first procedures validated by the CEPPIM.

Informing patients about the imaging examinations and the use of ionising radiation

It has always been the policy of SFR to inform and communicate with the patients and the public on the imaging examinations and the effects of ionising radiation. It has created a group dedicated specifically to providing information for patients. It comprises medical imaging professionals and patients' representatives. The "radiation protection" and "patient information" groups have worked together to produce an information sheet on ionising radiation which is available to patients and the public on the SFR's official web site (sfrnet.org). The SFR has also organised open sessions at its Annual Convention where the general public can discover the recent advances in diagnostic and therapeutic imaging.
The SFR also plays a role in other working groups dedicated to informing patients. It participates in a working group created on the initiative of the IRSN (Institute for radiation protection and nuclear safety) and the AVIAM (Association to help victims of medical accidents). The aim of this working group is to:
- identify patients' needs for "radiation protection" information in radiology and nuclear medicine. Identify the needs of the health professionals in order to fulfil their role in informing patients ;
- define recommendations and/or propose actions to develop information;
- initiate the production of standard information (or training) modules for patients and healthcare professionals.

SFR publications, *www.sfrnet.org*

SFR contacts with official organisations and participation in international initiatives

The SFR intends working with all the major actors in radiation protection. Its relations with ASN are formalised by an agreement. The SFR and the professional radiology commission signed an agreement binding them to ASN during the SFR's Annual Convention of 2009. The broad lines of this

Training at the INSTN (National Institute for Nuclear Sciences and Techniques) – tutorial on the phenomenon of radioactive decay

agreement concern:
- the regulations relative to the radiation protection of patients and workers, and the tools that facilitate its implementation; the training of professionals in patient radiation protection;
- informing the patients and the public;
- the good practices to improve patients and worker radiation protection, particularly in interventional radiology;
- the evaluation of professional practices that use ionising radiation, particularly in computed tomography.

In application of the agreement, the SFR has placed its expertise at the service of ASN inspections with, for example, the inspection of an interventional radiology department. It is also working with the FRI and ASN on the drafting of recommendations relating to interventional practices. Meetings between the professional radiology commission and the ASN commission are organised each year, and agreement amendments are signed.

The SFR maintains close ties with the IRSN, assisting it in its work where necessary. It is proud to have helped produce the ExPRI report (Exposure of the French population to ionising radiation associated with medical diagnostic procedures in 2007) published jointly by the IRSN and the InVS (French health monitoring institute) in 2010. It is delighted with the joint actions undertaken and wishes to formalise its relations with the InVS.

The SFR also participates in the teaching council for the Diploma in radiological and medical physics (DQPRM). The aim of the DQPRM is to train medical radiation physicists, whose main role is to guarantee quality and safety in the medical use of ionising radiation. The SFR supports the joint work of the radiologists and medical radiation physicists within the imaging structures to optimise the acquisition protocols.

The SFR participates in various international working groups. It is represented by one of its members in the World Health Organisation (WHO) in a working group on radiation protection. The WHO is currently behind a global initiative on radiological safety in healthcare. It is working in close collaboration with the International Radiology Quality Network (IRQN) to produce directives based on proven facts for an appropriate selection of medical imaging examinations.

The SFR is also takes part in the work of the "radiation protection" group of the European Society of Radiology (ESR). One of its members leads one of the working groups (interventional radiology group) of the EMAN (European Medical ALARA Network) project. This project, which is supported by a European contract, has several objectives, namely to create a European network on radiation protection, to promote the ALARA (As Low As Reasonably Achievable) principle and to make optimisation proposals in various sectors such as computed tomography and interventional radiology within or outside imaging departments. The interventional radiology working group, for example, comprises professionals from various sectors: physicists from EFOMP (European Federation of Organisations in Medical Physics), from EURADOS (European Radiation Dosimetry Group) and from the CEPN (Nuclear Protection Evaluation Centre), radiological technician (EFRS - European Federation of Radiographers Society), cardiologist (ESC - European Society of Cardiology) and radiologists (CIRSE - Cardiovascular and Interventional Radiology Society of Europe, ESNR - European Society of Neuroradiology, ESR - European Society of Radiology).

To conclude, in partnership with the medical imaging professional council, the SFR works to ensure progress in the concepts of radiation protection within the profession. It offers the necessary aids by drafting and publishing guides, by organising continuous medical training and promoting research, by informing patients about imaging examinations and the use of ionising radiation, and by remaining in close contact with the official organisations and taking part in international initiatives. ■

Computed tomography examination

CONTEXT AND STAKES

Medical imaging exposure in 2007 – Evolution at national and international levels

by Bernard Aubert, Head of the medical radiation protection expertise unit – Institute of Radiation Protection and Nuclear Safety (IRSN), **Cécile Etard,** Research engineer – IRSN, and **Dr. Sandra Sinno-Tellier,** Project supervisor – InVS (French health monitoring institute)

Medical applications of ionising radiation represent by far the biggest source of exposure to ionising radiation of man-made origin. Thus, diagnostic procedures account for more than 97% of the artificial exposure[1] and almost 26% of the total exposure of the population[2][1]. It is therefore important to make regular estimates of this medical exposure and to analyse how it evolves over time. By way of example, a recent publication on population exposure to ionising radiation in the United States underlines the fact that medical exposure per year and per individual has been multiplied by six since the 1980's [2].

Directive 97/43/Euratom indicates in its article 12 relative to the estimation of radiation doses received by the population: "Member States shall ensure that the distribution of individual dose estimates from medical exposure ... is determined for the population and for relevant reference groups of the population as may be deemed necessary by the Member State" [3]. Furthermore, the ongoing revision of Directive 96/29/Euratom on the basic standards of radiation protection should introduce an additional requirement: "Member States must ensure that the distribution of individual doses from medical exposure is determined and takes into account the distribution according to the age and sex of the exposed population".

An actions plan for implementing and developing patient exposure monitoring activities was set up in 2003 by the DGSNR[3] (General directorate of nuclear safety and radiation

1. Without considering therapeutic applications.
2. The mean annual exposure in France results from different sources of exposure: radon (43%), natural radiation from minerals (excluding radon), cosmic radiation and foodstuffs (30%), medical diagnostic exposure (26%) and human activities (1%) [1].
3. Act 2006-686 of 13 June 2006 relative to transparency and security in the nuclear field sets down the roles of ASN (Nuclear Safety Authority), the independent administrative authority that succeeded from the DGSNR.

protection) to meet these demands. In this context, the action that aims at "knowing and monitoring the frequency and distribution of the types of examination in the different categories of the French population" has been entrusted to the InVS and the IRSN. The aim is to provide the public authorities with up-to-date information on the level of medical diagnostic exposure of the French population, so that they can judge the effectiveness and appropriateness of the provisions to protect patients against the harmful effects of ionising radiation.

Since 2003 the InVS and the IRSN have been coordinating their efforts to bring this action to a successful conclusion. This collaboration, which has led to the creation of the ExPRI system (Exposure of the population to ionising radiation), meets two specific objectives:
- make as exhaustive a survey as possible of the information sources and data available in the medical literature and health service databases, then determine whether they can provide information on the nature and frequency of the examinations that expose patients to ionising radiation, and the associated doses, for entry into the ExPRI system;
- regularly update the contribution of medical diagnostic exposure to the exposure of the French population, identifying the uncertainties of the estimate and any shortcomings that must be remedied for the ExPRI system.

This collaboration resulted in the publication in 2005 of a first report based on data from 2002 [4]. A second report published in March 2010 based on the data from 2007 describes the medical exposure of the population by type of imaging (conventional radiology, including dental radiology, computed tomography, nuclear medicine and interventional radiology), by anatomic region explored and according to the age and sex of the patients [5].

This document presents the methodology used, a synthesis of the main results concerning the study of the 2007 data, and a comparison of French and international data.

Source of the data on procedure frequency and effective dose

According to the recommendations of EC report 154 [6], the dosimetric quantities used to characterise population exposure are the "collective effective dose" and the "annual mean effective dose per individual". To determine these quantities, the following information is necessary:
- the number of examinations by type of procedure;
- the distribution of these procedures according to age and sex;
- the mean effective dose associated with each type of procedure.

In France, each type of procedure is defined by a unique code in the CCAM (common classification of medical procedures). For the four studied imaging methods, 376 codes were retained and two data sources were used to list the procedures:

- for the liberal sector, a representative sample of 1/100 of the beneficiaries of the National General health insurance scheme (about 485,000 beneficiaries) has been monitored by National health insurance since 2006. All the medical care delivered by private practitioners to the individuals in this sample is recorded. The data for 2007 relative to the 376 studied codes were extrapolated to the whole of France, then analysed according to the type of examination, and the age and sex of the patient.

As no global data were available for the public sector, two national surveys were carried out for this specific purpose:
- a survey in 50 radiology departments of hospitals representative of public sector practice: the total activity of each department in 2007 and dosimetric information for each examination (DAP[4] or DLP[5]) was collected and analysed according to the type of examination and the sex and age of the patient;
- a questionnaire sent to the 127 nuclear medicine departments of the public hospitals: the total activity of each department in 2007 and dosimetric information for each examination (nature of the radiopharmaceutical and the administered activity) were collected and analysed according to the type of examination. Of the 127 departments polled, 92 responded to this survey (i.e. 72% participation).

4. DAP : Dose-Area Product
5. DLP : Dose-Length Product

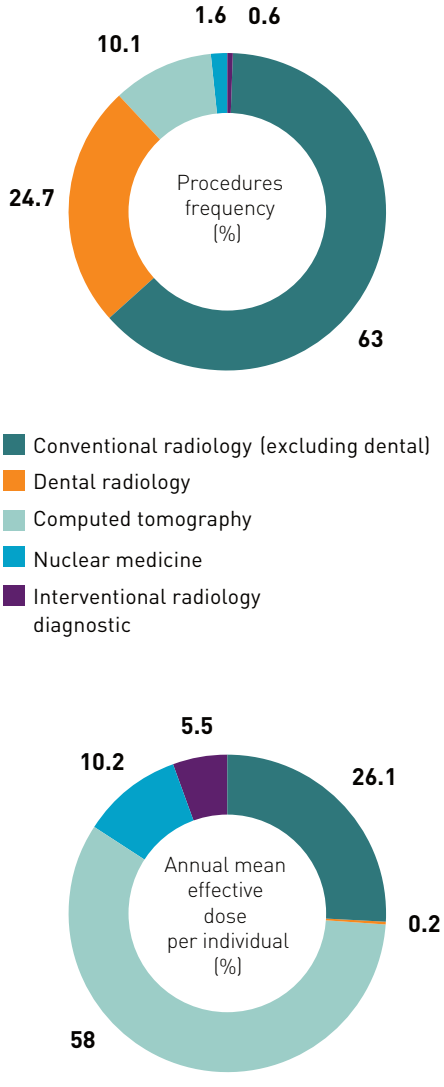


Figure 1 : Distribution of examinations and associated effective dose according to imaging methods in 2007

The mean effective dose associated with each type of procedure was established using various sources of information: the national recommendations for radiology (SFR[6]) or for nuclear medicine (SFMN[7]), the data collected to update the diagnostic reference levels in France, recent French and European studies, and the dosimetric information obtained in the two national surveys. For each type of procedure the collective effective dose corresponds to the number of procedures multiplied by the mean effective dose per procedure. The mean annual effective dose per person corresponds to the ratio of the total annual collective effective dose multiplied by the population headcount. As the majority of the dosimetric data relate to 2007, the effective doses were calculated using the conversion coefficients defined in publication 60 of the ICRP [7] and taken up in the Public Health Code.

6. SFR : Société française de radiologie - French society of radiology
7. SFMN : Société française de médecine nucléaire et imagerie moléculaire - French society of nuclear medicine and molecular imaging

Frequency of procedures and annual effective dose per person in 2007

The results of the study concern some 74.6 million diagnostic procedures carried out in 2007 for a population of 63.8 million persons. Conventional radiology represents 63% of these procedures, dental radiology 24.7%, computed tomography 10.1%, nuclear medicine 1.6%, and diagnostic interventional radiology 0.6% (figure 1).

Figures 2, 3 and 4 detail the distribution of the examinations and effective doses by type of procedure for conventional radiology (dental radiology excluded), computed tomography and nuclear medicine respectively.

In all, the annual mean effective dose was estimated at 1.3 mSv/year/person in 2007. Computed tomography accounts for 58%, conventional radiology for 26% and nuclear medicine for about 10% (figure 1). It is 57% higher than that of 2002, which was estimated at 0.83 mSv/year/person.

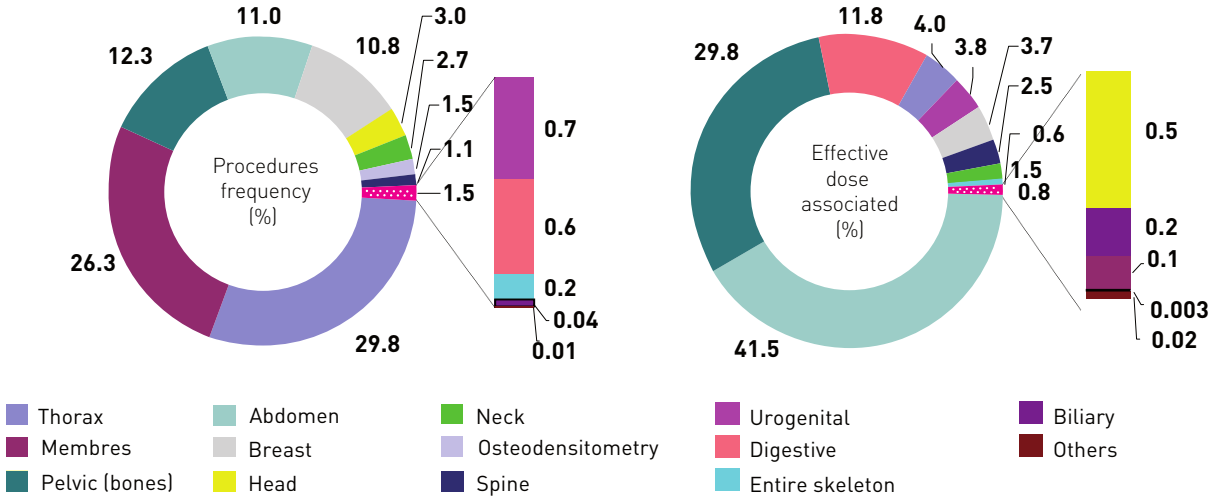
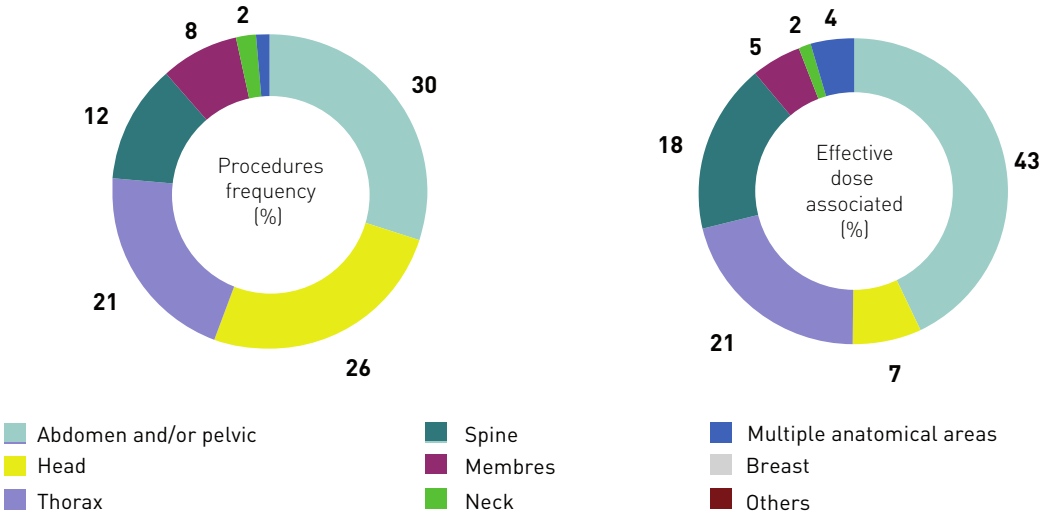


Figure 2 : Distribution of examinations and associated effective dose by type of procedure in conventional radiology (excluding dental radiology) in 2007

Figure 3 : Distribution of examinations and associated effective dose by type of procedure in computed tomography in 2007



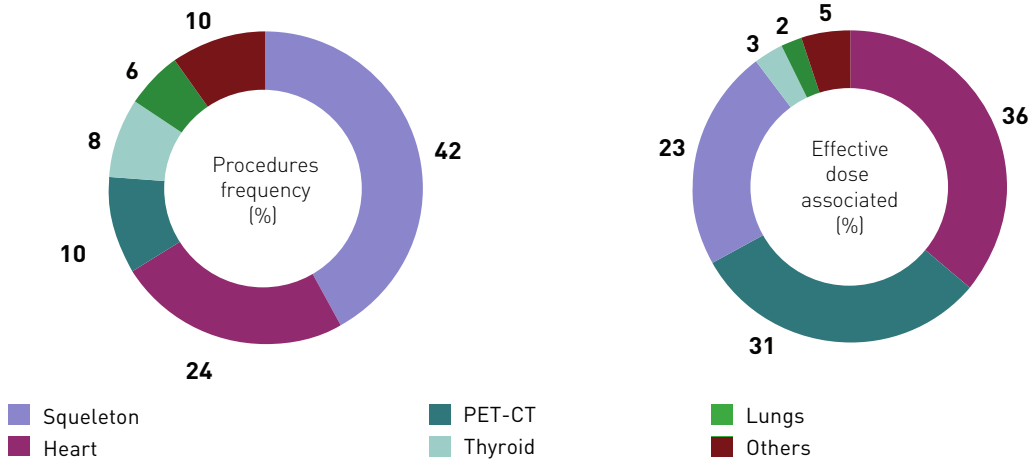


Figure 4 : Distribution of examinations and associated effective dose by type of procedure in nuclear medicine in 2007

Distribution according to age and sex

No information on the sex and age of patients was available for the public sector, and only for conventional radiology and computed tomography in the private sector. It was therefore possible to study the distribution for the latter two imaging methods according to age and sex and the associated effective dose (figures 5 and 6). Two "peaks" can be seen, one corresponding to children under one year of age, relating to examination of the thorax and pelvis, and one corresponding to children aged between 10 and 15 relating to examinations of limbs and dental panoramas. Then, upwards of 40-50 years of age, these curves rise steadily due to aging of the population and the increase in pathologies. The larger number of conventional radiology examinations of women aged 40 and upwards is accounted for by mammographies and limb examinations.

As is shown in figure 6, these variations in the number of examinations explain the variation in the mean effective dose per individual. It can also be noted that if the mean dose value is 1.1 mSv/year/person (for radiology and computed tomography), it in fact varies from about

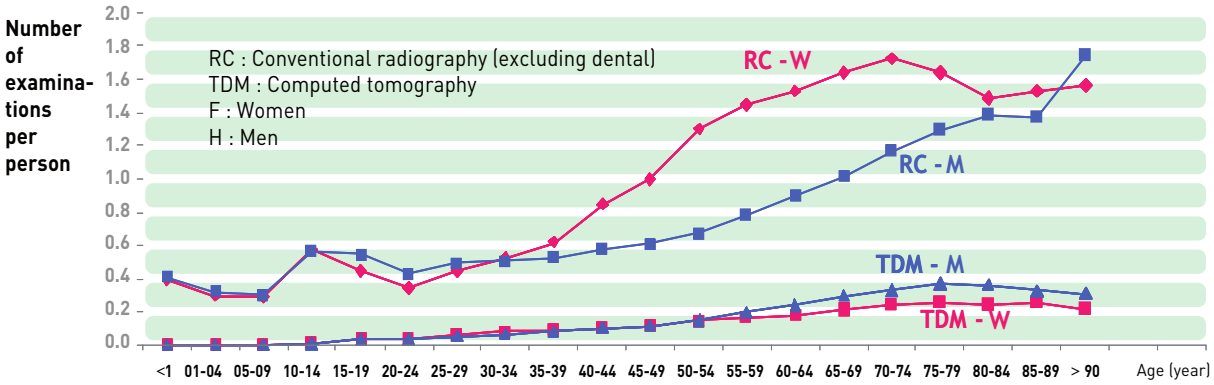


Figure 5 : Distribution of the number of diagnostic procedures (radiology and computed tomography) per person according to age and sex, in 2007

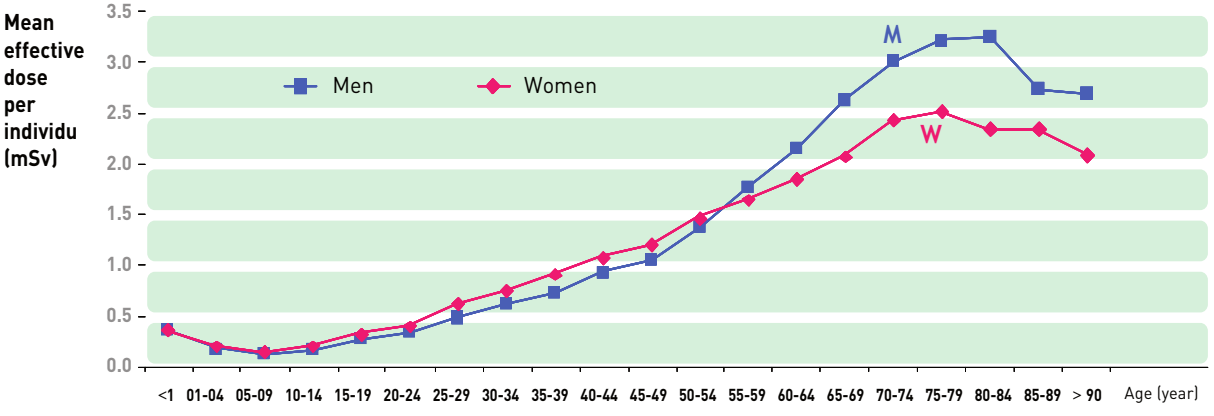


Figure 6 : Distribution of the mean effective dose per person according to age and sex, in 2007

0.1 mSv/year/person for the 5-9 years age group to more than 3 mSv/year/person in men from 70 to 85 years of age.

Population effectively exposed to ionising radiation for medical purposes

The estimated mean effective dose per person is 1.3 mSv for 2007. This mean value does not reflect the true situation however. This is because some people had no medical examinations in 2007 whereas others had numerous examinations and received more than 1.3 mSv. It is therefore worthwhile knowing the proportion of the population that is actually exposed and to estimate its exposure. Only private sector data are available to provide this information.

In 2007, 27.7% of the French population was exposed to at least one examination in this field (radiology, computed tomography or nuclear medicine). With regard to the effective dose, the distribution among the 27.7% of exposed population is as follows: 17.9% of the population received less than 1 mSv, 6% received between 1 and 5 mSv, and 3.8% received more than 5 mSv. If the exposed population alone is considered, the mean effective dose per person rises to 2.5 mSv/year.

Comparison with the international data

Figure 7 shows a comparison of the annual effective dose per person resulting from medical exposure in radiology and computed tomography (nuclear medicine excluded) for a number of countries that have published data for the 2006-2008 period.

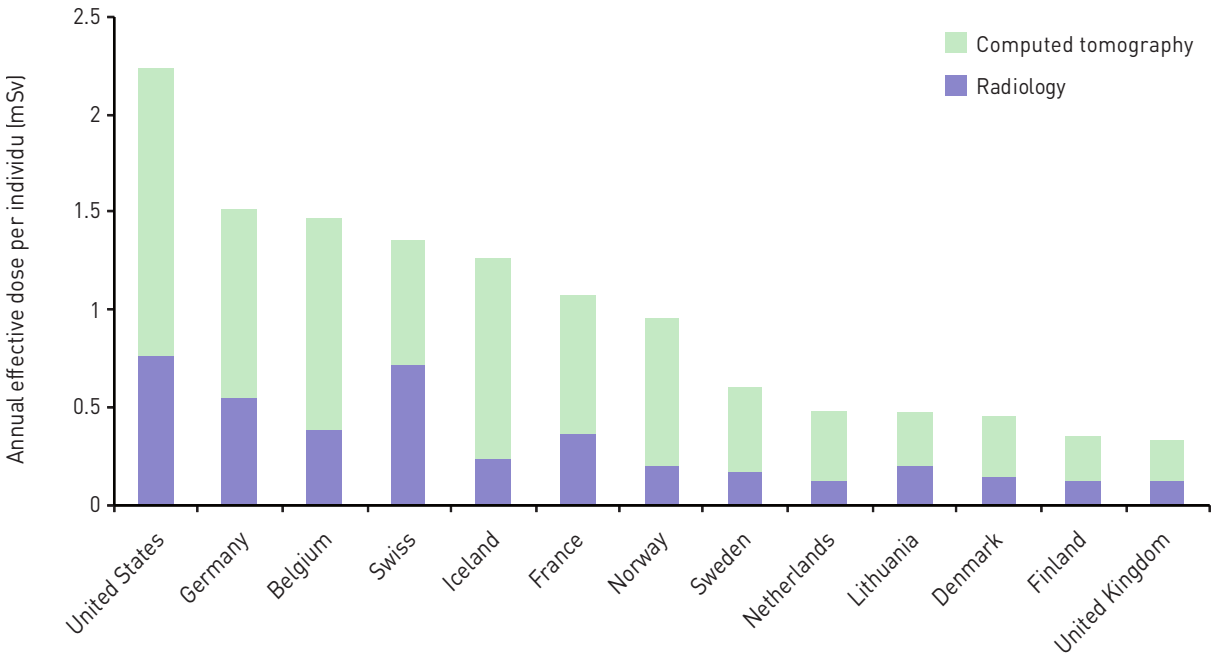


Figure 7 : Contribution of radiology and computed tomography to the mean annual effective dose per person for different countries

It can be seen that the value for France (1.1 mSv) is in the average for these countries where the annual effective dose ranges from 0.3 mSv (United Kingdom) to 2.2 mSv (United States).

If all medical applications are considered, France, with 1.3 mSv/year/person, is far below the United States (3 mSv/year/person in 2006) and in the middle of the range of published European values: from 0.4 mSv in the United Kingdom to 2 mSv in Belgium [6].

Conclusion

To summarise, the analysis of medical imaging exposure in France in 2007 reveals a 57% increase in the annual mean effective dose per person between 2002 and 2007 (0.83 vs 1.3 mSv/year/person). This increase is essentially due to:

- better knowledge of examination frequency thanks to the CCAM classification;

- a large increase in the number of computed tomography and nuclear medicine examinations (+26% and +38% respectively);

- a larger proportion of CT examinations of the thorax and abdominopelvic region, which make a substantial contribution to the effective dose;

- in nuclear medicine, a large increase in examinations by positron emission tomography associated with a CT scan (PET-Scan).

It must also be pointed out that the indicator used - the collective effective dose or mean effective dose per person - does not adequately describe the medical exposure of the population. These two quantities characterise exposure,

most often localised, by an average value for the entire organism and whatever the age of the individual. It would be appropriate to adapt these quantities for children and young adults, whose tissues are more radiosensitive, and to supplement them with data relative to the doses delivered to the most exposed organs and expressed in (mGy).

Ultimately, it would seem advisable to assess whether this increase in mean effective dose per person is associated with an increase in the health benefits expected from diagnostic imaging radiological procedures. ■

References

[1] Rannou A., Aubert B. et Scanff P. Exposition de la population française aux rayonnements ionisants. Rapport IRSN / DRPH/ SER 2006-02, 2006.

[2] National Council on Radiation Protection and Measurements. Ionizing radiation exposure of the population of the United States. NCRP report n°160, 2009.

[3] Directive 97/43/Euratom du 30 juin 1997, relative à la protection sanitaire des personnes contre les dangers de rayonnements ionisants lors d'expositions à des fins médicales.

[4] P Scanff, PhD, J Donadieu, MD, P Pirard, MD and B Aubert, PhD. Population exposure to ionizing radiation from medical examinations in France. The British Journal of Radiology, 81, 204–213, 2008.

[5] Etard C., Sinno-Tellier S., Aubert B. Exposition médicale de la population française aux rayonnements ionisants liée aux actes de diagnostic médical en 2007. Rapport conjoint IRSN-InVS, 2010 (download on: *www.irsn.org ou www.invs.sante.fr)*.

[6] European Guidance on Estimating Population Doses from Medical X-Ray Procedures, RADIATION PROTECTION N°154, European Commission, DG Energy-Transport, 2008.

[7] ICRP Publication 60. 1990 Recommendations of the International Commission on Radiological Protection. Annals of the ICRP; 1-3, 1991.

CONTEXT AND STAKES

Forming an opinion on the concept of average individual effective dose where medical imaging is concerned, and of its use in the modelling of the radio-induced cancer risk

by Dr. Yves-Sébastien Cordoliani, CT Scanning-MRI Department, Parly2 Private Hospital – Le Chesnay

It is commonly accepted that annual individual exposure to ionising radiation can be broken down into natural radiation, radiation associated with human nuclear activities and medical exposure. The "pie chart" showing this breakdown (figure 1), attributes about 2 mSv to natural radiation, a few microsieverts to human nuclear activities, and a little more than one third of the total - that is to say about 1 mSv - to medical exposure. This graphic representation has the advantage - above all in information published by the nuclear industry - of reminding the public that the vast majority of their exposure to radiation comes from good old mother nature on the one hand, and the trusted medical profession on the other.

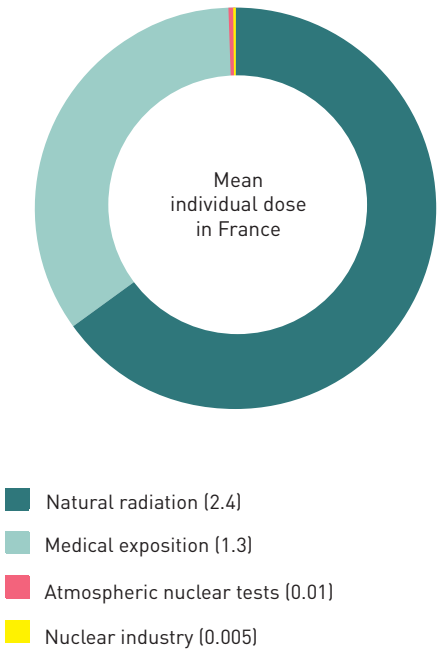


Figure 1 : Classical (but incorrect) illustration of annual individual exposure from different radiation sources.

This average individual effective dose resulting from medical exposure, sometimes referred to as the "medical millisievert" in France, has become so widely accepted over time that nobody has even questioned the relevance of the notion. Much more importantly, on this basis - validated by usage in numerous lectures and scientific papers - the "medical millisievert" has started to produce alleged effects, and mainly deaths. These deaths were quite naturally attributed to the radiologists, and the weekly magazine "Le Point", in an article entitled "Les dangers de la Radiologie" (The Dangers of Radiology) " [1], gave an unabashed estimate of 2500 deaths per year in France on the basis of the IRSN's calculations. At that time we brought to light the idiocy of the nonsensical accounting that resulted in this alleged carnage [2], not so much by the use of the linear no-threshold relationship (LNTR) as by the very absurdity of the notion of "average individual effective dose" (AIED), then evaluated at 0.8 mSv per person in France. The recent report from the IRSN (Institute for Radiation Protection and Nuclear Safety) and the InVS (Health Monitoring Institute) on the exposure of the French population to ionising radiation associated with medical diagnostic procedures in 2007 (3), nevertheless repeats the dubious practice of spreading the total annual radiological exposure in a thin coat over the entire French population, obtaining an AIED of 1.3 mSv - that is to say an increase of 62.5% - that will not fail to incite the LNTR calculation enthusiasts to update their simplistic equation, crediting radiologists with an even more horrifying total - albeit just as theoretical and far-fetched - of 4000 deaths per year.

But let's not get it wrong: the data collected for the report and the authors' method of allocating the doses by type of activity are perfectly satisfactory, and provide all those interested in radiation protection in the medical environment with valuable data and an innovative tool for assessing practices. The authors must be thanked and congratulated for this vast undertaking and the useful data resulting from it. The synthesis that leads to the contestable notion of AIED, however, should not be presented without caution. Indeed, as is said at the end of the report, only a small proportion of the population is actually exposed each year, and the radiological procedures on young patients tend to be "low-dose exposures": X-rays of teeth and limbs, whereas elderly patients accumulate higher exposure levels (the curves of exposure as a function of age speak for themselves). Average exposure for the under 24-year olds is 0.4 mSv, whereas that for people over 70 is 2.5 mSv. We know from professional experience - and the abovementioned report confirms it - that the very large majority of the highest-dose exposures concern elderly patients, and that a given patient usually undergoes several of these high-dose explorations during hospitalisation. Furthermore, these explorations increase in number as the

patient approaches end of life (one third of a person's health-care costs are incurred in the last year of life [4] and these costs include the high-dose radiological explorations). Elderly and very sick end-of-life patients undergoing multiple computed tomography scans are therefore over-represented in the collective dose. The collective dose (82,630,630 mSv) is therefore largely due to the exposure of persons for whom the stochastic risk is nil given their low life expectancy. Dividing this dose by the total French population of the last census (63,753,753 persons) to obtain this AIED of 1.3 mSv therefore makes no sense (figure 2).

