Dosimetric and Quality Assurance Studies in High Dose Diagnostic Imaging Modalities to Establish National Radiation Protection Programme

By

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DECLARATION

I, hereby declare that the investigation presented in the thesis has been carried out by me. The work is original and has not been submitted earlier as a whole or in part for a degree / diploma at this or any other Institution / University.

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List of Publications arising from the thesis

Journal

1. Investigation of skin reactions in complex interventional radiology procedures, A. R. Kulkarni, P. Akhilesh, S. Mahalakshmi and S.D. Sharma, *Radioprotection* 2019, 54, 61–65.
2. Measurement of patient skin dose and establishment of local diagnostic reference levels for interventional cardiology procedures, A. R. Kulkarni, P. Akhilesh, S. D. Sharma, Radiation Protection and Environment 2019, 42, 28 – 33.
3. Estimation of eye lens dose during brain scans using Gafchromic XR-QA2 film in various multidetector CT scanners, P. Akhilesh, A. R. Kulkarni, S. H. Jamhale, S. D. Sharma, R. Kumar, D. Datta, *Radiation Protection Dosimetry*, 2017, 174, 236 – 241.

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Dedicated to,

My 'Guru', who is always with me in all my good and bad times.

My parents, who loved me unconditionally and encouraged me to reach this stage of success.

My in laws, who equally feels proud on me as my parents.

&

My beloved husband, who completes me and is strength of mine.

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Arti Kulkarni

SUMMARY

In Interventional Radiology, the patients are at relatively higher risk of developing malignancy than other radiology based procedures and in certain complex procedures there is even a probability of skin reactions. There is also a concern of developing cataract for the medical professionals performing IR procedure. This research work is focused on overall radiation safety aspects in the field of Interventional Radiology.

The entire work concludes with the salient features of proposed national radiation protection program, which is an essential part of the quality management for the catheterization laboratory.

The important outcomes of the work are summarized here, this derives methodology for skin dose measurements in the complex IR procedures, formation of local Diagnostic Reference Levels (DRLs)for common cardiac procedures, assessment of operator doses in the cardiac catheterization laboratory, quality assurance audit of interventional radiology facilities and proposal to regulatory body for implementation of National Radiation Protection Programme in the country for interventional radiology practice. Implementation of the proposed program requires coordinated and collaborative effort involving physicians, staff, medical physicists, and hospital administration.

Interventional cardiologists are an essential part of this process and need to ensure the best possible outcomes for radiation safety of operators and for patients. The skill of the medical practitioner, knowledge about the equipment and inclination towards radiation safety are the key parameters for minimizing radiation exposure to the patient and the operators. It suggests about the future scope of large-scale studies for establishment of national DRLs involving good representation of number of facilities all over the country for data collection for different types of procedures and a national dose registry can be generated.

CONTENTS

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Chapter 1

Introduction and objectives

1.1 Introduction

Medical imaging uses the electromagnetic radiation and certain other technologies to produce images of internal structures of the body for the purpose of diagnosis. Diagnostic radiology is the branch of medicine that uses radiation to diagnose and treat diseases. Magnetic Resonance Imaging uses magnetic field and RF power, ultrasound employs sound waves to visualize tissues, and endoscopy uses a flexible optical instrument equipped with a camera for imaging.

Medical imaging has come a long way in the past 100 years. The improvements have reflected developments in the modern technology. This has brought faster imaging times, improved anatomical detail and recently, molecular imaging. As a result, medical imaging is an important and integral part of modern medical practice. Future developments promise to build on these capabilities and support to provide insight into the cause of disease, improved diagnosis, early detection, and targeted treatment protocols. Availability of such multifarious modalities for the unique set of problems, makes it difficult to decide the best suited modality for a given situation. However, the in depth knowledge of the different imaging modalities and their relative costs and benefits is vital for proper management of patients.

1.2 Diagnostic radiology

X-rays, used since 1895, were the first type of radiation to provide images of the interior of the body. X-rays pass through body tissues and also have the property of darkening photographic

film when they strike it. As they penetrate tissues, the x-rays are absorbed differentially and produce varying density patterns carrying anatomical information. Thus, bones show up as lighter areas and soft tissues show up as darker ones on the exposed film.

Subsequently other imaging techniques have been developed using x-rays. In computed tomography (CT) cross sectional images of body parts are obtained by rotating the x-ray beam around the patient and collecting the transmitted beam through multi array detectors. Although these studies have proven to be a useful tool for clinical diagnosis, most imaging studies are associated with radiation risks to the patients. Inappropriate study may lead to no diagnosis or wrong diagnosis and unnecessary dose to the patient. As, x-rays are the ionizing radiation that can cause tissue reactions, it is important to minimize any associated risk to the patient. This is done by limiting the radiation exposure to the minimum required to create the clinical images with requisite information. The various x-ray based diagnostic modalities are described in this chapter.

1.2.1 Radiography

The images in radiography are created by passing an x-ray beam through some section of a patient's body. They are recorded either on film or some form of digital media. Generally, the images recorded on film are viewed on a lighted view-box and the digital images are viewed on computerized display systems. Recently, radiography is in a transition from film-based to computed radiography (CR) and CR to digital radiography. Digital radiography (DR) offers definite advantages of image quality and reducing retakes however it has more risk of over sighting under or over exposure as it doesn't reflect in the printed film.

Fig. 1.1 X-ray radiography equipment
(Ref: siemens-healthineers.com)

Fig. 1.2 X-ray film screen cassette
(Ref: asomerville.ltd.uk)

Computed radiography (CR) is the technique that uses photo-stimulable phosphor plates to obtain the digital images. The CR can be used with any existing x-ray systems just by changing the cassettes. DR requires the use of newer x-ray systems with an integrated digital detector.

Fig. 1.3 Computed radiography (CR) cassettes(Ref: spectrumxray.com)

Digital radiology represents the greatest technological advancement in medical imaging in the last decade. Images can be immediately acquired, deleted, modified, and subsequently sent to a network of computers. The digital radiography facility is filmless and eliminates chemical processing of films. The images can be seen simultaneously by many physicians located apart.

Patient can also have the x-ray images on a compact disk to take to another physician or hospital.

Although the doses in digital imaging could be potentially reduced, the experience shows that many facilities impart more doses to patients. The wide dynamic range of digital detectors and the automatic post-processing create difficulty in recognizing over exposures. The primary reason is that over exposure goes undetected, unlike with film where the image turns dark or black. However, in digital imaging the image becomes better when there is over exposure. Further, there is a tendency to take more images than necessary or larger coverage of area to be radiographed than necessary.

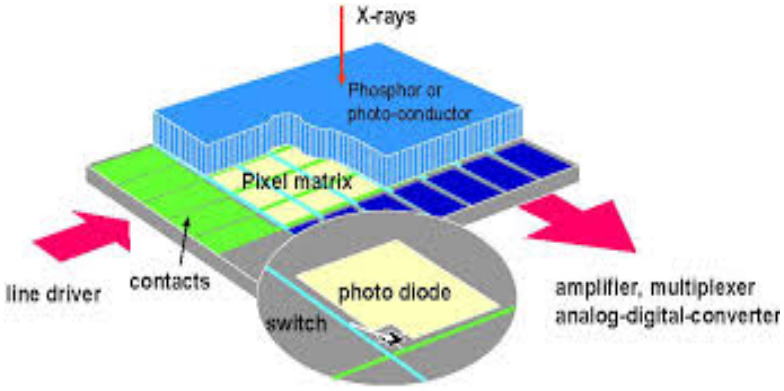

Fig. 1.4 Digital radiography (DR) detector

The rating of radiography equipment is around 150 kVp and 500 mA. The patient radiation doses ranges from 0.2 mGy for chest radiography to about 7 to 10 mGy for lumbar spine or Lumbo-Sacral Joint. This modality is used for radiography of almost all parts of the human body other than dental and breast for which specialized equipment are available.

1.2.2 Mammography

Mammography is an imaging modality specifically used for breast imaging. Here the focus of imaging is on two factors, patient dose management and risk reduction. This is because breast tissue has a relatively high sensitivity to the adverse effects of radiation and also mammography requires a higher exposure than other radiographic procedures to produce the required image quality. The higher exposure, compared to other radiographic procedures, is because the breast is composed of soft tissue (no bones or air) and has very low subject contrast. Relatively higher radiation exposure is required to produce visible images of both normal breast anatomy and signs of disease. In mammography, the objective is to produce images that provide maximum visualization of breast anatomy and the signs of disease without subjecting the patient to unnecessary radiation.

Fig. 1.5Mammography equipment
(Ref: itnonline.com)

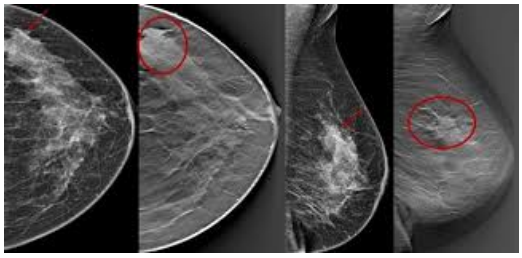

Fig. 1.6 Mammography images
(Ref: densebreast.info.org)

1.2.3 Computed tomography (CT)

Computed Tomography is a method that extends the clinical capabilities of x-ray imaging. Its high contrast sensitivity visualizes soft tissues and produces tomographic (cross sectional) and three-dimensional (3D) volumetric images. CT can be used for a wide range of clinical applications including several procedures for evaluating heart disease. With the help of CT, it is possible to optimize images for a wide range of anatomical sites and visualization of pathologic conditions.

With all these advantages CT scanning delivers quite high dose to the patient than the radiography technique. As the imaging techniques are different than radiography, special radiation dose quantities are used for monitoring of patient doses.

Fig. 1.7 Computed tomography (CT) equipment (Ref: philips.co.in)

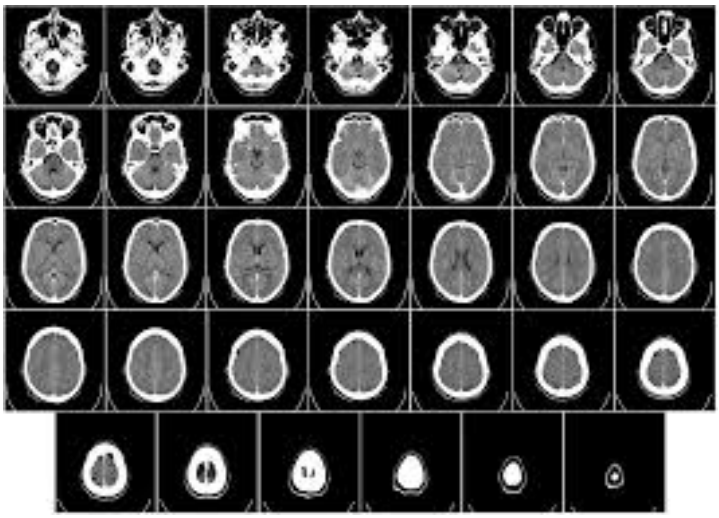

Fig. 1.8 Computed tomography images (Ref: en.wikipedia.org)

CT Angiography

CT has been utilized for i) coronary angiography (coronary CTA) and ii) coronary calcium scoring. The coronary arteries had conventionally been visualized using invasive coronary angiography that requires inserting a very small tube called catheter into a blood vessel in the groin or arm and injecting a contrast agent when the catheter tip is at a desired location. The images are taken under the x-ray guidance. CT scan is also used for visualizing the coronary arteries as an alternate modality. This is usually done with multi-detector CT (MDCT) but was earlier also done with electron beam CT (EBCT).

Multi-detector Computed Tomography

Multi-detector computed tomography (MDCT) is a form of CT technology used for diagnostic imaging. In MDCT, a two-dimensional (2D) array of detector elements is used in place of the linear array of detector elements, which is used in the conventional helical CT scanners.

Hencethe development of MDCT has resulted in the development of high-resolution CT applications such as CT angiography and CT colonoscopy.

1.2.4 Fluoroscopy

Fig. 1.9Interventional radiology equipment
(Ref: indiamart.com)

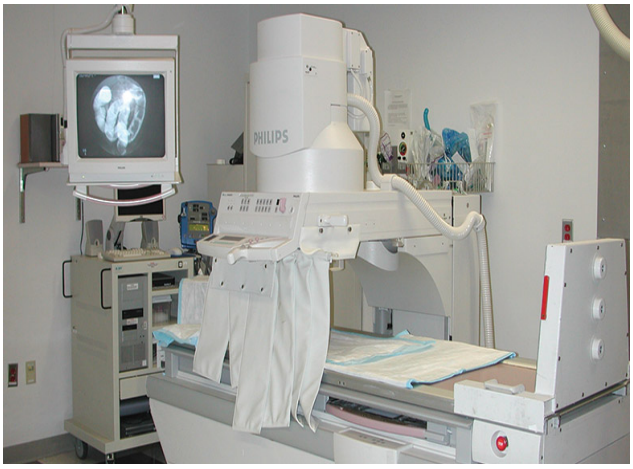

Fig. 1.10 Fluoroscopy equipment
(Ref: chop.edu)

Fluoroscopy is a method that provides real-time x-ray imaging. This is especially useful for guiding a variety of diagnostic and interventional procedures. The ability of fluoroscopy to display motion is provided by a continuous series of images produced at a rate of 25-30 images per second.

While the x-ray exposure needed to produce one fluoroscopic image is low (compared to radiography), high exposures to patients can result from the large series of images that possible in fluoroscopic procedures. Therefore, the total fluoroscopic time is one of the major factors that determines the exposure to the patient from fluoroscopy.

Because the x-ray beam is usually moved over different areas of the body during a procedure, there are two different aspects to consider with respect to radiation dose to the patient. One is the area most exposed by the beam, which results in the highest absorbed dose to that specific part of the skin and to specific organs. Another is the total radiation energy imparted to the patient's body, which is related to the Kerma Area Product (KAP), a quantity that is easily measurable.

