Basic recommendations for Interventional procedures

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Abstract

Introduction: Given the importance of the risks involved in Interventional Cardiology the Argentine College of Interventional Cardioangiólogist (CACI) has appointed a task force composed of cardiologists and specialists in Medical Radiation Protection for establishing recommendations in order to prevent deterministic effects systematically and control stochastic risks for the patient and the attending physician team.

Objective: To determine the courses of action and appropriate techniques to ensure that doses are as low as possible (optimization of practice) without affecting the therapeutic goals or the quality of the procedures.

Methods: We evaluated various procedures under controlled conditions in a number of services Hemodynamics of the City of Buenos Aires, determining the radiation dose to the patient and staff, for different working conditions and operating parameters. It was estimated in each case the peak skin dose, the alarm values for deterministic effects and patient follow-up. We estimated the "patient-specific factors" that determine the onset of effects and risk assessed procedures inherent complexity.

Results: Once the data collection work in different operating conditions was established, several sets of recommendations for different stages of intervention and different recipients as follows:

What the cardiologist should know before entering the operating room:

1) What the cardiologist should check before starting a film sequence?
2) Criteria to be applied during a film sequence.
3) What must register the wizard at the end of an intervention?
4) The measures to be taken by the Director of Hospital
5) The measures to be taken by the competent authority
6) Factors to minimize dose to the patient and physician.
7) How to estimate the dose in the staff involved.
8) The Proper use of protective gear.
9) General recommendations

Conclusions:

The set of recommendations resulted in the publication of leaflets and posters aimed at medical staff, technicians and nurses.

We confirmed the urgent need for the presence of a specialist in radiation protection to ensure the protection of patient and staff.

KEYWORDS: Radiological Protection of the Patient, Interventional Radiology, Reference Levels, Doses

Introduction: The Interventional radiology is one of the medical applications that produce the larger doses of radiation in the patient and in the operating personnel as well as the possible occurrence of serious injuries.

The use of RI's technologies has multiplied in dizzy form in the last times and in some services come to duplicating the number of interventions in three years.

The use of these technologies was originally an exclusivity of the radiologists but the multiplicity of applications determined then the participation of the cardiologists and later that of other specialists as

urologists, gastroenterologists, vascular surgeons, neurosurgeons, pediatricians, and orthopedic surgeons without a suitable training in Radiological Protection, Dosimetry or Radiopatology.

This situation has determined that patients and operators receive excessive doses and there are reported patients' cases by very serious injuries in skin that they have been treated in the Institute of the Burnt one and also some clinical interventionists have suffered hurts in his hands and eyes.

This scenario will be accenting surely in the near future for what it seems to be urgent take measurements in order that to the clinical qualification a suitable specific training in radiological protection and safety.

Also there is recommended that the services of personnel dosimetry take part in the work of dosimetric evaluation in order to be able to establish practical procedures of work that allow to do a systematic follow-up of the doses of the patients and of the operators of a reliable way.

The national program of Radiological Protection of the Patient recommends that the procedures should be evaluated from time to time in order that the radiological risks are optimized.

In general if the patient is protected it protects also the operator and vice versa for what always suits to make a joint evaluation and optimize both situations.

The new ICRP recommendations and the project RELID:

The International Commission on Radiological Protection has reviewed recent epidemiologic evidence and determined that there are some effects of tissue reaction to deterministic effects in the threshold dose may be much lower than previously thought, particularly for the lens eye to the risk of opacity or cataracts and heart or brain to the risk of cardiovascular diseases.

This new evidence determines the need to take protective measures for physicians in the case of the eye lens and for patients undergoing complex interventional procedures.

Evaluations in the last congress in Buenos Aires SOLACI under the auspices of the IAEA (International Atomic Energy Agency) give cause for some information on the current status of the situation in regard to doses and effects to establish appropriate protective measures.

We conducted a retrospective evaluation of lesions of the lens in interventional cardiologists and endovascular surgeons.

The study was a comprehensive review with an "slit lamp" to assess changes in the lens of a group of volunteers who attended the conference as well as conducting a detailed written questionnaire on occupational radiation exposure, workplace practices and medical history.

A total of 131 people: including 56 interventional cardiologists, and 65 nurses and technicians of the catheterization laboratories were included in the cohort.

Results: 52% of interventional cardiologists and 42% of nurses / technicians showed changes (posterior sub capsular) in the lens a characteristic type of exposure to ionizing radiation. In the other hand, in the control group, changes were found in only 10-12% of the individuals..