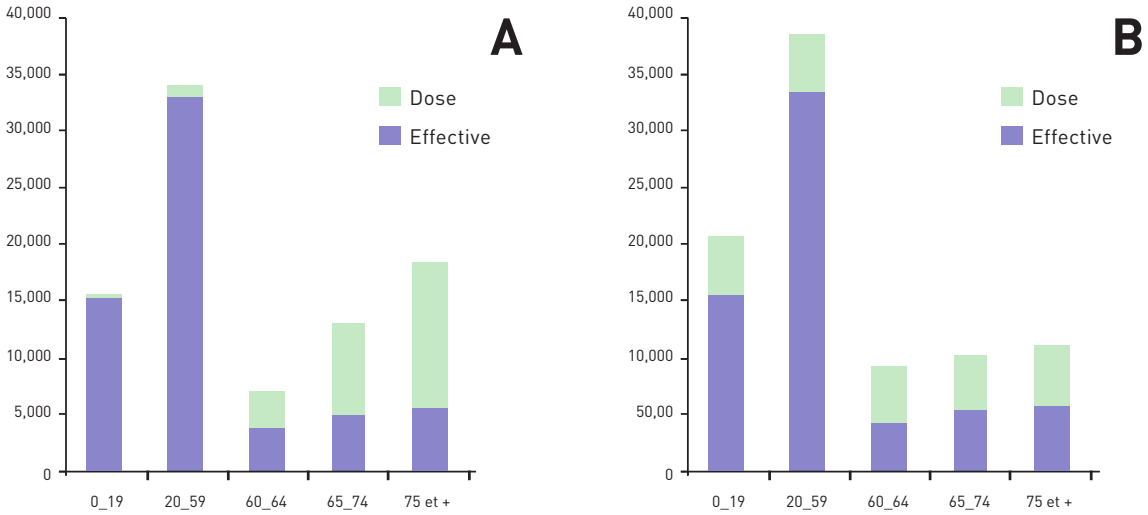


Figure 2 : Actual distribution (A) of medical exposure by age bracket, and distribution purported by the notion of average individual effective dose(B)

Moreover, the effective dose has been calculated using the ICRP 60 tissue weighting factors in effect in 2007. This means that for abdominopelvic explorations in women, an aberrant weighting factor of 20% for the gonads has been conserved, whereas this over-weighting was originally adopted to protect against the detriment of possible genetic effects in a population of workers. Not only has this detriment been substantially revised downwardly by the ICRP 103 (5) but above all it is inappropriate to apply it to the elderly population concerned by the majority of explorations of this type, and for whom the genetic risk is no longer relevant. The notion of effective dose expressed in millisievert, is, in the minds of a majority of those who use it, inseparable from the LNTR for the inducing of cancers. Maintaining this outdated and inappropriate weighting from medical exposure makes no sense and has far-reaching consequences.

This conscientious and useful report would therefore have gained had it underlined that although the notion of collective dose and average individual effective dose remains of value in human nuclear activities as a global indicator and for the management of interventions in situations of worker exposure, it is neither coherent nor even useful with regard to medical exposure. ■

References

(1) Labbé C, Recasens 0. Santé publique: Les dangers de la radiologie. Le Point, octobre 2006

(2) Cordoliani Y-S. Parlons dose ou "ne dites pas à ma mère que je suis radiologue: elle lit "Le Point". J Radiol 2007; 88:329-330.

(3) ETARD C, SINNO-TELLIER S, AUBERT B. Exposition de la population française aux rayonnements ionisants liée aux actes de diagnostic médical en 2007. IRSN/INVS

(4) R M Friedenberg. "The end of life." Radiology 2003; 228(2): 309-12.

(5) International Commission on Radiological Protection: Publication 103: The 2007 Recommendations of the International / Annals of the ICRP; Volume 37, Issues 2-4, Pages 1-332.

CONTEXT AND STAKES

Interview

with Philippe Ménéchal, Bordeaux division - ASN (French nuclear safety authority)

Monitoring interventional radiology is one of the priorities of the ASN inspections programme. The reason for this is that interventional radiology has major implications in terms of medical exposure for the patients and occupational exposure for the workers, which Philippe Ménéchal tells us about in this issue of ***Contrôle.***

After qualifying and working as a PCR (person competent in radiation protection), Philippe Ménéchal is now senior inspector at ASN, and on this account is a member of the Advisory Committee of Experts for medical exposure (GPMED).

Contrôle : **How have ASN's monitoring actions evolved over the last five years?**

The TSN Act on transparency and safety in the nuclear field brought the monitoring of patient radiation protection into ASN's remit, in addition to the monitoring of worker occupational exposure. Briefly, before 2006 the inspections consisted in checking that the standards for the facilities and the requirements relative to labour regulations were correctly applied. They now also include the verification of optimisation of doses delivered to patients. Consequently, the inspector must be able to assess the optimisation of performance of the procedures, in interventional radiology for example, in accordance with controlled technical criteria. It must be noted that although the inspector is not qualified to assess the justification of a procedure, he is qualified to verify that the justificatory elements figure in the medical report. The examination of the written procedure must be supplemented by observation of the professional practises during the intervention. Interventional radiology and the use of image intensifiers in surgery rooms have been national priorities for ASN since 2009.

Dosimetry inspection by ASN inspectors during an interventional radiology examination at the Villefranche-de-Rouergue hospital (Aveyron *département*)

Contrôle : **What are the main findings in interventional radiology?**

Interventional radiology is characterised by a multidisciplinary approach and can be carried out in extremely diversified and heterogeneous structures. The equipment used is also highly varied.

Numerous medical disciplines now use radioscopic guidance when positioning prostheses. This applies in radiology, cardiology and neuroradiology, where the procedures are generally performed on purpose-built, high-performance fixed facilities, with teams trained in worker and patient radiation protection. Other specialities such as urology, gastroenterology, orthopaedics and spine surgery frequently use image intensifiers in surgery rooms for guidance purposes. This can be likened to the use of the dental light in conventional operations. The findings in radiation protection reflect the awareness of the users and the levels of training of each team.

Regarding worker occupational exposure, the proximity of the PCR and the means at this person's disposal are essential. It often happens that PCRs have difficulty in doing their job because of their hierarchical position. Private structures accommodate numerous legal entities and the responsibilities of each employer are not clearly defined. Private practitioners are not always aware of their obligations to comply with the labour code, particularly in terms of their own medical monitoring by an occupational health physician. Paramedical teams on the whole are well-monitored medically, in spite of a serious shortage of occupational physicians in certain regions and institutions. Passive dosimetric monitoring is widespread, but particular importance must be placed on the evaluation of extremity doses. The incidents reported to ASN (one radiologist exceeded the annual dose limit within four months, and another received a dose exceeding 1 Gy on a hand) show that dosimetric monitoring by finger rings is essential in this field, and must be generalised. Active dosimetry is beginning to be well implemented in all the inspected sites. The training of radiographers complies with the regulatory requirements. Although

Discussions between the ASN inspectors and the PCR of the Villefranche-de-Rouergue hospital (Aveyron *département*)

cardiologists and radiologists are usually trained in the radiation protection of patients, this is rarely the case with the other categories of practitioners. Consequently the installations are used far below their potential performance level. Only 15% of sites in 2010 have radiographers working in the surgery room, and mainly in structures where the activity is low. The training of practitioners and users is therefore vital.

Contrôle: **How has ASN developed inspector training to meet the new priorities, particularly in the field of patient radiation protection?**

The ASN inspector training programme is important and the qualification course is highly demanding. The difficulty with medical radiation protection is that people who initially tend to be qualified in industrial inspection have to be trained in a completely new field. Given that inspectors are normally assigned to the ASN for 3-year periods, they are often moved on shortly after acquiring the necessary experience. The idea of specialising the radiation protection inspectors is currently being considered, with some devoted to the medical sector and others to the industrial sector. This system is already applied by the Bordeaux division, enabling the inspectors to go more deeply into the subjects, notably regarding their knowledge of the equipment and the organisations. Resources are available within ASN and it is important to use them and give them a lasting status. On-the-job training is also of great importance; it is regrettable that cross-inspections between divisions - encouraged by ASN - are not more common.

Contrôle: **How are the inspections perceived by the medical personnel? Is the publication of the inspection follow-up letter on the ASN web site taken positively?**

The inspection is generally perceived as an audit of the structure. The inspector must therefore explain the roles of the ASN and what it expects from the very first day. It is only recently that medical structures have accepted to be inspected, but it is something they are being increasingly confronted with in other domains. The personnel of the inspected structures - the medical operators in particular - are attentive to the technical competence of the inspectors and generally expect them to have sufficient expertise to answer their questions. The moment the inspectors show that they can discuss matters, even from the medical aspect, they are better accepted.

As for the PCRs, they often feel supported in their views, but which seem to go unheard when expressed to the decision makers.

The publication of the follow-up letters has not raised any particular objections to date. This practice is already applied with the accreditation inspections of the National Authority for Health and the sites accept it without any particular objections.

Contrôle: **Do you see improvements from one year to the next?**

Very distinctly. The fixed structures in radiology, cardiology and neuroradiology - which are already well organised - regularly seek to improve their practices, and radiation protection has become one of the priorities of these activities. The awareness of potential incidents affecting operators or patients means that radiation protection is developing positively. We regret not having sufficient declarative data on the events that are regularly notified to us, but the professionals often fear the consequences of these notifications. This is why we are attentive to the wearing of finger ring dosimeters by operators. The impact of the ICRPs findings on the increase in radiation-induced cataracts will also require evaluation tools that are currently lacking. Work must also be undertaken with the professionals, the manufacturers and the suppliers of protection equipment to develop the protection means that are available but little or badly used because they are impractical.

The introduction of quality control is a good measure because it enables the actual status of an establishment's radiological fleet to be assessed objectively and easily.

The findings are however much less reassuring for surgery rooms and structures not dedicated to the use of ionising radiation. There are huge training needs, and the radiation protection culture is not yet instilled. The absence of "someone who knows" within an surgery room prevents the personnel from having an objective attitude and taking reasonable measure of the radiological risk. The resulting reactions are therefore often inappropriate. ■

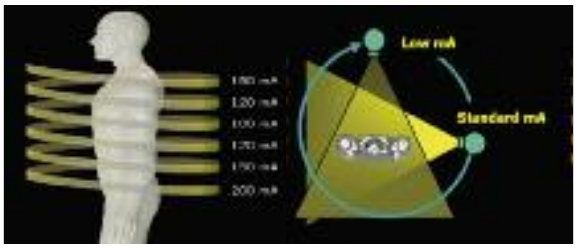
TECHNICAL OVERVIEWS: COMPUTED TOMOGRAPHY

Recent developments in radiology and computed tomography devices

by Roger Delepaule, Director of CT scanner market of Toshiba Médical France for the SNITEM (National Union of the Medical Technologies Industry)

Reductions in delivered doses can be obtained by professional practice and equipment innovations. The first dose reduction aids appeared about ten years ago, and manufacturers have been constantly improving them and proposing new ones. Dose reduction has become an absolute priority in the development of new computed tomography (CT) scanners. Several innovations have been introduced recently:

Adaptation to the patient by adjusting the dose according to morphology: this makes it possible to use just the necessary dose and obtain a constant noise level1 over the entire volume.



Modulation of mA in the three planes (x,y,z)
E.g.: Thoracic exploration: dose reduction of 40%

Prospective acquisition technique in cardiology: when the patient's heart rate is stable and not to high (up to 70 BPM). This new technique enables the dose to be reduced by almost 80% and be below that of diagnostic coronarography.

Sequential or helical prospective mode (it is the ECG (electrocardiogram) signal that triggers projection of the X-rays)

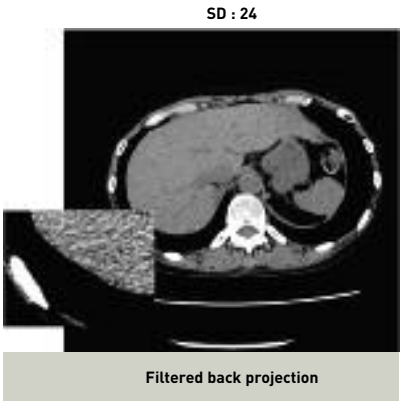
Image reconstruction methods have been improved by the introduction of iterative reconstruction algorithms.

The reconstruction techniques used until now were based on filtered back projection: this analytical method has the advantage of speed of image reconstruction (which is vital given the number of slices to reconstruct) but the drawback of generating a high level of noise.

Iterative reconstructions, which use an algebraic method, lead to longer reconstruction times but greatly reduce the noise level (by up to 50%) and therefore the dose. The development of computing power means that today they can be applied to the CT scanner while maintaining a good daily throughput.

Iterative reconstruction loop

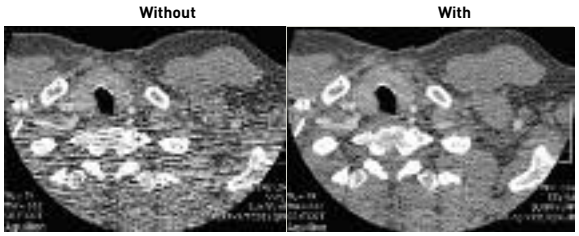
* Adaptative Iterative Dose Reconstruction (Toshiba)



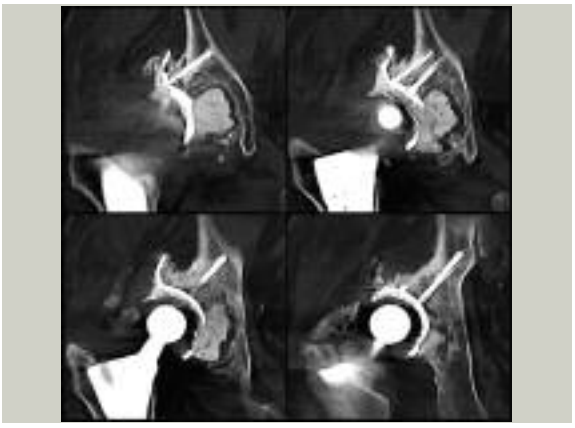
Identical acquisition reconstructed with the two methods: 50% noise reduction, that is to say a 75% reduction in dose for identical image quality

Correction of artefacts: in anatomical zones where absorption is high (hyperdensity associated with bone or the presence of orthopaedic material) doses had to be increased in order to minimise the generation of artefacts.

The development of algorithms correcting these hyperdensities enables them to be partly eliminated without having to increase the acquisition parameters. This also makes it possible to better study the prostheses, which was previously very difficult owing to the presence of metal.



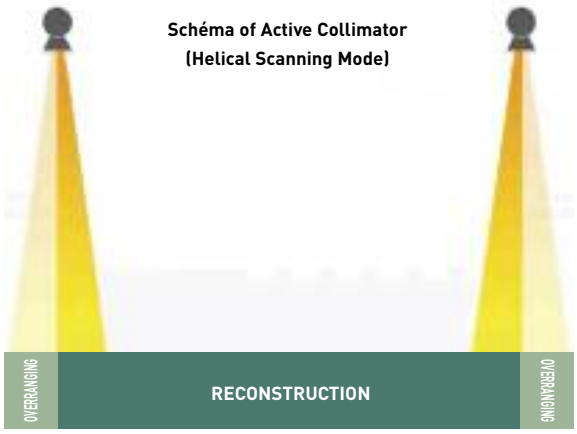
Cervico-dorsal junction: region that is particularly subject to artefacts due to the shoulders



Total hip prosthesis

Actions on the beam:

• Beam collimation slaved to acquisition: during helical acquisition, projection of the X-rays must start before the anatomical region to explore and stop shortly after it. This extension of the scanned area is called overranging, and it results in unnecessary irradiation of these areas.



Left-hand section collimated at start **Right-hand section collimated at end**

Full opening

Overranging can be limited by opening the collimator at the start of the explored zone and closing it at the end of the explored zone.

• Beam filtering, which enables the most effective radiation spectrum to be selected by reducing the number of low-energy photons (source of scatter) and of more harmful high energy photons.

When installing CT scanners the manufacturers propose protocols that are optimised according to the anatomical regions and different morphotypes.

Today the prospective dose information (before acquisition) is given to the users and recalculated in real time if one of the parameters is modified in any way. As of lately, some systems proposes a visual alert on the control console before starting the X-rays if the DRLs (diagnostic reference levels) will be exceeded.

The introduction of these new tools means that the manufacturers must train the users in their utilisation and provide permanent support to optimise them.

Some of the technological innovations described here are proposed in the basic configuration on virtually all the latest generation CT scanners currently on the market. It is sometimes possible to retrofit these new technological features onto existing older devices, but the cost can be high (dynamic collimation, iterative reconstruction, etc.).

Conclusion

The latest technological developments in radiology and computed tomography have essentially concerned dose reduction. This is a question of major importance given that these are fundamental means of diagnosis, and that new applications such as dual energy CT and functional imaging will undoubtedly widen the fields of application. ■

TECHNICAL OVERVIEWS: COMPUTED TOMOGRAPHY

Justification and dosimetric issues in the new CT practices: CT coronary angiography, virtual colonoscopy and full body scan

by Prof. Vincent Vidal, prof. of radiology.
Prof. Guy Moulin and Prof. Jean-Michel Bartoli, radiology department heads – Timone Hospital of Marseille

Manufacturers develop new tools that push back the investigative limits of slice imaging. These new computed tomography (CT) techniques are rapidly put into standard practice by radiologists, essentially with the aim of improving diagnostic quality and reducing the invasiveness of certain examinations. The question is therefore to justify the proposed examination, that is to say to provide the argued confirmation not only of the clinical indication but also that CT scanning is the most appropriate imaging technique. The learned societies concerned are currently examining these approaches, particularly with respect to two highly demonstrative examples namely CT coronary angiography and CT colonography (also called virtual colonoscopy).

The purpose of the CT coronary angiography is to view the coronary arteries in order to detect atheromatous stenosis that causes myocardial infarction (heart attack). The reference method for viewing the lumen of the coronary arteries is coronarography. This is an "invasive" examination, as it requires puncturing of the femoral artery, endovascular navigation, and catheterisation of the ostium of the coronary arteries. It also involves exposure to radiation, as it is carried out under pulsed fluoroscopy with continuous graphic acquisition. The development of CT coronary angiography (CTCA) has stemmed from recent technological developments of multidetectors. Image acquisition has to be coupled with the heart rate (ECG - electrocardiogram) to avoid reconstruction artefacts. The big advantage of this examination lies in its high negative predictive value which exceeds 97% (the detection sensitivity for tight stenoses is higher than 95% but with a specificity that can still be improved). This examination is therefore indicated in cases of atypical chest pains in patients having intermediate risks of coronary artery disease. Several studies have demonstrated that with this clinical indication, use of CTCA not only reduced hospitalisation times and costs, but above all - more interestingly - the number of recurrent post-hospitalisation examinations. In an international multicentric study, Hausleiter reported practices concerning the performance of 1,965 CTCAs in 50 centres. The average of the dose-length product (DLP) was 885 mGy.cm, i.e. an effective dose of 12 mSv, with considerable variability in the median DLP values per centre, ranging from 331 to 2146 mGy.cm, i.e. effective doses of 4.5 to 29.2 mSv. This reflects a large variability in practices concerning the use of dose-reduction techniques, and their under-utilisation on the whole. By way of comparison, the effective dose values for diagnostic coronarography range from 2.1 to 10 mSv.

CT scan of the colon, 3D reconstruction of a virtual colonoscopy

CT colonography (CTC) encroaches on the territory of colonoscopy, which raises a different question concerning its justification, as it compares an examination involving radiation exposure with one that does not. A colonoscopy is usually carried out under general anaesthetic with either short-stay hospitalisation or on an ambulatory (outpatient) basis. This is the reference technique for detecting colon wall lesions. At the same time it allows the resection and subsequent histological examination of any lesion found. It can sometimes be incomplete or fail to detect lesions situated behind a bend or fold. The essential possible complication with colonoscopy is perforation of the wall, which is rare (0.1% for diagnostic colonoscopies). CTC associated with a 3D endoluminal reconstruction, also called virtual colonoscopy, is carried out on an ambulatory basis after bowel preparation relatively similar to that for a colonoscopy. The risk of perforation is practically zero with CO_2 insufflation and pressure monitoring. The recently published large series purports that the detection rate for colon polyps of more than 5 mm is about 90%. Flat lesions, even of large size, can nevertheless go undetected. This detection rate, obtained by experienced teams, would thus be

comparable with that of the standard colonoscopy, the reference examination. CTC is indicated if a colonoscopy is unsuccessful or contraindicated. Some American experts have recently proposed performing CTC as the first option on medium or high-risk patients, and only referring those patients found by this examination to have one or more polyps exceeding 9 mm, for colonoscopy. In France, this screening strategy is not yet considered validated.

Why the increase in slice imaging, and is it justified?

Computed tomography examinations are extremely fast, readily accessible, not very costly and minimally invasive. They thus correspond to criteria that both the medical staff and the patients seek. In the particular cases of CTCA and CTC, these examinations are rightly praised because they satisfy these criteria. Speed: a CTCA examination lasts 15 minutes compared with a coronarography which, even if carried out on an ambulatory basis, will take a day. Ease of access: the waiting time for a CT scan appointment in public or private radiology departments is usually a few days, whereas for MRI (magnetic resonance imaging) - the reference substitute examination - it is generally a few weeks and often a few months. Low cost: a CT examination involving the study of one or perhaps two anatomical regions, including the flat-rate technical cost, remains an examination that will cost less than €100. Minimally invasive: whether for the CT colonography or CT coronary angiography, the risks are limited. A coronarography exposes the patient to the risk of puncturing the femoral or radial artery (hematoma, dissection), the risk of the endovascular navigation (detachment of atheromatous plaque that can lead to a cerebrovascular accident), the risk of catheterisation of the coronary arteries (spasm, dissection). The CTCA exposes the patient to the risk of puncturing a vein to introduce a contrast medium. The contrast medium itself can represent a risk factor if it causes an allergic reaction, but the risk is the same for both type of examinations. The CT colonography will be carried out without anaesthesia, unlike the colonoscopy, and represents extremely limited iatrogenic risks (perforation, haemorrhage).

These various arguments explain the general attraction of these techniques, but that are not enough to totally justify these examinations. As we have seen, clinical studies are still in progress to demonstrate the sensitivities, specificities, the positive and negative predictive value, the impact on survival and the impact on hospital costs.

The justification of new CT practices is moreover always weighed up against the estimated relative risks of "scanner-induced" cancer. The most alarming scientific articles can effectively worry the medical and non-medical population at first sight. In the USA, 70 million CT examinations were carried out in 2007, with an estimated cancer rate attributable to them that could reach 2%. Although these figures comply well - perhaps even "too well" - with the principle of precaution, they are established from a linear no-threshold relationship whereas the probability of cancer is not clearly demonstrated for doses below 100 mSv. It is therefore essential to consider the ratio of the benefit on the survival of the screened populations to the potential risk of "radio-induced" cancer. For example, the probabilistic risk of "radio-induced" cancer resulting from a CT colonoscopy is 0.14% at 50 years and 0.07 at 70 years, which must be compared with the risk of colorectal cancer, which is 5-6%. In this case the risk-benefit ratio is identified as being greater than 1. Furthermore, a significant number of adjacent and curable pathologies are discovered during these examinations (abdominal aortic aneurysm, *in situ* lung cancer).

If the probability of developing a disease is very high, the risk associated with the radiation and the contrast medium can be easily justified. Asymptomatic patients represent a special group because their risk of developing a severe and specific illness is lower than that of symptomatic patients. The medical justification in this particular case is therefore to detect an illness displaying high mortality with long pre-symptomatic

CT coronary angiography

CT coronary angiography (CTCA) is a virtual coronarography. CTCA is indicated for patients having atypical pains or displaying intermediate risks of coronaropathy. It is therefore a screening test for identifying patients requiring invasive examination. It is possible to have a long acquisition time without excessively high radiation exposure by adjusting the parameter settings.

CT colonography

CT colonography or virtual colonoscopy produces a virtual reconstruction of the colon in 3D from CT scanner images. Virtual colonoscopy is less invasive and less costly than optical colonoscopy. It causes fewer complications and patients can resume normal activities immediately afterwards. Detection sensitivity is 90% for lesions larger than 1 cm. Observed performance levels are comparable with those of optical colonoscopy. In March 2008 in the USA, CT colonoscopy was recommended for the screening and prevention of cancer of the colon in patients aged over 50 years. Optical colonoscopy is the reference method for detecting lesions of the colon wall, and at the same time it allows the resection and subsequent histological examination of any lesion found.

The justification of CT examinations for clinical surveillance must be considered in relation to the clinical characteristics of the patient. For cancer patients aged over 50, the CT examination presents a low risk. For children aged 5, for example, with an inflammatory intestinal disease (ulcerative colitis or Crohn's disease), MRI is indicated.

The cancer risk associated with CT is 1/2000 compared with 1/5 in the general population. This risk must be adjusted according to age and sex. A publication dating from 2007 attributes 2% of cancers in the United States to computed tomography.

Where these procedures are justified, practitioners must take the technical advances into account, and above all optimise the doses. A simple modification of the acquisition parameters can reduce the dose by 40% while still producing an image that provides the required diagnostic information. Likewise, dual-energy CT generates lower doses than single-energy CT. ■

development and a potentially effective treatment, which is the case for CTC and CTCA. Examinations that are not justified are those for which either there is no medical indication, or there is another non-irradiating diagnostic method that is just as effective.

A lot of research work on dose limitation is currently in progress. Many factors influence the dose delivered to patients in CT procedures. The technical characteristics specific to each type of scanner, the procedure parameters: tube voltage (kV) and current (mA), primary collimation aperture, explored volume, etc. By optimising these various parameters, doses can be drastically reduced. Consequently, the currently published figures from clinical studies are already out of date, because most of them were collected in 2008, 2009. Out of date is to be taken in the positive sense, that is to say the figures are lower in 2011.

The use of multislice helical CT scanners improves our diagnostic capacities and the service to patients. Rational utilisation of these devices ensures a risk-benefit ratio for patients that is often higher than that for other medical explorations. New procedures like CTC and CTCA are still being assessed, even if these examinations are already justified from the aspects of better patient tolerance, speed and cost. The justification of these examinations, particularly in patients aged over 60, is hardly debatable given the virtually inexistent carcinogenic risk. Whatever the case, as with any irradiating examination, it must comply with the ALARA[1] principle in all respects. ■

1. As Low As Reasonably Achievable.

References

Hausleiter J, Meyer T, Hermann F et al. Estimated radiation dose associated with cardiac CT angiography. JAMA 2009;301:500-7.

Willoteaux S, Sibileau E, Caroff J et al. La réduction de dose en coroscannographie. J Radiol 2010;91:1220-4.

McCollough CH, Guimaraes L, Fletcher JG. In defense of Body CT. AJR 2009;193:28-39.

Flicek KT, Hara AK, Silva AC, Wu Q, Peter MB, Johnson CD. Reducing the radiation dose for CT colonography iterative reconstruction : a pilot study. AJR 2010;195:126-31.

Huda W, Schoepf UJ, Abro JA, Mah E, Costello P. Radiation-related cancer risks in a clinical patient population undergoing cardiac CT. AJR 2011;196:159-165.

Cordoliani YS. Les enjeux de la radioprotection en imagerie médicale. J Radiol 2010;91:1184-5.

Cordoliani YS, Boyer B, Le Marec E, Jouan E, Hélie O, Beauvais H. Vademecum du scanner hélicoïdal. Estimation des doses, choix des paramètres. J Radiol 2002;83:685-92.

TECHNICAL OVERVIEWS: COMPUTED TOMOGRAPHY

Magnetic resonance imaging: round-up of current applications and outlook

by Prof. Jean-François Meder, Head of the morphological and functional imaging department – Sainte-Anne Hospital centre, deputy secretary-general of the French Society of Radiology (SFR), and **Prof. Jean-Pierre Pruvo,** Head of the neuroradiology department, Roger Salengro Hospital, LILLE University Hospital, secretary-general of the SFR

Magnetic resonance imaging (MRI) is more than a simple diagnostic aid. It is a decisive tool in making therapeutic decisions and evaluating responses to treatment, as well as being a component of the future hybrid imaging units, and a platform open to many professionals, whether physicians, scientists, engineers or technicians.

In order to inventory the uses and limits of MRI in its various medical applications, a questionnaire was sent out to the heads of the medical societies affiliated to the French Society of Radiology (SFR) and to the heads of two unions, one for hospital personnel and one for independent professionals. The aim was to identify the imaging technique of choice in the speciality, the main and emerging indications for MRI, the diagnostic fields not modified by this, any reductions in the indications for other techniques, the limits on wider utilisation of MRI, and the benefits of a dedicated machine. The main results are presented in this article:

– MRI is (or is becoming) the diagnostic imaging method of choice in increasingly diverse domains: nervous system, osteoarticular, hepatic, pelvic, cardiovascular pathologies;

– generally speaking, oncology is the leading domain, but other indications are emerging, such as rheumatic pathologies, exploration of the digestive tract, of ventilatory disorders, of artery walls, etc.;

– the anatomic precision, the development of full body imaging, and the metabolic and functional approach explain the growing number of emerging indications;

– if MRI has had little or no impact on the examinations in certain pathological areas (breast cancer screening, traumatic injuries, etc.), it has almost completely replaced some examinations, which have thus practically disappeared (arthrography in paediatrics for example,...);

– all the medical societies are conducting evaluations comparing MRI and X-ray imaging techniques;

– the main limit on the use of MRI arises from the difficulties of access and therefore the lack of MRI facilities. With slightly over 500 MRI machines (two time less than the European average and three times less than in the Scandinavian countries), waiting times for appointments are still abnormally long (between 20 and 65 days for cancer patients, depending on the regions);

– there does not appear to be a demand for MRI machines dedicated to individual pathological areas at present.

MRI indications

MRI has replaced computed tomography (CT) scanning as the diagnostic aid for the majority of central nervous system diseases, whether in emergency situations (cerebrovascular accident, intracranial hypertension, infectious pathology, radiculomedullary compression, etc.) or chronic diseases (Alzheimer's disease, inflammatory pathologies, etc.). CT scanning remains very useful for disease staging in the acute phase of traumatic cranio-cerebral lesions, in the diagnosis of subarachnoid haemorrhages and bone injuries at the base of the skull and the spine. The information obtained from MRI has resulted in changes in the therapeutic approach to a large number of diseases. As an example, in neuro-oncology, spectroscopy and functional MRI techniques (diffusion, perfusion and activation imaging) have improved the delineation of intracranial tumour boundaries; this in turn has improved the quality of surgical treatment and reduced the level of perioperative complications [1, 2].

If the CT scanner remains irreplaceable in *thoracic pathology* for studying the pulmonary parenchyma (airways and interstitial sector), MRI is the rule for exploring the mediastinum, the pleura and the pulmonary blood vessels. It is in oncology that new indications are emerging for MRI, mainly due to improved performance in the exploration of pulmonary nodules. Pulmonary functional imaging today applies the techniques of nuclear medicine (perfusion and ventilation scintigraphy); the role of MRI is marginal, and all the more given that MRI necessitates means poorly compatible with a routine clinical utilisation (polarised helium). Highly promising MRI techniques studying perfusion and ventilation without using intravenous or gaseous contrast media are currently being studied [3, 4].

In *osteoarticular pathology*, MRI is now the method of choice, even in standard radiography's "reserved field" of traumatology. By way of example, MRI has become the gold standard for diagnosing fractures of the small bones of the hand, particularly the scaphoid (or navicular) bone [5]. There are numerous indications for MRI: diagnosis and staging of bone and soft tissue tumours, sports traumatology (sprains, etc.), chronic articular and soft tissue traumatic pathologies, degenerative pathologies, particularly spinal (disco-radicular conflict, lumbar canal stenosis), bone marrow pathologies (aseptic osteonecrosis, stress fracture, algodystrophy, etc). The importance that MRI has acquired has led to a reduction in the indications for techniques using ionising radiation, such as arthrography. The field of application of MRI is going to widen further as other

Cardiac imaging research protocols: 3 Tesla MRI and display console in the laboratory of the technological innovation clinical investigation centre at the University Hospital of Nancy (Meurthe-et-Moselle *département*)

indications are confirmed, such as the early diagnosis of inflammatory rheumatisms [6].