The absorbed dose to a specific part of the skin and other tissues is of concern in fluoroscopy. The need for minimizing the dose to sensitive organs, such as the gonads and breast, by careful positioning of the x-ray beam and using shielding when appropriate. There is also a possibility of radiation injuries in cases of very high exposure incident on the same area. On the other hand, the total radiation energy imparted to the patient's body during a procedure is closely related to the effective dose and to the risk of radiation induced cancer.

1.2.5 Dental imaging

Dental examinations are the frequent type of radiological procedure. X-ray examinations help dentists to diagnose, plan and monitor treatments. There are four types of dental radiological procedure - intraoral (bitewing, periapical and occlusal) radiography, panoramic radiography, cephalometric radiography, and cone-beam CT (CBCT). Individual doses are small but collective doses cannot be ignored due to the high volume of procedures. The most effective way to reduce dose in dental radiography is to avoid unnecessary x-ray examinations by justification. Routine dental x-ray examination for all patients is not justified. It is also important that the equipment is subject to acceptance testing, routine quality control, undergoes proper maintenance, and has all the standard dose reduction features.

Fig. 1.11 Dentalx-ray equipment (IOPA, OPG and CBCT)
(Ref: IOPA- indiamart.com, OPG - indiamart.com, CBCT- stanleyinstitute.com)

The most common factor among all the above discussed diagnostic modalities is that all are associated with radiation risk smaller or higher. Radiation dose is a measure of energy absorbed when a person is exposed to x-rays. It may cause health effects to a person in complex procedures. Different quantities are used to express the radiation dose received by patient and operators. These quantities and units are discussed in the later section of this chapter.Typical radiation doses to patients in various x-ray examinations are given in Table 1.1.

Table 1.1 Typical radiation doses to patients in various x-ray examinations

X-ray modality	Type of procedures	Dose quantity used for patient dosimetry	Radiation doses to patients	Effective doses
Dental x-ray practice	Intra oral radiography	Entrance surface Kerma	0.65 to 3.7 mGy	1–8 μSv
		kerma-area product	26 to 87 mGy.cm2	
	panoramic radiography	Entrance surface Kerma	3.3 to 4.2 mGy	4-30 μSv;
		kerma-area product	84 to 120 $mGy.cm^2$	
	cephalometric radiography	kerma-area product (Adult)	41 to 146 $mGy.cm^2$	2-3 μSv
		kerma-area product (Children)	25 to 121 $mGy.cm^2$	
	CBCT	kerma-area product		50 μSv-100 μSv
Mammography	Screening	MGD	~ 2-3 mGy	0.4 mSv
Radiography		Entrance surface Air Kerma	0.2 mGy-7 mGy	
Computed Tomography		CTDI		7-15 mSv
		DLP		
Interventional Radiology		KAP		8-70 mSv
		Cumulative Air Kerma		

1.3 Quantities and units used for radiation dose measurements

The amount of radiation dose delivered to patient for any of the imaging modality depends on several factors contributing to the complexity. Determining and expressing the radiation to the staff and other persons in an imaging facility is also somewhat complex and depends on various factors. To express and monitor the radiation doses received by the patient and the operator/medical practitioner the various quantities used are discussed below:

Radiation quantities

There are different physical quantities used to express the amount of radiation delivered to a person. There are two types of radiation quantities used to measure dose(i) to specific tissue or organ, and (ii)to the total radiation delivered to a person (whole body radiation). The concentration quantities integrated over the area or mass of the human body exposed or by applying weighting factors gives total radiation [www.sprawls.org].

The radiation quantities and their associated units are described below

1.3.1 Energy

The radiation deposits energy in the patient's body. This happens when the radiation interacts with and is absorbed by the tissues. This is the concentration of energy absorbed in tissue and is called as the quantity, Absorbed Dose, and the total energy absorbed in a body is the Integral Dose.

1.3.2 Exposure

The exposure, X, is the quotient of dq by dm, where dq is the absolute value of the mean total charge of the ions of one sign produced when all the electrons and positrons liberated or created by photons incident on mass dm of dry air are completely stopped in dry air, and is given by

$$X = \frac{dq}{dm} \qquad (1.1)$$

[ICRU Report No. 85, 2011]. There are two units used for expressing Exposure. The conventional unit is the roentgen (R) and the SI unit is the coulomb/kg of air (C/kg of air), the roentgen, is officially defined in terms of the amount of ionization produced in a specific quantity of air. The quantity can be used to compare different imaging techniques with respect to radiation delivered to patients, especially for the same anatomical coverage and to calculate the absorbed dose to underlying tissues and organs.

1.3.3 Air kerma

Air kerma is another radiation quantity that is sometimes used to express the radiation delivered to a point, such as the entrance surface of a patient's body. The quantity, kerma, originated from the acronym, KERMA, for Kinetic Energy Released per unit MAss (of air). It is a measure of the amount of radiation energy, in the unit of Joules (J), actually deposited in or absorbed in a unit mass (kg) of air. Therefore, the quantity, kerma, is expressed in the units of J/kg the special name of the unit, isGray (Gy).

The quantity, air kerma started to replace the quantity, exposure, for expressing the amount of radiation delivered to a point, like the entrance surface to a human body.

1.3.4 Absorbed Dose

Absorbed Dose is the radiation quantity used to express the amount of radiation energy actually absorbed in a specific tissue. This quantity is directly related to biological effects. It is measured in the traditional unit of the rad or the special unit of the Gy. The rad is equivalent to 100 ergs of energy absorbed in a gram of tissue and the Gray is one joule of energy absorbed

per kilogram of tissue. It is defined as ‘Absorbed dose, D, is the quotient of dE by dm, where dE is the mean energy imparted by ionizing radiation to matter of mass dm, thus

$$D = \frac{dE}{dm} \qquad (1.2)$$

The quantities relating to radiation outside of a human body, such as exposure, air kermaand dose area product (DAP), are relatively easy to measure because a measuring device, ionization chamber or DAP meter, can be placed at the location of interest. However, absorbed dose in tissue cannot be measured directly by any practical methods. Dose measuring devices, dosimeters, can be placed on the surface, but it is generally not reasonable to insert them into most internal tissues or organs. Hence, the absorbed dose in most body tissues is usually determined by indirect means.

It can be estimated by two methods (i) measuring entrance surface exposure, or air kerma, over the tissue or organ of interest and then use published conversion factors to calculate the dose in a specific tissue location (ii) actually measuring the dose in a "phantom". Tissue equivalent phantoms of approximately the same size and shape as the body organ are used. A dosimeter is inserted into the phantom and it is then exposed to radiation using known exposure factors. Applying appropriate correction factors for different exposure conditions patient doses can be estimated [www.sprawls.org].

It is difficult to determine the absorbed dose to a specific tissue location in a patient undergoing an imaging procedure. There are several complicating factors, including variations in organ size and location, variations in body size and composition, and the non-uniformity of

the radiation distribution within the body. To overcome some of these difficulties several special radiation dose quantities have been developed for specific imaging procedures, such as CT and mammography. These special quantities make it possible to determine a dose value that is a reasonable estimate of the "true dose" that is actually delivered to the tissue. This makes it possible to compare dose values for different imaging techniques, among institutions, and from country to country.

1.3.5 Equivalent Dose

All of the above quantities discussed are physical quantities. That can be measured and expressed in terms of fundamental physical quantities like energy. However, a major reason for determining the amount of radiation delivered to a body is to relate it to biological effects on the body. The various types of radiation do not produce the same biological impact, even when the dose or energy delivered to the tissue is the same. Hence, Equivalent dose is a quantity that expresses the relative biological impact of the radiation by including a radiation weighting factor (W_R).

Equivalent dose is a dose quantity H representing the stochastic health effects of low levels of ionizing radiation on the human body which represents the probability of radiation-induced cancer and genetic damage. It is derived from the physical quantity absorbed dose, but also takes into account the biological effectiveness of the radiation, which is dependent on the radiation type and energy. In the SI system of units, the unit of measure is the Sievert (Sv).

The radiation weighting factor represents the relative biological effectiveness of the radiation and modifies the absorbed dose to take account of the different biological effects of various

types and energies of radiation. The ICRP has assigned radiation weighting factors to specified radiation types dependent on their relative biological effectiveness.

Calculating equivalent dose from absorbed dose;

Equivalent Dose (Sv) = Absorbed Dose (Gy) x $W_{\mathbf{R}}$,

$$H_T = \sum W_R \, . D_{T,R} \qquad (1.3)$$

Where,

H_T is the equivalent dose in Sieverts (Sv) absorbed by tissue T

$D_{T,R}$ is the absorbed dose in Gray (Gy) in tissue T by radiation type R

W_R is the radiation weighting factor defined by regulation

The value of the radiation weighting factor ($W_{\mathbf{R}}$) is a characteristic of each specific type of radiation. The x-ray, gamma, beta, positron all have radiation weighting factor ($W_{\mathbf{R}}$) values of one (1). Therefore, for x-rays, Equivalent Dose (Sv) = Absorbed Dose (Gy)

This quantity is often used in expressing the radiation received by personnel working in radiation environments, etc. For example, the values measured with personnel monitoring devices (TLD badges) are usually reported in Sieverts.

1.3.6 Effective Dose

Effective dose is used for expressing relative radiation risk to humans, both patients and other personnel. It takes into account the radiation sensitivity of specific organs and areas of the

body that are exposed. For the purpose of determining effective dose, the different organs have been assigned tissue weighting factor (W_T) values. For a specific organ or body area the effective dose is:

$$\text{Effective Dose (Gy)} = \text{Equivalent Dose (Sv)} \times W_T \qquad (1.4)$$

If more than one area has been exposed, then the total body effective dose is just the sum of the effective doses for each exposed area. By using effective dose, it is possible to put the radiation received from diagnostic procedures into perspective with other exposures, especially natural background radiation.

Effective dose is the tissue-weighted sum of the equivalent doses in all specified tissues and organs of the human body and represents the stochastic health risk to the whole body, which is the probability of cancer induction and genetic effects, of low levels of ionizing radiation. It takes into account the type of radiation and the nature of each organ or tissue being irradiated, and enables summation of organ doses due to varying levels and types of radiation, both internal and external, to produce an overall calculated effective dose.

The SI unit for effective dose is the sievert (Sv). The effective dose is not intended as a measure of deterministic health effects, which is the severity of acute tissue damage that is certain to happen, that is measured by the quantity absorbed dose.

$$E = \sum_T W_T . H_T = \sum_T W_T . \sum_R W_R . \overline{D}_{T,R} \qquad (1.5)$$

Where:

H_T is the equivalent dose in Sieverts (Sv) absorbed by tissue T

$D_{T,R}$ is the absorbed dose in Grays (Gy) in tissue T by radiation type R

W_R is the radiation weighting factor

W_T is the tissue weighting factor

E is the effective dose in Sieverts (Sv)

1.3.7 Surface integral exposure

The quantities exposure and air kerma have useful applications in the dosimetry field, however they are limited in that they do not give information on the total radiation delivered to a body. For that several other quantities are defined. The first is the Surface Integral Exposure (SIE). It is just the product of the exposure value (mR) and the size of the exposed area (cm^2). The unit for SIE is the R-cm^2. An alternate name that is sometimes used for this quantity is Exposure Area Product. The quantity is indicative of stochastic risk to the patient but it has very poor correlation with the entrance skin doses as the large dose received in small area and small dose spread over the large area of the skin will show the similar results. The risk of skin injury is more related to exposure than SIE.

1.3.8 Dose area product

Dose Area Product (DAP) is similar in concept to surface integral exposure and exposure area product in that they all express total radiation delivered to a patient. The principle difference is in the units used. DAP is in dose units, such as Gy-cm^2. For a uniformly exposed area, the DAP is just the product of the air kerma, in Gy or mGy, and the exposed area in cm^2. DAP

provides a good estimation of the total radiation energy delivered to a patient during a procedure.

Both radiographic and fluoroscopic machines can be equipped with devices (DAP meters) or computer programs that measure or calculate the DAP for each procedure. It is the most practical quantity for monitoring the radiation delivered to patients. The Dose Area Product is also known as Kerma-Area product (KAP).

1.3.9 Computed tomography dose index

The Computed Tomography Dose Index, CTDI, is the special dose quantity that is used extensively to express absorbed dose in CT. In CT scanner the x-ray beam is rotated around the patient and passes through from all sides. This gives a relatively uniform distribution of absorbed dose within each slice. Values for the CTDI are determined by a measuring protocol that makes a reasonable estimate of the dose contribution from scatter.