Conclusions: Injuries in the lens of the population of cardiologists, nurses and technicians talk about the urgent need for measures to increase the use of suitable devices for radiation protection and strengthen training programs in radiation protection.

The new epidemiological evidence on threshold values for deterministic effects required the optimization of the intervention procedures to limit the absorbed dose in the heart and brain to just 0.5 Gy to avoid any diseases of the circulatory system.

Practical Guidelines released

Recommendations for interventional physicians

The intervening physician before entering the operating room for intervention must KNOW:

- What is the dose rate you can get the patient in fluoroscopy and movie.
- How the doses vary with different oblique positions.
- How the dose varies depending on the thickness of the patient, particularly in obese.
- How do they compare doses with some "Reference Levels" applicable.
- The threshold values for deterministic effects in the patient's skin.
- What to do when surgery is prolonged by difficulties or complications.

The interventional physician, before starting a film sequence MUST verify that:

- All staff in the operation room has wear the protection devices.
- The image intensifier is as close as possible to the patient.
- The field is focused and the iso-centric is at the point of greatest interest
- The X ray tube is as far as possible from the patient skin
- The collimation tube fits the area of interest.
- In the field there is not very different densities that are not compensated (and that the wedge filter is available for use)
- The appropriate wedge filter is placed (if not automatic)
- The patient's arms do not stand in the primary beam of the X ray tube.
- If it is a young patient have been protected sensitive parts which are not of interest.
- No people unnecessarily close of the X ray arm
- It has all the elements and devices for the intervention.

The interventional physician during a movie sequence MUST apply the following criteria:

- Start the acquisition of images only when the field is right focused and well defined
- Release the pedal when not watching the screen or when you can work with the frozen image.
- Do not use movie when fluoroscopy gives sufficient image quality.
- Using pulsed fluoroscopy when available.
- Use only the appropriate magnification the object of interest, and no more.
- Avoid if possible very long film sequences freezing the image.
- Release the pedal when the contrast has already reached the maximum value and begins to wash.
- Always know what dose the patient is receiving.

An assistant at the end of the intervention of a patient MUST record the following information: (in the case there is no ionization chamber at the exit of the x-ray tube for dose assessment, neither a dosimétric film)

- Fluoroscopy time and mode has been used (eg 25 minutes of low fluoroscopy)
- Number of images and height and intensity of the pulses (eg 240 images of 80kV and 30mA)
- Approximate weight or thickness of the patient.
- Index complexity of the protocol used
- Kind of projections or C-arm positions that were used
- Any other information related to the patient dose.

Responsibilities of the Hospital Management

- That the equipment is well maintained and calibrated, for what will be periodic testing of Quality Control and Radiation Protection by competent personnel.

- Have the Radioprotection devices for all staff (aprons, goggles, Pb, fixed screens and thyroid protectors)
- Having curtains sliding on the table and transparent mobile screens.
- Having a trained person, at least part-time, for tasks on Radiological Protection.
- Compare the dose of the patient for each protocol with the Reference Levels.
- Elements provide protection for young patients (gonads, thyroid and breasts)
- Check the periodic recertification of doctors and their training in Radiation Protection
- Provide a radiation monitor and / or electronic monitor system to measure the dose.
- Implement a quality system appropriate to the needs of the service
- Have protocols for monitoring patients who have passed the set alarm values (we recommend using a value of 200 $Gy.cm^2$)

USEFUL INFORMATION FOR CONTROL PROCEDURES

The most important values to assess the risks of radiation are:

- The peak skin dose (Gy) to assess "deterministic effects"
- The product "dose area" ($Gy.cm^2$) to evaluate "stochastic effects".
- It is desirable to have the advice of a specialist in radiation protection to get these values from the operating parameters used.

Patient-specific factors that increase the occurrence of effects are:

- The patient's weight.
- The complexity of the procedure.
- The tortuosity of the vascular system (increases with age).
- The doses received recently (other interventions, radiation therapy, CT scans).
- Individual sensitivity.
- Some diseases (diabetes mellitus).