In *cardiovascular pathology,* the CT scanner - due to its excellent spatial and contrast resolution - and Doppler ultrasonography remain very widely used. Nevertheless, we are witnessing an increase in the place occupied by MRI where the principal indications are the diagnosis of vascular malformations (MRI coupled with doppler ultrasonography), myocardial pathology and the monitoring of chronic pathologies (aortic dissection, aortic surgery, etc.), ischemic and non-ischemic cardiac diseases (which leads to a reduction in the indications for myocardial scintigraphy and pericardial imaging [7]). The 3 Tesla (3T) MRI scanners offer advantages over the 1.5T scanners, which opens new fields: perfusion imaging, myocardial tagging, coronary artery imaging [8].

In *genito-urinary pathology,* MRI has become the must useful technique for studying the reproductive system and the pelvis. It is once again in the field of oncology that the indications for MRI have increased: diagnosis and staging of cancers of the kidney, the prostate, the cervix and the endometrium, or ovarian tumours. Moreover, it allows the study of pelvic statics. Other indications are going to develop: diffusion imaging for the diagnosis of upper urinary tract cancer [9], functional renal MRI [10].

In breast cancer screening of the general population, MRI has not changed the position of the mammography. It is nevertheless gaining ground, its main indications being the suspicion of a local recurrence after conservative treatment, the assessment of the response to a neoadjuvent therapy, local staging of cancers of the breast with search for multifocalities in lobular cancer and the monitoring of high-risk patients [11].

In *digestive system pathology* there is no preferred imaging technique. Basically, MRI is the most appropriate technique for studying the liver (combined with ultrasonography), the pelvis and the pathology of the bile duct, while CT remains widely used for examining the digestive tract and the peritoneum. The main indications for MRI are the detection and characterisation of hepatic nodules, the diagnostic and pre-therapeutic work-up of bile duct and pancreatic pathologies and the staging of rectal cancers. This technique is even sufficient for the diagnosis of hepato-cellular carcinomas of more than two centimetres and certain benign hepatic tumours such as hemangioma and intraductal papillary mucinous tumours [12]. MRI allows the quantification of hepatic overloads : hepatic steatosis [13], hemochromatosis. One indication for which MRI is replacing computed tomography and standard radiology is the monitoring of inflammatory pathologies of the digestive tract after opacification (Crohn's disease). Previously this was limited due to the absence of 3D sequences in certain weightings, excessively long acquisition times and poor resolution. As MRI develops, exploration of the small intestine or the colon will undoubtedly be the next major morphological application of MRI.

In paediatrics, MRI has not changed the diagnostic approach for certain pathologies: respiratory affections, trauma in the initial phase, acute bowel obstructions. The main indications for MRI are central nervous system diseases, oncology (diagnostic, ranging and monitoring of tumoural lesions), musculoskeletal diseases and, in specialised centres, exploration of congenital heart diseases and their evolution under treatment. MRI has brought a very significant reduction in the use of computed tomography in the first two areas.

Limits on the use of MRI

The main factor limiting the use of MRI is the difficulty of access resulting from the shortage of MRI facilities. With slightly over 500 MRI machines (two time less than the European average and three times less than in the Scandinavian countries), waiting times for appointments are still abnormally long (between 20 and 65 days for cancer patients, depending on the regions). The low availability as well as the low CCAM[1] rating with respect to the examination time hinder the expected development of this technique; recognition of the complexity of certain procedures is necessary: activation MRI, MRI procedures on children where sedation is sometimes indispensable, emergency examinations and, in the near future, full body examinations [14].

1. Common classification of medical procedures.

Positioning a healthy volunteer subject in a 3 Tesla MRI scanner for a research protocol examination

Is there a place for dedicated MRI scanners?

At present there seems to be no demand for MRI scanners dedicated to a particular topographical region; a good example is the low-field MRI scanners for examining the extremities in osteoarticular pathologies, which do not provide information of good enough quality.

This being said, having MRI scanners dedicated to emergencies, to oncology, to paediatrics (which involves specific measures due to the length of certain examinations, the necessary environment - anaesthetic in particular, pre- and post-exam monitoring and surveillance system), or to interventional imaging, would probably have fundamental consequences for patient care. Assigning dedicated time-slots for shared equipment is also a solution advocated by the polled specialists. The grouping of particular activities (MRI biopsies, etc.) on certain MRI scanners, rather than having them all do everything, would undoubtedly lead to more specific and therefore higher performance tools. Furthermore, in university hospital departments it is vital to have time-slots or machines dedicated to research or the evaluation of techniques.

Finally, MRI is - or is becoming - the diagnostic imaging technique of choice in increasingly diverse domains. The most important applications are exploration of the nervous system and oncology, but other indications are coming to the fore, such as trauma, rheumatic and cardiovascular pathologies. Full body imaging will enable multifocal pathologies to be studied, for both malignant and benign diseases. Wider access to MRI and recognition of the complexity of certain examinations are absolutely necessary, as this is the alternative to examinations involving exposure to ionising radiation - an alternative desired by patients and health professionals alike.

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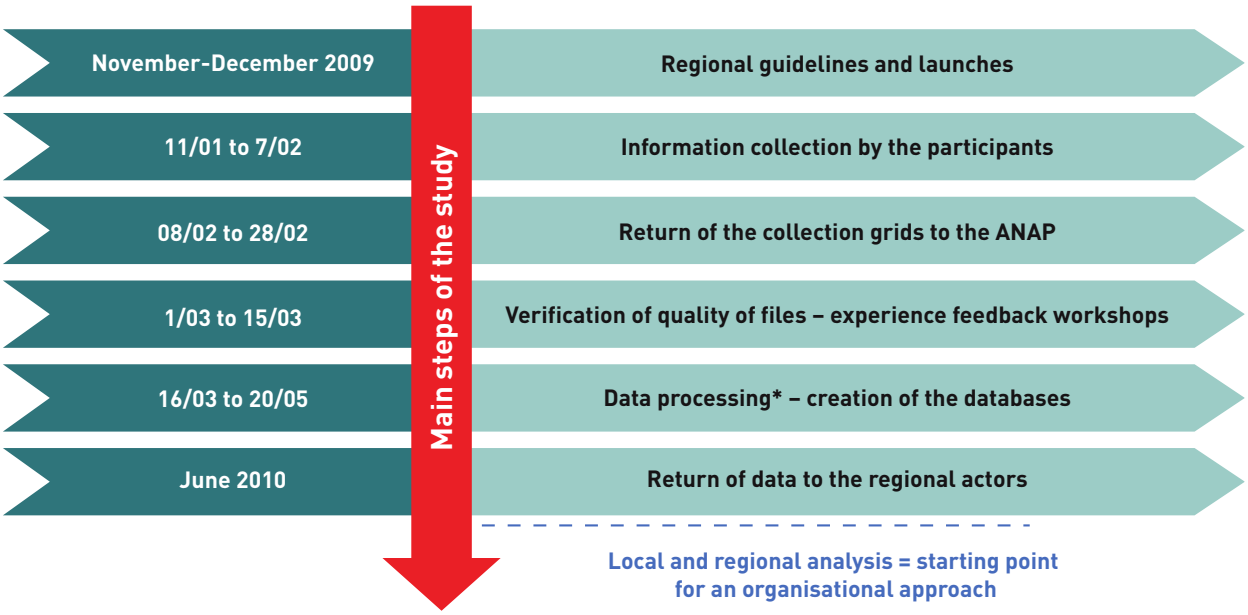
References

1. Sherman JH, Hoes K, Marcus J, Komotar RJ, Brennan CW, Gutin PH. Neurosurgery for Brain Tumors: Update on Recent Technical Advances.Curr Neurol Neurosci 2011
2. Feigl GC, Ritz R, Moraes M, Klein J, Ramina K, Gharabaghi A, Krishek B, Danz S, Bornemann A, Liebsch M, Tatagiba MS. Resection of malignant brain tumors in eloquent cortical areas: a new multimodal approach combining 5-aminolevulinic acid and intraoperative monitoring. J Neurosurg 2010;113:352-7
3. Bauman G, Puderbach M, Deimling M, Jellus V, Chefd'hotel C, Dinkel J, Hintze C, Kauczor HU, Schad LR. Non-contrast-enhanced perfusion and ventilation assessment of the human lung by means of Fourier decomposition in proton MRI. Magnet Reson Med 2009;62:656-64
4. Lederlin M, Corneloup O, Latrabe V, Montaudon M, LaurentF. MRI and the thorax. Rev Mal Respir 2010;27:395-402
5. Blum A, Sauer B, Detreille R, Zabel JP, Pierrucci F, Witte Y, Drap F. Le diagnostic des fractures récentes du scaphoïde : revue de la littérature. J Radiol 2007;88:741-59
6. Feydy A, Gossec L, Bazeli R, THévenin F, Pluot E, Rousseau J, Lenczner G, Campagna R, Guerini H, Chevrot A, Dougados M, Drapé JL. Spondyloarthropathy: MR imaging features. J Radiol 2010;91:1057-67
7. Thuny F, Jacquier A, Jop B, Giorgi R, Gaubert JY, Bartoli JM, Moulin G, Habib G. Assessment of left ventricular non-compaction in adults: side-by-side comparison of cardiac magnetic resonance imaging with echocardiography. Arch Cardiovasc Dis 2010;103:150-9
8. Hays AG, Schär M, Kelle S. Clinical Applications for Cardiovascular Magnetic Resonance Imaging at 3 Tesla. Current Cardiology Reviews, 2009, 5, 237-242
9. Yoshida S, Masuda H, Ishii C, Tanaka H, Fujii Y, Kawakami S, Kihara K. Usefulness of diffusion-weighted MRI in diagnosis of upper urinary tract cancer. AJR 2011;196:110-6
10. Durand E, Chaumet-Riffaud P, Grenier N. Functional renal imaging: new trends in radiology and nuclear medicine. Semin Nucl Med 2011;41:61-72
11. Daguet E, Malhaire C, Hardit C, Athanasiou A, Thibault F, Ollivier L, Tardivon A. MR breast screening in patients with genetic mutation. J Radiol 2008;89:783-90
12. Choi JY, Kim MJ, Lee JM, Lee JY, Kim SH, Han JK, Choi BI. Magnetic resonance cholangiography: comparison of two- and three-dimensional sequences for assessment of malignant biliary obstruction. Eur Radiol 2008;18:78-86
13. Cesbron-Metivier E, Rouillier V, Boursier J, Cavaro-Ménard C, Lebigot J, Michalak S, Calès P Aubé C. Noninvasive liver steatosis quantification using MRI techniques combined with blood markers. Eur J Gastroenterol Hepatol 2010;22:973-82
14. Luciani A, Lin C, Beaussart P, Zerbib P, Haioun C, Rahmouni A. IRM fonctionnelle corps entier : applications hématologiques. J Radiol 2010;91:375-380

TECHNICAL OVERVIEWS: COMPUTED TOMOGRAPHY

Comparative study of computed tomography and magnetic resonance imaging: report covering fourteen regions

by Prof. Elisabeth Schouman-Claeys, François Richou and Dr. Béatrice Falise Mirat – ANAP (National agency for supporting medical institution performance)



* The indicators, grouping rules and data return sheets were developed jointly by the ANAP and the SFR.

Diagram 1: Project schedule

In early 2010, the ANAP (French national agency for supporting medical institution performance) ran a benchmarking campaign on medical imaging facilities operating CT and MRI devices in 14 regions of France. This innovative approach, resulting from close collaboration with the regional health agencies (ARS) and representatives of radiologists (SFR, FNMR, SRH, CERF[1]) provides the first large-scale comparison of the performance of these two techniques, which are of constantly increasing importance in patient care.

This qualitative and quantitative assessment was applied at three levels:

– nationwide, to observe the broad trends concerning the efficiency of the functional organisation implemented for the MRI and CT devices, to make an objective assessment of their accessibility to patients and to understand the clinical examinations performed for both scheduled procedures and emergencies;

– in the participating regions, to map the diagnostic supply and the ability to meet the populations' need for major imaging facilities. The waiting time for appointments can be compared with the map of the machines and their uses, as well as the radiologist population, so as to create an appropriate regional response;

- the participating establishments receive a comparative analysis of the organisation applied for their CT or MRI devices, and can thus identify areas for improvement and implement action plans.

Methodology

Based on voluntary participation further to a call for candidates sent out to the regional hospitalisation agencies (ARH) and the regional health agencies (ARS), the study is based on the collection of quantitative and qualitative indicators set up for the CT and MRI scanners. The indicators focused on all the examinations performed on 313 CT scanners and 182 MRI scanners over 28 consecutive days. More than 250,000 imaging examinations were thus inventoried, giving a view of the performance of more than three-quarters of the equipment of

1. French society of radiology, National federation of radiologists, Union of Hospital radiologists, French commission of teachers of radiology.

the participating regions. It is noteworthy that, depending on the sites, between 40% and 80% of the indicators were obtained from information systems existing on the sites.

The measured indicators gauged the quality of the service (appointment times for true clinical cases and examination report return times) and the efficiency of the imaging platforms (MRI and CT equipment occupancy levels, opening times, production of examinations measured in relative cost index (RCI) produced per opening hour).

The study also gives access to more clinical data: types of examinations performed with MRI and CT scanners, duration of the examinations, profiles of patients undergoing these examinations (ambulatory, lying down, etc.), origin of patients (hospitalised or outpatients, emergency service, intensive care, etc.)

National results and trends

The broad national trends in MRI and CT scanning reveal two different situations:

As regards the CT scanner, a wide diversity of uses (scheduled, emergency, interventional examinations, etc.) and organisational methods result in extremely varied (utilisation rate, operating hour ranges, etc.). It is indeed a versatile and relatively widespread machine that is well mastered and can ensure scheduled (including interventional) and emergency examinations, and out-of-hours (OOH) services. The median waiting times for appointments are 6.75 days for outpatients and 2 days for hospitalised patients. The results according to the chosen clinical cases are relatively uniform, with a few extreme values that require attention and improvement actions on the part of the entities concerned. The CT scanner occupancy rates vary considerably (median of 60.1%), as do their operating hours (median of 47.5 h per week excluding emergency service time slots), in part reflecting a diversity of activity.

The MRI data are much more uniform. In the majority of cases MRI scanners are used for scheduled examinations on able-bodied patients, and have high occupancy rates (median of 81.4%) over extended operating hours (57 h per week). Waiting times for appointments on the other hand are much longer in MRI than in CT scanning, with a median for outpatients of 23 days for the panel of respondents. This median time applies uniformly to the 5 clinical cases defined in the context of the survey, with the exception of the paediatrics case: "4-year old girl suffering focal epileptic seizure. Etiologic research" for which the median waiting time for an appointment is 17 days. For hospitalised patients the median waiting time is 7 days. The responses for this indicator vary widely from one establishment to another.

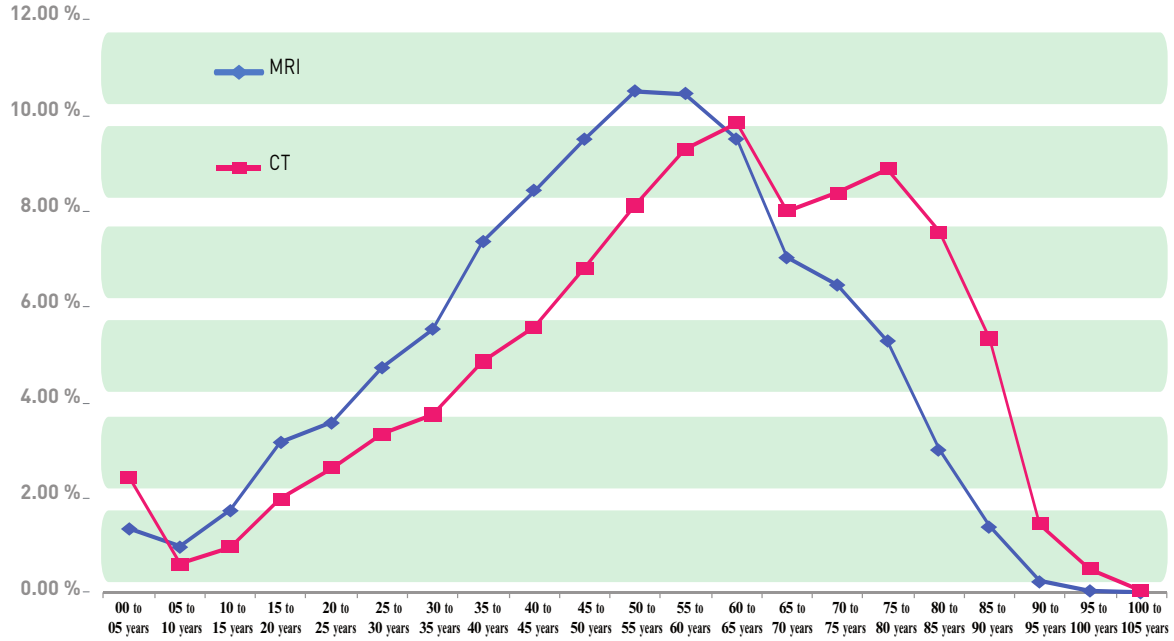
The patients and the clinical indications

The major differences between the pathologies and patient profiles examined using MRI and CT partly explains the varied results in the analysis of the organisational setups (figure below).

Physical condition of the patients

The profiles of the patients examined by the two methods are very different: people receiving MRI examinations are usually able-bodied, scheduled, often outpatients (almost half are outpatients undergoing osteoarticular examinations), whereas for CT examinations a large proportion of the patients arrive on stretchers and are not scheduled (sent from the accident and emergency (A&E) department, intensive care, or any other hospitalisation department). Consequently, one of the major organisational challenges for health establishment technical platforms operating a CT scanner is to cater for both the scheduled patients and unscheduled emergencies.

The patients



MRI does not use ionising radiation, and compared with CT, tends to be used on slightly younger patients.
The 2nd peak of CT examinations observed in patients around 75-80 years old is essentially due to skull scans.

The examinations performed with the two techniques

Image acquisition times are longer for MRI than for CT examinations[3] (10mn on average for CT examinations of outpatients compared with 20mn for MRI). Thus, in this study the CT scanners performed 180 examination per week on average, whereas the MRI machines, despite higher occupancy levels and longer operating times, performed just 119.

Regarding the anatomical regions explored by CT, 30% of examinations concern the trunk (20% digestive system and pelvis, 10% respiratory system) and 25% the central nervous system, although MRI is considered to be particularly appropriate in this area. Osteoarticular examinations represent 19% of CT procedures, the cardiovascular system 5%, and multi-region examinations 16%. The study did not address the examination indications or the criteria on which the choice of technique was based (clinical reasons, accessibility, etc.), or the question of patient radiation exposure, which remains a concern for everyone.

For MRI, 51% of the procedures are osteoarticular examinations, with just 28% of procedures for the central nervous system, 12% for the exploration of the trunk (12% digestive system and pelvis), 3% for the cardiovascular system.

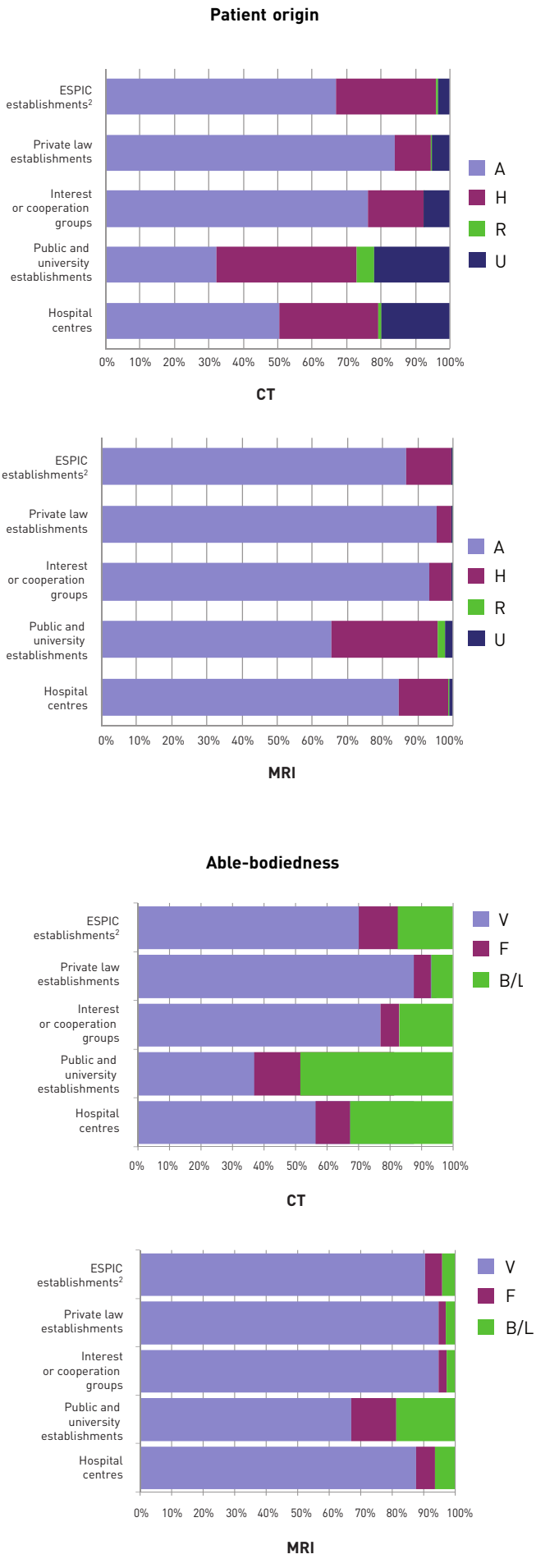
Out-of-hours services

For out-of-hours (OOH) services, the study shows - beyond the organisational differences in departments - a disparity in activity between CT and MRI scanners. The CT scan remains the reference emergency examination (70% of the CT scanner studies make a significant contribution to OOH services), unlike MRI which remains a scheduled examination technique (only 21% of the MRI machines in the scope of the study are open for OOH services, and some of these only on a partial basis). More than 5,000 out-of-hours examinations were performed on the CT scanners during the 28 days of the study, whereas the figure is only about 200 for MRI scanners. Lastly, the night activity (20 h - 7 h) is unequally distributed: some twenty CT scanners (i.e. between 5 and 10% of the panel) are used fairly intensively (at least 10 patients per night during the week), while two-thirds are used for 5 patients per week or less.

Conclusion

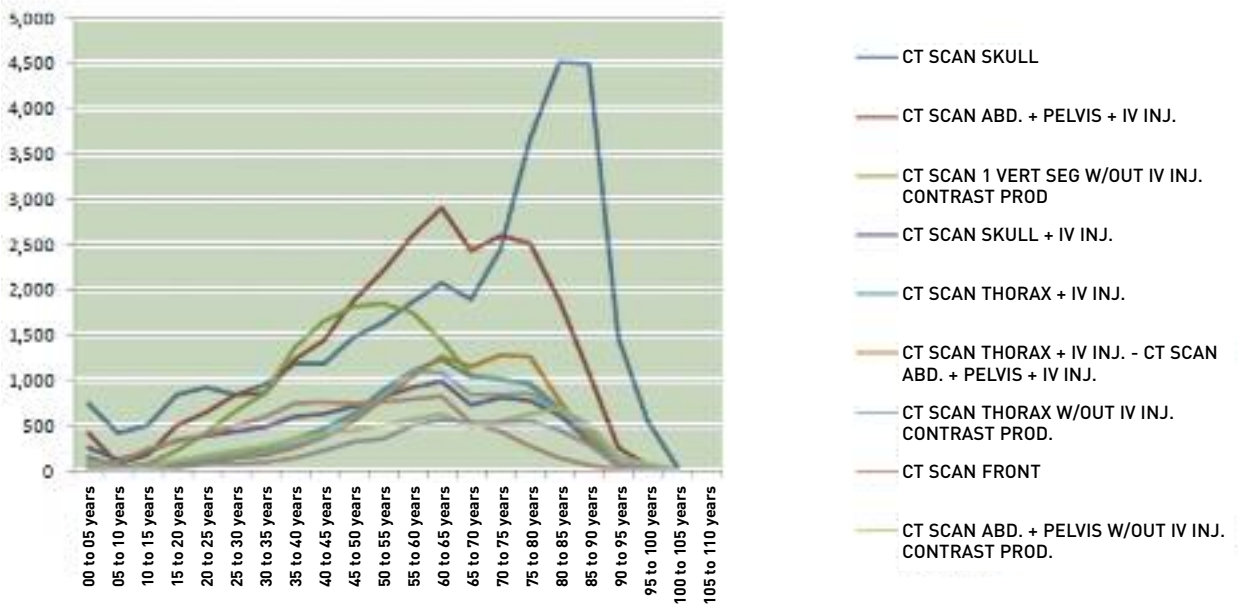
If the operational performance of the imaging platforms is frequently studied in the international literature, to our knowledge no other study exists with a comparable diversity of participants and regional contexts.

The study has provided an objective assessment of the diversities in the functioning and organisation of the use of these machines. One could be tempted to draw hasty conclusions from reading just one indicator taken individually, but the performance and aptness of an imaging platform often result from a balance between the different measured dimensions and not the maximising of one to the detriment of the others. Each participant ARS must therefore make a detailed and critical study of the report, with the close involvement of its imaging professionals.

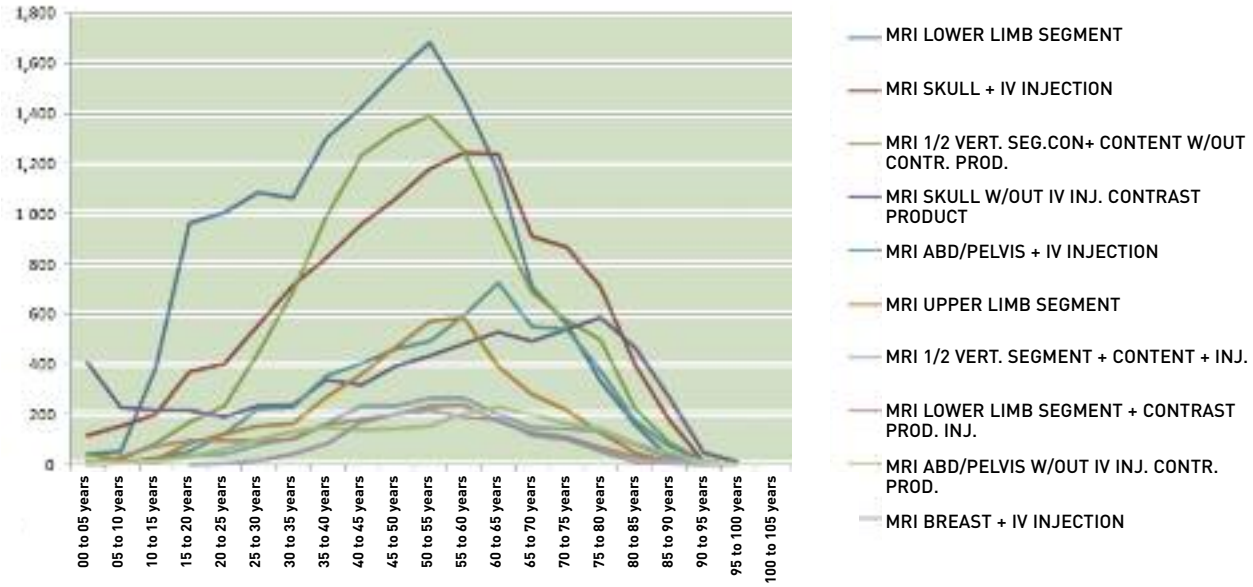


2. Private health facilities of collective interest.

3. The times correspond to the time the patient spends in the image acquisition room, but not the time spent in the imaging unit (time before and after the examinations), or the time for processing and interpreting the images.



Breakdown of the age curves for the 10 most frequent CT procedures



Breakdown of the age curves for the 10 most frequent MRI procedures

The study presents identified limits: some of the data (equipment occupancy rate for example) must be treated with some caution (data entry difficulties - quite considerable on some sites, unreliable content of statements), and certain aspects have not been broached, such as the appropriateness of the examinations performed: validity of the indication, quality of examination performance and of the report, exhaustiveness, etc.; the study does not consider compliance with good practices, the times of the medical personnel, etc.

Nevertheless, the data collected provide a wealth of information and, over and above these first returns, can be used for example to:

– establish regional action plans to optimally adapt the services to the needs of the populations;

– identify the margins for organisational improvements on each imaging platform so that the health professionals can ensure the appropriate utilisation of their resources.

Deeper analyses of this database by the regions, the learned societies, or other authorised actors, will provide useful information on the clinical and organisational practices or realities of CT and MRI examinations, and help all the actors progress towards an organisation allowing the right examination to be offered to the right patient. ■

TECHNICAL REVIEWS: COMPUTED TOMOGRAPHY

Optimising doses in paediatric CT scanning

by Dr. Hervé Brisse, Ph. D, Imaging Department , Institut Curie – Paris

Computed tomography (CT) is still extensively used in paediatric imaging. The technique remains a benchmark for bone, lung and cardiovascular exploration and for emergency imaging. Multi-slice technology has revolutionised image quality by improving spatial resolution and reducing acquisition times to a few seconds, almost completely eliminating the problems of movement artefacts common with children. This technique will therefore not be abandoned any time in the near future by paediatric radiologists.

However, these multi-slice CT scanners today allow rapid and repeated exploration of large volumes, which can lead to high individual radiation exposure[1]. A number of surveys have shown that the exposure parameters used in paediatrics are too high in comparison with adult protocols [2, 3], even though a lower dose can provide equivalent image quality [4]. These paediatric CT optimisation measures are currently the subject of an extensive campaign in the literature [5-7].

There are relatively few data relating to CT scanning exposure of children in France. In 2007, 14% of conventional radiological procedures and just 4% of CT procedures were performed on children [8]. It is nevertheless a fact that although CT scanning represents just a small proportion of the acts, it is nevertheless the main source of medical exposure, currently accounting for 8% of all the radiological procedures in France, but 39% of the collective exposure [9].

A national retrospective multicentric study conducted by the IRSN (French institute of radiation protection and nuclear safety) in collaboration with the SFIPP (French-speaking society of paediatric and prenatal imaging), recently analysed the population of under 5-year olds [10]. The data for about 30,000 children were analysed for the period from 2000 to 2006: CT scans of the skull represented 63% of the examinations, the thorax 21%, the abdomen and pelvis 8%, and 8% for the other locations. 43% of the children had their first CT examination when less than 1 year of age, and 9% were exposed in the first month of their life.

Children's organs are more sensitive to ionising radiation than adults', and as their life expectancy is higher, the stochastic risk - essentially the risk of radiation-induced cancer - is also higher. The lifetime risk attributable to death by cancer and per sievert (for a single exposure) has thus been estimated by the ICRP (International Commission on Radiological Protection) at 14% at birth compared with 1% at the age of 75 years [11]. These figures must be borne in mind when discussing exposure risks in children.

And since the effective dose is still used as the risk indicator, it must not be forgotten that its individual use in adults, which is already subject to much debate[12,13], is even more questionable in children, since the factors used to calculate it exclude the age factor, leading to an underestimation of the risk [14].

Putting on a contention mask and positioning a child for a proton-therapy treatment

There is a lasting debate on the risk entailed by the low doses used in diagnostic imaging. The literature on this subject is difficult to analyse for two main reasons, the first being methodological. These studies contain biases associated with the quality of dosimetric information collection and the size of the analysed cohorts, which limit the statistical power. The second reason is technological: the improvements in the technology and practices have over time resulted in a steady decrease in the doses used in conventional radiology, rendering the initial publications null and void.

Historically, back in the 1950's, Alice Stewart was the first to report a link between the risk of leukaemia in children and in utero medical exposure to radiation [15]. Two studies of cohorts have secondarily demonstrated a significant link between repeated exposures of the thorax in the young girl and an increased risk of breast cancer in adulthood. The first study concerned children monitored for pulmonary tuberculosis [16] between the 1920's and the 1950's, while the second concerned young girls monitored for scoliosis between 1910 and the 1960's[17]. However, the cumulative dose levels in these series (120 to 750 mGy on the breast) were globally very high due to the techniques used at the time, such as fluoroscopy.

The present-day risk in children must therefore be reassessed in the light of more recent publications, resulting from studies of cohorts of children exposed between 1990-2000. Over this period, no significant link has been demonstrated between prenatal exposure associated with radiodiagnostic exams and an increased risk of leukaemia or solid tumour

during childhood, even on large series [18, 20]. As regards postnatal exposure, the published results are contradictory [19], with some large series finding no increase in risk for these low doses [21], while others on smaller series show a slight but possible increase in the risk of leukaemia in the event of repeated exposure[22].

This being said, the majority of these studies focused on conventional radiology, not on computed tomography. A multicentric cohort study was recently organised in France by the IRSN and the SFIPP to try to identify a possible risk associated with this technique. It will involve 90,000 children between now and 2013, and will be cross-referenced with the national registers of tumours and blood diseases in the child. Another European project ("EPI-CT") is currently in progress and should ultimately integrate the data from 11 national cohorts.