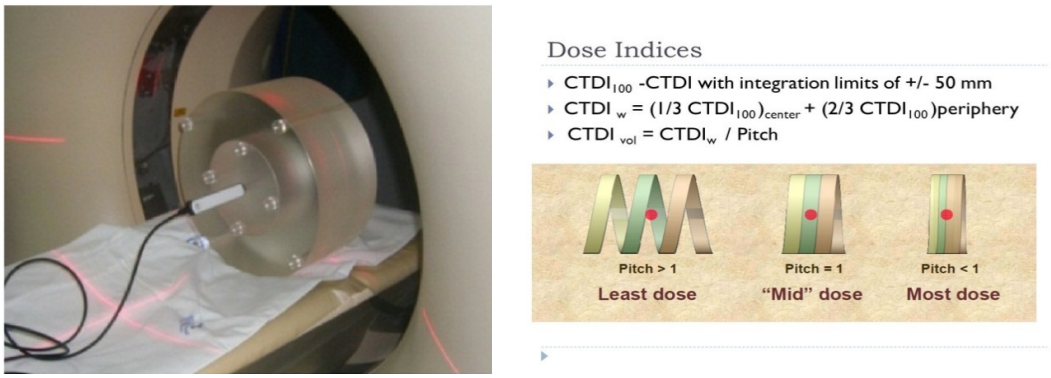

Fig. 1.12 Set up of CTDI measurement (Ref: researchgate.net)

$$CTDI_{100} = \frac{1}{NT}\int_{-50\,mm}^{50\,mm} D\,(z)dz \qquad (1.6)$$

$$CTDI_w = \left(\frac{1}{3} . CTDI_{100}\right)_{central} + \left(\frac{2}{3} . CTDI_{100}\right)_{periferal} \quad (1.7)$$

1.3.10 Mammography mean glandular dose

The Mean Glandular Dose (MGD) is the special dose quantity used in mammography. It is defined as the mean dose to the glandular tissue within the breast. The assumption is that the glandular tissue, and not the fat, is the tissue at risk from radiation exposure. The MGD is based on some standard breast parameters. For comparison of imaging techniques, evaluation of equipment performance, general dose management, and regulatory and accreditation purposes, the MGD to a "standard" breast is used. The standard is a 4.2cm thick compressed breast consisting of 50% glandular tissue and 50% fat. This corresponds to the standard phantom that is used for image quality evaluation and comparative dose determinations. MGD can be calculated from a measured incident air kerma at the top of the breast, K as follows,

$$D = K.g.c.s \quad (1.8)$$

g - Converts from incident air kerma to MGD, with a glandularity of 50%, based on breast thickness and HVL.

c- corrects for glandularity other than 50%, depending on the breast thickness and HVL, with two versions for ages 50–64 and 40-49

s- corrects for the x-ray spectra in use with a table of target/filter combinations

1.3.11 Integral Dose

Absorbed dose, including the special dose quantities CTDI and MGD describe the amount of radiation energy absorbed per unit mass of a tissue, however it does not tell about how much

total radiation energy is deposited in a body. Integral dose is the radiation quantity that is equal to the total energy absorbed by the body. The SI unit for integral dose is the joule (the standard unit of energy), and the conventional unit is the gram-rad. It is generally assumed that the risk of cancer induction is related to the integral dose because it takes into account the amount of tissue exposed.

1.3.12 Computed tomography dose length product (CT-DLP)

CTDI is the practical quantity for specifying dose in CT procedures. The associated quantity for specifying the "total radiation" to a patient is the dose length product (DLP). It is the product of the CTDI value and the length of the body area scanned. It has the units of either rad-cm or Gy-cm. It is a useful and practical quantity for comparing the total radiation to patients for various CT procedures.

1.3.13 Cumulative air kerma at reference point (K_a)

In the interventional radiology, a quantity used to indicate the total dose received in a procedure, Cumulative Air Kerma at reference point. The reference point is the Interventional reference point (IRP).The International Electrotechnical Commission (IEC) defines K_a as the air kerma accumulated at patient entrance reference point which lies on the central axis of the beam, 15 cm on the x-ray tube side of isocentre for isocentric IR equipment [IEC, 2010; Miller et al., 2010].

1.4 Interventional radiology

Reviewing the range of doses associated with all the radiology practices discussed above, interventional radiology is the only practice that can lead to tissue reactions such as epilation,

skin injuries and cataract to the patient as well to the operators owing to the procedure requirements. In the present study measurements and experiments were carried out in the interventional radiology practice to identify the causes and improve the radiation safety status of the patient and operators.

In the past two decades the use of fluoroscopically guided interventional procedures (IR) has been increasing around the world. These minimally invasive procedures are used as an alternative to conventional surgery, resulting in reduced patient morbidity and mortality. However, radiation doses to patients from fluoroscopically guided interventional procedures may be high enough to cause skin injuries and increased probability of developing cancer/heart diseases in future years. There is also a risk to staff members of deterministic effects such as cataract formation. Hence the practice demands attention towards optimization of radiation doses to both patient as well as operator. Establishment of Diagnostic Reference Levels (DRLs) is one the important dose optimization tool for improving radiation safety of the patient. In European countries, there are many studies performed in this area for establishment of DRLs for various IR procedures. International Atomic Energy Agency (IAEA) and International Commission on Radiological Protection (ICRP) has many publications to provide the guidance on methodology, requirement and international data in this regard. In India, although some studies have been performed in the field of radiography and computed tomography, the field of interventional radiology is largely unexplored and there is a wide scope for improvement in the radiation safety status. Some work has been carried out in the southern and northern part of the country for establishment of local DRLs but that was limited to the individual institution. Hence this is a major gap area in the perspective of growing practice and implementing the requirements for improving safety. Establishment of DRL

ensures harmonization in similar procedures by comparative analysis of radiation doses. The present work is targeted to fill the gap and open-up opportunity to improve radiation safety in the field of interventional radiology.

Thus, primary objectives of the work undertaken in this thesis were:

(i) Dosimetric studies in interventional radiology practice for selected procedures to propose diagnostic reference levels.

(ii) Quality assurance studies of IR equipment to verify the compliance with regulatory limits and suggest improvements.

(iii) Estimation of occupational doses for verifying the adequacy of existing protective accessories.

(iv) To establish a national radiation protection programme for interventional radiology practice in India.

The interventional radiology procedures are broadly categorized in the two types i.e. Vascular and non-vascular procedures and are performed for peripheral, coronary and neurology parts of the body. There is large difference in the complexity of the procedure for all the types, and risk associated also increases proportionate to the complexity as it needs longer time and subsequently higher radiation doses to the patient.

Procedures such as endovascular aneurysm repair (EVAR), renal angioplasty, iliac angioplasty, kidney stent placement, therapeutic endoscopic retrograde cholangial-pancreatography (ERCP) and bile duct stenting and drainage have the potential to impart high radiation doses to patients, as much as procedures in interventional radiology and interventional cardiology, with a possibility of the skin dose exceeding one Gy.

Any fluoroscopic procedure when prolonged may impart high radiation dose. Many of these procedures might be conducted outside the radiology department. Without appropriate staff training and implementation of radiation protection measures, dose to patients and risks may be high. These procedures require a higher level of optimization.

1.5 Interventional radiology practice in India

The practice of interventional radiology in India began in the early 1970s. It has grown from 19 interventional radiology specialists in nine institutions performing around 2,000 procedures in 1999, to 363 members of the Indian Society of Vascular and Interventional Radiology (ISVIR) from 56 institutions reporting over 50,000 procedures last year (2017). Apart from this, there is a Cardiology Society of India, started on 4th April, 1948 at Calcutta, which is another large group of specialists in the field of interventional radiology. Over the years, there has been a gradual and steady growth in this exciting radiology subspecialty in India. In the seventies and eighties, IR practice was limited to hospitals in New Delhi, Mumbai, Trivandrum, and Lucknow, but over the years there has been an expansion in the practice of IR in India as a whole.

The increasing number of these procedures is due to a combination of factors, which include increasing demands from referring physicians, the widespread availability of imaging equipment for guided procedures, IR's potential to serve as a convenient alternative to open surgical procedures and reduce recovery time, and the tremendous advances in IR hardware.

Today, IR is an integral part of various clinical procedures, finding a role in vascular diseases, oncology, stroke management, women's health, paediatrics, and back pain. Comparing the Indian practice with other countries, it is observed that, the devices have similar approval

states, such as FDA and CE marks. The interventional radiology specialists practicing in India are often trained with similar backgrounds and share similar levels of expertise in handling devices and techniques. The specialists are well trained in research methods and in the designing and implementation of clinical and experimental projects and trials [www.isvirindia.org]. However, the important gap area observed was, there are no considerable studies on patient dose management and optimization has been carried out in India compared to European countries. There is no system for comparison of procedures and analysis among the IR field to establish the national diagnostic reference levels.

Chapter 2

Diagnostic reference levels (DRLs)-concept and practice

2.1 Introduction

The International Commission on Radiological Protection (ICRP) first introduced the term 'diagnostic reference level' (DRL) in 1996 [ICRP PUB 73, 1996]. The concept was subsequently developed further, and practical guidance was provided in its supporting guidance 2 [ICRP Annual Report, 2001] and publication 103 [ICRP PUB 103, 2007]. In practice, the values are selected on the basis of a percentile point on the observed distribution of doses to patients. Diagnostic reference levels are values which should be easy to measure and have a direct link with patient doses. They are established for efficient radiation dose management of patients. If such doses are found to exceed the corresponding reference dose, possible causes should be investigated and corrective action should be taken accordingly, unless the unusually high doses could be clinically justified.

The ICRP publications recommended that the DRL values should be selected by professional medical bodies in conjunction with national health and radiological protection authorities and reviewed at intervals that represent a compromise between the necessary stability and the long-term changes in the observed dose distributions. The concept of diagnostic reference level is started to be a well-defined tool in many countries and is used to reduce patient dose during medical interventions and examinations.

2.2 Need for establishment of DRL

The optimization of patient protection in diagnostic radiology and image guided interventional procedures requires the application of examination-specific protocols tailored to patient size, region of imaging and clinical indication. This ensures that the patient doses are optimum for the required image quality to achieve clinical purpose of the examination. Surveys of dose estimates from different imaging modalities highlight the substantial variations in dose between some of the healthcare facilities for same examination and similar patient group (adults or children of defined sizes). Such observations indicate the need for standardization of dose and reduction in variation in dose without compromising the clinical purpose of each examination.

In establishing values for the DRLs, typical (Mean or Median) doses for patients are obtained from a representative sample of facilities where these procedures are being performed. In this way, a sample value of DRL of current practice in the state or region is obtained, reflecting both good and poor practices, for that particular imaging procedure.

The value of the DRL for a specific procedure is typically the rounded 75^{th} percentile of the distribution of typical doses for that facility as per recommendations of ICRP publication 135, 2017. In establishing DRLs, it is important to include only radiological procedures whose image quality is adequate for the medical purpose. After establishing DRL, interventional radiology facilities should compare their typical doses with the relevant DRL. The use of the median value rather than the mean value of the distribution of data collected from a representative sample should be preferred for comparison with DRLs, as the average value

could be substantially lower. Optimization of protection for a particular radiological procedure should be reviewed if the comparison shows that the facility's typical dose exceeds the DRL, or that the facility's typical dose is substantially below the DRL and it is evident that the exposures are not producing images of diagnostic usefulness.

2.3 Process for establishment of DRL

The process of DRL establishment involves many systematic steps and methodology. The various parameters to be considered in the process are discussed in this section.

2.3.1 Selection of methodology for studies

There are several steps for establishment of DRL. It can be actual patient data collection or by simulation experiments with phantoms to represent a 'standard patient' for each procedure. As far as possible, DRLs should be established on the basis of surveys of procedures of appropriate sample of patients. The use of phantom avoids most of the issues with variations in patient size indices however, it does not truly represent clinical practice and clinical images and considered to be less appropriate for use in establishing DRLs. Nevertheless, a phantom based approach, in the absence of adequate patient data, can be used first to establish DRLs and further strengthened by actual patient examination data analysis.

2.3.2 Selection of procedures

It is essential that, health authority and professional bodies adopt a common terminology for procedures. The selection of imaging procedures for which DRLs are to be established depends on their relative frequencies and magnitude of the doses incurred. A graded approach should be used for selection of procedures for which DRLs are to be established, the more frequent and higher dose procedures should have a higher priority.

2.3.3 Patient selection, data survey and analysis

A representative widespread survey should be conducted considering types (government/private) and sizes (patient foot fall) of facility, the type of equipment and the geographical locations. A larger sample size reduces the statistical uncertainties. Considering the variation in patient age and size, a window should be selected for range of age, weight and height for the sample selected for analysis, for example 75± 15 kg. Normally data should be collected for all adults in the initial sample but should be excluded extreme outliers in terms of patient size indices. The dose quantities used to represent the dose to the patient should be easily measurable and should be in accordance with the recommendations of the ICRU, as established in para. 1.46 of GSR Part 3 [General Safety Requirements Part 3, IAEA, 2014]. For Fluoroscopy and interventional radiology procedures air kerma-area product (P_{ka}) is the recommended primary DRL quantity. Air kerma at patient entrance reference point ($K_{a,r}$), fluoroscopy time and number of images are recommended as useful additional DRL quantities. Before collecting the dose data, the adequacy of the image quality needs to be confirmed for the clinical purpose. The data to be collected in the initial survey can employ a paper-based approach/ web based or electronic submission approach. Standard format should be used for data collection. It should be ensured by training that all the relevant members involved in the process of data collection (technologist, medical physicist and medical practitioners) are aware about the purpose and significance of the survey, standard terminology of the procedures, assessment of clinical complexity of the procedures, patient classification (age, weight) and review & verification of data collected. The data collection to be carried out for a definite time frame. The facility should submit its data to a centralised database.

At the end of collection of sufficient data, an analysis of the submitted facility typical doses will be carried out for generating value of the DRL. With the increased digital connectivity data collection and analysis will be easy in future.

The process towards establishing DRLs, as described above, involve many parties, including the imaging facilities, the health authority, professional bodies and the regulatory body.

2.3.4 Responsibility of generation and establishing DRL

International Atomic Energy Agency recommends that, the collaborative work from all the above agencies would provide the expected results in the formation of DRL[IAEA SRS-59]. There should be collective decision on, which procedures and age groups will be considered, data collection methodology, data management, and when the DRLs should be reviewed and updated. A national governmental body may administer the national patient dose database that underpins the establishing of DRLs or this role may also be taken by the regulatory body or a professional body. There is no preferred ownership, the important is that a patient dose database for DRLs is established and maintained, DRL values are set and then promulgated through the regulatory processes, and a process for periodic review is established. It may be appropriate to take a regional rather than a national approach to DRLs. With which close conformance would be possible.

2.3.5 Performance evaluation of x-ray system used for DRL formation studies

The accuracy of the reported dose quantities should have been verified in acceptance testing by means of quality assurance procedures. This approach is applicable to all digital modalities of dose display quantities. For verification of accuracy of such quantities, direct dose measurements for selected organs, such as the skin for interventional procedures may be used. This can be carried out using thermo- luminescent dosimeters, optically stimulated luminescent

dosimeters, radiochromic films or silver halide films. All these dosimeters are required to be calibrated for all the parameters used during procedures such as various kV stations of the IR equipment and expected dose range.