Some procedures are associated with increased risk due to their complexity:

- Embolization (including chemo-embolization)
- Renal angioplasty
- Complex biliary intervention
- Nephrostomy for kidney stones

Recommendations and general criteria to apply in Interventional Radiology:

- The equipments of interventional Radiology are not inherently sure in order that they have the flexibility that is needed in a great variety of procedures " but this needs a great knowledge of the risks and the measures to take to achieve the best relation cost-benefit ". This task needs a good communication and the joint work of the professionals, technical personnel and the specialists of the providing company of the equipment, and the advice of a health physics.
- The most determinant factor in the doses both of the patient and of the operators is the speed of the medical professional to perform the intervention which depends on his skill and experience.
- To collimate the field to reduce it to the zone of interest minimizes the integral doses of the patient and of the operator and diminishes the probability of which the radiologist or his assistants interpose his hands in the beam.
- That the tube possesses the filters most adapted for every energy it allows to improve automatically the image and to diminish the doses in the patient and the operator.

- The distance between tube and the intensifier is constant but what can be changed is the relative position of the patient in the way of both. As larger is the distance tube/ patient lower is the dose in skin for what it is necessary to keep the intensifier as close as possible…
- The operator should know the impact of image adjustments such as brightness and contrast in the doses received by the patient and operators.
- In some cases adjustments acting on the gain amplifier video or on the optical approach with a diaphragm optical and in other cases the adjustment involves changing the voltage of the tube or the intensity of supply. So in some cases the adjustments do not affect the doses and in other cases yes.
- Also in some equipments automatic gain control can maintain the brightness down to a certain thickness but on top of it changes the exit tube RX. In this case there is also an area where the dose is unchanged and one in which if done.
- The aim is to know how to get the best image with the minimum dose but this must be tried or tested previously without the patient and a phantoms.
- The radiologist must at all times be able to assess the risk / benefit to achieve optimal working conditions which does not mean always get the best image quality
- We must also bear in mind that a picture with a lot of noise makes it difficult to comment or make the procedure more complex, requiring more flour time leading to higher doses. We must also remember that the smaller are the elements to introduce into the blood vessels , should be better image quality.
- And that better image quality also reduces the concentration of contrast.
- The teams have programmes with predetermined parameters established for each type of intervention. It is appropriate that the optimization of these programmes is carried out by a team comprising a senior doctor, the specialist team and a dosimeter to achieve the best alternatives.
- In short, the operator should always get very clear what happens with the image and the doses when are changed settings. But this can not be determined during a procedure when the mind of the radiologist should be focused on the clinical objective without being interfered with by the needs of protection and safety of the patient and his own protection ....
- Of course, get in the screen integrated dose values is the most appropriate. The ideal scenario is when you can make the monitoring of the skin dose in real time during the procedure .. but unfortunately not all equipments have this information.
- Equal knowledge clear dose rates of entry into skin and the use of a timer is a tool of decision simple and effective.
- Another important asset is the product between the area irradiated by the expected dose which is a valuable decision factor in assessing risks and stochastic for monitoring patient. In some European protocols recommended value of 200 $Gy.cm^2$ as trigger level for the subsequent follow-up of patients. It should always determine when this level is passed with continuous flour
- All evaluations that have been mentioned previously should be made before the start of practice considering all possible scenarios to avoid having to make calculations during intervention.
- We must think about the scenarios before we are part of such scenarios..
- Training with phantoms, even partially, is an irreplaceable element for proper planning the procedures and the experience naturally plays a vital role in optimizing.
- The training is always in knowing how to avoid unnecessary doses.
- The best alternative is to always turn off the tube when not really needed, not stepping on the pedal unnecessarily and frozen and keep the last image on the monitor.
- The interposition of hands on the RX beam should naturally avoided but when it is imperative to do so should ask the technician to record the exposure times to keep a record that can make evaluations.
- The development processes requires intervention decision-making swift and sound, without having too much time for reflection, so that planning and prior training, and assuming all possible scenarios, is a key element for success.

- Experience and Training of interventional radiologist is the highest value for radiation protection of patients. If is also advised by specialists in the adjustment of equipment and health physics the situation is ideal.

Recommendations for the protection of the patient:

- **Built-in ionization Chamber :** An element of value for the protection of the patient is that the equipment relies on a Built-in ionization Chamber interposed in the beam that it should allow a direct reading of the doses on the screen.

  In some modern equipments the ionization Chamber is the optional one that is recommended to acquire emphatically.

  Anyway when there are several changes of projections and some of them superposed it is not easy to determine which is the maximum administered dose.
- **Personal Dosimetry of the patient**: If one does not possess a Built-in ionization Chamber it is necessary to assess the dose for calculation or using a dosimeter in the cases of long or repetitive interventions that there involves dose in skin near to the thresholds of deterministic effects (from 1 to 3 Gy).

  The most appropriate dosimeters are the radiographic plates of high dose that are used in radiotherapy and that can be placed in the stretcher under the patient.