Pending the results of these studies however, the practitioners who request and perform these procedures must have a medically coherent and pragmatic attitude with respect to this potential risk. This attitude must be situated somewhere between outright rejection of techniques exposing patients to ionising radiation, which today is unjustified, and the irresponsible denial that any risk exists. It can be based on few essential principles: justification, limitation, optimisation and substitution.

Justification

Justification of the procedures must remain the priority. Radiological examination indications are of course decided case by case, but for the more common indications, any examination prescription must comply with the recommendations of the Guide to good medical imaging examination practices[23], published in 2005 by the SFR (French Society of Radiology) and currently being updated, and those published by the HAS (National Health Authority. The regulations divide the responsibility for verifying examination justification between the persons prescribing and those performing the procedures.

Limitation

It is vital to check the radiological precedence to avoid redundant examinations. The repetition of procedures is the highest-risk attitude, as it can ultimately lead to high cumulative levels of exposure, especially with CT.

Paediatric specialities using CT must bear this notion in mind when establishing surveillance strategies, particularly for chronic illnesses. Even in paediatric oncology, where the justification of the procedures is obvious for diagnosis and monitoring, the risk of a second tumour in exposed territory is probably even higher on account of the genetic diathesis and the associated treatments (some chemotherapy treatments favour the occurrence of second cancers).

One of the priority means for preventing the unnecessary repetition of procedures is the setting up of computerised medical files that are shared, efficient, and ergonomic, including the transfer of DICOM[1] images between imaging centres (hospitals or other medical establishments), themselves equipped with PACS[2]. By improving the speed and quality of medical information transmission, these tools not only help reduce examination numbers and exposure levels, but also improve the overall quality of patient care. These networks already exist but should be much more widely deployed.

Optimisation

When a CT scan is justified, the dose must be optimised, that is to say maintained at the "as low as reasonable achievable" (ALARA) level.

The first aim is to obtain an examination of excellent quality first time round, without risking having to re-expose the child to radiation. To achieve this, all the preparatory and supervision measures contributing to examination comfort and quality must be taken. This demands genuine experience acquired through regular paediatric practise. It also has a cost in terms of medical personnel and an impact on the activity of an imaging site, which is not taken into account in the pricing structures.

The preparation starts as soon as the appointment is made, explaining the constraints to the parent(s) by means of information sheets. The child's fear is generally focused on the installation of the peripheral venous catheter, therefore analgesic measures are very important. Local anaesthetics are used as a matter of course. The use of an equimolar mix of nitrogen protoxide and oxygen is a good complementary measure in children aged over 4 years. This non-sedating gas has an anxiolytic effect and causes surface anaesthesia; training in its use is nevertheless required.

Multi-slice scanners have considerably reduced image acquisition times, and the use of sedative medication in young children is virtually unnecessary now. Constraining their movement does however remain essential (bandages or vacuum mattress). The use of lead protections on unexposed areas is not recommended, as it complicates the installation of the patient for not great dosimetric benefit. The benefit of bismuth shields for the breasts, the thyroid or the crystalline lens is debated [24, 25] and their use - which is not simple - risks causing image artefacts.

The second aim is have parameter settings appropriate for the patient. Today manufacturers propose paediatric protocols adapted to the age and/or weight of the child. These protocols must nevertheless be adapted to the indications and inspired by the paediatric protocols of the SFR's Practical guide for radiologists [26]. Unlike adult protocols which are easier to standardise, paediatric examinations almost always have to be "tailored to fit". Because of this, a specialised paediatric radiologist should always be present to adjust the parameters to the patient, the explored region and the indications, and the younger the child the more this is important.

The optimisation of exposure parameters is based on general principles that must be adapted to each particular case. Good laser centring is essential for radiation protection and image quality. The topogram[3], centred solely on the region to explore, must be produced with minimum constants (80-90 kV, mAs min), with a single angle of incidence usually being sufficient (anteroposterior for the front views).

A single passage (without injection or with immediate injection depending on the indication) is usually sufficient. The helical sequence must be limited to the volume to explore, avoiding the thyroid in particular in the thoracic stage and the

1. DICOM: Digital Imaging and Communication in Medicine (Standard d'images médicales).
2. PACS : Picture Archiving and Communication System (Système d'archivage et de gestion des images médicales).
3. Image produced prior to acquisition of the CT scanner images, to define the region to explore.

testicles in the pelvic stage. The parameters must be adapted to the age, the organ, its volume, its spontaneous contrast and the size of the lesion to be detected. The required doses depend on what is being explored: low-density structures with high spontaneous contrast (lungs, sinuses) require lower doses, whereas explorations to detect small lesions in soft tissue with low contrast (encephalon, abdominal viscera) or in very dense regions (petrous part of temporal bones) require higher doses. One must also distinguish examinations that must be of excellent quality (screening, initial diagnosis) from surveillance examinations which can be of lower quality.

The high voltage values used in paediatrics are usually between 80 and 120 kV for the trunk and 120 kV for the skull and extremities. A voltage of 140 kV is not justified in paediatrics.

Collimation and pitch[4] must be defined first, as they depend on the indication and the explored region. The shorter the acquisition time, the lower the risk of movement artefacts (minimum tube rotation time and pitch as high as the desired z-axis resolution (in the head/feet direction) permits). Current intensity (mA) must be adjusted last by checking the dosimetric result of the protocol before acquisition via the displayed CTDIvol[5]. This must be compared with the dosimetric recommendations already published [26] by the SFIPP, the IRSN and the SFR (table 1), which are destined to become regulatory diagnostic reference levels (DRL).

CT scanner manufacturers have made substantial technological efforts over these last years to improve dose optimisation.

The first aids proposed were automatic dose modulation or automatic exposure control . In the light of the published studies, the dosimetric benefit of these systems is still under debate for children, and appears to be less than initially suggested [28, 29]. In pelvis examinations they can unnecessarily increase the dose to the pelvic organs [30]. If they are used, the quality indices must be adjusted on a case-by-case basis to the required examination quality and the patient morphotype [31]. This adjustment is still relatively empirical and not readily controllable by the technicians and radiologists.

More recently, systems using iterative reconstruction algorithms have been introduced. This computerised process gives an image which, for an equivalent delivered dose, has a higher signal-to-noise ratio than with the old systems using filtered back-projection. Several publications report on studies of the use of these systems in the adult [32-35]. No specifically paediatric study is available yet, but this new process seems highly promising.

Substitution

Substitution still remains the best radiation protection method. Ultrasonography and MRI, which do not expose the patient to ionising radiation, must be the preferred methods for children whenever possible. Ulstrasonography is readily accessible at present, but it cannot be used for all pathologies and does pose problems of reproducibility. MRI is an exploration method that is perfectly adapted to children, providing essential diagnostic information in areas as vital as neurology, cardiology and oncology, and its indications are constantly progressing in all domains. Unfortunately, despite the measures taken, the French MRI equipment fleet is still too small to allow complete substitution.

Furthermore, it must be borne in mind that MRI examinations of children require special preparation and supervision and, for the youngest of them, medical sedation or a general anaesthetic, as the patient must remain completely immobile during the examination. Unfortunately, these aspects are not taken into consideration and there is no specific pricing structure for these examinations. With the present "T2A" activity-based pricing system in France, paediatric MRI - even more than computed tomography is an activity that is not very attractive for healthcare establishments, therefore few teams practice it. Today many children are still examined by CT because MRI is inaccessible.

4. Pitch of the helix during acquisition in helical mode corresponding to the ratio between the distance travelled by the scanner table in on rotation and the collimation.
5. Computed Tomography Dose Index.

Table 1: 2008 SFIPP / IRSN dose recommendations for paediatric MDCT (kVp, CTDIvol, DLP)

	1 year (size 75 cm, weight 10 kg)				**5 years** (size 110 cm, weight 19 kg)				**10 years** (size 140 cm, weight 32 kg)			
	HV[1] (kV)	CTDIvol[2] (mGy)	Length (cm)	DPL[3] (mGy.cm)	HV (kV)	CTDIvol (mGy)	Length (cm)	DPL (mGy.cm)	HV (kV)	CTDIvol (mGy)	Length (cm)	DPL (mGy.cm)
Skull	120	30	14	420	120	40	15	600	120	50	18	900
Facial mass	120	25	8	200	120	25	11	275	120	25	12	300
Sinus	100-120	10	5	50	100-120	10	6	60	100-120	10	10	100
Petrous part of temporal bone	120	45	3,5	157	120-140	70	4	280	120-140	85	4	340
Thorax standard	80-100	3	10	30	80-100	3.5	18	63	100-120	5.5	25	137
Lungs "low dose"	80	2	10	20	80-100	3	18	54	100-120	4	25	100
Abdomen and pelvis	80-100	4	20	80	80-100	4.5	27	121	100-120	7	35	245
Bone	100-120	7	-[4]	-[4]	100-120	10	-[4]	-[4]	120	12	-[4]	-[4]

1. High Voltage.
2. Index $CTDIvol_{16}$ for "head and neck" scans, and $CTDIVol_{32}$ for trunk and bones.
3. Dose-Length Product , Index DPL_{16} for "head and neck" scans, and DPL_{32} for trunk and bones, for one pass.
4. Value not provided, dependent on the osseus segment examined.

By way of example, according to a December 2010 report of the ANAP (French national agency for supporting medical institution performance), the median waiting time to obtain an appointment in France for a cerebral MRI for a 4-year old child further to a focal epileptic seizure is 19 days, a delay that is incompatible with the urgency of the situation.

Conclusion

Given the relatively high doses delivered by CT scans and the potential risks for children, it is indeed in paediatric radiodiagnostics that the greatest optimisation efforts must be made. But dosimetric optimisation firstly requires the optimising of medical practices as a whole, both to avoid unnecessary repetition of irradiating procedures and to allow effective substitution by non-irradiating methods such as MRI. All these measures have a cost, which must be accepted if we really want to reduce the exposure of this population.

Children represent a small group of patients in terms of numbers, but which finally constitutes the best justification for all the actions taken to enhance patient radiation protection. ■

References

[1] Brenner DJ, Hall EJ. *Computed tomography: an increasing source of radiation exposure.* N Engl J Med 2007; 357:2277-2284.
[2] Hollingsworth C, Frush DP, Cross M, Lucaya J. *Helical CT of the body: a survey of techniques used for pediatric patients.* AJR Am J Roentgenol 2003; 180:401-406.
[3] Paterson A, Frush DP, Donnelly LF. *Helical CT of the body: are settings adjusted for pediatric patients?* AJR Am J Roentgenol 2001; 176:297-301.
[4] Singh S, Kalra MK, Moore MA, et al. *Dose reduction and compliance with pediatric CT protocols adapted to patient size, clinical indication, and number of prior studies.* Radiology 2009; 252:200-208.
[5] Strauss KJ, Goske MJ, Kaste SC, et al. *Image Gently: Ten Steps You Can Take to Optimize Image Quality and Lower CT Dose for Pediatric Patients.* Am. J. Roentgenol. 2010; 194:868-873.
[6] Nievelstein RA, van Dam IM, van der Molen AJ. *Multidetector CT in children: current concepts and dose reduction strategies.* Pediatr Radiol 2010; 40:1324-1344.
[7] International Commission on Radiological Protection. *Managing patient dose in multi-detector computed tomography.* ICRP Publication 102. Ann ICRP 2007; 37:1-79.
[8] Etard C, Sinno-Tellier S, Aubert B. *Exposition de la population française aux rayonnements ionisants liée aux actes de diagnostic médical en 2007.* In: Institut de Veille Sanitaire et Institut de Radioprotection et Sûreté Nucléaire, 2010; 104.
[9] Scanff P, Donadieu J, Pirard P, Aubert B. *Population exposure to ionizing radiation from medical examinations in France.* Br J Radiol 2008; 81:204-213.
[10] Bernier MO, Rehel JL, Brisse H, et al. Radiation exposure from computed tomography in early childhood: a French large scale multicenter study. . Br J Radiol 2011:(sous presse).
[11] International Commission on Radiological Protection. *The 2007 Recommendations of the International Commission on Radiological Protection.* ICRP publication 103. Ann ICRP 2007; 37:1-332.
[12] Brenner DJ. *Effective dose: a flawed concept that could and should be replaced.* Br J Radiol 2008; 81:521-523.
[13] Dietze G, Harrison JD, Menzel HG. *Effective dose: a flawed concept that could and should be replaced.* Comments on a paper by Brenner DJ (Br J Radiol 2008;81:521-3). Br J Radiol 2009; 82:348-351.
[14] Li X, Samei E, Segars WP, et al. *Patient-specific radiation dose and cancer risk estimation in CT: part II.* Application to patients. Med Phys 2011; 38:408-419.
[15] Stewart A, Webb J, Giles D, Hewitt D. *Malignant disease in childhood and diagnostic irradiation in utero.* The Lancet 1956; 268:447.
[16] Boice JD, Jr., Preston D, Davis FG, Monson RR. *Frequent chest X-ray fluoroscopy and breast cancer incidence among tuberculosis patients in Massachusetts.* Radiat Res 1991; 125:214-222.
[17] Ronckers CM, Land CE, Miller JS, Stovall M, Lonstein JE, Doody MM. *Cancer mortality among women frequently exposed to radiographic examinations for spinal disorders.* Radiat Res 2010; 174:83-90.
[18] Ray JG, Schull MJ, Urquia ML, You JJ, Guttmann A, Vermeulen MJ. *Major radiodiagnostic imaging in pregnancy and the risk of childhood malignancy: a population-based cohort study in Ontario.* PLoS Med 2010; 7:e1000337.
[19] Schulze-Rath R, Hammer GP, Blettner M. *Are pre- or postnatal diagnostic X-rays a risk factor for childhood cancer? A systematic review.* Radiat Environ Biophys 2008; 47:301-312.
[20] Rajaraman P, Simpson J, Neta G, et al. *Early life exposure to diagnostic radiation and ultrasound scans and risk of childhood cancer: case-control study.* BMJ 2011; 342:d472.
[21] Hammer GP, Seidenbusch MC, Schneider K, et al. *A cohort study of childhood cancer incidence after postnatal diagnostic X-ray exposure.* Radiat Res 2009; 171:504-512.
[22] Bartley K, Metayer C, Selvin S, Ducore J, Buffler P. *Diagnostic X-rays and risk of childhood leukaemia.* Int J Epidemiol 2010; 39:1628-1637.
[23] *Société Française de Radiologie. Guide des Procédures Radiologiques.* In. Paris: Société Française de Radiologie, 2005.
[24] Kim S, Frush DP, Yoshizumi TT. *Bismuth shielding in CT: support for use in children.* Pediatr Radiol 2010; 40:1739-1743.
[25] Geleijns J, Wang J, McCollough C. *The use of breast shielding for dose reduction in pediatric CT: arguments against the proposition.* Pediatr Radiol 2010; 40:1744-1747.
[26] *Société Française de Radiologie. Guide Pratique à l'Usage des Médecins Radiologues.* In. Paris: Société Française de Radiologie, 2009.
[27] Brisse HJ, Aubert B. *Niveaux d'exposition en tomodensitométrie multicoupes pédiatrique : résultats de l'enquête dosimétrique SFIPP / IRSN 2007-2008* [CT exposure from pediatric MDCT: results from the 2007-2008 SFIPP/ISRN survey]. J Radiol 2009; 90:207-215.
[28] Papadakis A, Perisinakis K, Damilakis J. *Angular on-line tube current modulation in multidetector CT examinations of children and adults: The influence of different scanning parameters on dose reduction.* Med Phys 2007; 34:2864-2874.
[29] Papadakis A, Perisinakis K, Damilakis J. *Automatic exposure control in pediatric and adult multidetector CT examinations: A phantom study on dose reduction and image quality.* Med Phys 2008; 35:4567-4576.
[30] Brisse HJ, Madec L, Gaboriaud G, et al. *Automatic exposure control in multichannel CT with tube current modulation to achieve a constant level of image noise: experimental assessment on pediatric phantoms.* Med Phys 2007; 34:3018-3033.
[31] Brisse HJ, Brenot J, Pierrat N, et al. *The relevance of image quality indices for dose optimization in abdominal multi-detector row CT in children: experimental assessment with pediatric phantoms.* Phys Med Biol 2009; 54:1871-1892.
[32] Sagara Y, Hara AK, Pavlicek W, Silva AC, Paden RG, Wu Q. *Abdominal CT: Comparison of Low-Dose CT With Adaptive Statistical Iterative Reconstruction and Routine-Dose CT With Filtered Back Projection in 53 Patients.* Am. J. Roentgenol. 2010; 195:713-719.
[33] Marin D, Nelson RC, Schindera ST, et al. *Low-Tube-Voltage, High-Tube-Current Multidetector Abdominal CT: Improved Image Quality and Decreased Radiation Dose with Adaptive Statistical Iterative Reconstruction Algorithm: Initial Clinical Experience.* Radiology 2010; 254:145-153.
[34] Hara AK, Paden RG, Silva AC, Kujak JL, Lawder HJ, Pavlicek W. *Iterative Reconstruction Technique for Reducing Body Radiation Dose at CT: Feasibility Study.* Am. J. Roentgenol. 2009; 193:764-771.
[35] Prakash P, Kalra MK, Ackman JB, et al. *Diffuse Lung Disease: CT of the Chest with Adaptive Statistical Iterative Reconstruction Technique1.* Radiology 2010; 256:261-269.

Interventional radiology examination, interventional cerebral angiography

TECHNICAL OVERVIEWS: INTERVENTIONAL RADIOLOGY

An approach to patient dose optimisation in interventional radiology at the Clermont-Ferrand University Hospital Centre (CHU)

by Joël Guersen, Health executive, assistant PCR, medical imaging centre, Dr. Pascal Chabrot, MCU - PH Radiologist, Dr. Lucie Cassagnes, PH Radiologist and Dr. Jean Gabrillargues, PH Radiologist and Prof. Louis Boyer, PUPH Radiologist – Clermont-Ferrand CHU

In late October 2009 a serious event occurred in the imaging unit of the Clermont Ferrand University Hospital (CHU), corresponding to localised pruritic erythematous skin lesions which resemble radiation-induced damage, following a double pelvic arterial embolisation, which saved the life of a young female patient.

The imaging unit and the General Management of the CHU notified ASN of the event, and an on-site appraisal carried out by the IRSN (Institute of Radiation Protection and Nuclear Safety) confirmed that there was a very strong probability that the cutaneous symptoms were caused by radiation.

An internal enquiry concluded that there was a problem with optimisation of the machine parameters in the angiography facility concerned.

The imaging unit then initiated a patient dosimetry optimisation process for the 3 vascular radiology and vascular neuro-radiology facilities in the establishment, divided into three main phases that addressed:
- image acquisition rates,
- the high-voltage settings of the facility concerned, following notification of the event to AFSSAPS (French health product safety agency) and involving the manufacturer,
- the fluoroscopy and radiography image acquisition parameters, following intervention by the IRSN experts at the request of the imaging unit.

On the facility concerned, the reduction in the X-ray dose delivered to the patients was initially 30%, then 35% and finally 25%, representing a total reduction by a factor of 3.

This article presents the patient dose optimisation approach implemented in interventional radiology and the specific procedure devised to respond to an unavoidable radiation-induced complication.

The context

General context

The general context of our approach to optimise patient dose exposure in interventional radiology is firstly related to the constant increase over the last 20 years in the number of interventional radiological procedures. The proportion of these procedures today largely exceeds 50% of the activity of the vascular radiology, neuroradiology, and cardiac catheterisation facilities. These examinations allow non-invasive or minimally invasive treatment by percutaneous tract of, for example, cardiovascular, traumatic or tumoural pathologies, in scheduled or emergency situations.

The therapeutic benefit of interventional radiology today is unquestionable, but these procedures can nevertheless deliver significant X-ray doses to the patients.

The risk of deterministic cutaneous effects appearing cannot be excluded in procedures that are technically difficult to perform and require long X-ray exposure times. To give an example, in neuroradiology is not unusual when embolising intracranial arteriovenous malformations (AVM) to require more than two hours of X-ray fluoroscopy to guide the movements of the radiologist. In this case there is a very real risk of alopecia (hair loss) occurring. In peripheral vascular radiology in the thoracoabdominal region, with long procedures, oblique or lateral incidence angles can cause cutaneous lesions in obese patients. The medical necessity for iterative procedures at very close intervals in certain patients (recurrent haemorrhages for example) can also result in the delivery of significant doses to the exposed cutaneous region.

For information, the risk of a radiation-induced deterministic cutaneous effect appears at absorbed skin doses of the order of 2 to 3 Grays in a single dose (threshold dose for the appearance of a transient erythema); beyond this threshold, the severity of the effects increases with the dose received (dry desquamation: 10 Gy – skin necrosis: 18 Gy)[1].

Such deterministic skin effects or alopecias must not mask the risk of stochastic effects for the patients. Uterine embolisations for post-partum haemorrhages, genital venous embolisations for varicocele or pelvian congestion that expose the gonads are habitually carried out on young patients with normal life expectancy. Post-trauma pelvian embolisations and vertebral cementoplasties can also be performed on young patients. The need to verify the result of remote procedures, in vascular neuroradiology for embolised intracerebral aneurysms in particular, induces a build up of X-ray doses that must also draw the operators' attention to the risk of stochastic effects in the patients.

The operators performing these examinations are also concerned by the deterministic (crystalline lens, extremities) and stochastic risks associated with exposure to X-rays.

Exposure of patients to ionising radiation, and particularly to X-rays in interventional radiology, has thus become a growing concern for national and international health authorities and ASN (French Nuclear Safety Authority). ASN tends to orient its inspections in the medical field towards interventional radiology, where it ensures among other things that the regulations on the traceability of doses delivered to patients are applied. ASN thus seeks to promote dose optimisation initiatives in a field where there is room for improvement. These initiatives must enable the skin exposure risks to be controlled and the stochastic risk to be fully grasped.

The implications of patient dosimetry in interventional radiology therefore lie at two levels: radiation protection of both the patients and the operators with respect to the risk of deterministic effects and random effects (stochastic risk for which theoretically there is no threshold dose, as any dose - no matter how low - can result in a risk, no matter how low that risk).

Our dosimetric optimisation actions are therefore globally in line with an approach supported by those in charge of the radiological discipline and the control Authorities, who clearly state the need to take into account the X-ray doses delivered to patients. In our hospital we relay this through our explicit determination to control exposure in radiology and interventional cardiology for patients and operators alike.

The local context that triggered our initiative

The two main sites of the Clermont-Ferrand CHU accommodate nine fixed interventional radiology facilities:
– two facilities are dedicated to peripheral vascular radiology,
- a dual-plane unit is dedicated to neuroradiology procedures,
– another facility is used mainly for digestive examinations,
– three facilities (two single-plane and one dual-plane) are used for cardiac and coronary catheterisations, and two specific rooms are allocated to implantology and cardiac rhythm study.

In October 2009 a serious adverse event (SAE) occurred in interventional vascular radiology. A 30-year old patient having received two emergency uterine embolisations 24 hours apart for recurrent postpartum haemorrhaging linked to a serious anomaly in placental insertion, creating a life-threatening situation, displayed clinical cutaneous signs (pruritic erythematous lesion situated on the median lumbar region, having evolved into a sclerodermiform cutaneous induration, about the size of the palm of the hand, macroscopically characterised by the skin being slightly more pigmented and with numerous telangiectasias running through it) that could correspond to radiation-induced lesions as a result of the X-rays received during the two embolisation procedures.

Faced with this presumption of a radiation-induced mechanism causing cutaneous lesions observed after embolisation, the imaging centre and the general management of the Hospital notified the event to ASN.

An on-site dosimetric appraisal demanded by ASN and conducted by the DRPH (Human Radiation Protection Department) of the IRSN confirmed the high probability that the patient's cutaneous symptoms were caused by radiation, and estimated the dose delivered to the skin at between 12 and 16 Gy, and to the entire volume of the ovaries at between 1 and 1.5 Gy.

An internal investigation in parallel with the IRSN's appraisal concluded that the parameters of the angiography facility concerned were poorly optimised.

At the same time as the SAE was notified to ASN and the AFSSAPS, the imaging centre initiated a patient dosimetry optimisation approach for the hospital's three peripheral vascular radiology and vascular neuroradiology facilities, in which almost 60% of the procedures performed are interventional radiology procedures.

Backing this internal initiative, ASN sent our CHU management a letter demanding concrete actions based on the

1. Rosenstein M, 1996, Practical approaches to dosimetry for the patient and staff for fluoroscopic procedures, IRPA : proceedings.

Dosimetry verification and radiation protection awareness raising by the ASN inspectors during an interventional radiology examination at the Villefranche-de-Rouergue Hospital (Aveyron *département*)

recommendations of the IRSN's appraisal report and intended to optimise the delivered doses, to limit the risk of comparable events occurring on other patients.

The dose optimisation approach

The patient dose optimisation approach set up as from January 2010 comprises two parts:
– a technical dose optimisation part, divided into three main phases and relying on contributions from the IRSN experts, the practitioner radiologists, the radiographers, the persons competent in radiation protection (PCR), the biomedical technical team of the Clermont-Ferrand CHU and the medical physicists from the regional medical radiation physics platform set up by the Auvergne regional health agency (ARS).
- anticipation of the risk and organisation of the management of patients who could display an unavoidable cutaneous effect.

Steps and result of the technical part of the optimisation approach:

Image acquisition rate - January 2010

The first step in the approach was collective reflection by the practitioner radiologists and the radiographers on the choice of image acquisition rates in radiographic mode on the angiography facilities; the DRPH-IRSN advised this approach:
– was the habitually used rate of six images per second still justified?
– was this setting used by default at the opening of the work protocols appropriate?
– could a lower acquisition rate be used in certain cases?

Conclusive tests were carried out using an acquisition rate of three images per second for four weeks by all the senior practitioners in the department, covering the widest possible range of venous and arterial procedures.

A default setting rate of three images per second for all the protocols of the two interventional angiography rooms was thus applied during January 2010. This first optimisation action took place a few weeks after notifying ASN of the SAE. In vascular radiology it is the radiographic mode that contributes the most to the X-ray dose delivered to patients: **a reduction in the total X-ray dose of about 30%** resulted from this first action. Naturally, although all the examinations today are initially carried out with an acquisition rate of three images per second, the operators have the option, if they consider it necessary, of changing this parameter during the procedure.

Technical intervention by the manufacturer - May 2010

Notification of the SAE to ASN and the IRSN's appraisal led notably to the declaration of the event to the AFSSAPS. This was followed by a technical intervention by the facility manufacturer in May 2010, which involved:
– increasing the high voltage at the terminals of the X-ray tube (+ 5 kV), producing more energetic X-rays that pass more easily through the attenuating medium and contribute in greater number to image forming. Increasing this parameter enabled the radiation intensity to be reduced.
– the addition of spectral filters (Cu and Al) in order to have a more uniform X-ray beam and to limit the low-energy "soft" X-rays that are absorbed by the tissues and do not contribute to image forming.
– the setting up of a "-25% dose" fluoroscopy mode.

The comparison involving 55 examinations performed before and immediately after these parameter changes, validated by the medical team / radiographer, revealed **a reduction in the X-ray dose of 13% in fluoroscopy mode and 44% in radiography mode, i.e. globally of about 35% per procedure.**

Intervention of the experts from DRPH – IRSN to support the dose optimisation approach – October 2010

The third step of the technical part of the imaging centre's approach was the three-day on-site intervention of the experts from the DRPH – IRSN in October 2010 with the aim of :
– analysing the feasibility of a further reduction in dose delivery on the three vascular radiology and interventional neuroradiology facilities, based on the analysis of the parameters used in the abdomino-pelvian and cerebral procedures;
– proposing new parameters by demonstrating - backed by measurements - that image quality is conserved;
– remind users of the usual dose reduction means and inform them of the specific means associated with the makes and ages of the facilities.

Analysis of the parameters demonstrated that the skin entrance dose rates of patients, particularly in fluoroscopy, could be further optimised. The practitioners were informed of these possibilities, and a series of significant proposals was communicated to them by the IRSN, before they were effectively implemented by the biomedical technical team at the radiology centre.

Significant examples among these proposals illustrate the approach

Vascular radiology room – with flat panel detectors

– reprogramming the fluoroscopy modes in accordance with the following scheme, with the recommendation to start procedures in "New low-dose fluoroscopy" mode, and rise gradually up the range if necessary:
– reminder of the importance of selecting the patient weight range: a precise example (Radiography at 3 i/s; field 48 cm; patient weight 55 – 70 kg) shows a 30% dose reduction compared with selection of the 70 – 90 kg patient weight range.

The measures applied in October 2010 to this facility installation equipped with flat panel detectors brought a total reduction of about 25% in patient doses.

Preceding situation		**"Low dose" fluoroscopy 27 cm** Spatial resol. = 2.5 Low contrast resol. = 8 Dose rate on skin = 176 µGy/s	**"Normal" fluoroscopy 27 cm** Spatial resol. = 2.8 Low contrast resol. = 9 Dose rate on skin = 350 µGy/s	**"High" fluoroscopy 27 cm** Spatial resol. = 2.8 Low contrast resol. = 10 Dose rate on skin = 590 µGy/s
IRSN proposal	**"New low dose" fluoroscopy 27 cm** Spatial resol. = 2.5 Low contrast resol. = 6 Skin dose rate = 142 µGy/s	**"New normal" fluoroscopy 27 cm** Spatial resol. = 2.5 Low contrast resol. = 8 Skin dose rate = 176 µGy/s	**"New high" fluoroscopy 27 cm** Spatial resol. = 2.8 Low contrast resol. = 9 Skin dose rate = 350 µGy/s	

This measure limited the use of the "high fluoroscopy" setting which is associated with a high dose rate of 590 µGy/s.

Vascular radiology facility with image intensifier

- the main proposal was to create an intermediate fluoroscopy mode between the "Fluoroscopy 15" and the "Fluoroscopy 30" modes, called "Fluoroscopy 15+", to be used in priority before employing the highest exposure mode.

This measure enabled the "Fluoroscopy 30" mode (corresponding to a dose rate of 220 µGy/s) to be avoided whenever possible, in favour of a dose rate of 158 µGy/s.

The measures applied in December 2010 to this facility featuring an image intensifier resulted in a Dose-Area Product (DAP) per minute of fluoroscopy of about 25%.

Preceding situation		**Fluoroscopy "15" 28 cm** Spatial resol. = 1.6 Low-contrast resolution = 7 Skin dose rate = 103 µGy/s	**Fluoroscopy "30" 28 cm** Spatial resol. = 1.8 Low-contrast resolution = 8 Skin dose rate = 220 µGy/s
IRSN proposal	**Fluoroscopy "15" 28 cm** Spatial resol. = 1.6 Low-contrast resolution = 7 Skin dose rate = 103 µGy/s	**Fluoroscopy "15+" 28 cm** Spatial resol. = 1.8 Low-contrast resolution = 8 Skin dose rate = 158 µGy/s	**Fluoroscopy "30" 28 cm** Spatial resol. = 1.8 Low-contrast resolution = 8 Skin dose rate = 220 µGy/s

Dual plane vascular neuroradiology facility

No technical action was applied to this facility. Operators were simply given renewed advice on how to conduct the procedures:
– as first-line treatment use the "Low dose" fluoroscopy mode, which has been demonstrated to give image quality equivalent to that of "High dose" mode, but with a dose rate that is three times lower;
– avoid using "High dose" fluoroscopy for "skull" procedures;
– if possible, adapt the image rate in radiography to the blood flow (two to three images per second);
– if possible, avoid using the grid for the "encephalon" procedures.

On this facility, the IRSN's advice and heightening of operator awareness of the importance of patient dose optimisation, enabled doses delivered during intracranial aneurysm embolisation procedures to be significantly reduced (35% reduction in dose-area product - DAP).

	"Low dose- standard" fluoroscopy		"High dose - standard" fluoroscopy	
	Field 22 cm	**Field 16 cm**	**Field 22 cm**	**Field 16 cm**
Spatial resolution (lp/mm)	1.4	**1.8**	1.6	**1.8**
Low-contrast resolution (number of visible inserts)	10	**12**	12	**12**
Patient entrance dose rate (µGy/s)	23	**30 µGy/s**	65	**86 µGy/s**

Anticipating the risk and managing an unavoidable cutaneous effect

The dose optimisation measures implemented have reduced the risk of radiation-induced effects on patients. Nevertheless, faced with the possibility of an unavoidable radiation-induced cutaneous effect following an X-ray guided interventional procedure, the imaging centre of the Clermont-Ferrand CHU has put in place a risk anticipation and management system:
- systematic monitoring and archiving of the patient dosimetric reports produced by the interventional radiology facilities (vascular and digestive radiology, neuroradiology and cardiology). If it is impossible to have all the image production parameters, as can be the case with the oldest facilities, the fluoroscopy times and the dose-area product are recorded.
– the technologists inform the operators in the room as soon as the Air Kerma, if it is indicated on the facilities, reaches 2 Gy (AK can be considered like a skin dose indicator). This enables the operator, insofar as possible, to vary the beam incidences used in order to better distribute the skin dose and avoid "hot spots".
– an up-to-date list of the most exposed patients, kept available in the interventional radiology room, enables the practitioners to take into account the doses already received by patients requiring further irradiating interventional therapeutic procedures, so that the procedures can be modulated and exposure incidence angles varied, thereby limiting re-irradiation of the same skin area (if the clinical indications so permit).
– entry of the AK in the procedure medical reports if it reaches or exceeds 3 Gy.
– clinical monitoring 3 to 4 weeks after performing a procedure presenting a risk, of patients having received a dose assumed to be 3 Gy or higher, at a clinical appointment specifically for this purpose, or during a radiological morphological check-up (CT scan, Doppler ultrasonography, MRI).
– clearly informing the patients as soon as the risk is confirmed, by urging them not to miss the scheduled check-up appointment.
– if a confirmed effect is observed at these consultations, the patient is referred to the dermatology department: this process has been defined and clearly identified with the dermatologists of the CHU.
– the observed adverse events are reported to Quality and Risk Management Department of the CHU.
– each reported situation gives rise to investigations to improve practices (experience feedback in the framework of morbidity and mortality follow-up), with a view to limiting its recurrence.