In addition, accuracy of exposure parameters and image quality evaluation is also important.

2.3.6 Dosimetry of patients for evaluation of tissue reaction probability

In interventional radiology procedures, cumulative dose to the area of skin exposed is also required to be monitored to assess the potential for reaching the threshold for tissue reactions in complicated cases. The determination of the peak skin dose to the most exposed area of skin is not straightforward, since exposure parameters and projection angles change during the procedure and the most exposed area cannot always be anticipated. This makes knowledge of the dose mapping over the skin necessary.

Dose mapping can be carried out using low sensitivity x-ray films and radiochromic films. Films are positioned below the expected peak dose area of the skin during the procedure. Exposed films then scanned to provide the estimate of peak skin dose. Cumulative reference air kerma at the patient entrance reference point, defined as the kerma in air at 15 cm from the isocentre in the direction of the x-ray tube, these values are displayed during the procedure and can be used as a conservative estimate for peak skin dose. The degree of overestimation depends mainly on the change of beam projections.

2.3.7 Implementation of DRL in the interventional radiology facility

For each IR system, typical level of dose in respective quantities(P_{ka}, K_a, Fluoroscopy time) for each type of examination should be determined as the median values observed for representative samples of patients of a particular group (adults and children of defined

sizes). These median doses should be compared with the relevant DRL. Clinical protocols for performing a particular examination should be reviewed for observing any over exposures or substantially lower dose values of DRLs. In case of lower values, there is a probability that the exposures are not producing images of diagnostic usefulness or not yielding the expected medical benefit to the patient. Appropriate corrective measures should be implemented as deemed necessary for improving patient safety. In the individual optimization process, the DRL can be used as a starting point and as a benchmark to compare the individual applied dose to the reference dose values. The dose indicators such as alarms at some pre-set values or automatic dose tracking tools help in the optimization process.

2.3.8 Periodic review of DRL

At some definite interval, at least once in five years, The DRLs should be reviewed. Frequent surveys may be required when substantial changes in technology, new imaging protocols or image post-processing become available. After initial evaluations, it is likely that the new values of the DRLs will be lower than the previous values. This cycle of establishment of national or regional DRLs, their use by imaging facilities, corrective actions by imaging facilities, and periodic review of national or regional DRLs brings about a steady improvement in the practice.

2.4 Status of establishment of DRLS in various countries

As discussed above the use of DRLs is an important tool for improving radiation safety in interventional radiology practice. International Atomic Energy Agency has provided guidance for establishment of DRLs in the IAEA safety series 59. Many countries are working towards establishment of DRLs in this field for different procedures. The initial work in US is published by Miller et al. [Miller et al., 2009], they have carried out survey for 21 IR

procedures and analysis has been compared with published Europeanreference levels for similar procedures. They have collected data of KAP, reference dose, fluoroscopy time and number of images. The DRLs were proposed in terms of KAP ($Gy.cm^2$) values recorded by the system. Work in France has been published for fifteen interventional procedures in neuroradiology, vascular radiology and osteoarticular procedures by analysing the KAP, fluoroscopy time (FT), reference air kerma and number of images recorded for 10–30 patients for every procedure, total 4500 procedures from 36 departments were observed [Greffier et al, 2017]. Similar studies in the field of cardiology were performed in Torbica, Italy, Spain, Luxembourg, Leuven Belgium, Turkey, Poland, Austria, Estonia, Ireland, Romania, Athens, Greece, Slovakia, Bulgaria, Newcastle, UK to establish the European reference levels for cardiac interventional procedures [Padovani et al., 2005]. In Australia, local DRLs were published for angiography and fluoroscopy procedures at the Alfred Hospital in Melbourne, Australia.They have categorized 38 type of procedures and good sample data was collected for the period of 2.5 years. The DRLs were published in terms of quantity KAP ($Gy.cm^2$). 75^{th} percentile of the data was used as DRL values for all types of procedures [Brendan et al, 2014]. In many countries there is a regulatory initiative towards establishing DRLs in various diagnostic procedures.

State and territory regulatory bodies require implementation of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice (RPS 14), which requires the development and application of diagnostic reference levels. The ARPANSA Code of Practice (RPS 14), states that “the Responsible Person” mustestablish a program to ensure that radiation doses administered to a patient for diagnostic purposes should be: i) Periodically compared with DRLs for diagnostic procedures for which DRLs have been established in

Australia; and ii) If DRLs are consistently exceeded, the practice should be reviewed to determine whether radiation has been optimized."

Diagnostic reference levels for adult x-ray examinations have been established in 72 % of the 36 European countries and in 81 % of European Union (EU) and European free trade association (EFTA) countries i.e. Iceland, Norway and Switzerland [RADIATION PROTECTION N° 180, 2014]. The report publishes DRLs for all the interventional procedures in the various European countries. Summary of the DRL formation and establishment process in European countries is described below:

In Greece, the requirement for the establishment and application of diagnostic reference levels is imposed by the Greek Radiation Protection Regulations. The Greek Atomic Energy Commission (GAEC) as the national authority for radiation protection, is responsible for the establishment and enforcement of the national DRLs. The DRLs are published for radiography and computed tomography examinations. The determination of DRLs is based on the data collected during the on-site inspections performed by GAEC in radiology and nuclear medicine laboratories. The on-site inspections are carried out as a part of the licensing procedure of the laboratories periodically (5 years for radiology laboratories). As it concerns the radiological examinations, adequate dosimetric measurements are performed for the different types of examinations. The DRL for each examination is determined as the rounded third quartile value of the distribution of the corresponding dosimetric values registered. The Greek radiation protection regulations require that the medical physicists employed as radiation protection experts (RPE) in radiology and nuclear medicine departments are responsible for organizing and running adequate programs for the determination of local reference levels. GAEC, as the competent authority on radiation protection issues, organizes special courses on the

establishment and the implementation of DRLs for personnel in radiology and nuclear medicine departments. Moreover, the RPEs in large hospitals are responsible for providing the required training on the use of DRLs to the medical staff. In Netherlands,the Decree on radiation protection of 2001 stipulates that the Minister of Health, Welfare and Sport shall promote the establishment and use of DRLs.

In United Kingdom, a Department of Health has set a DRL Working Party in the UK to formally adopt national DRLs in compliance with the requirements of the Ionising Radiation (Medical Exposure) Regulations 2000. The Working Party will consider proposals for DRLs from relevant professional groups and organisations (primarily National Radiological Protection Board/Health Physics Association and Administration of Radioactive Substances Advisory Committee ARSAC)based on published patient dose data from UK national surveys. Medical applications for which DRLs had been proposed by 2005 include radiography procedures, fluoroscopy examination, CT scan examinations, fluoroscopically-guided interventional procedure and nuclear medicine procedures. The Ionising Radiation (Medical Exposure) Regulations 2000 require all hospitals, that carry out medical exposures should develop written procedures for the establishment, use and adherence to DRLs. Further guidance on how to do this is provided by Institute of Physics and Engineering in Medicine (IPEM) Report 88, 2004.

In France, the methodology followed for establishing DRLs is described here. The first step consisted of making a list of the most common radiological procedures and in writing down the corresponding standardized protocols with the French Society of Radiology (SFR), the Institute of radiation protection and nuclear safety (IRSN). On the basis of protocols and data sheets established with the French Society of Medical Physics (SFPM). TLD measurements (entrance

dose) and examinations data (quantities used for DRLs) were measured, recorded and analysed. Data has been collected from the volunteer institutions. Mean dose values and third quartile values were determined for collected data. Studies were initially carried out for conventional radiography and computed tomography examinations, later continued for other practices including interventional radiology procedures.

Enforcement of DRL requirement in France: The DRLs were set in the ministerial order in 2004 as a part of the transposition into French regulation of the European directive 97/43/Euratom. According to this order, each radiologist or nuclear medicine practitioner must evaluate every year for 20 standard patients (or on an anthropomorphic phantom) and for 2 types of procedures defined in the order, the parameter chosen for quantifying DRLs (Entrance skin dose, dose length product or activity). The procedures must be different every year and the data must be sent to IRSN, who is in charge of data collection and analysis and determine the possible need to change DRLs.

In Germany, the initial values of the DRLs in diagnostic radiology were proposed by an expert group of physicians and medical physicists chaired by the Federal office for Radiation Protection, including representatives of the professional medical societies. For radiography of adult patients, the European DRLs were adopted. For fluoroscopy examinations, a restricted survey of current practices in university hospitals, and for CT examinations, a national survey of CT practice performed were used to derive the DRLs. The proposal was finally discussed with members of the German Radiation Protection Commission.

In Italy, the values of the DRLs were established on the basis of a survey of data reported in the literature, with particular regard to Guidelines published by the European Commission. For all examinations for which a DRL exists, hospitals have to determine the dose for a standard sized patient, whose values are compared with the corresponding DRL. If the level is exceeded actions have to be taken in order to reduce the dose. The DRLs were set in the Legislative Decree n., 187 in2000 that implemented in the Italian law 'the European Directive 97/43/Euratom'. According to this Decree, each radiological or nuclear medicine department must set up a suitable quality control programme, aimed at the optimisation of the procedures. Moreover, the doses delivered to patients in each procedure must be evaluated every two years, checking their compliance with the DRL. All the personnel engaged in the use of ionising radiation for medical purposes must participate every five years to a refresher course on radiation protection, with special regard to the exposure of the patient.

In Sweden, diagnostic reference levels were implemented into the national regulations in 2002. The determination of standard doses and administered activities is mandatory according to these regulations and have to be determined for the first round within two years. The national authority requires the reporting of the determined standard doses at any time. Normally the determination of standard doses is also checked in connection with inspections.

In Switzerland, the method adopted to determine the diagnostic reference levels varied according to the modality. In 2002, Switzerland took part in a Europe-wide survey on computed tomography. In this case, data from Swiss hospitals was used to establish the DRLs in the CT examinations. In the following years 2003 and 2004 the Institute of Applied Radio physics (IRA) was commissioned by the Swiss Federal Office of Public Health (SFOPH) to study high-dose applications in interventional radiology and cardiology. For conventional

radiography, the SFOPH adopted the values recommended by the European commission. A programme was designed to provide a broader basis for the DRLs in interventional radiology and cardiology. The DRL system was incorporated in the legislation. The applicable DRLs were published in the Directives of the Swiss Federal Office of Public Health.

Several other countries have also shown progress in establishing DRLs in the various diagnostic procedures including interventional radiology examinations. Certain work has also been carried out in India regarding establishing local DRLs in common procedures, which is described in further chapters of this thesis.

Chapter 3

Quality assurance of interventional radiology equipment

3.1 Introduction

Interventional radiology and computed tomography are increasingly important areas of radiology because of the multifarious applications and concerns regarding higher patient doses per examination. Quality control (QC) of such equipment is of particular importance to avoid unnecessary higher doses to the patient without compromising the required image quality. As per Rule 3 of Atomic Energy (Radiation Protection) Rules-2004, all the medical diagnostic x-ray facilities are required to obtain the License for Operation for equipment and the facility. One of the licensing conditions is that the x-ray equipment shall undergo periodic quality assurance (QA) checks once in two years and after any major repair of the equipment. The facilities are required to maintain such records and the same are verified by AERB during regulatory inspections.

Interventional radiology has multidimensional aspects that are unique in the radiology specialty. To ensure patient safety and quality of services, it is of paramount importance to establish an accurate verification system that should be in compliance with the standards in practice of the country. Establishing a program that includes continuous assessment of clinical outcomes, identification of problems in the process and required actions to eliminate the discrepancies is desirable to minimize the risks. In spite of the variation and heterogeneity of procedures performed in IR, there are several safety practices that can substantially reduce errors, medical complications and provide an optimal standard of patient care. This review of

the process of quality assurance in IR focuses on identification of misbehaviour of equipment leading unnecessary exposures to patients and establishing process of preventive and corrective actions periodically to ensure reliable performance. Such records should be maintained by the facility.

For radiation safety of patient and medical personnel working in the IR facility, AERB has developed specific guidelines on operational safety aspects. However, with respect to clinical guidelines professional associations should bring out practice specific guidelines for improving the safety culture at all the facilities and to share their experiences. These guidelines should include labelling medications, preventing wrong site, wrong procedure, and wrong person's surgery in the preoperative verification process. Further availability of required resources and materials should be verified before the procedure. Moreover, ongoing evaluation of the performance of medical devices used for a given procedures is necessary for safe patient care and for establishing a regular program of equipment maintenance.

Quality assurance evaluation should be performed systematically with following goals in mind: (i) identification of problem, (ii) application of corrective measures, and (iii) improvement of clinical guidelines. Therefore, incorporation of continuous data collection, assessment of potential risk and complications, and the use of external and internal benchmarks are essential to achieve a high level of care in interventional radiology suite.

To verify the performance status of interventional radiology equipment and to review its adequacy in the light of increased radiation safety concerns in this field, a technical survey has been carried out. In the present study 39 interventional radiology equipment of different makes and models available in Mumbai, Pune and Coimbatore at various institutions were tested as

per established AERB quality assurance protocol for fluoroscopy x-ray equipment. Additional tests for accuracy and consistency of KAP meters were also performed. The existing protocol for quality assurance tests has been revised by incorporating the additional tests for improving the patient and operator safety. Revised QA protocol includes test for various parts of the imaging chain, i.e. x-ray tube and generator, radiation dose display parameters, image quality, patient dose and shielding adequacy of protective accessories and devices.