  There is recommended the use of these plates in the cases of interventions by obese patients in whom complications or repeated interventions are waited.

Recommendations for the use of protective devices for staff:

- **Shielding shade below**: Another option is an important curtain sliding plumb bob located at the bottom of the table by shielding the legs of the Rx tube and the scattered radiation that occurs down that given the exposure to which the lower extremities is an important protection that does not cause greater interference in the work.
- **Hanging mobile screens**: It is important to have as screen covering the intensifier when it is not necessary to work under it because it protects particularly in the most exposed person in general lowering the dose by a factor 5 since the arms can not be protected
- **Leaded aprons:** It must be used by all staff that is even the farthest or who was admitted for a short time. The doses are very important and unprotected is not justified under any circumstances. The aprons must cover the front and the back from shoulders to knees and will have a shielding factor for average radiation scattered in normal operating conditions, better than 25 (to miss less than 4% of the scattered radiation at the site located. While there is thicker aprons should be considered that are heavier and to be carried for several hours and taking into account that 20% of the body has always uncovered it makes little sense raise more shielding for the protected part because the final outcome for all organs, varies very little ...!!! It is more efficient use mobile screens and curtains for armoured exposed parts ...
- **The protector of thyroid:** We must know that the difference between using and not using a thyroid protector involves doubling the dose given the weighting factor of the thyroid and neck.
- **The protective eyeglasses:** The most important risk to the doctor is the opacity of the lens and cataracts where the threshold is 100 and 150 mSv in the year. Whereas the usual exhibitions are the order of mSv / h there is no need to stress the importance of a doctor who is exposed to several hundred hours of fluoro per year can in no way stop using them at all times. It is appropriate that the glasses have a lateral protection since scattered radiation coming from any side ... (or even up from the ceiling)

- **The surgical gloves lead**: They offer a low protection factor, not better 50%, and slowed the work of the doctor as it loses sensitivity and are expensive and therefore does not seem an appropriate recommendations. What is important is to avoid interfering with the beam fingers even for a few seconds because the dose is multiplied by 100 instantly…

Recommendations for personal dosimetry:

- To check compliance with the dose limits by staff is necessary to convert the absorbed doses (D) informed by the personnel dosimetry service in effective dose (E). Using a leaded apron some parts of the body are exposed to radiation and others are protected. If the dosimeter is used above the leaded apron is obtained information from bodies exposed if used under information obtained the bodies protected. To determine the dose must be taken information from the exposure of the whole body or an extrapolation must be performed taking into account the leaded apron shielding factor.
- For practical reasons should use double dosimeter and have a more precise data on the cases of more exposed personnel (doctors) and use a dosimeter only when the doses are expected at 30% below the limits set (technical)
- The criterion to use depends on the closeness of the values of doses received with the limits. If the doses are well below the limits, for example 20%, not worth putting too much effort into improving the accuracy. If instead the values are close to those limits then it must exercise extreme measures to improve control increasing information and hence the number of dosimeters used.
- In the case of medical doctors should use at least two dosimeters, one below the leaded apron (away from the edges) and another above in the left side of the chest.
- Technicians for which, according to its location in the operating room, receive a dose is estimated that approximately one tenth of that received by the doctor may use a dosimeter just above the leaded apron in his right side. If the dosimeter is used under the leaded apron below the expected values, which are very low, are well below the detection limit declared by the dosimetry service so it can not be used.
- To estimate the effective dose "if not done a specific study" it will be used an algorithm that takes into account the shielding factor of the leaded apron.
- In the case of double dosimeter and provided that the attenuation factor of 30 is better than canopy will be used the following algorithm:

  $$D_{ext} \times 0{,}025 + D_{int} \times 0.5 = E$$

  So, the effective dose is obtained by adding the external dose multiplied by 0.025 plus the internal dose multiplied by 0,5.
- In the case of single dosimeter used by the agency or the anesthetist above the leaded apron on the right side and provided the attenuation factor greater than 30 will be used empirical factor of 0,043

  $$D_{ext} \times 0{,}043 = E$$

  So, the effective dose is obtained multiplying the external dose by 0,043
- The attenuation factor of the leaded apron should be measured in normal operating conditions using the higher tension value of the tube.

- If the annual effective dose received by a person exceed 15 mSv, given the uncertainty in some factors there are recommended to conduct a more detailed dosimetric study..
- On the doses received by the doctor, which is the most exposed, it shall apply the safety factors necessary to affirm that whatever the operational condition "doses will in any case lower than the limits and as low as reasonable achievable. "