Conclusion

In all, a significant dose reduction was obtained for our three interventional vascular radiology facilities, the sum of savings resulting from several elementary technical decisions. On one of the facilities the combined actions enabled the X-ray dose delivered to patients to be reduced by a factor of 3.

A specific process for the dermatological care of affected patients has moreover been set up.

As ASN requested in its letter demanding concrete measures, we asked the interventional cardiologists to participate in this dose optimisation approach, and today the majority of cardiac and coronary catheterisations are performed in first-line with an image acquisition rate of 7.5 or 10 images per second. This image rate can only be increased if necessary once the procedure is in progress. The Air Kerma for these procedures has thus been reduced by 35%.

Our approach and the tangible improvements we have obtained show that there was indeed margin for manoeuvre. They also teach us that every-day vigilance is necessary because our vascular interventional activity is evolving towards complex and long procedures in fragile patients (sometimes obese, therefore requiring increased doses), sometimes treated several times over. These interventional procedures can

be destined to save lives and must not be called into question, but we must endeavour to apply practices that involve as low doses as possible.

In evaluating the achievement of our objective, we must underline firstly the quality of the dialogue and cooperation between ASN, the IRSN and the hospital staff - facilitated by a longstanding, tried and tested culture of discussion between technologists, practitioners, technicians, PCR and medical physicists in our hospital - and secondly the vital need for closer discussion with the equipment manufacturers, something we established for all our facilities.

We would like to extend this approach by specifying the absorbed dose delivered to the skin of patients, particularly for the procedures involving a risk. The data provided by the facilities, such as dose-area product (DAP), fluoroscopy time, image acquisition rate, or the Air Kerma, do not give a perfect picture of the dose actually received and its distribution over the patient's skin. Yet ASN asked us "that dose information be available in real time for the interventional practitioner [...] from the moment the skin dose exceeds 2 Gy" and the organisation of "particular medical monitoring to detect the appearance of any cutaneous lesions when the maximum cumulated dose on the skin reaches or exceeds 3 Gy".

Like the Strasbourg CHI, we envisage positioning gafchromic® films (which blacken under the effect of X-rays) on the patients' skin during the procedures, and which can then be calibrated and read to inform the practitioners of the actual skin dose delivered and whether there are areas of convergence or overlapping of the beam incidences, leading to cumulative doses exceeding 3 Gy. This would undoubtedly be an important step forward, but it nevertheless implies settling the problems of cost beforehand. ■

TECHNICAL OVERVIEWS: INTERVENTIONAL RADIOLOGY

Optimisation of interventional cardiology procedures

by Dr. Olivier Bar, Interventional cardiology SELARL Interventional Cardiology Cardiac Imaging – Tours

Radioguided interventional cardiology includes diagnostic and/or therapeutic procedures, the main ones being coronarography and coronary angioplasty. Applying the principles of radiation protection and using optimised procedures help reduce doses while maintaining the radiological image quality necessary to perform the procedures. The regulatory training in patient radiation protection and technical training in the use of the radiology devices allow the practical implementation of a continuous procedure optimisation approach. This approach is the bedrock of patient radiation protection; associated with the use of protective equipment, it also helps reduce the occupational exposure of the cardiologists.

The first therapeutic procedure performed on the coronary vessels by Andreas Gruntzig in Switzerland more than 30 years ago marked the beginning of uninterrupted technical and medical progress allowing the treatment of narrowing of the heart arteries. These small arteries of 2 to 5 mm diameter situated on the surface of the heart are in constant movement and poorly accessible (remote manipulation of catheters measuring almost a metre in length). The manipulation of this equipment is only made possible by the use of X-ray attenuation imaging, whose indissociable corollaries include the depositing of energy in the tissues and radiation scattering, exposing not only the patient but also the operator to potential deleterious effects in the short and long term.

As the blood vessel walls have an X-ray attenuation coefficient very similar to that of blood, a highly attenuating product (iodinated contrast medium) must be injected into the coronary vessel lumen) for a short lapse of time - compatible with the temporal resolution imposed by the kinetics of the vessel - to view the irregularities of its internal lumen, while minimising disturbance of the cardiac function which depends directly on the oxygen supplied by the coronary blood.

The search for therapeutic methods that are ever-less traumatic, combined with the technological progress in the imaging equipment and medical devices explain the development and extension of medical activities using X-ray imaging in interventional cardiology.

The recent possibility of implanting a biological cardiac valve by percutaneous tract in an surgery room environment marks a new step by uniting multidisciplinary teams with little experienced in radiation risk management.

Coronarography (diagnostic procedure) and coronary angioplasty (therapeutic procedure) are the most widely used and proportionally the most frequent techniques (80% of interventional cardiology procedures). The benefit of treating coronary artery stenosis by balloon dilation (angioplasty) and implanting a metallic endoprosthesis (stent) is clearly established.

In emergency situations of coronary vessel occlusion (myocardial infarction), application of the treatment for repermeabilising the vessel is a race against time (treatment within six hours maximum): coronary angioplasty is the reference technique for reducing mortality, giving better results than the medicated alternatives (fibrinolysis).

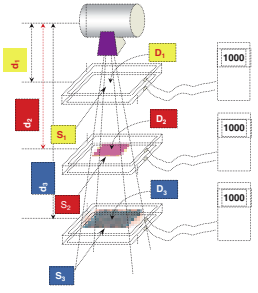
In scheduled treatment of angina pectoris, angioplasty has proved is capacity to reduce the symptoms under exertion and the extent of the medical treatment.

The medical justification of interventional cardiology procedures therefore exists, on condition that the indications adopted by the medical teams are in agreement with the major studies published. However, justification in terms of radiation protection requires knowledge of the delivered dose, so that the radiological risk can be integrated in the evaluation of the risk-benefit balance.

Assessment of the dose delivered during an interventional cardiology procedure necessitates the placing of a measuring device, usually a transmission chamber, at the X-ray tube output. This device provides a quantitative indication of a dosimetric parameter, the dose-area product (DAP), whose use is not intuitive.

This quantity has the particularity of being independent of the position of the chamber with respect to the tube or the patient (diagram 1). It is obviously necessary to know the beam projection surface area on the patient's skin to determine the dose delivered to the skin (is noteworthy that this value does not include the contribution of back-scattered radiation, which is about 30% for the energy levels usually found in this domain).

Dose-area product (DAP)



- The dose decrease is inversely proportional to the square of the distance
- The surface area increase is directly proportional to the square of the distance
- The DAP does not depend on the distance

Diagram 1

The introduction of digital flat panel detectors allows the number of pixels of the detector exposed to X-rays, and therefore the irradiated surface area, to be known at all times; by associating the tube/detector distance and the table height, the dimensions of the primary beam on the patient's skin can be calculated and therefore the skin dose can be evaluated in real time.

The DAP also allows an approximation of the effective dose received by the patient; several studies has revealed a correlation factor of about 0.2 between the DAP(Gy.cm²) and the effective dose (ED) (mSv).

Interventional cardiology procedures expose patients to EDs varying typically from 1 to 15 mSv (DAP value of 5 to 75 Gy.cm²); these exposures can sometimes reach or even exceed 50 mSv (DAP value of 250 Gy.cm²).

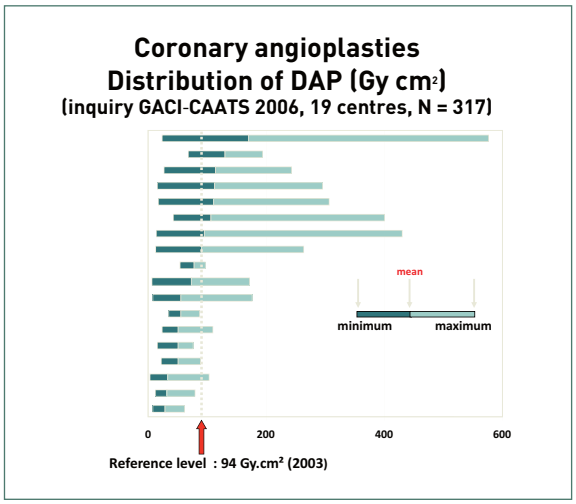


Diagram 4: This graph shows the mean distribution of DAP per centre for coronary angioplasties, in comparison with the reference level (RL) published in 2003 for coronary angioplasty: 97 Gy.cm². The large variability between centres reflects differences in practices

Optimisation

It is vital for all radiology equipment operators to understand the three physical factors that govern the dose delivered to the patient; it is an essential requirement to enable the increasingly complex radiology equipment to be used to optimise the procedures. Below is a brief outline of the particularities of the physical quantities of radiation protection in the field of interventional cardiology.

Time is a factor that seems simple to understand, if considering the time for which the operator has depressed on the pedal that triggers exposure. This time however is not representative of the actual duration of tube emission: this is because to improve the temporal resolution and limit the dose, the emission of X-rays is pulsed and the pulse width is variable (5 to 10 milliseconds). It is therefore indeed the frame rate multiplied by the pulse width that is representative of the emission time (diagram 2). The operators often do not know the frame rate in fluoroscopy. Furthermore, the machine manufacturer may have included a function that adjusts pulse duration to compensate for thermal constraints and is transparent to the operator.

Given the additional fact that the manufacturer's algorithm can make pulse duration and height vary simultaneously, one can understand why the fluoroscopy time is no longer a reliable indicator of the delivered dose.

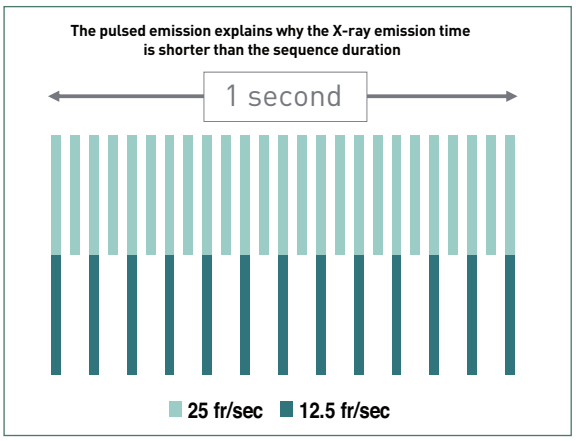


Diagram 2: Duration of an imaging sequence and X-ray transmission time

The pulsed nature of X-ray emission in medical imaging is highly specific; application of the regulations must take this into account to allow an exact assessment of the dose rates to which the patients and medical teams are exposed.

Distance and the inverse-square law of distance are simple (diagram 3), but come in many forms: tube-patient distance, patient-detector distance, patient-practitioner distance, for example. Reducing the distance from the source increases the skin dose, but it is the opposite if one considers the distance between the patient and the detector: keeping the detector in contact with the patient increases the dose rate received by the detector which leads to reduction in beam intensity through operation of the automatic exposure control system. Failing to position the detector close to the patient can triple the patient dose (diagram 3). It is a simple action, but not always applied.

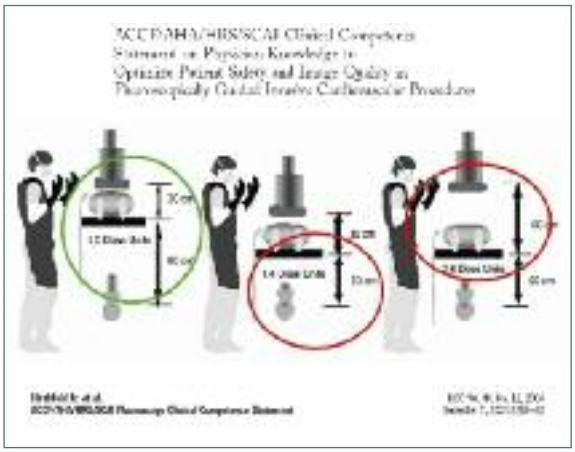


Diagram 3: Importance of tube-patient and patient-detector distance in patient exposure

The attenuation, when one considers the interaction between the primary beam and the patient's body, is responsible for the dose delivered to this patient but also for the scattered radiation to which the operator is exposed. Conversely, attenuation of the primary beam by the collimation leaves or the edge filter reduces the patient dose and the secondary radiation. It is obviously the attenuation of the apron and lead glasses that explain their protective action. However, it is important to know the exponential nature of the law of attenuation: the increase in exposure is not linearly proportional to the increase in patient

weight: being 30 kg overweight can increase exposure by a factor of 2 to 5[1].

Conclusion

Interventional cardiology is a fascinating activity and beneficial for the patients. The practitioners must acquire the necessary knowledge to use the equipment to the best of its possibilities. However, available practitioner time is limited and it seems indispensable to have appropriate resources (physicist, technician, software) available to assist the practitioner during complex procedures that leave him or her with little capacity to manage the radiological risk alone and in real time. ■

1. Scott G. Bryk et all. Endovascular and interventional procedures in obese patients: a review of procedural technique modifications and radiation management; J. Vasc Interv radiol2006; 17:27-33.

Some optimisation examples

First case: ensure the right focal spot-detector distance (flat panel) and patient-detector distance

It is frequently observed that interventional cardiology operators forget the importance of ensuring an optimum distance between the primary beam emission focal point and the entrance surface of the detector situated beyond the patient. There is an optimum distance that corresponds to the focus distance of the anti-scatter grid, which is usually 100 cm. This distance is indicated on the display modules situated near the viewing image, showing the operator in real time at what distance the detector is positioned. This parameter is usually identified by the acronym FID (Focus-Intensifier Distance).

To improve the signal-to-noise ratio, the anti-scatter grid can significantly reduce the scattered rays which do not contribute to the information. This anti-scatter grid is made up of lead strips which are mutually parallel but in fact focused at a certain distance (usually one metre); complying with this distance ensures that the benefit provided by the grid is obtained with minimum signal loss (associated with the thickness of the lead strips).

Second case: use of collimation and edge filters

These two devices, which are controlled by the operator on the examination table, are situated directly at the X-ray tube output: their utilisation always results in a reduction in the quantity of energy emitted by the tube and therefore a reduction in the dose delivered to the patient and in the scattered radiation, hence the dose exposure of the personnel.

The aim of collimation is to limit the irradiated region to the region of medical interest. As the sensors have predefined magnification fields (for a flat panel detector for example: diagonal of 25, 20 and 15 cm), it often happens that the region of interest is smaller than the area offered by the chosen magnification field. Collimation is used to reduce the surface area of the primary beam at the patient entrance and thus reduce the region of skin exposed to the X-ray beams. This reduction is also beneficial with regard to scattered radiation since the volume of the patient's tissues exposed to the X-rays is also reduced. It must be noted that collimation does not alter the quantity of energy deposited on the patient's skin; however, its utilisation during long examinations (coronary recanalisation for example), is a means of avoiding overlaping of the incident beams and thus avoiding exposing a given skin area to repeated doses, which can cause deterministic effects.

Edge filters serve to attenuate the primary beam when applied to tissues which themselves are poor attenuators (the lungs). The use of edge filters improves contrast constantly and therefore the quality of the information obtained.

Some machines feature automatic pre-positioning of the edge filter, a function that should be recommended in the specifications for interventional radiology equipment.

Third case: selecting different fluoroscopy modes

The organs that can be involved in interventional radiology procedures do not all have the same characteristics in terms of mobility, size and attenuation. Consequently, different fluoroscopy modes must be available according to the activity performed. When several different activities are carried out in succession on the same given machine, several fluoroscopy programmes must be available.

A fluoroscopy mode is more specifically a combination of a pulse frequency, pulse intensity, pulse width and a focal spot. The manufacturers do not always make these parameter setting accessible.

When the operator uses large-diameter guide wires (1 or 2 mm diameter), their high radio-opacity allows low energy flow fluoroscopy modes to be used. When fine guide wires (a few 1/10 of mm) are used, particularly in neurology, higher pulse intensities must be used to maintain a contrast that allows the material to be viewed. Likewise, in interventional cardiology the cardiac kinetics require a certain temporal resolution, which means that fluoroscopy modes with appropriate frame rates must be selected.

It is the role of the medical physicist, who is familiar with the different types of procedures, to act as an interface between the medical team and the manufacturer in order to define fluoroscopy parameter settings adapted to the different practices.

TECHNICAL OVERVIEWS: INTERVENTIONAL RADIOLOGY

Optimisation of radio-guided interventional procedures in vascular surgery

by Dr. Jean Sabatier, Vascular surgery department, Clinique de l'Europe – Rouen

Medical imaging department in the Meaux Hospital Centre (Seine-et-Marne): thyroid shield, mobile door screen, leaded apron

Vascular surgery is a relatively recent discipline that began developing in the second half of the 20th century. Arterial repairs were initially performed almost exclusively by open surgery. In the 1980's however, endovascular techniques appeared and have since been constantly developing. These techniques consist in treating the lesions without surgical opening, by introducing a guide tube into an artery (usually the femoral or radial artery). Controlling navigation inside the arteries (endovascular) of the organism and treating the lesions require the use of a radiological device comprising an X-ray source and an X-ray image intensifier (XRII) or brightness amplifier to detect the beam and convert the X-ray photons into light photons. The accessory equipment used (guide wire, catheter, dilation balloon, stent) is radio-opaque, allowing monitoring by fluoroscopy. Opacification of the arteries is achieved by intra-arterial injection of a contrast medium. The fluoroscopy time can be reduced by using "road mapping". This process consists in leaving an overlay image of the arterial network on the monitoring screen to precisely identify the pathological region and reduce the irradiation time and the injected dose of contrast medium. The patient is placed on a radiotransparent examination table with a carbon tabletop. The XRII is a mobile C-arm with two screens allowing permanent visual monitoring of the procedure.

The medical staff present in the intervention room comprises an anaesthetist-resuscitator, an surgery room nurse, the surgeon and the surgeon's assistant. Radiation protection of the anaesthetist-resuscitator and the nurse is ensured by individual protective equipment (lead apron, thyroid shield) and collective protection by a mobile transparent screen door. They are further protected by their distance from the source, the irradiation dose being inversely proportional to the square of the distance. The surgeon and assistant, who are often near the beam, are more exposed to direct and scattered radiation. Their personal protection comprises lead aprons, leaded glasses and a leaded protective screen mounted on table. The wearing of radiation attenuation gloves is much debated and difficult to apply in these surgical techniques that require very precise manipulations. The operator must use the diaphragms to limit the diffusion of the X-rays to the treated region.

The more complex the techniques, the higher the radiation exposure, necessitating the use of all the optimisation procedures: pulsed fluoroscopy at 8 images/sec for the simplest catheterisation phases, then 12 images/sec for the more complex phases. The use of continuous fluoroscopy at 25 images/sec is never necessary, particularly with the new generation XRIIs. Use of the zoom function must be minimised. The surgeon must maintain control over the exposure time by actuating the fluoroscopy pedal and adjusting the height of the table to move the patient away from the X-ray source by putting him/her in contact with the XRII.

The irradiation area is signalled outside the intervention room. The medical workers involved wear a passive dosimeter with monthly record keeping, an active dosimeter, and ideally a complementary ring dosimeter, but this is rarely used in daily practice.

Endovascular surgery of the thoracic aorta and the abdominal aorta

The most frequently encountered lesions are aneurysms of the thoracic and/or abdominal aorta and dissections of the thoracic aorta. Until a few years ago, these lesions were treated exclusively by open surgery. During the 1990's, treatment by endovascular route developed with a major technical innovation: the aortic endoprosthesis. This technology allows the introduction, via the femoral artery with fluoroscopic guidance, of a vascular prosthesis - also called a stent graft or covered stent - which is placed in the aorta to treat the lesions (figure 1). These interventions involve high exposure to radiation because of their duration, their technical complexity, and the proximity of the worker to the X-rays. The

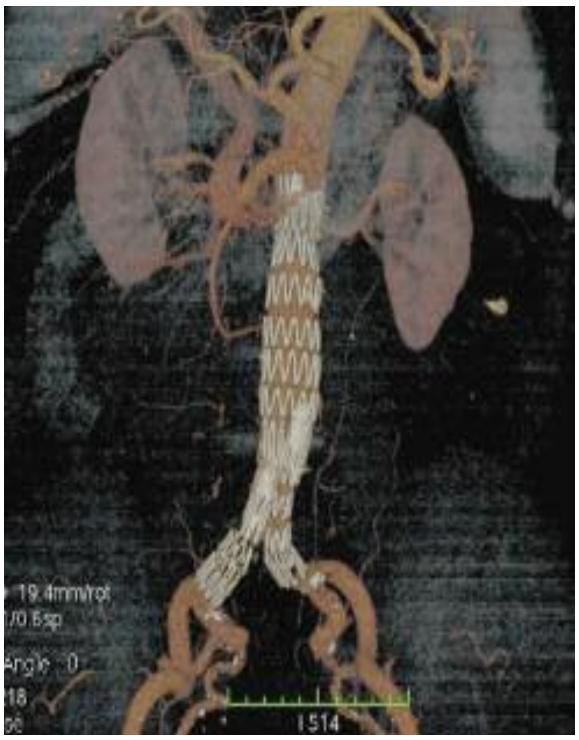


Figure 1: Aortic stent graft (endoprosthesis)

complexity of the procedure is related to the need for catheterisations that are often complex. Progress in the technologies developed by the vascular prosthesis manufacturers is allowing the indications to be progressively extended to lesions that were hitherto treated exclusively by open surgery. This is the case in particular with fenestrated stent grafts which allow a larger number of aneurysms to be treated by the endovascular route. This technique necessitates catheterisation of the renal arteries, sometimes even the digestive arteries, and this increases the irradiation time and dose, which are reduced in turn by the use of pulsed X-rays and diaphragms.

Endovascular surgery of the visceral arteries

Endovascular surgery is used to treat arterial stenoses situated most often in the renal arteries and the upper mesenteric artery (figure 2). Visceral artery aneurysms are often treated by embolisation which also requires the use of ionising radiation. As the most frequent approach route is the femoral artery, the operators are not working under the X-ray flux which is situated over the patient's abdomen. Pulsed fluoroscopy (8 or 12 images/second) and diaphragms are used to reduce irradiation levels. These procedures are generally relatively short.

Endovascular surgery of the arteries leading to the brain

The lesions are most frequently situated on the internal cervical carotid artery. The reference treatment is carotid endarterectomy by open surgery, but endovascular techniques with carotid angioplasty are developing, with indications that will probably widen in the coming years. The femoral approach route distances the operator from the treated region and reduces the irradiation dose, but catheterisation of the carotid can sometimes be complex, which increases the length of the procedure.

Figure 2: Aortic stent graft (endoprosthesis)

Endovascular surgery of the arteries of the limbs

Upper limb arteries

The lesions most frequently treated are stenoses of the subclavian artery. The treatment is moderately irradiating, as the operator is at a distance from the treated region and the procedures is often rapid. Endovascular treatment of complications concerning vascular approaches for hemodialysis is more irradiating because the operator is very close to the treated region, as both the puncture to introduce the arterial guide and the lesions are situated in the upper limb. The use of an extension when injecting the contrast medium enables the operator to work at a distance during the

Figure 3 : Carotid angioplasty technique

Interventional radiology examination

injection times, but the use of an angioplasty dilation balloon near the region of the arterial entry puncture remains highly irradiating. The fluoroscopy time must be reduced by using pulsed fluoroscopy at a frame rate of 8 images/sec.

Lower limb arteries

The indications for endovascular treatment of stenosing lesions of the lower limb arteries have greatly increased in recent years, particularly in the leg arteries. This trend results from the development of small diameter equipment allowing catheterisation of these arteries and treatment by balloon dilation, sometimes with the placement of a stent. With lesions situated above the knee joint, the operator is close to the radiation source, with the hands sometimes directly under the beam when treating high-placed lesions of the femoral artery. Adopting a contralateral approach route reduces this exposure risk. The operator introduces the arterial guide into the contralateral femoral artery and navigates it through the aorta and the iliac artery of the side being treated. This keeps the operator's hands away from the X-ray beam. The treatment of lesions situated below the knee joint is less irradiating.

Conclusion

Vascular surgery is increasingly becoming an endovascular surgical activity exposing the patient and the operators to ionising radiation. The techniques are becoming more complex, increasing radiation times and doses. A few years ago, medical and paramedical personnel awareness of questions of radiation protection was low, given that the use of X-ray imaging was rare. The evolving of vascular surgery towards these endovascular techniques has brought a change of mentality and awareness of the harmfulness of ionising radiation in the surgical environment. Medical personnel awareness of the problem of exposure to radiation has been enhanced by the ASN (French nuclear safety authority) inspections in healthcare establishments and in surgery rooms in particular, and by the obligation for users to have approved training in radiation protection. Radiation protection will be further improved in the coming years with the development hybrid rooms, providing true radiology rooms in a surgical environment. ■

TECHNICAL OVERVIEWS: INTERVENTIONAL RADIOLOGY

Interventional radiology and its risks: a clinical case study

by Dr. Francine Thouveny, Radiology Department, Angers University Hospital (CHU)

General

Interventional radiology (IR) comprises all the invasive medical procedures serving to diagnose and/or treat pathologies, and which are carried out with guidance and monitoring by an imaging means. This is the definition adopted by the French federation of interventional radiology (FRI) and the French society of radiology (SFR)[1].

Alongside, but independently of, the all-important development of diagnostic imaging using ionising radiation with the advent of multi-detector computed tomography (MDCT) scanners, the last decades have seen the more discrete but just as important development of X-ray guided interventional techniques. The development of therapeutic tools of ever-finer dimensions, of implantable materials that are safer and withstand the biological constraints, and the minimally invasive nature of these techniques have enabled them to compete with and sometimes completely replace conventional surgery in many area.

These constantly evolving techniques are the legacy of pioneers of surgery and radiology who attempted, initially in difficult situations, to treat lesions in vessels inaccessible to conventional surgery. The first examples were the embolisation of intracranial aneurysms and interventional cardiology, with the rapid development of coronary angioplasty. The low morbidity of these interventions compared with surgery for the same pathologies, the technological improvement of endovascular materials which are now miniaturised and extremely flexible to minimise endovascular aggression during their placement, the development of implantable materials that conform better to the human anatomy and are adapted to limit biological reactions, have made interventional radiology the technique of choice in the treatment of an ever-increasing range of pathologies.

Image guidance has made it possible to treat tumours, drain abscesses, consolidate bones, and so on, with reduced anaesthesia, fewer complications, shorter hospital stays - above all in intensive care -, drastically reducing hospitalisation costs, and all for the joint benefit of the patient and society.

The treatment of vascular pathologies occupies a remarkable position in this area, as it includes the most complex procedures that can involve prolonged irradiation. Treatment of the most complex pathologies can only be envisaged in large medical centres, usually those performing medicine, surgery and obstetrics (called "MCO" in France), equipped with high-tech digitized radiology rooms - image quality is vital for the safety of the procedure - a large arsenal of navigation tools and implantable materials capable of dealing with a wide variety of situations and coping with complications, not to mention full teams of hyperspecialised practitioners, nurses and radiographers, well practised in these high-precision interventions. In the context of out-of-hours (OOH) service, the majority of these facilities and teams are available24h/24 to handle emergency situations (traumatic or other haemorrhages, post-partum haemorrhages, thrombolysis of cerebro-vascular accidents, etc.).

In these high-risk medical situations, ionising radiation is the practitioner's chief ally. The risk it represents is secondary in comparison with the risk of the pathology itself and the risk of the therapeutic procedure. The need for rigorous dose limiting and monitoring aids will be discussed later in this article.

The position of interventional radiology procedures in the therapeutic arsenal

Diagnostic radiology initially involved numerous invasive and potentially dangerous procedures (myelography with injection into the spinal canal at the limit of the spinal cord, arthrography with the risk of septic arthritis in an articular cavity, arteriography with its risks of haemorrhagic and thrombotic complications associated with the entry puncture and endovascular navigation, etc.). Thanks to the technological developments of the X-ray CT scanner and magnetic resonance imaging (MRI) over the last 20 years, we can now obtain three-dimensional images and precise views of the anatomy and of the pathologies for diagnostic purposes without having to use these invasive techniques. Alongside the progress in diagnostic possibilities, it became possible to use these techniques for interventional procedures, reaching anatomical regions poorly accessible by conventional surgery. Allied with the development of miniaturised materials, they enable the percutaneous approach to be used to treat blood vessels (angioplasty, embolisation), destroy tumours (alcoholisation, radiofrequency ablation), consolidate bone (cementoplasty), etc.

The interventional radiology procedures practised are increasingly numerous and diversified, with the treatment of vascular pathologies representing about a third of them (FRI survey in 2009 (1)). Vascular radiology is thus the biggest generator of medical irradiation. Although it represents just 1% of the radiological procedures performed (diagnostic imaging included), it accounted for 20% of the dose exposure of the French population in 2005 [2].

An interventional radiology procedure is first developed in situations where the reference surgical procedure cannot be envisaged: patient inoperable, lesion inaccessible to open surgery. Once the procedure has demonstrated its feasibility and

effectiveness, and often with improvements in the technology, it takes its place among the therapeutic references as an alternative to conventional surgery, possibly even replacing it altogether.

If we take the example of interventional cardiology, as from the 1980's, the large demand in the activity and the risks entailed by conventional heart surgery rapidly established percutaneous angioplasty as the first-line treatment for coronary diseases in an increasing proportion of indications, supported by high levels of scientific evidence [3, 4]. Back in the 1960's, the idea of using angiographic catheters to remove solid elements (fragments of muscle, blood clots, etc.) led to the development of arterial embolisation, which rapidly emerged as a therapeutic alternative to surgery, particularly in the cases of haemorrhagic lesions (trauma, post-partum haemorrhage, digestive tract haemorrhages, etc.). The embolisation of intracerebral aneurysms was first adopted in cases affecting the posterior (vertebrobasilar) circulation, where surgery was prone to serious complications, then extended to the entire cerebral circulation [5, 6]. In the case of peripheral angioplasty, the indications evolved more slowly because conventional surgery already produced highly satisfactory results. It was used first for simple lesions, then extended to more and more severe ones, particularly when surgical access was difficult[7].

For certain complex lesions, and arteriovenous malformations in particular, endovascular techniques supplement or replace surgical treatment, with the initial arteriography providing a better understanding of the architecture and functioning of the anomalies [8].

Interventional radiological techniques are also finding their place in the therapeutic arsenal alongside diagnostic radiology. The French (and European) conception favours the division of radiology into organ specialisations, where the radiologist becomes a diagnostic expert and therapist fully competent to participate in the care of patients, multidisciplinary consultation meetings, and be a particularly well-informed advisor to the clinician [1].

Interventional radiology fits into a battery of therapeutic means ranging from conventional surgery to the "simple" medical treatment. It remains weighted in each case by the local availability of the technical and human competence, and by the individual therapeutic risk (and the risk of spontaneous development of the pathology) specific to each situation. The therapeutic decisions are thus very widely discussed in the multidiciplinary consultation meetings where the presence of the various specialists involved enables the most appropriate solution for the patient to be chosen, without excluding the possibility of combined therapeutic proposals, these procedures remaining mutually complementary (in the case of arteriovenous malformations: possibility of endovascular, surgical, radiosurgical treatment; in the case of hepatocellular carcinoma: surgery, radiofrequency ablation, chemical embolisation, chemotherapy administered by general means [9]. The proposed treatment is thus the most appropriate solution for the patient in the centre that is providing it.