3.2 Objective of quality assurance and responsibility

World Health Organization (WHO) defines QA as "systematic actions necessary to provide adequate confidence to the end-user(s) that a medical diagnostic x-ray equipment will perform satisfactorily in compliance with safety standards specified by the Competent Authority". Quality assurance consists of structured procedures and actions aimed at maintaining a high level of quality diagnosis or treatment of patients. Increasing complexity of medical technology requires specialized and systematic verifications to ensure quality and effectiveness. The periodic quality assurance program enables the facility to recognize when parameters are out of limits, which will result in poor quality images and can cause unnecessary radiation exposure to patients. Simply performing the quality control tests is not sufficient, when quality control test result exceeds the established tolerance, appropriate corrective action must be taken immediately and should be documented for future reference.

The responsibility of conducting the quality control tests lies with radiological safety officer (RSO). The RSO should plan the QA program in co-ordination with associated physician, medical physicist, and quality control personnel. The team working together is the key for providing optimum quality of fluoroscopic images with minimum possible dose to the patient. A periodic training is necessary for all the above personnel to assess the image quality and to

understand the associated radiation doses to the patient and workers in routine operation. In India, there are approved agencies having qualified and trained personnel for providing QA services in Diagnostic Radiology (DR) facilities. The agencies have appropriate QA tools/instruments for carrying out performance verification tests of DR equipment.

3.3 Materials and methods

A quality assurance test tool kit comprising of following was used for measurements:

Table 3.1 List of quality assurance tools and instruments used

Sr. No.	Tools	Make
1	kVp meter	Raysafe AB, Sweden
2	Dose meter	Raysafe AB, Sweden
3	Survey meter	Raysafe AB, Sweden
4	PMMA phantom	(30 x 30 x 30) cm
5	Gafchromic film	International Specialty Products (ISP), Wayne, NJ, USA
6	Low contrast resolution test tool	Circular depressions (holes) of various diameters in an aluminium disk.
7	High contrast resolution test tool	Image quality test tool containing a series of cooper mesh patterns, line pairs

The various tools and instruments of quality assurance kit are shown in Fig. 3.1.

Fig. 3.1 Quality assurance tool kit

3.4 Performance verification parameters

The quality assurance tests carried out on interventional radiology equipment are described below:

The tests are broadly divided in to three parts:

- Performance of exposure parameters (Accuracy/consistency)
    - Operating potential
    - Operating current
    - Exposure time
- Image quality parameters
    - Low contrast resolution
    - High contrast resolution
    - Effective focal spot size
- Radiation safety, dose monitoring and display verification
    - Kerma-area-product meter display accuracy
    - Table-top dose rate

- Built-in safety features
    - Total filtration
    - Leakage from x-ray tube

Operating potential (kVp)

Operating potential affects overall output of the x-ray equipment and beam quality. Also, high kVp images produce lesser contrast however benefits in the patient dose reduction. Low kVp technique provides good contrast resolution but increases the patient dose. Accuracy of the operating potential is verified at all the available mA stations using calibrated kVp meter. The tolerance of kVp accuracy is ± 5 kVp.

Operating current

Operating current and time product (mAs) decide the intensity of the x-ray beam. X-ray beam output varies linearly with the mAs. Linearity of the mA, linearity of timer or linearity of mAs is verified using calibrated dosimeter in the useful range of available mA or mAsstations. The coefficient of linearity (CoL) is calculated by using the formula

$$CoL = \frac{x_{max} + x_{min}}{x_{max} - x_{min}} \qquad (3.1)$$

The tolerance for Coefficient of linearity is (CoL) ≤ 0.1.

Exposure time

Output of x-ray beam is directly proportional to time. Time accuracy is verified using timer (inbuilt with the dose meter) and % error is calculated. The tolerance for accuracy of timer is ± 10 %.

Effective focal spot size

Focal spot size is an important component of image formation, as it affects the resolution of the image. This is verified using high contrast resolution test tool using appropriate magnification geometry. This can be calculated using following formula

$$S = \frac{M}{(M-1)(lp/mm)} \qquad (3.2)$$

Where:

S = Focal spot size, mm

M= Magnification $\left(= \frac{\text{sourcetoimagedistance}}{\text{sourcetoobjectdistance}}\right)$

lp/mm = number of line pairs per mm resolved

Output consistency

Output consistency measures the overall performance of the equipment. The combination of all exposure parameters and set up conditions are reproduced a number of times say 5-10 and standard deviation in the form of Coefficient of Variation (CoV) is calculated using the following formula. The measurement was repeated for commonly used range of kVp and mAs values. The tolerance is $\text{CoV} \leq 0.05$

$$CoV = \frac{\sigma}{\bar{x}} = \sqrt{\frac{\sum_{i=1}^{N}(x_i - \bar{x})^2}{N-1}} \qquad (3.3)$$

A photograph of dosimeter used for output consistency measurement is shown in Fig. 3.2.

Fig. 3.2Photograph of dosimeter (Ref: teambest.in)

Total filtration

Filtration impacts on patient dose. Nominal filtration of 2.5 mm of Al is mandatory for x-ray equipment having more than 100 kV, which removes low energy components preventing unnecessary skin dose to the patient. Further higher filter thicknessesincrease tube loading but useful in the patient dose reduction. This is measured using Al filters and calculating percentage transmission. Now a days the multi-o-meter has provision of direct display of total filtration.

Leakage from tube housing

Leakage from x-ray tube shall not be more than 115mR in one hour. Measurements are carried out with highest loading of x-ray tube from all the sides at the level of focal spot and collimator. A photograph of survey meter is shown in Fig. 3.3.

Fig. 3.3 Radiation survey meter (Ref: avanttec.net)

High contrast resolution and low contrast resolution test

Various phantoms with resolution test pattern are available for image quality verification. High contrast resolution or spatial resolution is the capability of equipment to clearly produce the image of the smaller object/discontinuity/tissue when the difference in the atomic number of background and tissue to be imaged is higher. And the low contrast resolution is the capability of the equipment to produce the image of the smaller objects when the difference in the atomic number of background and the object to be imaged is relatively low. The image quality is normally specified by the manufacturer with imaging parameters. While carrying out image quality parameters verification, same conditions to be used. Results to be verified with the tolerance as per QA format. As per AERB QA protocol it is 2.8 lp/mm and 3mm hole visibility for high contrast resolution and low contrast resolution respectively. A photograph of the test tool used for measurement of high contrast and low contrast sensitivity is shown in Fig. 3.4.

Fig. 3.4 High contrast resolution test tool and Low contrast resolution test tool

Table top dose rate

This test is important to limit the skin dose of the patient. Table top dose rate is required to be measured in all the fluoroscopy modes available in the equipment such as continuous fluoroscopy, pulsed fluoroscopy and cine radiography. It is measured at nominal working height of the couch from the floor. Distance from focal spot size to table top should not be less than 30 cm.

Performance verification of kerma area product (P_{ka}) meter

One of the objectives of present study is establishing local reference levels for interventional procedures. The quantity used for reference levels in these procedures is the kerma–area product of the radiation incident upon the patient. This requires determination of the P_{ka}that enters the patient after attenuation and scattering in the patient's couch and mattress. Since these conditions depend on each radiological unit, calibration of the Pka meter needs to be done for each unit.Calibrations weremade against reference dosimeter (Raysafe AB, Sweden). The dose rates are measured using semiconductor based Xi light detector (Raysafe AB,

Sweden) dosimeter. Unfors Light detector calibration is traceable to PhysikalischTechnische Bundesanstalt (PTB), Germany, with calibration uncertainty of 2%.

The calibration has to account for the differences between the P_{ka}displayed by the transmission chamber placed on the collimator and the $P_{ka}$of the radiation incident on the patient. These differences are due tothe attenuation and scattering in the patient's couch and mattress, Energy dependence of the transmission chamber (which usually contains metal electrodes), inhomogeneity of the beam throughout the cross-section. Extra focal radiation and radiation scattered in the collimator and filters, which may cross the P_{ka} meter but not reach the patient. [IAEA SRS 59]

The calibration factor is the ratio between the air kerma–area product for the radiation that actually incidents on the patient and the value displayed by theP_{ka} meter. The beam has been attenuated in the couch and mattress and there is some scatter radiation produced in the couch and mattress, but there should not be backscatter radiation from the patient or phantom.

$$K = \frac{K\text{ref}.\text{A}}{P\text{ka}} \qquad (3.4)$$

Where:

- k is the calibration factor to be applied to the transmission chamber to obtain the patient's P_{ka};
- K_{ref} is the air kerma value measured by the reference chamber on the top of the patient's couch and mattress;
- A is the area that can be determined by exposing a film placed on the table top.

The distance from the tube to the table top should be similar to the one used in practice for an average patient. The distance of the imagereceptor (flat panel detector) to the reference

chamber should be sufficient to minimize the backscatter radiation from the copper absorber reaching the referencechamber.The values of the measurements were recorded. Everymeasurement was performed three times and the averagewas taken for calculation purpose.

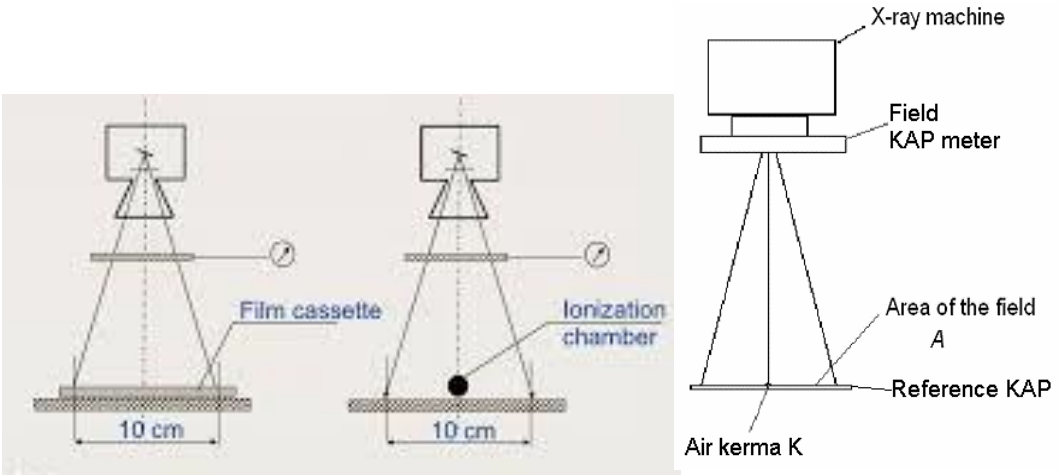

Fig. 3.5 Measurement set-up of kerma area product (KAP) (Ref: slideshare.net)

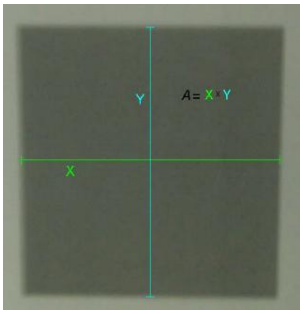

Fig. 3.6 Exposed film for area measurement in the measurement of KAP

Area (A) of exposure was determined by placing a film on the table top. The collimation of about 100 cm^2 at the level of the film was selected. Exposures were made and respective readings of auto selected kVp, reference dosimeter reading (mGy), displayed values of KAP($\mu Gy.cm^2$) and area of the exposed films (cm^2) are noted. The films were scanned and the field sizes were evaluated.

Shielding adequacy of protective accessories

Lead Aprons, Gloves, Gonad and Thyroid shields were tested in the fluoroscopy mode using survey meter. Sufficient number of measurement points was used for verification of any defects such as breaks, cracks, porous or discontinuities. All the protective accessories shall be checked periodically at least annually for its uniform shielding adequacy. Precaution should be taken in the storage of protective accessories so that it should not get folded during storage. Cracks in the lead lining can develop at the fold, reducing the useful life of the apron. It should not assume that brand new aprons, gloves, etc. contain no defects. Visual examination is not sufficient to ensure integrity of shielding. New aprons, gloves, etc. should also be examined under x-ray immediately upon arrival and returned to supplier if defects are found.

Fig. 3.7 Protective eye wear and protective aprons
(Ref: goggles-medicalexpo.com, apron- xenashield.com)

3.5 Results and discussion

Licensed interventional radiology facilities were selected for studying the status of quality assurance and review the stability of various exposure parameters and equipment components.

The list of facilities and details of equipment tested are given in Table 3.2. Before every planned QA, equipment warm-up was done by giving few exposures to the phantom with dosimeter. After stabilizing the output and exposure parameters QA was carried out. The QA results of 39IR facilities are analysed and summary is provided in Table 3.3.