Interventional radiology as an activity covers a large number of procedures. It offers ever-wider possibilities thanks to the constant progress in imaging techniques and therapeutic equipment, and the ingenuity of the practitioners. A description of these procedures is available on the web site of the FRI [1]. They are classified as simple, intermediate and complex procedures (table 1). This inventory results from the surveys conducted since 2006 by the national institutes and learned societies (INCa: National cancer institute, SFICV: French society of cardiovascular imaging, FRI), and is probably underestimated since a large number of procedures are performed by specialists who do not belong to any of these learned societies. The setting up of an observatory to obtain a more precise estimation of this activity depends on the creation of a national database (EPIFRI) which is currently being certified by the HAS (national health authority) and whose first version is planned for autumn 2011. This database will, among other things, provide a description of the doses emitted for a given procedure, knowing that the large variety of situations encountered (inherent to the morphotype and vascular anatomy of the patient, and to highly heterogeneous pathologies found under a given definition), will undoubtedly reveal major standard deviations in the "therapeutic" benchmarks. ■■■

Table 1: FRI classification of IR procedures

Structure	**Simple procedures Any versatile radiologist**	**Intermediate procedures IR structure integrated in the imaging platform, attached to an "MCO" establishment**	**Complex procedures Specialised structure Team ensuring OOH care**
Types of procedures	**Biopsies** **Guided injections** **Articular infiltrations**	**Simple angioplasty** **Scheduled embolisations** **Tumour treatment by guided injection** **Drainage** **Spinal infiltration**	**Emergency embolisation, Aortic stent grafts** **Transjugular intrahepatic protosystemic shunt (TIPS)** **Carotid angioplasty**

Clinical case: occurrence of undesirable tissue reaction in interventional vascular radiology

Our analysis concerns the case of a 65-year old patient with alcoholic cirrhosis of the liver, with a moderate severity score. The patient, now alcohol-abstinent, displays android obesity (105 kg) affecting the abdomen in particular. The cirrhosis is accompanied by hyperactivity of the spleen (hypersplenism) with a large increase in size and associated with thrombocytopenia. A suspected tumoural complication led to the performance of an abdominal CT scan in 2008.

This scan (Image 1) does not confirm the malignant hepatic lesion, but it reveals a very large spleen and above all voluminous arterial aneurysms on the gastroduodenal junction, the collateral branch of the hepatic artery communicating with the upper mesenteric artery (vascularising the digestive tract). There is also a cluster of "spleno-renal" varices linked to the increase in pressure in the portal venous system secondary to the cirrhosis. The analysis of the images in the three spatial planes (Image 2) reveals an arched ligament (crossing of the musculo-tendinous fibres of the diaphragm in front of the aorta) severely stenosing the coeliac trunk (at the origin of the hepatic and splenic arteries). The hyperactive spleen is therefore vascularised via the highly dilated gastroduodenal junction (average diameter 12 mm compared with 4 to 5 mm normally) on which 4 aneurysms of 3 to 5 cm diameter have developed due to the high blood flow.

The presence of these voluminous intraperitoneal aneurysms, which risk rupturing, represents a life-threatening risk for the patient. The case was discussed in a vascular surgery meeting with the intention of unblocking the coeliac trunk and closing the aneurysms by surgery. However, the existence of cirrhosis with thrombocytopenia, and above all the presence of varices in the spleno-renal space, constitute a formal contraindication to the surgical procedure. Unblocking the coeliac trunk by angioplasty was discussed, but it is acknowledged that stenting cannot withstand the pressure of the diaphragmatic fibres over time [10]. Monitoring revealed an increase in the size of the aneurysms and therefore in the risk of rupture.

After further discussion in a multidisciplinary consultation meeting, the solution finally proposed was endovascular unblocking of the coeliac trunk followed by embolisation of the aneurysms.

The intervention was carried out on a regularly maintained and inspected interventional radiology facility type LCA Advantx® General Electric Healthcare put into service in 1997, equipped with an image intensifier coupled with an analogue pick-up tube (Primicon©) (Image 3).

The first procedure to perform a morphological and above all functional analysis of the hepatic, splenic, mesenteric

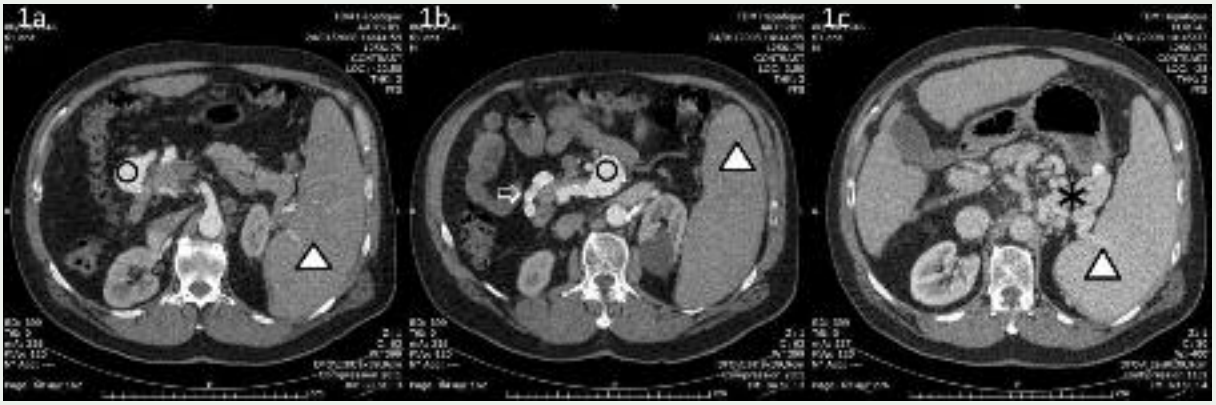


Image 1: Initial CT scan in the arterial phase (1a-1b) and portal phase(1c). Hypertrophy of the spleen (△), dilation of the gastroduodenal junction (⇨), arterial aneurysms, (○), cluster of varices in the left spleno-renal space (✱)

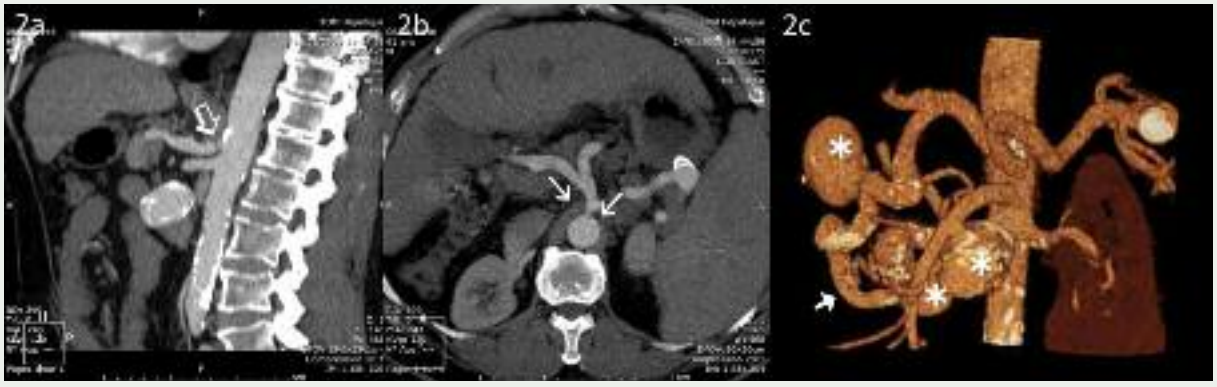


Image 2: Multiplanar reconstructions: severe stenosis of the coeliac trunk (⇨) by the vertebral part of the diaphragm (→) on the sagittal (2a) and transaxial (2b) reconstructions. Volume reconstruction (2c) showing the dilation of the gastroduodenal junction (➡) and the aneurysms.(✱)

Image 3: LCA Advantx facility. 3b: Position of operators during embolisation for gastrointestinal bleeding

and gastroduodenal circulation was carried out on 16 November 2010. The catheterisation difficulties associated with the implantation and compression of the coeliac trunk and the poor image quality induced by the patient's morphotype resulted in 45 minutes of fluoroscopy for this first intervention.

Embolisation was organised six days later (Image 4). A protective stent was placed at the origin of the upper mesenteric artery, then a large number of coils (metal spirals) were placed in the gastroduodenal junction via the upper mesenteric and coeliac access routes. The practitioners encountered the same difficulties of catheterisation and poor image quality . The extreme high blood flow in the gastroduodenal junction finally prevented the material used from satisfactorily closing the gastroduodenal junction and the aneurysms. The procedure was stopped after 5 hours, and included 152 minutes of fluoroscopy and 16 dynamic radiography acquisitions.

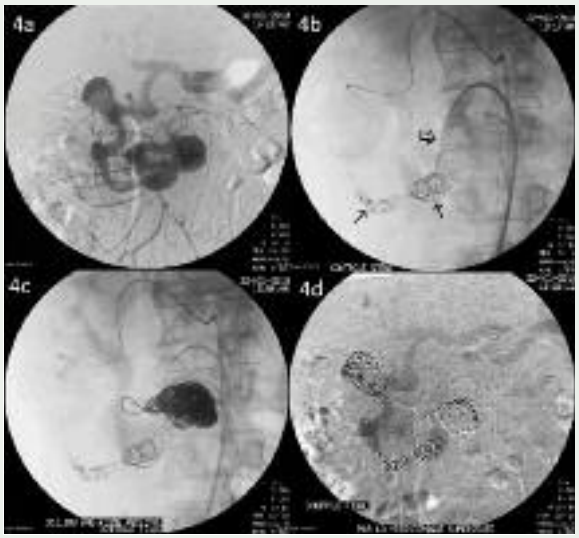


Image 4: Embolisation procedure of 22/11/2010. Opacification of the dilated gastroduodenal junction via the upper mesenteric artery (4a). Placement of a stent in front of the first aneurysm on the upper mesenteric artery and positioning of the first coils in the gastroduodenal junction (4b). Filling of the gastroduodenal junction and the aneurysms with numerous coils (4c). Final check (4d): presence of numerous coils in the gastroduodenal junction which is still permeable

Thirty-three days after the procedure, the patient felt a relatively sudden burning pain. In the subsequent days a large area of vesiculous erythema appeared (Image 5), rapidly diagnosed as radiodermatitis. The treatment protocol implies immediate consultation with a dermatologist and obligatory notification to ASN. The patient was examined by Professor P. Gourmelon, the director of the DRPH (Human radiation protection department) of the IRSN on 20 January. Image 5 shows the skin lesions 58 days (5a) and 67 days (5b) after exposure. Image 6 (Pr P. Gourmelon) shows the development of the radiation burn from the 67th to the 83rd day.

Using measurements carried out on a patient of the same build and on the basis of the number of radiography images acquired and the fluoroscopy times (the facility

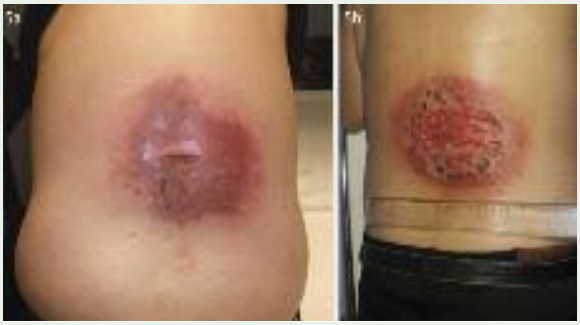


Image 5: State of the cutaneous lesions 58 days (5a) and 67 days (5b) after exposure

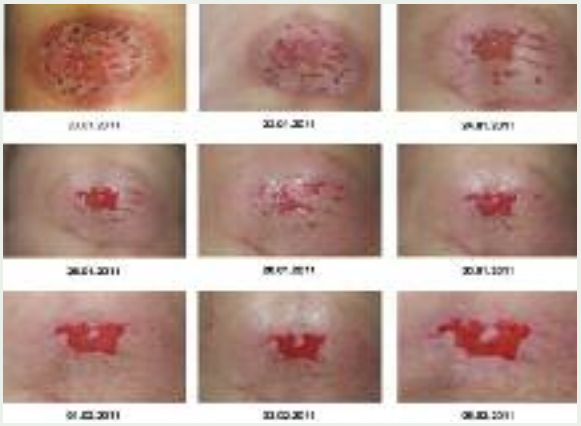


Image 6: Development of the cutaneous lesions from day 67 to day 83

does not have a dosimetric indicator and does not record the image parameters), the IRSN experts were able to evaluate the doses received by the patient during the two closely spaced interventions with a minimum uncertainty estimated at +/- 15%. The skin dose was thus estimated at between17 and 23 Gy on the most exposed area. The radiodermatitis with wet desquamation displayed by the patient and the time taken for it to appear are in conformity with the estimated doses [11].

As the analysis of severe accidents often reveals, many explanatory factors were found, the accumulation of which led to a tragic conclusion: factors associated with the patient's morphotype, the complex pathology and an anatomy rendering access difficult, resulting in prolonged

interventions; the fact that the medical team's concentration was focused on a particularly difficult procedure with the patient's life at risk, making dose monitoring a secondary concern; lastly, the age of the facility that did not provide for optimum dose control.

The great difficulty with the catheterisation (navigation) of the stenosed coeliac trunk and the poor quality of the guidance imaging (fluoroscopy) due to the patient's morphotype in themselves necessitated consequential fluoroscopy time even before the coils were placed.

The severe narrowing of the coeliac trunk and the need to cover the upper mesenteric access by a stent (presence of a large contact aneurysm) meant that the gastroduodenal junction could only be catheterised using small-calibre material. Yet the abnormally large calibre of the gastroduodenal junction and the size of the aneurysms would have required the placement of large-calibre embolisation material to ensure optimal effectiveness. Furthermore, the extreme high blood flow in this gastroduodenal junction prevented the coils used from achieving a complete and rapid thrombosis. Numerous coils had to be positioned, extending the duration of the intervention. The working beam incidence used, centred on the area of interest and the only one allowing optimal viewing of the lesions, remained in virtually exactly the same position throughout the intervention.

Lastly, throughout the procedure, the poor fluoroscopy imaging quality due to the patient's morphotype made necessary a large number of radiography image acquisitions to check the intervention times.

With the increasing length of the operation, the tiredness and stress resulting from its technical complexity and the danger for the patient meant that the attention of the surgeons and paramedical team was focused on the need to find suitable material to cope with the difficulties, while elements not essential for the performance of the operation (including dosimetry) were neglected.

The old-generation radiology facility used is equipped with a system for filtering the X-ray beam but has no additional filters (copper or aluminium) to block the low-energy X-rays (which constitute the majority of the radiation that is toxic for the skin).

With the exception of a timer set to 5 minutes and reset to 0 by the technologist, the facility is not equipped with an ionisation chamber indicating the dose delivered to the patient. The machine does not display the accumulated fluoroscopy time in real time during the procedure. During these long operations, the timer was reset to zero numerous times without the surgeons knowing just how many. The total fluoroscopy time was not counted until the end of the procedure.

Thus, the life-threatening clinical situation, the build-up of technical difficulties, the extremely high level of concentration required by the operators throughout the intervention, and the age of the facility all combined to result in an intervention time and radiation exposure that were as exceptional as they were excessive. Furthermore, the facility had no additional filtration to block the low-energy X-rays, which are harmful and do not contribute to the image. ■

The place of the risk associated with ionising radiation in interventional radiology procedures

Diagnostic risk: invasive diagnostic procedures (punctures, biopsies, arteriographies, athrographies) have specific non-negligible risks (haemorrhaging in particular, infection , trauma, etc.), which can have all the more serious consequences given that they occur on fragile ground. The frequency of occurrence and seriousness of these risks are lower than in therapeutic procedures, but in the latter case the higher risks are usually better accepted in the context of a therapeutic treatment. The risks in an invasive diagnostic procedure must be minimised and the procedure stopped if the operator becomes aware of a situation that could become dangerous. If faced with difficulties, an alternative solution - or at least another diagnostic discussion in a multidisciplinary consultation meeting to consider these difficulties - is usually proposed. The dose levels involved in these procedures remain low in comparison with those of therapeutic interventional radiology, and it must be possible to establish the diagnostic reference levels with a certain level of accuracy in spite of the disparity of situations encountered.

In therapeutic interventional radiology, the therapeutic radiologist and the patient are firstly confronted with an often potentially dangerous clinical situation, for which the "natural" scalable risks, often extremely serious - perhaps even life-threatening, must be set out. The risk is explained to the patient frankly but tactfully during the pretherapeutic consultation . The proposed procedure (decided in a multidisciplinary meeting) is likewise explained along with the risks it entails. The therapeutic risk is particularly high in vascular interventional radiology, including the risk of accidental occlusion of a vessel with ischaemia in a possibly dangerous area, or rupture of the malformation leading to a life-threatening risk. These risks are particularly carefully set out and explained to the patient. The risks associated with the use of iodinated contrast media (risk of allergy that can exceptionally - and in an unforeseeable manner - cause death), and the risks associated with the use of ionising radiation (often difficult to predict and generally associated with an unexpected difficulty or complication) appear negligible in comparison with the risk of the pathology and the risk of the intervention in itself, and are usually presented with moderation. Having thus been informed as fully and as honestly as possible, the patient makes the final decision to either accept or refuse the proposed operation.

Assessing the risk associated with ionising radiation during a vascular interventional procedure, which is generally correlated with the duration of the intervention, is a difficult and imprecise exercise. The practitioner's technical choices will be guided firstly by the need for a procedure offering maximum safety and effectiveness. The obsession for safety however does not go hand in hand with economies of dose, since it implies increased surveillance during the intervention, possibly even a succession of radiographic checks. A balance between these two opposing factors may be through the learning curve of experience. But as expertise is acquired, practitioners will be confronted with increasingly complex situations that will tax their acquired assurance. Even experienced practitioners performing procedures initially considered to be simple can encounter unforeseen difficulties.

Establishing reference levels ("therapeutic") for the interventional activity will therefore be a difficult and no doubt imprecise exercise. Significant differences are to be expected even with the same practitioner, according to the varying difficulties that can be met with in the treatment of theoretically identical pathologies. These reference levels will have to integrate the practitioner's experience, the organisation of the centres (practitioner working alone or with an assistant, facility allowing variable image quality, etc.), or event different practices for an equivalent intervention. Large differences are therefore foreseeable.

Dose limiting aids

Dose optimisation in interventional radiology must nevertheless remain an objective at all times during the procedures. It means using the lowest radiation dose possible that allows optimum guidance of the practitioners gesture. Several factors contribute to the reduction of patient exposure, including mastery of the medical gesture by the practitioner, equipment that offers all the necessary optimisation possibilities and optimised image acquisition parameters.

The dose limiting principles and aids must be regularly reiterated when drawing up professional practice recommendations. The technical parameters of each facility should be optimised with the manufacturer's assistance whenever a new facility is introduced, and be re-assessed periodically. The ergonomics of the facility must allow ready adjustment of the elements that influence the dose. Fluoroscopic imaging quality and the possibility of fluoroscopy loop replay should limit recourse to radiography.

The radiological equipment used must be adapted to the performance of the habitual interventional procedures by at least offering the possibility of additional filtering for the X-ray tube, the choice of one or more pulsed fluoroscopy modes, adjustment of the dose per image compatible with limited irradiation of the patients. Decree 2004-547 [14] relative to the safety requirements applicable to medical devices requires radiology devices to be equipped with a system can inform the user in real time of the quantity of radiation produced during the radiological procedure. The device must display the dose emitted and the cumulative dose in real time during the intervention. This information can be extremely useful to the practitioner, notably to vary the beam incidence angles during the procedure. The use of standardised quantities from one facility to the next should be an aid in establishing reference levels.

Training in the radiation protection of workers (occupational exposure) and patients is designed to enable the medical staff to acquire knowledge of the dose optimisation methods and the risks of ionising radiation as used in diagnostic or interventional radiology. It comprises an obligatory theory part mentioned in the order of 18 May 2004 [13] and allowing effective implementation and continuous improvement of the dose optimisation processes. The practical part must focus on the effective optimisation of the radiological procedures, evaluated by the final level achieved at the end of the procedure. This training must also address the interpretation of the dosimetric information displayed on the consoles and the dose thresholds that induce skin lesions. The practitioner will thus be able to determine the radiation dose beyond which the patient's monitoring will have to include surveillance for the occurrence of radiation-induced cutaneous lesions.

Apart from the collective protection equipment in the intervention rooms, operators must wear personal protective appropriate for the procedures to minimise their own exposure (leaded apron, protective screens, leaded glasses, thyroid shield, etc.); they must also were passive and operational dosimeters to monitor their exposure levels. The operational dosimeters are equipped with a system that informs the operator of any excessive exposure.

Radiology devices must undergo regular maintenance and internal and external quality inspections to ensure their level of performance is maintained. Thus, to reduce doses to patients, ICRP 85 [12] recommends the use of pulsed fluoroscopy, increasing the filtering of the X-ray tube, reducing the number of radiographic images taken or the duration of fluoroscopy, collimation of the X-ray beam or positioning the detector as close to the patient as possible, with the X-ray source being as far away as possible. Collimation enables patient exposure to be limited to the area of interest for the procedure. Changing beam incidence enables the practitioner to distribute the dose over a wider cutaneous region and delay the onset of deterministic effects.

Fluoroscopy remains the essential tool for radioguided procedures. In spite of concentrating on the medical or surgical gesture, the delivered radiation doses should also be taken into account. Practitioners must commit themselves to the optimisation of dose reduction, which often requires the assistance of a medical physicist. The radiological procedures of the equipment suppliers can thus be reviewed in the light of practices within the establishment, with the aim of improving the acquisition parameters by adjusting the dose per image while still maintaining image quality. The medical physicist will help define the dose reference level within the department for the most commonly performed procedures as in radiodiagnostics. For the most highly irradiating procedures, defining alert levels could be a major aid for instituting post-intervention surveillance for the occurrence of radiation-induced lesions. It must be possible to interpret the dose information by comparison with a reference value specific to the facility and the procedure, and to the threshold levels relative to the onset of cutaneous lesions.

By establishing reference and alert levels, practitioners will be able to pay attention to the quantity of radiation emitted during the procedures, and thus institute a dose limiting approach. Indicating this dose in the patients file is no longer a purely regulatory requirement but an aid to patient exposure management and differentiated monitoring of patients.

Independently of this, the continuous progress in biomedical research should bring alternative guidance tools. MRI offers real possibilities in this respect, but its development is limited due to the lack of machines. Here the involvement of the public authorities if indispensable if medical practices are to evolve.

Conclusion

The constant and growing concern of the health professionals, and radiologists in particular, about the increase in

medical irradiation, is demonstrated this year by the huge increase in the notification of events to ASN (+ 50% in 2010 compared with 2009). This more acute awareness must lead to the generalisation of optimised alert and dose limiting aids, allowing good quality guidance with limited irradiation, and a strong alerts in situations implying prolonged procedures. It is in this context that the French federation of interventional radiology and the French society of radiology are developing training aids and data collection aids, and a quality-oriented approach that implies increased interchanges with the authorities concerned, of whom ASN and the IRSN are prime representatives. ■

Bibliography

[1] La radiologie interventionnelle en France. Bilan descriptif de la Fédération de Radiologie Interventionnelle. 2010

[2] Scanff P, Donadieu J, Pirard P et Aubert B. Observatoire des pratiques médicales en radiologie : bilan de l'exposition de la population française à partir des données institutionnelles. Journal de Radiologie 2005 ; 86 (10): 1255.

[3] ACC/AHA/SCAI 2005 Guidelines Update For Percutaneous Coronary Intervention – Summary Article. Circulation 2005; 113: 156 – 175.

[4] Clinical Competence in Percutaneous Transluminal Coronary Angioplasty. A Statement for Physicians From the ACP/ACC/AHA Task Force on Clinical Privileges in Cardiology. JACC 1990; 15:1469-74.

[5] Actualisation du rapport d'évaluation sur les anévrismes sacculaires intracrâniens rompus : occlusion par voie endovasculaire versus occlusion par microchirurgie. Rapport d'évaluation technologique. HAS novembre 2009.

[6] International Subarachnoid Aneurysm Trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomized trial. Lancet 2002; 360: 1267-74.

[7] Inter-Society Consensus for the Management of PAD – TASC II Document 2007

[8] Recommendations for the Managment of Intracranial Arteriovenous Malformations. A Statement for Healthcare Professionnals from a Special Writing Group of the Stroke Council, American Stroke Association. Stroke 2001; 32:1458-71.

[9] Practice Guidelines Committee, American Association for the study of liver disease. Management of hepatocellular carcinoma. Hepatolgy 2005; 42: 1208-36.

[10] Median arcuate ligament syndrome : open coeliac artery reconstruction and ligament division after endovascular failure. Delis et col. J Vasc Surg 2007; 46:799-802.

[11] IRSN Rapport DRPH 2011-7 – Accident de surexposition en radiologie interventionnelle au CHU d'Angers.

[12] La publication 85 de la CIPR intitulé "Comment éviter les lésions induites par les rayonnements utilisées dans les procédures interventionnelles médicales" définit des recommandations pratiques pour optimiser les doses émises lors des procédures.

[13] Arrêté du 18 mai 2004 modifié le 22 septembre 2006 relatif aux programmes de formation portant sur la radioprotection des patients exposés aux rayonnements ionisants - J.O n° 141 du 19 juin 2004

[14] Décret n° 2004-547 du 15 juin 2004 modifiant l'annexe 1 du livre V bis du code de la santé publique relative aux exigences essentielles de santé et de sécurité applicables aux dispositifs médicaux

TECHNICAL OVERVIEWS: NUCLEAR MEDICINE

Development of techniques in nuclear medicine – Radiation protection issues for patients

by Prof. Xavier Marchandise, Prof. biophysics and nuclear medicine, Lille University Faculty of Medicine

Nuclear medicine, which uses radioactive isotopes, has known the hours of glory of cutting-edge techniques, well illustrated by the effectiveness of thyroid cancer treatment. However, since the Chernobyl nuclear power plant accident in 1986 and the very recent accident at Fukushima in Japan, it is on the contrary confronted with understandable but totally unjustified suspicion. Thus, the April 2011 issue of Sciences et Avenir, relaying ASN's presentation of its 2010 report on *The state of nuclear safety and radiation protection in France,* bore the title *"In the wake of the recent nuclear accident in Japan, the question of medical radiation protection re-emerges"!*

What is nuclear medicine?

A radioactive and pharmaceutical substance is administered to a patient. The very small quantity of this radiopharmaceutical tracer distributes itself within the subject according to their metabolism, normal or pathological. The radioactive emission from this tracer can then be used with a therapeutic aim to irradiate a lesion: this is referred to as metabolic, internal or vectorised radiotherapy. More frequently however, a much lower level of radioactive emission is used with a diagnostic aim, to view and characterise lesions using detection equipment - cameras - that provide images called scintigraphy scans.

The tracers and equipment are constantly evolving to provide the best possible results.

Whatever the case, the risks of exposure to ionising radiation must be controlled in nuclear medicine.

In fact, nuclear medicine - whether diagnostic or therapeutic - has always satisfied the requirements of radiation protection. The aspects of radiobiology, radiopathology and radiation protection are widely taught in the national framework of the DES (specialised studies diploma) in nuclear medicine, representing seven whole days in this national syllabus. The specific training in the radiation protection of patients is organised in 48 hours of effective and closely monitored teaching. But just like the practices in nuclear medicine, the very foundations of radiation protection evolve. In 1960, the "permissible annual dose" for population exposure was 5 mSv (0.5 rem) and the gonads represented 20% of the risk with respect to the whole body; today, the annual limit is 1 mSv per year and the gonads represent just 8% of the risk with respect to the whole body.

The principles of radiation protection in nuclear medicine

In nuclear medicine, what does the radiation protection of a patient to whom ionising radiation sources are going to be administered for medical reasons actually mean? Two principles must be applied:

– prefer an alternative solution: this solution must be effective, realistic and not induce is own specific set of adverse effects. For diagnostic purposes, the updated good practices guides are designed to help make the decision. For therapeutic purposes, and the most complex pathologies, multidisciplinary consultation meetings (MCM) between specialists from several disciplines are held to discuss the best strategies given the current state of the art in the techniques;

– reduce exposure during an examination (or a treatment): here, the most significant factor in nuclear medicine is the activity necessary for a given examination, that is to say the quantity of radioactive tracer - or radiotracer - usually expressed in megabecquerels (MBq), sometimes in millicuries (mCi), the former unit. Given that too low a level of activity will result in worthless examinations, this is the reasoning on which the diagnostic reference levels have been based since their introduction in nuclear medicine. These reference levels are destined to evolve: the IRSN has recently introduced children as a category for specific monitoring. Additional simple and effective precautions are moreover the rule, such as:

• to limit exposure of the bladder and the gonads, make patients who are administered tracers that are eliminated in the urine drink large amounts of water and urinate. This is the case with bisphosphonates for bone scintigraphy (bone scan), or fluorodeoxyglucose (FDG) for positron emission tomography (PET);

• to avoid exposing the thyroid to iodine 123 (the use of iodine 131 in diagnostic nuclear medicine was abandoned a long time ago), administer the patient potassium iodide tablets in preference to the classic Lugol's solution which tastes bad;

• to avoid colonic exposure, administer a laxative after a treatment with iodine 131, etc;

– optimise the ratio between the unavoidable exposure of the targeted organ and more regrettable exposure of the rest of the individual: the art of nuclear medicine is to best position specific tracers and appropriate detectors, to choose the most appropriate protocols, and in particular radionuclides with

optimum half-lives. It is this optimisation that has been the focus of recent technical developments.

These technical developments concern new equipment and new tracers.

New equipment

Initially all the scintigraphy scans obtained with the gamma cameras were "planar" (figure 1a), that is to say they superimposed in a given planar image all the events observed at a certain angle of incidence (front, lateral, etc.), with the possibility of multiplying incidence angles to better view the anomalies, as in conventional radiography but with two differences:
- in nuclear medicine, the radiation emitted from the front of the subject is better detected by the anterior face, while that emitted from the back of the subject is better detected by the posterior faces, whereas in radiology the X-rays pass through the entire organism from front or back;
- in nuclear medicine, once the radiotracer has been injected, the committed dose is independent of the number and duration of the incidences and can only be modulated by the precautions mentioned above.

SPECT (Single Photon Emission Computed Tomography): SPECT represents a major development. It is based on the same principle as X-ray computed tomography (CT) but using gamma rays, and taking up the 1960's cerebral emission tomography work of Kuhl and Edwards, which can be summed up as follows: once the detector has examined the subject from all angles, it has an in depth view of it. The events recorded by the gamma camera are used to reconstruct the images of the radioactivity distribution in different planigraphic planes of a given thickness. This brings a spectacular improvement in image contrast, thereby enhancing the sensitivity of detection of pathological anomalies (figure 1b).

The SPECT technique is used constantly in myocardial scintigraphy, and often in bone (figure 1) or lung scintigraphy. In truth, all gamma cameras are now equipped with this tomographic option.

However, to obtain a sufficient signal-to-noise ratio in each element of the reconstructed images, injected activities must be about 25% higher than in planar scintigraphy.

Combined CT scan. Since 2006 it has been possible to combine an X-ray CT scanner with the gamma cameras. The images obtained by the two methods can then be superimposed relatively precisely. The first function of this hybrid scanner is to help locate the lesions. It is very useful in bone scintigraphy, for example, to clarify the topography of the active lesions (although tracer uptake is not more specific than in planar scintigraphy). Furthermore, image reorientation based on the anatomical data improves the analysis by allowing selection of the tomographic images in the most appropriate planes (figure 2).

The hybrid scanner can also be used to apply the attenuation corrections. It allows anatomical anomalies and functional anomalies to be correlated so as to better characterise the lesions and clarify the diagnostic information. Making systematic use of these hybrid systems is a subject of debate [1]. Conversely, it is sometimes asserted that the X-ray CT and emission CT examinations should always be carried out at one and the same time, both morphological and functional. This narrow vision neglects certain practical aspects of nuclear medicine, and two in particular:
– firstly, the radiographic quality of this hybrid equipment is generally not optimised, which contributes to the limiting of their dosimetry. It is nevertheless conceivable that - under specific conditions of established interest, or when its generalised use has been unquestionably validated - a hybrid scanner offering high morphological resolution would be an advantage;
– secondly, the sequencing of isotopic explorations in practice is dependent on the radioactive decay of the radiotracer used. Bone scintigraphy for example uses a diphosphonate labelled with technetium 99m which has a biological half-life of three hours; the examination is performed optimally two hours after the injection, and many such scans are scheduled every day. In such cases it would be unreasonable to disrupt the scheduled successive examinations with unscheduled injections of radiological contrast media. This would only be possible in situations where equipment and personnel are underemployed.