Table 3.2List of interventional radiology equipment models for which performance verification was carried out

Sr.No.	Equipment model	Maximum kVp	Maximum (mA)	Manufacturer	No. of units
1	Artis Zee FMSC	125	800	Siemens	11
2	Innova 2100 IQ	125	1000	Wipro GE	2
3	Allura clarity family	125	750	Philips	3
4	Innova IGS 520	125	1000	Wipro GE	4
5	Allura Xper FD 10/20	125	1250	Philips	7
6	Artis Q	125	1000	Siemens	4
7	Intuis	125	1000	Philips	2
8	Axiom Artis Zee Biplane	125	800	Siemens	1
9	Axiom Artis Zeego	125	800	Siemens	1
10	Azurion 7 M20	125	813	Philips	1
11	Allura Centron	125	813	Philips	1
12	Innova-2000	125	1250	Wipro GE	1

13	Allengers Life FP	150	800	Allengers	1

Table 3.3 Summary of quality assurance tests results

Sr. No	Test parameter	Tolerance	Compliance	Range of observed values	Remarks
1	Accuracy of operating potential (kVp)	± 5	88 %	78 – 87 (80 kVp) 96 - 106 (100 kVp)	---
2	X-ray tube current (mA) linearity	CoL ≤ 0.1	94 %	0.01 – 0.14	---
3	Accuracy of timer	± 10 %	100 %	430 ms to 510 ms (500ms)	---
4	Output consistency	CoV ≤ 0.05	92 %	0.003 – 0.06	---
5	High contrast resolution	2.8 lp/mm should be visible	100 %	4 lp/mm to 6 lp/mm	---
6	Low contrast resolution	3mm hole should be visible	95 %	2mm to 5mm	---
7	Table top dose rate (continuous fluoroscopy)	≤ 5 cGy/min	97 %	3.5 cGy/min to 5.7 cGy/min	---
8	Table top dose rate (AEC/pulsed fluoroscopy)	≤ 10 cGy/min	91 %	7.8 cGy/min to 14.5 cGy/min	---
9	Table top dose rate (for cine radiography)	≤ 20 cGy/min	46 %	16 cGy/min to 38cGy/min	It is recommendatory
10	X-ray tube leakage	≤ 115 mR in one hour	100 %	22 mR to 38 mR in one hour	---
11	KAP meter performance	± 20 %	± 52 %	---	Recommendatory
10	Protective apron shielding adequacy	---	---	---	satisfactory
11	*Compliance to operational safety requirements	---	70 %	---	---
12	Status of Patient dose monitoring and recording	---	20 %	---	Poor compliance
13	Patient specific checklist	---	40 %	---	

*Compliance was verified against a checklist of five parameters (use of protective accessories, use of TLD, patient specific checklist, periodic QA status, involvement of RSO)

Conventionally, measurement of accuracy of exposure parameters such as operating potential, operating current and exposure time were considered as important parameters in the quality assurance. All of these parameters were found to be in good compliance with the regulatory limits. Although in the era of digital imaging, equipment selects the exposure parameters with a check exposure considering the attenuation of the patient. It uses different kV and mAs for various angulations based on antero-posterior and lateral orientation of the patient and entrance beam. Hence a small deviation in the displayed parameters than selected does not impact the image quality and radiation safety of the patient. Measurements have been carried out for a range of kVp values frequently used in the IR procedures i.e. 70, 80, 90, 100,110 and 120. It was observed that up to 100 kVp the performance of almost all equipment (about 88%) were within prescribed tolerance however some deviations observed for higher kVp stations.

Linearity of mA station was measured in the range of 150 mA to 700 mA which was noted for most of the procedures recorded. Linearity of current was found to be in compliance (94%) compared with accuracy of kVp. Timer accuracy was measured in the range of 100 ms to 2000 ms. Accuracy of exposure time measurement was found to be in compliance with the regulatory limits of ± 10 % for all the equipment.

Output consistency in terms of coefficient of variation was measured at 80, 100 and 120 kVp at different mAs values and found to be within the tolerance for 92 % of the facilities. This is one of the important parameters to verify reliability of the equipment performance because it can be affected by deviation in any of the exposure parameters.

Image quality tests for high contrast resolution and low contrast resolution were carried out using line pair phantom and low contrast resolution phantom made up of small air holes in the aluminium plates of 2 cm above and below. Tests were performed using perspex phantom for patient simulation. The results of high contrast resolution were found to be in close compliance than low contrast resolution which is in line with the practice requirement.

Table top dose rate was measured for two different modes provided in the system. i.e. fluoroscopy mode and cine radiography mode. Table top dose rate gives idea about exposure time in which skin reactions will be probable using threshold values of skin reactions. The table top dose rate for pulsed fluoroscopy mode was found to be within the tolerance for 91 % of equipment and the range was from 7.8 cGy/min to 14.5 cGy/min. For cine fluorography mode, mAs goes to very high values in addition to higher frame rates of 12 -15 frames/sec. Hence most of the equipment were shown much higher values of dose rate than the recommended tolerance. For obtaining good quality images of the moving organ like heart the dose rates are normally observed to be very high however cineradiographic mode is used for smaller time compared to fluoroscopy mode hence in normal cases patient does not show any skin reactions.

X-ray tube leakage was measured as a built-in safety feature of the equipment and found to be well within the tolerance for all IR equipment.All the above tests were part of the standard QA protocol prescribed by AERB. These tests seem to be adequate to provide confidence that the equipment performance is reliable and satisfactory to provide clinically acceptable image quality with optimum dose to the patient. However, considering the high hazard potential of interventional radiology practice, another important parameter required to be included in the

test protocol is performance of KAP meter in terms of dose parameters displayed on the monitor.

During the work for establishment of Diagnostic reference levels in the selected cardiology procedures it was required to collect and analyse the system displayed data given by KAP meters. Hence a method has been established and followed to verify KAP accuracy and consistency. For this purpose, a piece of Gafchromic XR-RV3 film (15 cm X 15 cm) and Xi dosimeter was placed at 60 cm from focal spot. Irradiated portion of film exposure provided the area (cm^2) and dosimeter provided the dose reading. Using the measured values of Kerma and area, KAP is calculated and compared with system displayed KAP values. The recommended performance was ± 20 %. It was noted that 40 % of the facilities were showing its performance within ± 35 %. All these facilities were advised to calibrate their KAP meter. It was observed that all these equipment were procured about 3-4 years back, however all the recent installations where the KAP meter was procured about a year back were in good compliance with recommended values.

The important outcomes of the technical survey of IR equipment for improving radiation safety culture in the interventional radiology practice were:

i. Inclusion of KAP performance verification test in the periodic QA protocol.
ii. Specifying the frequency for calibration of KAP meter
iii. Need for patient dose audits at a specified frequency
iv. Mandatory training requirement for the IR staff regarding QA and dose display parameters

The recommendations with supportive data will be provided to national regulatory authority AERB for consideration in revising regulation in the IR practice.

3.6 Conclusions

The QA test results for all the facilities were found to be satisfactory and implies the adequacy of QA frequency of once in two years. It is recommended that IR facility should develop a self-assessment checklist and verify its own performance against standard operating procedures via internal audit. The team for this purpose should consist of service personnel, medical physicist, technologist and medical professional (doctor) for effective optimization of protocols.

For implementation of patient dose monitoring and recording, the revision of established QA protocol is necessary and the same has been proposed here specifically by incorporating verification of KAP meter performance.

The technical audit of interventional radiology facilities is an important tool to verify the various safety aspects of the interventional radiology suit. This includes overall safety aspects such as built in safety design requirements, performance of the equipment, compliance to the operational safety requirements, patient dose data monitoring system, awareness of the medical professionals associated with these procedures, patient follow up, record keeping, self-assessment and compliance to the local regulations. The quality assurance studies and technical survey of 39 IR facilities shows that, there is lot of scope for improvement in the radiation safety status of the facility for patient, medical professionals and confidence to the regulatory body regarding its operation.

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Chapter 4

Patient dosimetry in interventional radiology-Skin dose measurements using Gafchromic XR RV3 film

4.1 Introduction

Fluoroscopically guided interventional procedures have become a vital tool in the diagnosis and treatment of vascular and non-vascular diseases. However, the clinical complexity leads to the higher procedure time and subsequently increases the risk of serious skin injury. Various methods have been developed to estimate or measure the skin dose received by patients during such procedures. These methods include the use of thermoluminescent dosimeters (TLDs), radiochromic film, metal-oxide semiconductor field-effect transistors (MOSFETs), kerma-area-product (KAP) meters and software-based dose calculators. Use of TLDs is a laborious methods, positioning of dosimeter is difficult and there is a probability of missing some of the high dose points, if not appropriately placed. Also, many of the TLDs are not tissue equivalent and may need various correction factors. There are many limitations for using KAP values for skin dose estimation as it is highly area dependent. Amongst all, radiochromic film offers high spatial resolution, large surface area (e.g., 14 in.×17 in.), and is easy to place under the patient, making it well-suited to measure skin dose during fluoroscopy. In addition, radiochromic film is self-developing and insensitive to visible light, making it easy to work with during analysis, and has been shown to have acceptable precision and accuracy for clinical measurements of skin dose.

In the present study the skin entrance dose measurements were carried out in 39 procedures of coronary angiography (CA) and 25 procedures of percutaneous transluminal coronary angioplasty (PTCA) using XR RV3 films.

4.2 XR-RV3 dosimetry film

XR-RV3 film is a reflective-type film consisting of five layers, including an opaque white backing. The five layers are composed primarily of carbon, hydrogen, and oxygen. The active layer contains small quantities (less than 2% by mass) of lithium, nitrogen, and chlorine, while the opaque white polyester layer contains quantities of sulphur (less than 4% by mass) and barium (less than 16% by mass). The active layer thickness was reported to vary by less than 5% and the thicknesses of other layers were estimated to vary by less than ±20%. The elemental composition was reported to vary slightly between batches. The effective *Z* of all the layers of the XR-RV3 film combined is approximately 7.3.

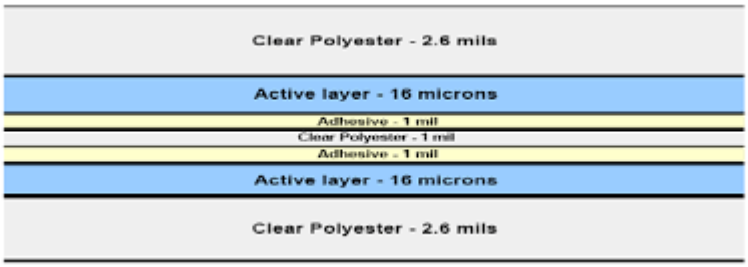

Fig. 4.1 Structure of XR-RV3 dosimetry film (Ref: efie.gr)

The large photoelectric cross-section of barium in the kilovoltage x-ray energy range used during fluoroscopy results in a high yield of anisotropically ejected, long-range secondary electrons. Because of the high probability of photoelectrons generated in the barium-containing white layer of the film with ranges sufficient to reach the active layer, the orientation of the film in relation to the incident x-ray beam may affect the dose deposited in the active layer.

Manufacturer of the film, International Specialty Products (ISP), Wayne, NJ, USA suggests that XR-RV3 reflective films to be used with the white side of the film facing the x-ray source.

4.3 Materials and methods

4.3.1 Film calibration

GafChromic XR-RV3 dosimetry films from ISP, Wayne, NJ, USA were used for patient peak skin dose measurements. The film was calibrated [McCabe et al., 2011] with a type approved fluoroscopy machine (Polydoros, Siemens: 125 kV, 800 mA) at the beam energy normally used during the procedure i.e. 80 kV and filtration of 3.5 mm of Al. The equipment performance was verified using calibrated dosimeter and kV meter. A phantom of PMMA (25x25x20) cm was used to simulate the patient. The dose rates were measured using semiconductor based Xi light detector (Raysafe AB, Sweden) dosimeter. Unfors Xi Light detector calibration is traceable to international standards PhysikalischTechnische Bundesanstalt (PTB), Germany, with calibration uncertainty of 2%. To increase the dose rates, focal spot to film distance of 50 cm was used. Sufficient time gaps were given between the successive exposures to allow cooling of x-ray tube. Six air kerma values (150 , 500, 1000, 3000, 4000, 5000 mGy) and one unexposed background value were used to create the calibration curve for 80 kVp beam quality "Free-in-air" indicates that the calibration films were exposed to the primary x-ray beam with minimal x-ray scatter. The film was cut in to pieces of 6cm X 6 cm prior to experiment, with extra care to protect it from any physical damage. The films were placed at the centre of the phantom for simulating the actual exposure conditions with patient. Field size of 10 cm X 10 cm is used for exposure. The films were scanned using Epson Expression 1000XL scanner in reflection mode. 1000XL is white light scanner having spatial resolution better than 50 microns. The film reflective density to air

kerma calibration curves was constructed. The response of Gafchromic film to exposure depends on film orientation and delay between irradiation and readout time and x-ray energy. The film calibration curve is shown in Fig 4.2.

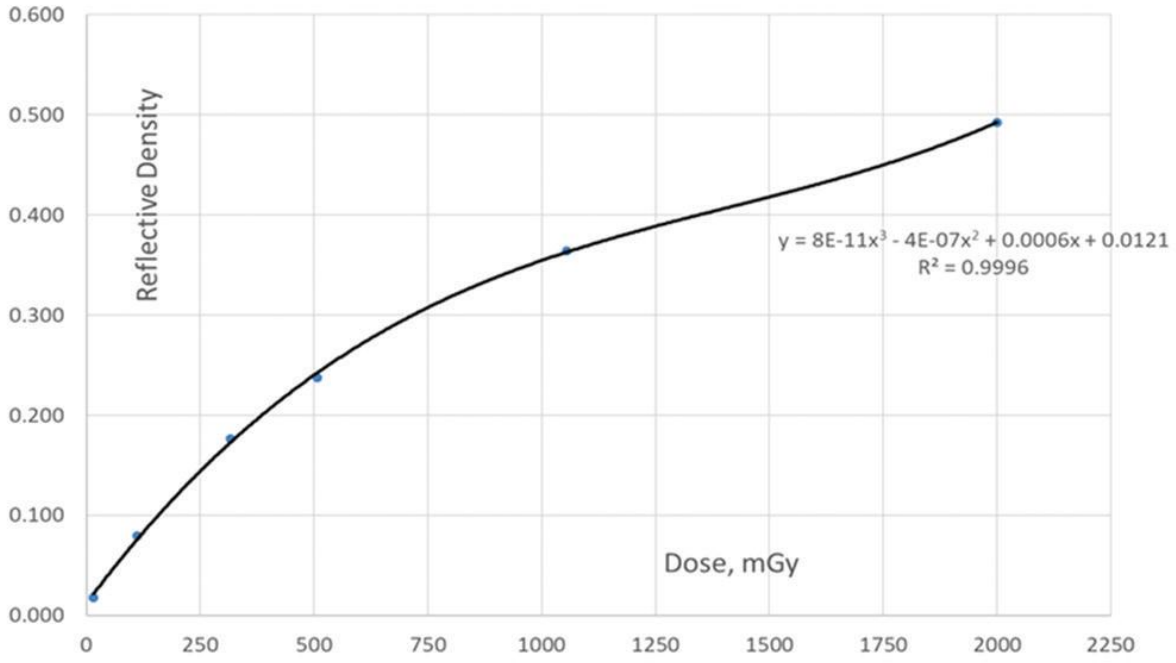

Fig. 4.2 Doseresponse calibration curve of GafChromic XR- RV3 film for 80 kV x-ray

4.3.2 Performance verification of interventional radiology equipment

The equipment performances were verified before starting these studies. The important parameters of performance i.e. operating potential accuracy (± 5 kV), output consistency (Coefficient of variation ≤ 0.05), contrast resolution (2.8 lp/mm), table top dose rate (≤ 10 cGy/min) and accuracy of KAP (within 20%) was verified using calibrated kVp meter and dosimeter . The numbers in the parenthesis are tolerance values of the parameters above as per AERB QA protocol for x-ray equipment. All the parameters were found within the permissible

limits. The periodic performance report (quality assurance report) was satisfactory at both the catheterization laboratories.