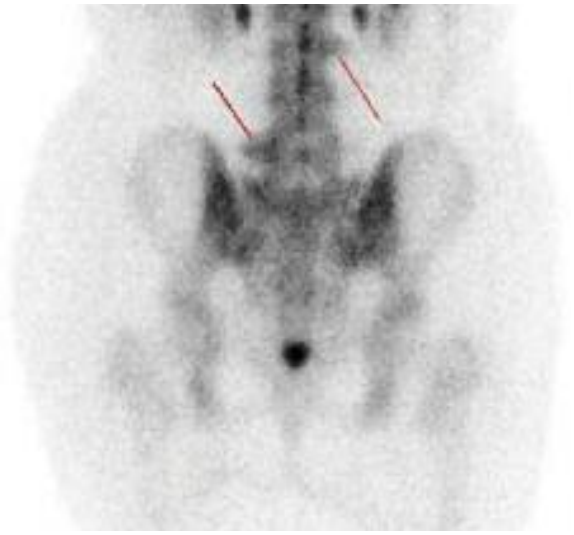


Figure 1a: In a patient monitored for breast cancer, some take-ups are still unclear with planar scintigraphy (arrows)

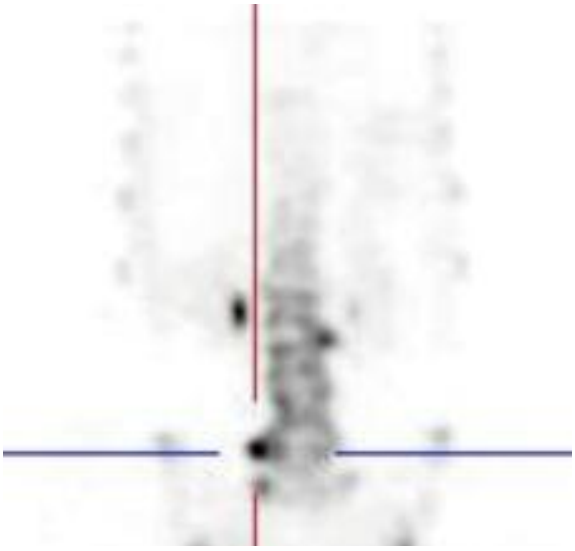


Figure 1b : The anomalies are clearer on the emission CT images

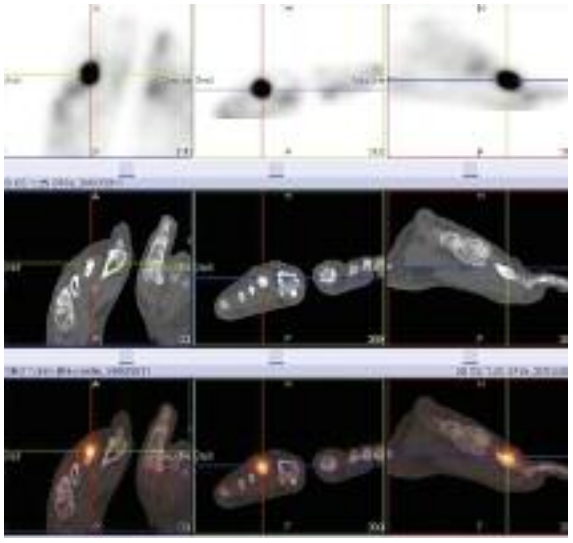


Figure 2a : The hyperfixation of the tracer in emission CT (top line) is correlated with the corresponding images of the scanner (middle line) and the fused documents are presented in different spatial planes

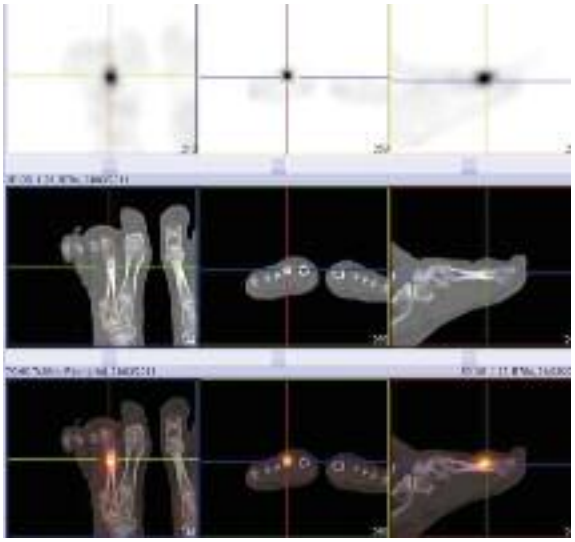


Figure 2b : Interpretation is greatly facilitated with optimal orientation of the planigraphic planes obtained from the morphological data of the scan

Image fusion. Probably the most effective alternative to the preceding dilemma of hybrid equipment is to perform each examination under optimum technical conditions and then to correlate them retrospectively on an image processing station which reproduces the images from the respective techniques at the highest possible quality standard. The results can then be put to maximum use at the multidisciplinary consultation meetings. Technically speaking, this retrospective fusion of images is well know and has been studied for a long time. It brings significant health savings, but demands close coordination between the specialities [2].

Regarding patient radiation protection, the combined use of emission CT and X-ray CT means that their extra exposure levels are summed with respect to planar images. Increasing the injected activity for a bone scintigrapy scan likewise increases the exposure, from example from 4 to 5 mSv. The associated X-ray CT scan, using a low dose with a dose-area product (DAP) of about 300 mGy.cm on a limited field, let's say the pelvis and hips, brings an additional exposure of the same order. These values vary according to the dimensions of the study field and the field itself (the head and legs for example are 20 times less critical than the pelvis). But these are just orders of size, and to optimise the new practice there is an urgent need to take true stock of the situation. Compared with planar scintigraphy, this increased exposure can be justified by the quality of the information obtained, but it must nevertheless have strong supporting arguments, and the younger the patient the more vitally important this is.

PET. The advent of positron emission (computed) tomography (PET) was a considerable development, deployed in France mainly between 2003 and 2008. Technically speaking, the principle of coincident (simultaneous) detection of a pair of gamma photons emitted during the annihilation of positrons provides resolution that is almost twice as good as that of conventional scintigraphy and therefore improves its sensitivity by as much. Medically speaking, PET using fluorodeoxyglucose (FDG) as the radiotracer is currently the best technique for assessing a large number of cancers and the effectiveness of their treatment. It can be pointed out that the exposure often concerns elderly patients with modest life expectancy, but not always. PET examinations can for example be performed to diagnose or monitor forms of lymphoma in adolescents whose life expectancies have been spectacularly prolonged, therefore their exposure levels must be tightly controlled.

Furthermore, today PET always includes a X-ray CT scan which is vital for radiation attenuation correction, without which the lungs, for example, would paradoxically appear to take up the tracer more than the other tissues(figure 3). Until 2002, this attenuation correction in PET was based on the transmission of gamma radiation from sealed radioactive sources rotating around the subject; using the CT scanner has reduced the time necessary for this correction by a factor of 4.

The use of X-ray CT combined with PET is not restricted to a limited field, but concerns all segments explored by the examination (apart from the limbs for which correction is not vital). As with SPECT, the hybrid scanner allows more accurate locating of the lesions and helps with their characterisation. The documents obtained are of particular interest for cancer monitoring because they enable the image of the active pathological volumes to be superimposed on the mass of visible residual volumes. But even more than with SPECT, it will be difficult to modify the scheduling of examinations to get immediate benefit from all the potential of a high-resolution scanner. This is because as the radioactive half-life of fluorine 18 - the most commonly used positron emitter - is about two hours, delaying an examination by 30 minutes requires, in order to maintain its quality using a constant activity level, extending its acquisition time by 10 minutes, which delays the following examination by 40 minutes, making it last even longer, and so on and so forth.

PET and MRI. In the same spirit of hybrid equipment, combining positron emission tomography with nuclear magnetic resonance imaging (MRI) is a topical scientific subject [3]. Indeed, identifying tissues by MRI enables them to be assigned the attenuation coefficients necessary for PET image correction. Above all, MRI characterisation of lesions of soft tissues is particularly rich in information, especially in the

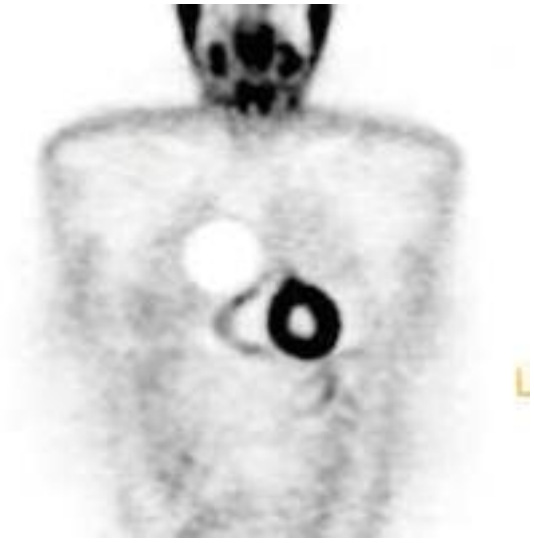


Figure 3a : PET imaging without attenuation correction: the broad thoracic formation does not capture the tracer which the lungs and skin would appear to take up relatively well; the cervico-facial region is very noisy

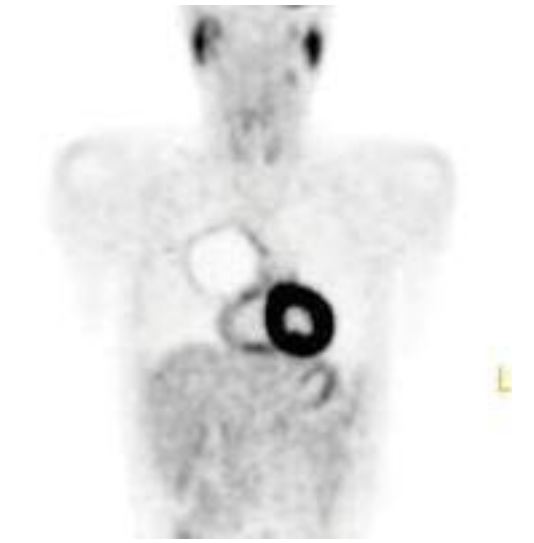


Figure 3b : Same image after attenuation correction: the edge of the hypofixating thoracic formation displays a raised metabolism; the air in the lungs and the skin show no particular takeup; the salivary glands and the thyroid can be clearly distinguished

brain where the contrast between the grey matter and white matte, and between lesions and healthy tissues shows up. Lastly, to date no clearly identified risk for the patient has been attributed to MRI. In fact, this PET-MRI combination constitutes a real and fascinating technical challenge given the high susceptibility of each machine to the influences of the other (influence of the magnetic fields of MRI on photon detection, influence of the PET detectors on the magnetic fields). This being said, here again a less ambitious solution could be obtained by retrospective fusion of the images.

Semi-conductor detectors. Another recent technological development is the introduction of semi-conductor detectors. Such devices were first used for the peroperative detection probes (for example to identify the sentinel node of a tumour and make an extemporaneous examination of its lymphatic invasion to decide whether lymph node dissection is necessary). In recent imagers the detection surface, instead of being an assembly of photomultipliers, is a matrix of numerous semi-conductor crystals, now commonly used in myocardial emission computed tomography. One of the chief advantages of these matrices is their very high sensitivity, which enables the administered dose - and therefore exposure - to be reduced by more than half [4]. Nonetheless, here again it is necessary to make a rigorous comparison between the results obtained with recent equipment.

New tracers

Changes in exposure levels have resulted from reducing or even abandoning the use of certain radiotracers.

The best known radiotracer in nuclear medicine is iodine 131 (radioiodine), the oldest time-proven radioisotope. It has the following physical characteristics:
– beta-minus particle (electron) emitter, which enables it - at high activity and by a deterministic effect - to destroy the cells that take it up, but also - at low activity and by a stochastic effect - to induce cancers;
– gamma ray emitter, which provides for easy detection at medium activity;
– radioactive half-life of 8 days, which ensures the therapeutic effect and enables the dynamics of the iodine metabolism to be monitored.

Thus, around the Chernobyl accident site, iodine 131 created cancers of the thyroid by the stochastic effect of beta-minus particle emissions on the growing thyroid cells of children. Thyroid scintigraphy, which uses the gamma emissions from iodine 131, shows up the tumourous tissue due to its lower uptake of iodine 131. Paradoxically, it is these therapeutic doses of iodine 131 that, following surgery, completed the healing of the large majority of these thyroid cancers, by the deterministic effect of the beta-minus radiation on all the remaining thyroid cells.

Today, iodine 131 is never used for the diagnosis of endocrine gland pathologies, having been replaced by iodine 123 (its gamma ray emissions give better detection, it does not emit beta-minus radiation, and it has a half-life of 12 hours). In addition, for the post-surgical monitoring of differentiated thyroid cancers, the injection of recombinant human TSH (thyroid stimulating hormone) enables the stage of cancer development to be determined by simply measuring the thryoglobulin level, without having to resort to whole-body scintigraphy with iodine 131. Nonetheless, iodine 131 remains essential in the treatment of differentiated cancers of the thyroid.

One might have thought, as was the case with iodine 131 for thyroid exploration, that the use of thallium 201 for myocardial exploration would be rapidly abandoned in favour of technetium-99m labelled isonitriles (MIBI - methoxy isobutyl isonitrile), which are significantly less irradiating (8 mSv versus 25 mSv with conventional equipment. However, in compliance with the Notice of Compliance (NOC), the injected activities vary according to the applied protocols: for example from 1 GBq to 1.5 GBq of Tc-99m). The actual situation has significantly altered this hypothesis. Firstly there is a lasting controversy regarding the quality of information obtained with one tracer or the other, with thallium being kept as the reference. Secondly, the crisis relating to shortages in the supply of molybdenum 99, which generates technetium-99m, has heavily underlined that in the absence of technetium-99m labelled isonitriles, thallium 201 remained the best alternative, in spite of its dosimetric drawbacks. In addition, the introduction of semi-conductor

detectors means that the use of thallium 201 with reduced activities can be once again be quite reasonably envisaged.

To summarise, the dosimetric trend for gamma-emitting radiotracers is clearly towards a reduction in exposure levels.

From another aspect, the rapid emergence of PET and positron emitters initially resulted in increased patient exposure. More sensitive PET machines were then developed (3D detection, time-of-flight), leading to a reduction of about 25% in the FDG activities necessary for the examination. Other tracers also labelled with fluorine 18 and with exposure levels quite similar to that of FDG are coming onto the market (e.g. sodium fluoride, fluorocholine, fluorodopa, fluoroestradiol). Other positron emitters are also being studied, labelled with iodine 124 or copper 68 for example, but whose exposure levels will not necessarily all be as acceptable as those of fluorinated radiotracers. Whatever the case, as has already been said, the pathologies investigated are serious (oncology, serious infectious diseases, dementia), and in their large majority concern elderly patients. In these applications the stochastic risk of secondary cancer is far less important than the immediate medical problem.

Attention must however be focused on younger patients, such as those suffering from lymphoma. The international learned societies propose various methods of dose adjustment for children, essentially weight-related. A minimum threshold level of activity does however remain necessary, which means that babies receive proportionally higher doses with respect to their weight.

Some therapeutic procedures require complex preparations. LipioCIS® was used for radioembolisation of liver tumours by selective intra-arterial injection; as the radiopharmaceutical was trapped by tumoural capillary blockade, its load of iodine 131 selectively irradiated the tumour. Its utilisation required an oncologist for the indication, a radiopharmacist to dispense it, a nuclear physician to ensure the dosimetric and radiation protection aspect, and a radiologist to administer the injection. Glass or resin microspheres containing yttrium 90 are a recent addition to the radiopharmaceutical arsenal and display the same characteristics; paradoxically they have not been registered as radiopharmaceuticals but as Implantable Medical Devices, for which responsibilities are much less clearly defined.

Lastly, the forthcoming development of alpha emitters by the Arronax cyclotron in Nantes will forcibly bring an original reflection on radiation protection in this new area.

Conclusion

Radiation protection for nuclear medicine patients has benefited from the progress in the sensitivity of the techniques and instruments, which help to overcome the problems posed by the increased use of radioactivity.
Even if radiobiological culture today remains strongly implanted in both the genes of nuclear medicine and the training syllabuses for its specialists, the efforts in radiation protection must concentrate on:
– upholding this culture;
– ensuring optimum control of the risk and optimum knowledge of the associated CT exposure levels;
– the dosimetric problem in young patients;
- the attention paid to new developments, particularly therapeutic. ■

Bibliography

[1] Ndlovu X, George R, Ellmann A, Warwick J. Should SPECT-CT replace SPECT for the evaluation of equivocal bone scan lesions in patients with underlying malignancies ? Nucl Med Commun 2010 ; 31(7) : 659-665.

[2] Giovanella L, Lucignani G. Hybrid versus fusion imaging : are we moving forward judiciously ? Eur J Nucl Med Mol Imaging 2010 ; 37(5) : 973-979.

[3] Wehrl HF, Sauter AW, Judenhofer MS, Pichler BJ. Combined PET/MR imaging technology and applications. Technol Cancer Res Treat. 2010 ; 9(1) : 5-20.

[4] Duvall WL, Croft LB, Godiwala T, Ginsberg E, George T, Henzlova MJ. Reduced isotope dose with rapid SPECT MPI imaging: initial experience with a CZT SPECT camera. J Nucl Cardiol. 2010 ; 17(6) : 1009-1014.

INTERNATIONAL INITIATIVES

Medical imaging initiatives in Belgium

by Dr. Patrick Smeesters, AFCN (Federal agency for nuclear control) – Belgium

A shared finding

Radiation protection has long been part of the radiotherapy - and more recently nuclear medicine - landscape in Belgium, as elsewhere, given the risks involved. Practitioners in these fields are usually aware of the risks associated with the tools they use – which unfortunately has not prevented the occurrence of a series of incidents and accidents. This risk awareness is moreover much less developed in medical users of X-rays, whether for diagnosis or for image guided therapeutic procedures. Paradoxically, considering all medical specialities as a whole, the culture of radiation protection based on the principles of justification and optimisation is significantly less widespread in the medical world than in other sectors using ionising radiation sources. This situation is all the more worrying in that these last years have witnessed the growth of new and fast-changing radiological techniques that have resulted in an increase in individual and collective doses for both the medical personnel and the patients.

The regulatory response and its limits

The increasing frequency of radiological examinations, and above all the large differences observed in doses delivered to patients, has made the medical field the focus of increasing attention throughout the world. The first consequence of this was the adoption of the European Council directive of 3 September 1984 setting the fundamental measures relative to the radiological protection of individuals undergoing medical examinations and treatments. The scope of this directive was relatively limited, but it nevertheless resulted in significant changes. One was that each physician using ionising radiation sources - whether already actively practising or not - had to have an accreditation in radiation protection recognised by the member state authorities, who consequently had to organise complementary training programmes. These programmes filled many a lecture theatre in Belgium.

Following this, in the period from 1984 to 1996, the European approach focused on support for research into quality assurance methods and criteria , image quality and patient exposure optimisation, the methodology and instrumentation for assessing doses and the formulation of guidelines for image quality criteria in diagnostic radiology. Many seminars and conferences were organised, but they were attended essentially by physicists, rarely physicians! The dissemination of knowledge and the culture of radiation protection thus remained an unsolved problem, especially in the X-ray radiology/medical imaging rooms.

International seminary about optimization of radiation protection for medical staff - European programme ORAMED – January 2011

The occurrence of acute accidents in radiology and the upward reassessment of the risk of radiation-induced cancer, among other things, incited the promulgation of the directive of 30 June 1997 relative to the health protection of individuals against the dangers of ionising radiation in relation to medical exposure. This directive was extremely demanding and led to significant changes in the regulations.

However, frankly speaking, the required changes were a long time in coming...

Reviewing the approach

The relative failure of the traditional regulatory approach led us to consider a fundamental revision of the strategy. Creating a regulatory framework and instituting checks was insufficient. The prime need was to influence the culture reigning in the medical sector, and to do this other avenues had to be explored.

The first avenue we explored and developed was based on providing information and enhancing awareness of the differences that existed in the delivered doses, and therefore in the quality of practice. It was decided to focus firstly on the radiologists and to work in close collaboration with their representatives (Consilium Radiologicum Belgicum: the representative body of Belgian medical imaging). A handbook on the medical use of X-rays was drafted in parallel with the initiation of a vast patient dosimetry survey.

This survey has two major objectives:

The first is to carry out periodic (three-yearly) dose studies in which the doses are precisely measured with the aid of a medical physicist, and compared with reference diagnostic levels with the aim of eliminating bad practices and optimising examination procedures. After the measurement campaign, each department is informed of its dosimetric performance and can thus situate itself with respect to the "good practice" (25 percentile) and the borderline of bad practice (75 percentile).

The second objective is to allow the on-line evaluation, by means of dose-area product (DAP) calculations, of individual doses in high-dose examinations (interventional radiology; dynamic examinations with fluoroscopy, etc.), or retrospective assessment of doses delivered in certain situations (essentially paediatric radiology and abdomen exposure in fertile women).

Things began slowly, but thanks to the support of organisations representing the physicians, the level of participation currently stands at 70% of the radiology departments. The target is 100% coupled with clinical audits, and the introduction of a form of "label" is currently being studied.

The second avenue has been to promote (and finance) various research actions, involving the collaboration and active participation of radiological departments in numerous universities and hospital institutions. The studies in interventional radiology not only confirmed that the doses associated with these procedures are very high, but above all they evidenced large disparities in dose delivery between centres and departments for the same diagnostic or therapeutic result. The causes of the "unnecessary" exposure were analysed. This work resulted in a series of good practices recommendations relating to the choice of equipment, equipment maintenance and quality assurance, and the techniques and procedures to use. The need to improve practitioner training and guarantee their continuing education also came to light. The studies also enabled alert levels that are easily checked during examinations (by measuring the DAP) to be defined for several procedures, enabling the practitioner to be warned of risks of causing lesions in the patient's skin. The importance of better protection for medical staff was also demonstrated, particularly by monitoring the dose received by the hands and eyes (multicentric study performed as part of the European programme ORAMED - Optimization of Radiation protection for Medical staff). One of the fundamental objectives of this research work with as wide-reaching participation as possible is to bring radiation protection out of its "restricting" regulatory framework (often badly perceived in the medical world) and reposition it in its scientific context.

The third avenue that we are currently following aims at the appropriation of the regulations by the medical sector via a thorough review of all the regulations in force.

A series of fundamental criteria has been adopted: the added radiation protection value, efficiency (optimum utilisation of resources), effectiveness (obtaining the intended results), a graduated approach (protection and safety measures commensurate with the risk), administrative simplification, legal security and attention to costs for both the public authorities and the user.

The AFCN made eleven reform proposals to the various groups concerned, namely:

– promotion of a "quality-based" approach;
– justification of medical exposures (through active promotion of prescription criteria, among other things);
– improvement of patient protection;
– improvement of personnel protection;
– more clearly defined responsibilities for the various actors;
– revising of training courses and the authorisation system;
– improvement of procedures;
– more energetic "upstream" action on the question of equipment;
– true prevention of unwanted and accidental exposure;
– improved communication and scientific information ;
– generalisation of the clinical audit approach (including in nuclear medicine and radiology).

These eleven proposals were approved by practically all the protagonists, who sometime turned out to be more demanding and ambitious than the authorities themselves.

It is on this basis that a series of round tables has been organised - some of which are still to be held - and working groups have been created to find consensual solutions to the problems encountered. (The general atmosphere is currently highly constructive, contrasting with the difficult relations of a few years back). The AFCN's next immediate intention is to extend this awareness raising and the various actions to groups as yet little concerned, such as non-radiologist specialists using X-rays, for example in the surgical sector, etc.

The Achilles heel

The existence of a true radiation protection culture with true implementation of patient dosimetry and, more broadly, the European directive on medical exposure will only be possible if all the actors concerned, especially the practitioners, commit themselves to a constant effort of exposure justification and dose reduction, while at the same time achieving the essential goal of ensuring appropriate diagnosis or treatment.

The profound motivation of the practitioners in this respect is essential, and it assumes the existence of satisfactory basic training (this is often deficient, and sometimes non-existent) and continuous training and information enabling them to keep up to date with progress in research, and not work on the basis of outdated concepts.

In this respect, we must underline the risk that the foundation of the radiation protection culture - still embryonic in the medical world - suffers from the negative effect of quarrels among experts regarding low doses, ambiguous statements on their "purely hypothetical" risks or peremptory assertions about the existence of a risk threshold of 100 mSv for radiation-induced effects, all of which can undermine the motivation to ensure radiation protection. Let's be clear: the doses used in medicine are very often not "low doses", they are moreover characterised by a high dose rate and lastly, even if uncertainties remain, the existence of risks associated with the doses used in medical imaging - even for purely diagnostic purposes - is supported by sound scientific arguments, as has been recently confirmed by credible organisations such as the International Commission on Radiological Protection (ICRP), the BEIR (Biological Effects of Ionizing Radiation) report of the US National Academy of Sciences, and the United Nations Scientific Committee on the effects of atomic radiation (UNSCEAR).

Furthermore, as regards these remaining uncertainties on the risks at low dose levels, it is important for practitioners not to get the context wrong: if everyone considers that the greatest caution is necessary in the "purely scientific" evaluation of the effects of an agent that is potentially toxic for human health, there are nevertheless two ways of being scientifically prudent. The first consists in being highly prudent before concluding on a causal relationship between exposure to a given agent (at a given dose) and a particular effect on health. As long as causality has not been demonstrated, one must "remain prudent" in this approach (in other words, wait for research to progress before making a definitive conclusion).

The second way of being prudent is likened to the application of the principle of precaution: when serious and scientifically plausible signs that a possible causal relationship exists between a potentially toxic agent (at a given dose) and an particular effect on health (which is the case for certain low-dose radiation-induced effects such as cancers), precautions must be taken immediately, even if uncertainties remain.

Clearly the prudence of researchers lies in the first category.

It is all the more important to clearly distinguish the precaution that is expected on the part of the national health authorities and of the practitioners themselves. The patients expect doctors and practitioners to take all necessary precautions in their respect.

It is this change in viewpoint and paradigm that must take place before a true ALARA (as low as reasonably achievable) culture can emerge among doctors. ■

INTERNATIONAL INITIATIVES

Patient doses in medical imaging including interventional Radiology International actions: ICRP recommendations and practices in Spain

by Prof. Eliseo Vano, Radiology Department. Complutense University. Medical Physics Service. San Carlos University Hospital. Madrid. Spain

Introduction and ICRP recommendations

The International Commission on Radiological Protection recommends that justification and optimization criteria be applied to medical exposures and that diagnostic reference levels (DRLs) be used in medical imaging including interventional radiology. With regard to medical exposure of patients, it is not appropriate to apply dose limits or dose constraints, because such limits would often do more harm than good [1,2].

In radiological protection, justification of patient exposures is different from justification in any other radiation applications. Generally the same person enjoys the benefits and suffers the risks associated with a procedure. There are three levels of justification of a radiological practice in medicine. At the first and most general level, the proper use of radiation is accepted as doing more good than harm to society. At the second level, a specified procedure with a specified objective is defined and justified (e.g. chest X-rays for patients showing relevant symptoms, or for individuals potentially at risk from conditions that can be detected and treated). At the third level, the application of the procedure to an individual patient should be justified (i.e. the particular application should be judged to do more good than harm to the individual patient). Hence all individual medical exposures should be justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved [2].

The optimisation of protection for patients is usually applied at two levels: (1) the design, appropriate selection, and construction of equipment and installations; and (2) the day-to-day methods of working (i.e. the working procedures). The dose to the patient is determined principally by the medical needs. Dose constraints for patients are therefore inappropriate, in contrast to their importance in occupational and public exposure. Nevertheless, the management of patient dose is important and can often be facilitated for diagnostic and interventional procedures by use of diagnostic reference levels (DRL), which is a method for evaluating whether the patient dose (with regard to stochastic effects) is unusually high or low for a particular medical imaging procedure. There is considerable scope for dose reductions in diagnostic radiology. Simple, low-cost measures are available to reduce doses without loss of diagnostic information, but the extent to which these measures are used varies widely [2].

Diagnostic Reference Levels

ICRP has provided advice on the use of DRLs in several publications [2-5]. DRLs are a form of investigation level, applied to an easily measured quantity in diagnostic radiology, usually the absorbed dose in air, or in a tissue-equivalent material at the surface of a simple standard phantom or representative patient. In nuclear medicine, the quantity will usually be the administered activity. In both cases, the DRLs will be intended for use as a simple test for identifying situations where the levels of patient dose or administered activity are unusually high or low. If relevant DRLs are consistently being exceeded during procedures, there should be a local review of the procedures and equipment in order to determine whether the protection has been adequately optimized. If not, measures aimed at reduction of the doses should be taken. DRLs are supplements to professional judgment and do not provide a dividing line between 'good' and 'bad' medicine. They contribute to good radiological practice in medicine.

For fluoroscopically guided interventional procedures, diagnostic reference levels, in principle, could be used to promote the management of patient doses with regard to avoiding unnecessary stochastic radiation risks. However, the observed distribution of patient doses is very wide, even for a specified protocol, because the duration and complexity of the fluoroscopic exposure for each conduct of a procedure is strongly dependent on the individual clinical circumstances. A potential approach is to take into consideration not only the usual clinical and technical factors, but also the relative 'complexity' of the procedure [2].

DRLs are not applicable to the management of deterministic effects (tissue reactions) (i.e. radiation-induced skin injuries) from fluoroscopically guided interventional procedures. In this case, the objective is to avoid deterministic effects (tissue reactions) in individual patients undergoing justified but long and complex procedures. The need here is to monitor, in real time, whether the threshold doses for deterministic effects (tissue reactions) are being approached or exceeded for the actual procedure as conducted on a particular patient [2].

ICRP Recommendations on patient dose management

In recent years , ICRP has published several reports advising on the good management of patient doses in diagnostic and fluoroscopically guided interventional procedures: Publication 85 "Avoidance of Radiation Injuries from Medical Interventional Procedures" [6]; Publication 87 "Managing Patient Dose in Computed Tomography" [7]; Publication 93 "Managing Patient Dose in Digital Radiology" [8]; Publication 102 "Managing Patient Dose in Multi-Detector

Computed Tomography (MDCT)" [9]; Publication 106 "Radiation Dose to Patients from Radiopharmaceuticals - Addendum 3 to ICRP Publication 53" [10].

Publication 113 "Education and Training in Radiological Protection for Diagnostic and Interventional Procedures" (including medical students) [11] is still in press and three more documents are ready for the public consultation period: "Radiological Protection in Paediatric Diagnostic and Interventional Radiology", "Avoiding adverse radiation effects to doctors and patients in fluoroscopically guided procedures - practical guidelines" and "Patient and staff Radiation Protection in Cardiology". The topic of justification is also being considered by Committee 3 (Protection in Medicine) of ICRP for some of the documents to be produced in the coming years.

ICRP Recommendations on Interventional Radiology

The key features of the recommendations made by ICRP for interventional radiology are good training in RP, knowledge of the x-ray systems and typical doses delivered to patients, procedures to audit practice and to ascertain radiation-induced complications including appropriate procedures for patient follow-up and inform patients on the likelihood of radiation effects. In accordance with these recommendations, manufacturers should provide: ergonomic radiation protection devices; dose reduction features; and appropriate indicators of delivered doses [6].

ICRP Recommendations on Digital Radiology

The main recommendations given by ICRP on digital radiology are: Appropriate training, particularly in the aspects of patient dose management, before clinical use of digital techniques; Review of local DRLs when new digital systems are introduced in a facility; Frequent patient dose audits; Optimization programs (for radiation dose) and continuing training whenever new digital systems or new post processing software are being introduced ; New procedures and protocols ensuring quality control in digital radiology ; Acceptance and constancy tests including aspects concerning visualization, transmission, and archiving of the images and of course, Specialists dedicated to maintaining the network and the PACS (Picture Archiving and Communication System) should be available; Industry should promote tools to inform radiologists, radiographers, and medical physicists about the exposure parameters and the resultant patient doses; The exposure parameters and the resultant patient doses should be standardized, displayed, and recorded [8].

ICRP Recommendations on Computed Tomography

The main findings and recommendations for patient dose management in computed tomography (CT) are the following ones: Multi Detector Computed Tomography (MDCT) may increase patient radiation doses in comparison to single detector CT; There is potential for dose reduction with MDCT systems, but the actual dose reduction achieved depends upon how the system is used; It is important that radiologists, cardiologists, medical physicists and CT system operators understand the relationship between patient dose and image quality and are aware that, often, image quality in CT is higher than that needed for diagnostic confidence; MDCT represents state-of-the-art CT technology and offers a number of technical measures for dose reduction; Justification of CT use is a shared responsibility between requesting clinicians and radiologists. It includes justification of the CT study for a given indication and classification of the clinical indications into those requiring standard dose CT and those requiring only low dose CT ; Scanning parameters should be based on study indication, patient size, and body region being scanned so that patient dose can be managed based on these parameters; Guidelines (selection criteria for CT examinations) are necessary so that inappropriate studies can be avoided. In addition, alternative non-radiation imaging techniques should be considered, when appropriate [7, 9].

Application of the ICRP recommendations and the European Directive on Medical Exposures in Medical Imaging in Spain

Spain, with its 47 million inhabitants (on 1st January 2010) is organized as a central government with devolved power for 17 Autonomous Communities. It tried to follow the recommendations of ICRP and the requirements of the European Directive 97/43/Euratom on medical exposures [12] and consequently enacted several Royal Decrees on Quality Criteria in Diagnostic Radiology, Nuclear Medicine, Justification and established the specialty of Medical Physics Expert (called in Spain "hospital radiophysicist") [13-16].