4.3.3 Peak skin entrance dose (PSED) measurements

The calibrated films were used for measurement of peak skin dose in the CA and PTCA procedures. Film was positioned on the patient table under the patient, in a position to intercept all the x-ray beams entering the patient with postero-anterior (PA) and oblique projections. The contribution from lateral field was not covered with this set up but this projection is rarely used in cardiac procedures. Film darkening includes back scatter, beam orientations and field non-uniformities. The only correction factor necessary is the conversion from entrance surface air kerma (K_e) to absorbed dose in the skin. As an approximation, recorded values are to be multiplied by 1.06 to find absorbed dose to skin [IAEA-SRS No.59]. Skin dose measurements were carried out for 39 cases of CA and 25 cases of PTCA at two hospitals in Mumbai. Study included both male and female patients. In this study, the complexity index and variation of dose with the weight of the patients or body mass index (BMI) were not considered as most of the selected procedures were standard (simple to normal) procedures and patient weights were within the range of 65-85 kgs. The interventional radiology equipment used for these procedures was Artis Zee and Axiom Artis both Siemens make. The equipment are type approved performances were found to be within the AERB tolerance limits. The performance of KAP meter was compared with the dosimeter and found to be within ± 20 % [James et al., 2014]. The films were cut as per the size of the patient and placed below the patient in the way similar to that of calibration set up (white color facing the source). The films of sufficiently larger size were used to cover the overlapping of AP-PA and oblique orientations.

A unique film number was allotted for every individual patient for their identification. The details of patient and procedure such as patient age, gender, average kVp, fluoroscopy time (FT in mins), frame rate, P_{ka} (µGy-m^2), K_a (mGy) and no. of acquisitions were recorded with their respective film numbers. The exposed films with variations in the density are shown in the fig. 4.3. The films were then scanned after 24 hours as per calibration conditions. The reflective density of the film was recorded using Epson Expression 1000XL scanner. The density distribution shown in figure 4.3 represents the distribution of dose in the field. Respective values of air kerma (mGy) were noted from the calibration curve generated earlier.

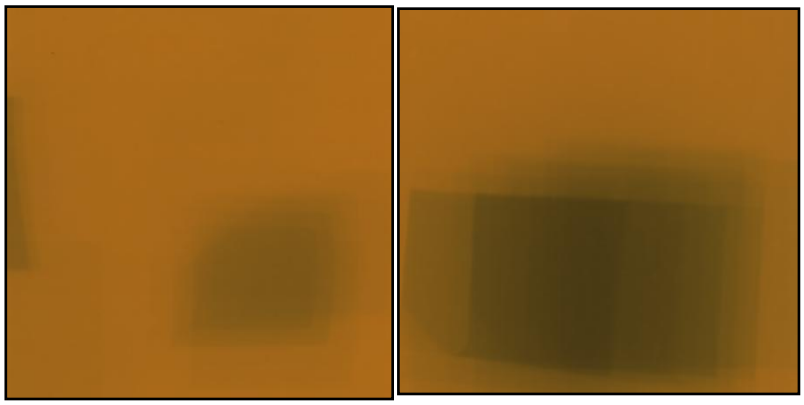

Figure 4.3 (a) Figure 4.3 (b)

Fig. 4.3 Sample of the film exposed for skin dose measurement during (a) coronary angiography and (b) percutaneous coronary intervention procedures

4.4 Results

Patient and procedure parameters were recorded along with peak skin doses. The age range of the patients on which measurements were carried out was 28 years to 86 years. The kVp values recorded were within 76 to 92 kVp. Frame rate of 15 frames/second was used. The recorded values of P_{ka}, K_a and measured peak skin dose in CA and PTCA procedures are given in Table 4.1a and Table 4.1b. The range of recorded P_{ka} values for CA and PTCA is 5.17 to 84.69 Gy.cm^2 and 15.65 to 172.25 Gy.cm^2 respectively. The range of K_a values for CA and PTCA is

83.5 to 1127 mGy and 212 to 3242 mGy respectively. The peak skin dose measured for CA and PTCA using gafchromic XR-RV3 films ranges from 48.2 to 740 mGy and 84 to 1242 mGy respectively. The correlation of various exposure parameters with measured peak skin dose was seen.

It is observed that the PSED is least correlated with FT. The correlation between K_a and measured peak skin dose is shown in Fig 4.4a and Fig 4.4b for CA and PTCA respectively and the co-relation of P_{ka} with PSED is shown in Fig 4a and 4b for CA and PTCA procedures respectively.

Table 4.1a. Summary statistics for coronary angiography (CA) procedure

	N	Mean	Median	SD	Range	75%
Age (Years)	39	55.4	52	8	38-86	55
Fluoroscopy Time (Mins)	39	4.41	3.3	3.27	0.6-15.5	6.5
Cumulative Air Kerma (mGy)	39	485	430	254	83.5-1127	658
DAP P_{kA}($Gy.cm^2$)	39	21.26	14.16	17.82	5.17-84.69	27
Peak Skin Dose (mGy)	39	210.39	130.3	181	48.2-740	320

Table 4.1b. Summary statistics for percutaneous transluminal coronary angioplasty

(CA+ PTCA) procedures

	N	Mean	Median	SD	Range	75%
Age (Years)	25	54.6	52	12.75	28-80	64.5
Fluoroscopy Time (Mins)	25	10.48	8.1	8.55	0.9-35.6	13.55
Cumulative Air Kerma (mGy)	25	1294.79	994.8	932.34	212-3242	1949.5
DAP P_{kA}(Gy.cm^2)	25	70.28	78.9	52.16	15.65-172.25	110.54
Peak Skin Dose (mGy)	25	490.68	319.81	368.28	84-1242	801.47

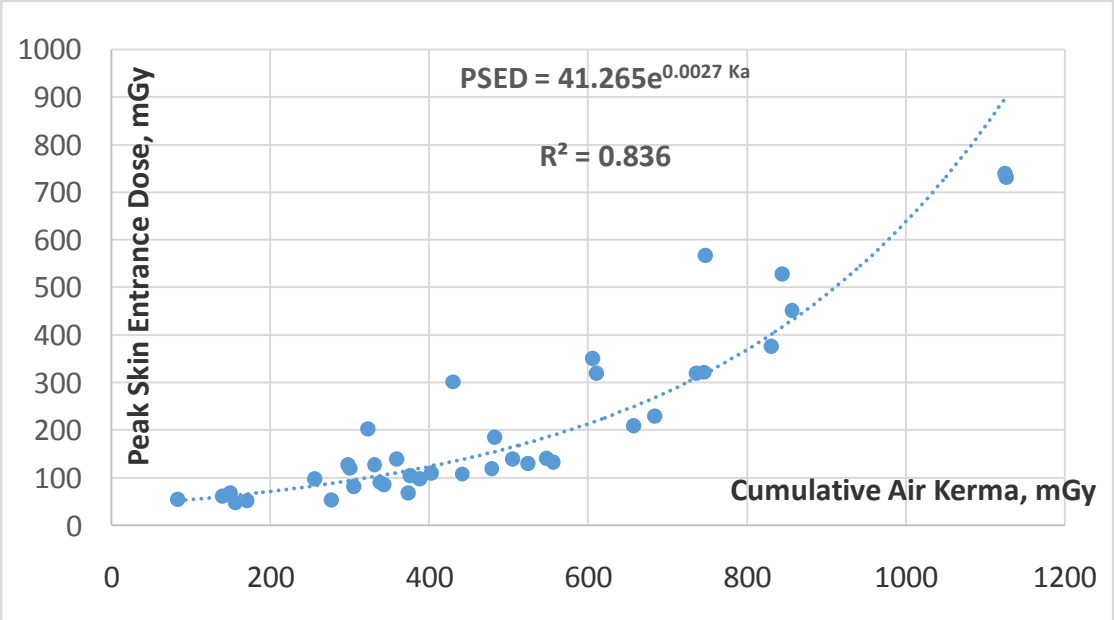

Fig. 4.4a Correlation between Cumulative air kerma (K_a) and measured peak skinentrance dose (PSED) using XR-RV3 film for CA procedures.

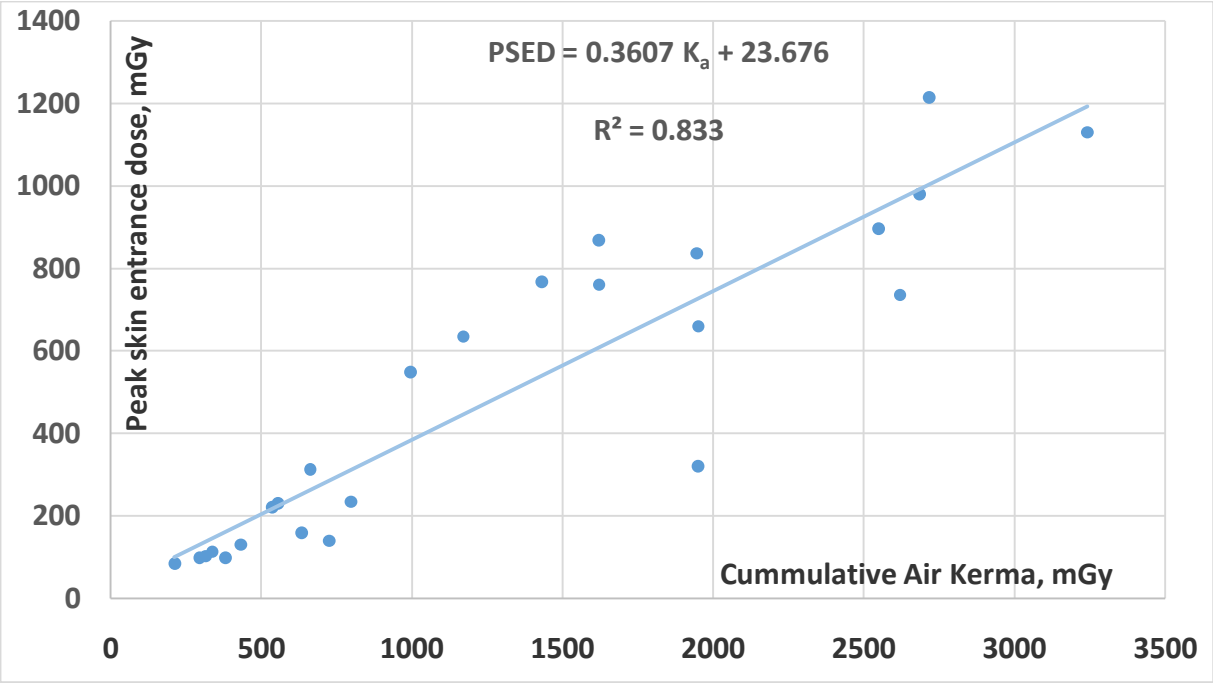

Fig. 4.4b Correlation between Cumulative air kerma (K_a) and measured peak skin entrance dose (PSED) using XR-RV3 film for PTCA procedure

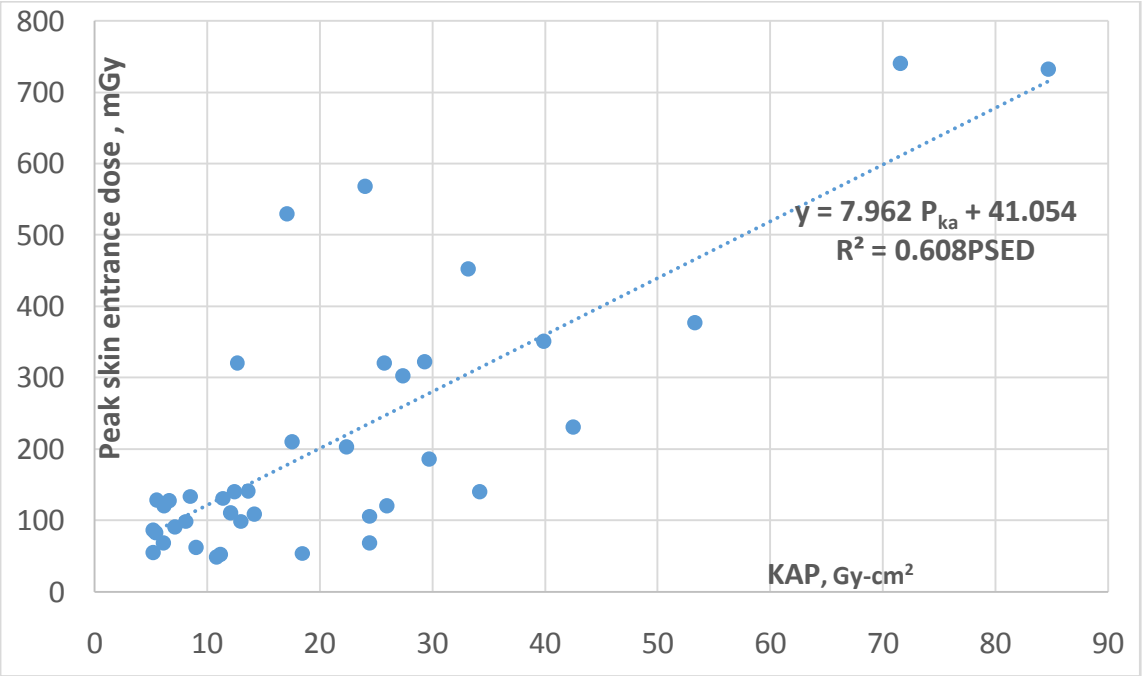

Fig. 4.5aCorrelation between KAP (P_{ka}) and measured peak skin entrance dose (PSED) using XR-RV3 film for CA procedure.