Radiation Protection Training for Medical Professionals

A significant effort has also been made during the last years to promote RP training for prescribers and users of x-rays in diagnostic or interventional fluoroscopically-guided procedures. Figure 1 shows the current structure of the training in RP for physicians in Spain [17].

Undergraduate level

The first cycle program in Medicine includes (in some medical faculties) basic medical physics as a compulsory subject (usually in the 1st course) with a total of 6 ECTS (European Credit Transfer System), 0.15 ECTS of which are devoted to radiation protection principles. The second cycle program (from 3rd to 6th course) includes, in some faculties, radiation protection as an optional subject with 6 ECTS.

Postgraduate level

For referrers: Physicians specializing at a hospital as residents receive, in the first year, 6 to 8 hours of theoretical training in RP regarding justification principle. In the third year, they must attend a 2 to 4 hour practical training course about their own practical implementation of the principle of justification. This training is regulated by the Spanish Ministry of Health.

For practitioners: the first level of training in RP is supervised by the Regulatory Authority ("Consejo de Seguridad Nuclear", CSN). To be responsible for an X-Ray diagnostics installation (with medical purpose), a medical doctor must have a certification issued by the CSN. Radiologists automatically receive this certification at the end of their residency period. Non-radiology specialists follow a separate training course of about 30 hours on RP, after or during their residency period.

For non radiology-specialists (radiographers, nurses, etc), a specific regulation makes certification mandatory to

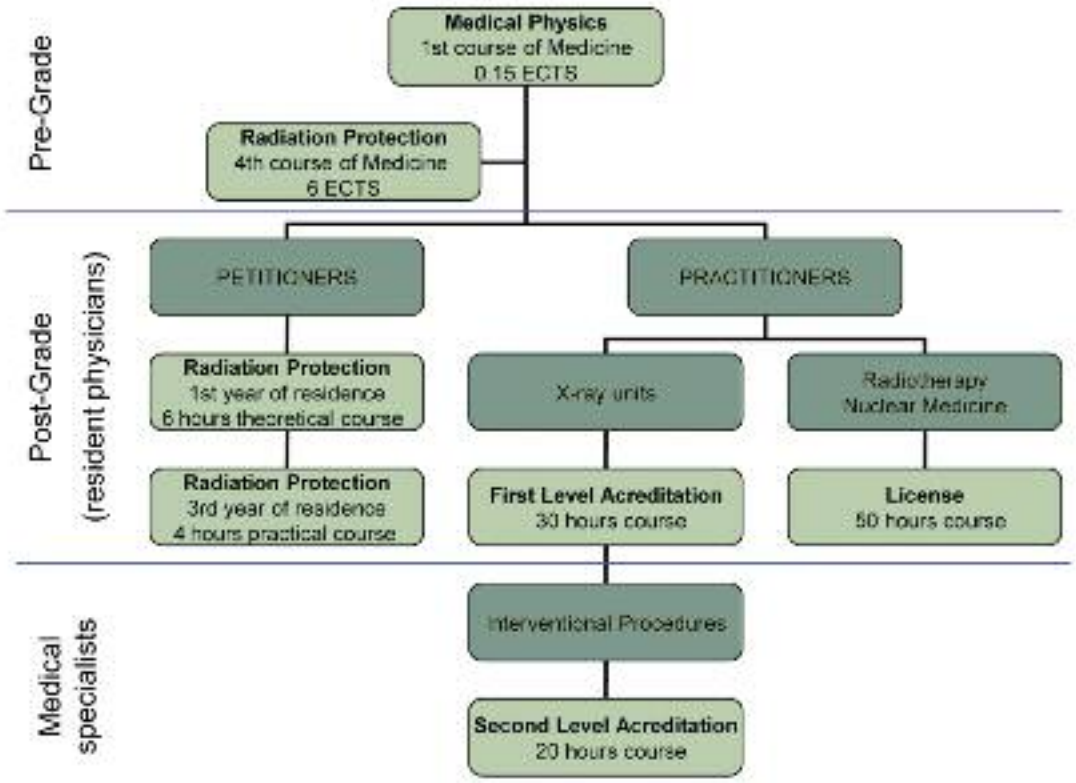


Figure 1: Current structure of the training in RP for physicians in Spain (from "Spanish experience on education and training in radiation protection in medicine" [17]).

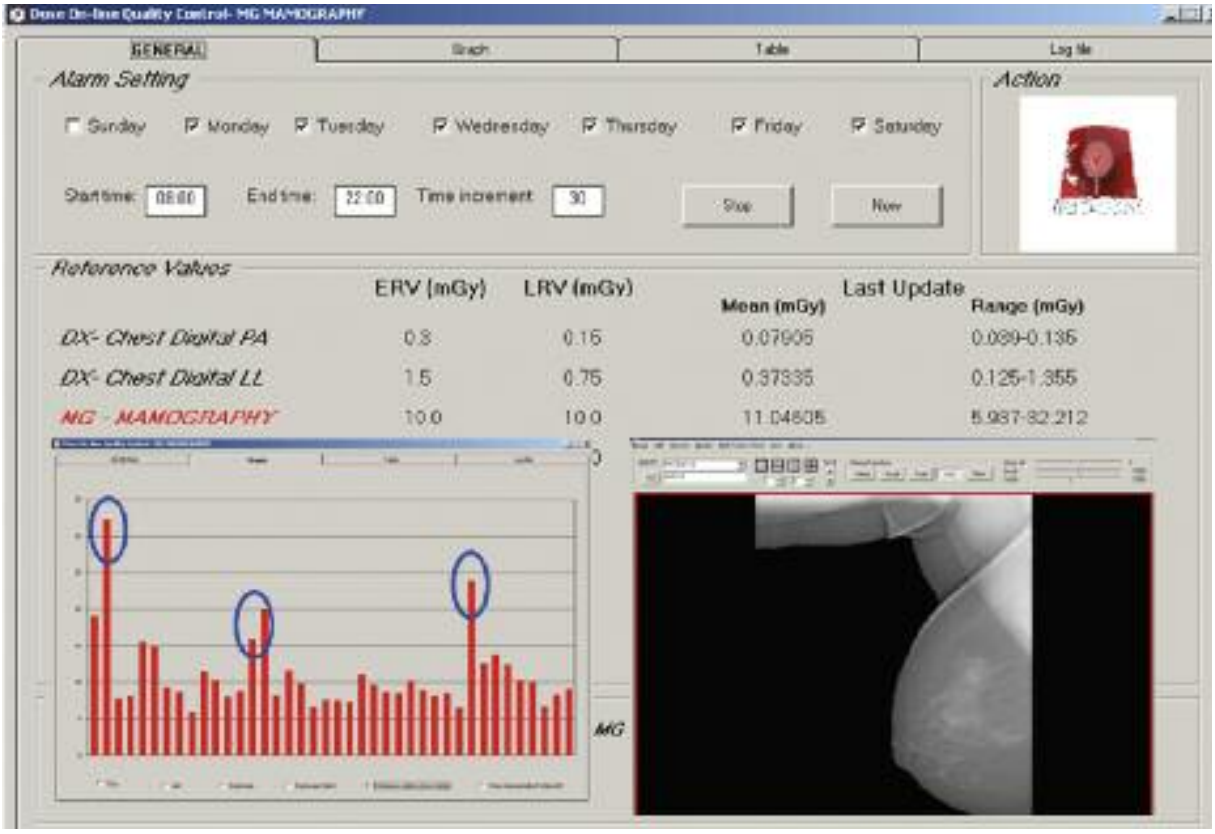


Figure 2: Example of one of the versions of the QC ONLINE made at San Carlos University Hospital in Madrid (from "Patient dosimetry and image quality in digital radiology from online audit of the x-ray system" [26]).

operate X-ray units (for diagnostic and interventional radiology purposes). This certification is issued by the CSN.

Second level of training in RP (for interventional radiology)

This level is intended only for medical specialists that perform fluoroscopically-guided interventional procedures. This training is audited and regulated by the Ministry of Health that issues a personal certification after an examination. When already in possession of the first level certificate, the medical specialist must follow a training course of 20 hours.

Medical Physicists in Spain, like other medical specialities follow a 3-year residency training program in a hospital (it is expected to be extended to 4 years). The training on radiation protection is acquired over a minimum period of 6 months during residency.

Medical Physicists support and audit

Most of the public and large private hospitals in Spain have medical physicists working full time for the imaging departments in cooperation with the medical specialists. The audit of this activity is made by the Health Authority (in the aspects related with patient protection) in cooperation with the Nuclear Regulatory Authority (CSN), responsible for controlling the RP of workers and the public and for providing technical reports to license medical installations using ionizing radiations. Since the introduction of a new regulation in 2010 [19] the CSN is also involved in radiation protection of patients, in cooperation with the Health Authority.

Patient doses

In Spain, a quality assurance (QA) program has been mandatory since 1999 in all the diagnostic and interventional radiology [13] (and nuclear medicine [14]) installations. This QA program requires the measuring of patient doses from most frequent procedures in all x-ray systems used for medical imaging (including dentistry) , at least once a year. Image quality evaluation and retake analysis are also mandatory. As for interventional radiology, the obligation concerns all the procedures and not just a sample of procedures. In theory, in Spain, since 1999, the dose value imparted to the patient should have been recorded during all the interventional procedures. Unfortunately to this day, all the hospitals probably do not fulfill this requirement for all the interventional procedures, especially when old x-ray systems without an automatic recording dose system are still being used.

Up to now, there is no formal procedure to collect and process all these data from the different Autonomous Communities although , in 1999,the Ministry of Health created a National Committee responsible for preparing the data requested periodically by UNSCEAR (and fulfilling article 12 on estimates of population doses of Directive 97/43/2007) [12] This Committee meets periodically to draw up documents on medical exposures representing the Spanish situation and submit them to the UNSCEAR Secretariat.

As for Interventional Radiology practices, two national pilot programs designed as a cooperation between the Medical Societies (Spanish Society of Vascular and Interventional Radiology and Spanish Society of Cardiology, Interventional Cardiology Section) and the Complutense University and San Carlos University Hospital [20-22] have been launched to collect patient doses and to propose national DRLs .The University of Malaga has recently been involved in the coordination of one of these programs. Ten major public hospitals from different Autonomous Communities take part in these programs. As a result of these actions, several provisional values of DRLs for interventional procedures have been published on the website of the Interventional Radiology Society.

Some hospitals have promoted pilot experiences as part of European Research Actions, to collect and process patient dose values in real time, to detect abnormal situations using local DRLs and other trigger levels and consequently produce alarms suggesting immediate corrective actions [23-26]. Figure 2 shows an example of one of such systems developed at the San Carlos University Hospital to facilitate the audit of patient doses in most digital modalities. The image shows an alarm for mammography with the red light at the right top of the figure, due that the mean value of entrance air kerma was higher than the DRL. It is also shown one of the clinical images obtained with a high dose due to a mistake in the positioning. A similar system has recently been set up to collect patient dose values from all interventional laboratories in a central computer so as to do the audit in real time [27]. Figure 3 offers an example of a screen showing the results from a cardiology catheterization laboratory. Dose Area Product values (PDA in the figure) for fluoroscopy and for cine acquisitions are shown for the different examinations and horizontal lines showing the median values (in the figure), DRLs and trigger levels can also be displayed to identify procedures with high doses requiring in some cases a clinical follow for some of the patients.

These activities have been carried out in accordance with the ICRP recommendations, several standardization committees (IEC, DICOM, etc) and the efforts of the manufacturers. In the coming years, the advances in this automatic processing of dose data are expected to facilitate the optimization of medical imaging, to improve the management of patient doses, to offer a better estimation of the population radiation doses derived from medical exposures and, in a near future, to improve personal dose records.

Conclusions

The recommendations of the ICRP and the requirements of the European Directive on Medical Exposures in diagnostic and interventional radiology are being reasonably followed. Several Royal Decrees have been enacted. In most hospitals, there are medical physicists supporting the application of the regulations. Patient dose values can be estimated (and should be recorded for all the procedures in the case of interventional procedures) and the effort to improve training and certification in RP of the medical specialists has had a very positive impact. Some medical societies have been directly involved in the process of optimization, which helped RP programs gain acceptance.

In the future, and considering the increasing use of digital radiology and of CT techniques, the complexity of the new interventional radiology systems and techniques, the global

demand for "safer medicine", more efforts will have to be put into the management of patient doses in imaging. With this view in end, it will also be necessary to get better support from the Medical Physics experts, to ask the industry and the standardization committees for more performing tools in the automatic registration of patient doses in the X-ray systems, to have medical specialists accept and demand enough training in RP and to have the Health and Regulatory Authorities implement a "friendly"-graded approach in radiation safety for patients. ■

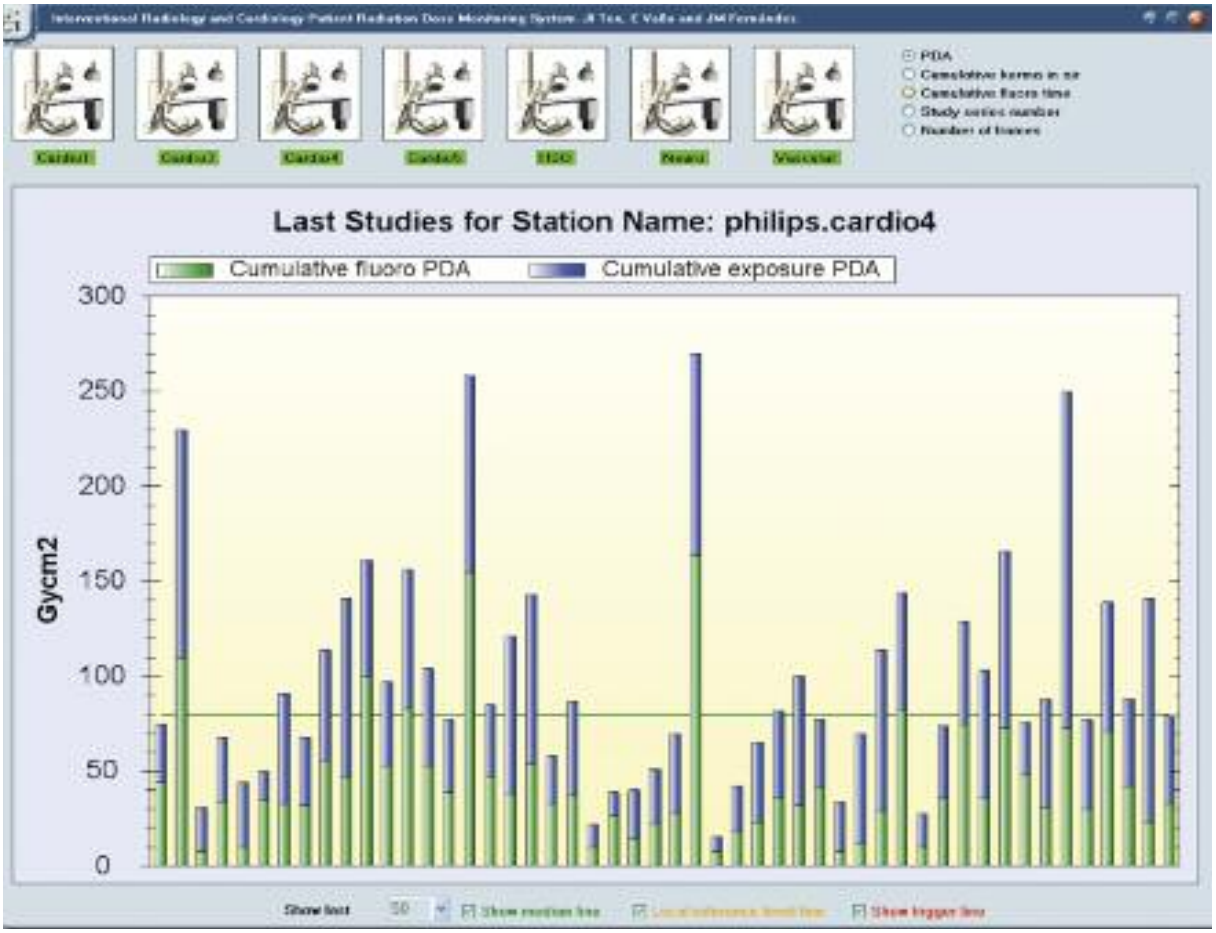


Figure 3: Example of the new pilot system installed at the San Carlos University Hospital for the audit of patient doses in interventional radiology [27].

Bibliography

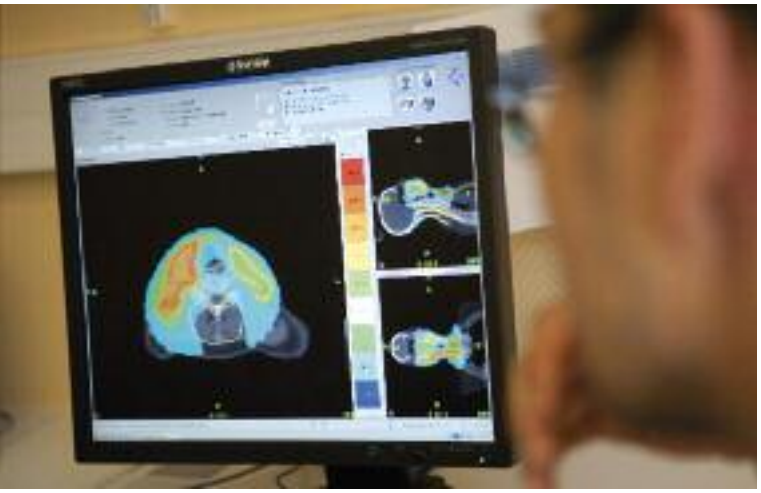
[1] ICRP Publication 103. 2007. The 2007 Recommendations of the International Commission on Radiological Protection. Ann. ICRP 37 (2-4).
[2] ICRP Publication 105. 2007. Radiological Protection in Medicine. Ann. ICRP 37 (6).
[3] ICRP Publication 60. 1990 Recommendations of the International Commission on Radiological Protection. Ann. ICRP 1991; 21(1–3).
[4] ICRP Publication 73. Radiological protection and safety in medicine. ICRP Publication 73. Ann. ICRP 1996; 26(2).
[5] ICRP. Radiation and your patient: a guide for medical practitioners. Also includes: Diagnostic reference levels in medical imaging – review and additional advice. ICRP Supporting Guidance 2. Ann. ICRP 2001; 31(4).
[6] ICRP Publication 85. 2000. Avoidance of Radiation Injuries from Medical Interventional Procedures. Ann. ICRP 30 (2).
[7] ICRP Publication 87. 2000. Managing Patient Dose in Computed Tomography. Ann. ICRP 30 (4).
[8] ICRP Publication 93. 2004. Managing Patient Dose in Digital Radiology. Ann. ICRP 34 (1).
[9] ICRP Publication 102. 2007. Managing Patient Dose in Multi-Detector Computed Tomography (MDCT). Ann. ICRP 37 (1).
[10] ICRP Publication 106. 2008. Radiation Dose to Patients from Radiopharmaceuticals - Addendum 3 to ICRP Publication 53. Ann. ICRP 38 (1-2).
[11] ICRP Publication 113. 2011. Education and Training in Radiological Protection for Diagnostic and Interventional Procedures. Ann. ICRP. In press.
[12] Council Directive 97/43 Euratom, 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 No L 180, 9th July 1997, 22-27.
[13] Real Decreto 1976/1999, por el que se establecen los criterios de calidad en radiodiagnóstico. Boletín Oficial del Estado de 29 enero de 1999 (in Spanish).
[14] Real Decreto 1841/1997, de 5 de diciembre, por el que se establecen los criterios de calidad en medicina nuclear. Boletín Oficial del Estado de 17 de diciembre de 1997(in Spanish).
[15] Real Decreto 815/2001, de 13 de julio, sobre justificación del uso de las radiaciones ionizantes para la protección radiológica de las personas con ocasión de exposiciones médicas. Boletín Oficial del Estado de 14 julio de 2001 (in Spanish).
[16] Real Decreto 220/1997, de 14 de febrero, por el que se crea y regula la obtención del título oficial de especialista en radiofísica hospitalaria. Boletín Oficial del Estado de 1 de marzo de 1997 (in Spanish).
[17] Fernandez-Soto JM, Vano E, Guibelalde E. Spanish experience on education and training in radiation protection in medicine. Radiat Prot Dosimetry. In press 2011.
[18] Vano E, Tobarra B, Bezares M. Los datos de las exposiciones médicas en España para el informe UNSCEAR 2000. Revista de Física Médica 2000; 1(0): 51-60 (in Spanish).
[19] Real Decreto 1440/2010, de 5 de noviembre, por el que se aprueba el Estatuto del Consejo de Seguridad Nuclear. Boletín Oficial del Estado de 22 noviembre 2010 (in Spanish).
[20] Vano E, Sanchez R, Fernandez JM, Gallego JJ, Verdu JF, de Garay MG, Azpiazu A, Segarra A, Hernandez MT, Canis M, Diaz F, Moreno F, Palmero J. Patient dose reference levels for interventional radiology: a national approach. Cardiovasc Intervent Radiol. 2009;32(1):19-24.
[21] Vano E, Segarra A, Fernandez JM, Ordiales JM, Simon R, Gallego JJ, del Cerro J, Casasola E, Verdu JF, Ballester T, Sotil J, Aspiazu A, Garcia MA, Moreno F, Carreras F, Canis M,

Soler MM, Palmero J, Ciudad J, Diaz F, Hernandez J, Gonzalez M, Rosales P. A pilot experience launching a national dose protocol for vascular and interventional radiology. Radiat Prot Dosimetry. 2008;129(1-3):46-9.
[22] Sánchez R, Vano E, Fernández JM, Sotil J, Carrera F, Armas J, Rosales F, Pifarre X, Escaned J, Angel J, Diaz JF, Bosa F, Saez JR, Goicolea J. A national program for patient and staff dose monitoring in interventional cardiology. Radiat Prot Dosimetry In Press 2011.
[23] Vano E, Fernandez JM, Ten JI, Guibelalde E, Gonzalez L, Pedrosa CS. Real-time measurement and audit of radiation dose to patients undergoing computed radiography. Radiology. 2002; 225(1):283-8.
[24] Vano E, Fernández JM, Ten JI, Prieto C, González L, Rodriguez R, de las Heras H. Transition from screen-film to digital radiography: evolution of patient radiation doses at projection radiography. Radiology. 2007;243(2): 461-6.
[25] Vano E, Fernandez JM, Ten JI, Gonzalez L, Guibelalde E, Prieto C. Patient dosimetry and image quality in digital radiology from online audit of the X-ray system. Radiat Prot Dosimetry. 2005;117(1-3):199-203.
[26] Vano E, Ten JI, Fernandez JM, Prieto C, Ordiales JM, Martinez D. Quality control and patient dosimetry in digital radiology. On line system: new features and transportability. Radiat Prot Dosimetry. 2008;129(1-3):144-6.
[27] Ten JI, Fernandez JM, Vano E. Automatic management system for dose parameters in interventional radiology and cardiology. Radiat Prot Dosimetry. In Press 2011.

INTERNATIONAL INITIATIVES

European Commission activities on radiation protection of patients

by Dr. Augustin Janssens, Georgi Simeonov, Remigiusz Baranczyk, European Commission
Directorate G ENER – D 4 Radiation Protection, Luxembourg



Planning the tomotherapy treatment of an ENT cancer

The European Union has a long and successful history of dealing with radiation protection of patients and other individuals submitted to medical exposure. This includes the adoption of specific Euratom legislation in 1984 and 1997, the issuance of guidance material on different aspects of medical exposure and support of research and exchange of information and experience among the stakeholders. Today, we experience rapidly developing medical radiation technology, increasing number of patients undergoing radiological procedures and, as a consequence, overuse of radiodiagnostic imaging, accidents in radiotherapy and growing population doses from medical exposure. This is happening in a situation of growing concerns regarding the justification of some procedures, the availability of appropriately trained medical personnel and shortage of reliable information in many areas. Therefore the European Commission's Directorate-General for Energy (DG ENER) is undertaking a series of initiatives including Euratom legislative changes, studies to collect data about specific aspects of medical exposure in Europe, update of existing, and development of new, guidance material and organization of stakeholder meetings. In August 2010 the Commission issued a Communication document on the medical use of ionizing radiation aiming to ensure visibility of the Community actions in this field and to define an approach to a common EC policy and strategy going beyond the revision of the Euratom radiation protection legislation.

Recent Commission's policy action

In August 2010 the European Commission adopted a Communication to the Council (of the European Union) and the European Parliament COM(2010)423 "on medical applications of ionizing radiation and security of supply of radioisotopes for nuclear medicine"[1]. The Communication is focused on two areas, namely: i) radiation protection of patients and staff, and ii) supply of radioisotopes for nuclear medicine. The document strives to give an overview of main challenges in those areas, provide visibility of Community actions, propose a long-term perspective and stimulate the discussion in the European Union institutions and Member States on the necessary actions, resources and distribution of responsibilities. It covers legislation and program also outside the scope of the Euratom Treaty. In the following sections only the radiation protection-related parts of the Communication are discussed, the emphasize put on the ongoing and needed action in the legislative and regulatory area, while the issues on the supply of radioisotopes for medicine are described elsewhere[2].

The way-forward

COM(2010)423 proposes a way forward for the Commission and for the EU member states to address the issues in radiation protection of patients and medical staff. The main proposals and the state-of-play in the different areas are described below.

Strengthening the existing regulatory framework

The Communication emphasizes the role of a strong European legal framework and efficient national regulators to address challenges in the medical exposure area. Improvement in this area is needed and, in the view of the European Commission, this should be achieved through revision of the applicable Euratom legislation, enhanced regulatory supervision of medical applications, motivating stakeholders and providing tools facilitating practical implementation of legislation, strengthening the role and mobility of the Medical Physics Expert (MPE) and continuous monitoring by the Commission of trends in medical exposures in the European Union.

As a first step in this area, the Commission started a revision and recast of the current Euratom Basic Safety Standards Directive (BSS)[3] and other relevant Community legislation, among them the Medical Exposure Directive

1. Communication from the Commission to the European Parliament and the Council on medical applications of ionizing radiation and security of supply of radioisotopes for nuclear medicine. COM(2010)423. http://eur-lex.europa.eu.
2. Security of Supply of Medical Radioisotopes in EU Member States, Proceedings of a meeting held in Luxembourg on 4-5 May 2010, http://ec.europa.eu/energy/nuclear/events/doc/2010_05_04_proceedings_meeting_isotopes.pdf

(MED)[4]. The changes in the current MED requirements are motivated by the need to have a coherent text of the revised Euratom BSS, the experience in the implementation of the legislation in the past ten years and the developments in the medical area which were not fully foreseen in the 1990s. The changes in the draft BSS[5], now approved by the Euratom Article 31 Group of Experts, include:

- *The medical exposure is defined* as exposure of patients resulting from their own treatment, diagnosis or health screening and of biomedical research volunteers and carers and comforters, excluding the current "medico-legal procedures" now treated separately as part of the newly defined "non-medical imaging exposure". The new definition incorporates the notion of the intended benefit to the exposed individual which, in an attempt to cover cases like sport and recreational medicine, diagnosis of child abuse, etc., now refers to not only the health but also to the wellbeing of the individual.
- Several important changes have been made in relation to *justification of medical exposure.* It is now required that: i) staff exposure is taken into account in justifying a medical procedure, ii) health screening procedures are justified by the health authority in conjunction with the appropriate professional bodies, iii) asymptomatic individuals are only exposed as part of an approved health screening program or if there is a specific documented justification by the practitioner in consultation with the referrer following guidelines from professional bodies or competent authorities and paying special attention to provision of information, and iv) the practitioner provides the patients with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure to enable informed consent.
- The use of *diagnostic reference* levels (DRLs) has been expanded to interventional radiology, when appropriate.
- *Recording and reporting of medical exposure doses* has been emphasized, as: i) systems used for interventional radiology and computed tomography shall have a device or a feature informing the practitioner of the quantity of radiation produced by the equipment during the procedure, ii) other medical radiodiagnostic equipment shall have such a device or equivalent means of determining the quantity of radiation produced, and iii) the radiation dose shall form part of the report on the examination.
- There is a new definition of the *medical physics expert* (*MPE*) and their responsibilities seeking to provide a link between her/his required competences and assigned responsibilities (in relation to medical exposure only). The requirements on involvement of the MPE in medical exposure procedures have been changed to strengthen her/his presence in high-dose radiological imaging examinations.
- The requirements for *education and training of medical professionals* have been strengthened and the introduction of a course on radiation protection in the basic curriculum of medical and dental schools was made mandatory. New legal provision requires that Member States shall ensure that mechanisms are in place for the timely dissemination of appropriate information relevant to radiation protection in medical exposure on lessons learned from significant events.
- The draft Euratom BSS Directive defines several new requirements on *accidental and unintended medical exposures:* i) the radiotherapy quality assurance programs will include a study of risk of accidental or unintended exposures, ii) the operators of diagnostic and therapeutic radiological equipment shall implement a registration and analysis system of events involving or potentially involving accidental or unintended medical exposures, iii) the operators shall declare to the competent authorities the occurrence of significant events, as defined by the authorities, including the results of the investigation and the corrective measures to avoid such events in the future, and iv) the referring and the radiological medical practitioners as well as the patient shall be informed about unintended or accidental exposures.

Training at the INSTN (National Institute for Nuclear Sciences and Techniques)

As long as the *regulatory supervision* of the implementation of radiation protection legislation is exercised on a national level, the Commission is engaging in a dialogue with national governments and regulators on how to achieve improvement in this area. The Heads of European Radiological protection Competent Authority (HERCA) network have very important role to play in this process.

The Commission commits to continue developing tools to *facilitate implementation of Euratom legal requirements* on medical exposure. In the recent years the Commission's Directorate-General for Energy (DG ENER) published guidelines on estimating population doses from medical exposure[6] and on clinical audit[7] and held several important meetings and seminars on issues like radiation-induced circulatory diseases[8], justification of medical exposure (jointly with the IAEA, proceedings in press) and medico-legal procedures[9]. Several other actions are underway, including the elabora-

3. Council Directive 96/29/Euratom of 13 May 1996, laying down basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation. Official Journal L-159 of 29.06.1996,
4. 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 L-180 of 09.07.1997, 22
5. http://ec.europa.eu/energy/nuclear/radiation_protection/doc/art31/2010_02_24_draft_euratom_basic_safety_standards_directive.pdf
6. Radiation Protection 154, European Guidance on Estimating Population Doses from X-ray Procedures
7. Radiation Protection 159, Guidelines on Clinical Audit for Medical Radiological Practices
8. Radiation Protection 158, EU Scientific Seminar 2008 - Emerging evidence for radiation induced circulatory diseases
9. Radiation Protection 167, Proceedings of International Symposium on Non-Medical Imaging Exposure

tion or update of guidelines on the MPE, on radiation protection education and training of medical staff and on acceptability criteria for medical radiological installations; DG ENER established in 2009 a European Medical ALARA Network (EMAN)[10] with a three-year funding agreed. The action in this year will continue in the following years and the preparation for launching in 2011 of projects on accidental and unintended exposures in radiotherapy and on referral guidelines for imaging is well advanced.

Monitoring the trends in medical exposure is important to defining an efficient radiation protection policy in Europe. Therefore the Commission launched in the end of 2010 the Dose Datamed-2 project to collect up-to-date data on population doses from diagnostic procedures in the EU, the results of which will be available in the end of 2012.

Raising awareness and safety culture

The Communication emphasizes the importance of raising the awareness and improving the radiation safety culture among national healthcare policymakers, medical professionals and patients and general population. Further action in this area will be decided in consultation with national regulators, professional bodies and international organizations.

Fostering radiation protection in medicine through research

COM(2010)423 recognizes the important role of research and development in addressing the challenges in radiation protection of patients. In the time, when the future European Framework Program is to be decided, the importance of the European support through both the Euratom and Health parts of the Program is emphasized.

Integration of policies in public health, research, trade and industry

The complexity of regulating medical exposure of patients, where different sectoral policies come into play, is recognized. An area of special interest is the regulation of medical devices under the EC legislation[11] (9) where a standing platform to look at radiation protection features of such devices is proposed.

International co-operation

The Commission commits to co-ordinate efforts with the International Atomic Energy Agency, the World Health Organizations and other players and to support international programs for improved radiation protection of patients.

Conclusions

Some of the proposed actions in the Communication are straightforward and the Commission will pursue them directly in line with the current practice. Some will need input from the EU member states through the Council in order to proceed with the relevant initiatives. In any case, a good and continuous joint effort is required from the different services, institutions and stakeholders to effectively address the issues outlined in the document. ■

10. http://portal.ucm.es/web/medical-physics-expert-project
11. www.eman-network.eu/
12. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Official Journal L-169 of 12 July 1993; amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007, Official Journal L-247 of 21 September 2007

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