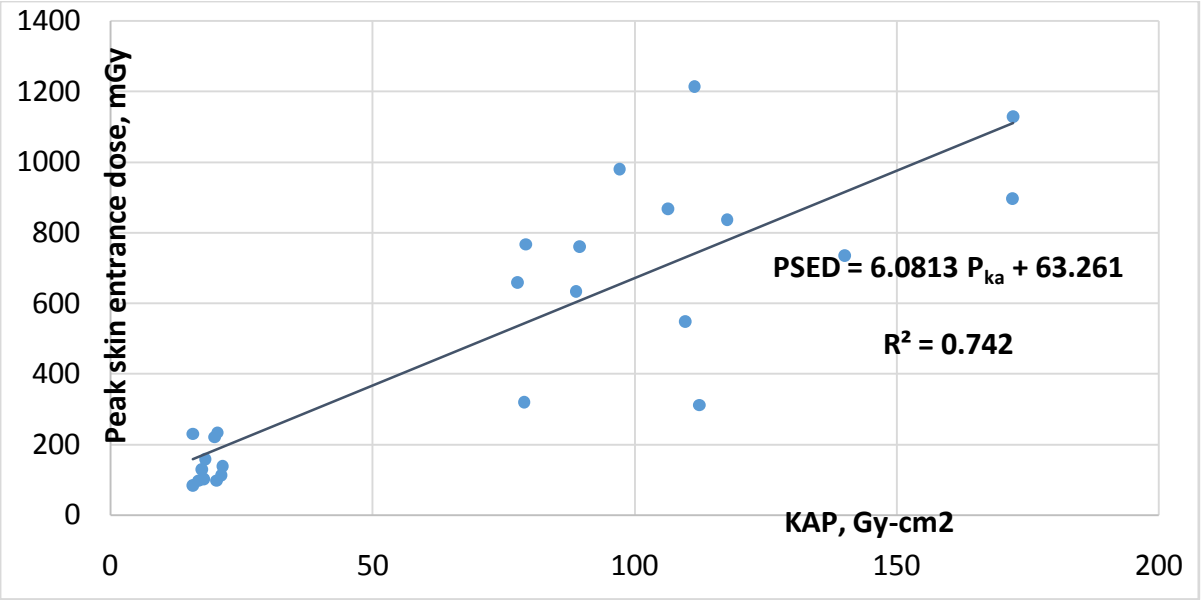

Fig. 4.5bCorrelation between KAP (P_{ka}) and measured peak skin entrance dose (PSED) using XR-RV3 film for PTCA procedure.

4.5 Discussion

The overall radiation risk to the patient in interventional cardiology procedures is attributed by stochastic risk of developing malignancy and deterministic risk of skin injury to the patient. The risk of cancer induction from medical imaging procedures is largely unknown but it is related to the cumulative effective dose received from imaging procedures. The effective doses can be estimated using the tissue weighting factors with the cumulative dose or P_{ka} values. The conversion factors are already published in the literature. However, the risk associated with coronary heart disease itself and the procedure of coronary angiography are relatively high compared to the hypothetical additional lifetime risk of malignancy in patients undergoing different radiological cardiac diagnostic procedures.

KAP values are the indicative of stochastic risk to the patient but it has very poor correlation with the peak skin dose as the large dose received in small area and small dose spread over the

large area of the skin will show the similar values. However, skin reactions will be highly dependent on the spread of the dose in the skin area. The KAP values can be used to estimate the effective dose for Adult patients using conversion factor as1 Gy.cm^2 (P_{kA}) yields 0.18 mSv effective dose [IAEA Safety Reports Series No.59].

Another quantity displayed on the system during and after the IR procedure is Cumulative Air Kerma at interventional reference point (IRP).

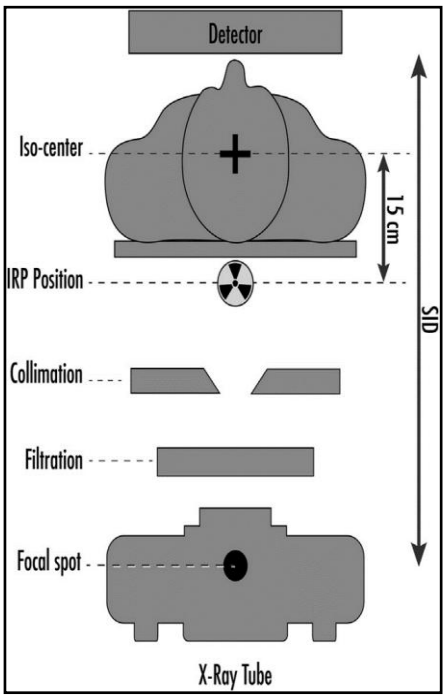

Fig. 4.6 Schematic of Interventional Reference point

Here the reference point may lie inside the patient, outside the patient or nearly on the skin of the patient depending on the site of procedure and thickness of the patient. This point dose calculation does not take into account the angulations used during the procedure. However, in the absence of any direct method for skin dose measurement the quantity cumulative dose is used as surrogate for estimation of skin entrance dose.

In addition to P_{KA} measurements, radiochromic films can be used on few patients submitted to cardiac procedures to determine the skin absorbed dose distribution. Film has the advantage that the readout is directly related to the radiation that enters locally on the skin, includes backscatter and is practically independent of the beam projection angle. The only correction factor necessary is the conversion from entrance surface air kerma (Ke) to absorbed dose in the skin. As an approximation, multiplying the recorded entrance surface air kerma (Ke) by 1.06 renders the estimated absorbed skin dose[IAEA Safety Reports Series No.59]. In the present study, as the films were calibrated with phantom, correction factor was not used with the dose recorded by the films.

Influence of operator on patient dose

Operator can influence P_{ka} in mainly three ways. Optimizing beam on time, careful collimation of the beam to the region of interest and minimizing source to image distance (SID). The degree of beam collimation can be estimated by the ratio of K_a and $P_{ka.}$ The ratio can be used to study the impact of collimation. Increasing SID simultaneously increases K_a and P_{ka}. However lowering the couch height by reducing the SID causes the higher dose rates at the skin entrance. Hence it should be selected judiciously. Increased P_{ka} usually result in increased operator exposure.

It appears that although CA and PTCA are the most common procedures all over the world, the procedures are standardized and not expected to result in the deterministic skin injury. However, for optimization of the radiation dose incurred, every institution needs to establish the local DRLs for common procedures and review the radiation dose by comparing among various practitioners for improving safety culture.

4.6 Conclusions

Radiochromic XR-RV3 films were used for PSED measurements. Sample study of the PSED measurements shows that the maximum localized skin dose received in CA and PTCA procedures are 740 mGy and 1242 mGy respectively which are well within the threshold of skin injury and also within the internationally published values in most of the developed countries. The measured PSED shows very poor correlation with FT. As seen in Fig. 4.4a and 4.4b. Cumulative air kerma can be used as close surrogate of skin entrance dose and are required to be monitored for avoiding probable skin injuries in the complex IR procedures. Such measurements are necessary, prior to establishing any DRLs to evaluate the common procedures for its optimization.

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Chapter 5

Establishment of diagnostic reference levels

5.1 Introduction

We have seen from the international practice that, many developed countries have established and implemented the Diagnostic Reference Levels (DRLs) for various x-ray radiographic procedures, computed tomography procedures and interventional radiology procedures. In interventional radiology till now entire proceduresare not covered, owing to the variations in the complexity and vast scope of applications in the field of peripheral, cardiac and neuro-interventional radiology. However, several papers have been published on such studies for common interventional procedures as referred in the earlier chapter.

In India, some studies have been conducted for proposing local DRLs in the field of diagnostic radiology for adult and paediatric patients [Sonawane et al., 2009, Sarvanakumar et.al, 2014]. Sonawane et al. has estimated Skin entrance doses (SEDs) by carrying out measurements of air kerma from 101 X-ray machines installed in 45 major and selected hospitals in the country by using a silicon detector-based dose Test-O-Meter. 1209 number of air kerma measurements of diagnostic projections for adults have been analysed for seven types of common diagnostic examinations, the proposed DRLs were compared with guidance levels published by the IAEA-BSS-Safety Series No. 115, 1996; HPA (NRPB) (2000 and 2005), UK; CRCPD/CDRH (USA), European Commission and other national values and found comparable. Although there was some work carried out in the interventional cardiology field also, the data covered was limited to individual institutions only [Uniyal et al, 2017]. It is required to cover a greater

number of institutions for representative reference levels in the interventional radiology practice.

An IR procedure often involves high dose and high dose rates. Hence, there is an increased potential to cause skin reactions to the patients in complex procedure. As per International Commission on Radiological Protection (ICRP), DRLs help in optimizing radiological protection in imaging procedures [ICRP-135, 2017]. It offers a method of discriminating unusually high or low patient dose for a particular procedure. Several investigators have reported the use of KAP (P_{ka}) and cumulative air kerma (K_a) values for interventional radiology procedures for establishment of DRLs and estimation of skin doses [Bogaert et al., 2009, Maghbool et. al., 2018, Van de Putte et.al, 2000, Kwon et. al., 2011] in complex procedures.

A wide variety of fluoroscopically guided procedures are performed using different types of equipment and clinical techniques, in different institutions. A comprehensive survey of the entire field is a long-term work and will require many professional associations to be involved with the regulatory body. Hence for developing the methodology of comprehensive patient dose surveys a sample study was taken up. As nationwide survey needs a longer duration and large number of data which was not possible owing to limited resources and lack of awareness of the professionals in the field, few multispecialty hospitals in Mumbai were contacted for collaboration and sharing of patient data. Based on the response received five hospitals were involved in the present work.

The aim of the present study was to analyse the system displayed dose quantities P_{ka} and cumulative air kerma at interventional reference point (K_a) to establish local DRLs for the selected interventional procedures.

As a step towards establishment of DRLs for interventional radiology practice in India, Atomic Energy Regulatory Board (AERB) has made mandatory that kerma area product (KAP) meters shall be available with every IR equipment for monitoring and recording of patient doses during the procedure(AERB safety code SC/MED-2). However, DRLs are not yet mandatory for IR facilities in India.

In this work, a sample study was performed for selected procedures in cardiology. A systematic plan was prepared for data collection and analysis. The interventional radiology staff at all the five institutions was not aware aboutradiation safety and patient dose data monitoring & recording requirements.

5.2 Materials and methods

The sample study was carried out involving five hospitals in Mumbai. Hospital representatives were trained for further communications in this work. Following are the steps involved in the process.

Selection of hospitals

The selection of hospital was based on the availability of radiological safety officer (RSO) and interventional radiology equipment with flat panel detector to maintain uniformity of data. In these hospitals no such type of projects was carried out earlier. All the five hospitals have more than 3-4 consultant cardiologists. The facilities and equipment selected for proposed study are as given in Table 5.1.

Table 5.1List of interventional radiology systems included in this study

Facility id	Equipment	Make
H-1	Artis Zee FMSIR	Siemens Ltd., Germany
H-2	Artis Zee	Siemens Ltd., Germany
H-3	Innova 2000	Wipro GE Medical Systems, Bangalore
H-4	Artis Zee	Siemens Ltd., Germany
H-5	Intus	Philips Healthcare, Netherlands

5.3 Selection of procedures

Initially data has been collected for various procedures in cardiology, peripheral interventions and neuro interventions. Later, based on the observed frequency, procedures performed on coronary arteries were emphasized. Therefore, two representative procedures were selected: Coronary Angiography (CA) - a diagnostic procedure, and percutaneous cardiovascular intervention **(**PCI) - a therapeutic procedure. These are also the most prevalent categories of fluoroscopically guided invasive procedures around the world.

5.3.1 Coronary angiography/ arteriography (CA)

Coronary angiography is an invasive procedure that is carried out by puncturing a peripheral artery. A catheter is advanced through the arterial branches to the heart. By injecting an iodinated contrast material, it is possible to selectively identify the lumen of each coronary artery. In order to obtain optimal images of the arterial segments, different projections are done from the left- and right-hand sides of the patient, with cranial or caudal angulations as a means to obtain a diagnostic view of the coronary artery. Usually, series of six to eight

cinefluorographic runs are acquired for the left coronary artery, and two to four cinefluorographic runs are acquired for the right coronary artery. Any bypass grafts are also imaged. In most cases, the procedure is completed by imaging the left ventricle in the right oblique projection and in the left oblique view when required by the clinical condition of the patient [IAEA SRS 59].

5.3.2 Percutaneous transluminal coronary angioplasty (PTCA)

In this procedure, coronary artery stenosis and occlusions are treated using angioplasty (balloon) catheters. A percutaneous approach is used, with puncture of a peripheral artery. The ostium of the coronary artery of interest is catheterized selectively using a guiding catheter. Through the guiding catheter, a guide wire with a very flexible distal tip, designed to be manipulated easily and safely in diseased vessels, is advanced through the area of stenosis. In some cases, is not easy to cross the stenosis or even to achieve a stable position in the coronary ostium as a consequence of anatomical variations among patients. An angioplasty catheter with a balloon diameter proportional to the size of the normal artery is placed in the stenotic segment over the guide wire and through the guiding catheter. The balloon is inflated with a contrast material solution to reach a pressure level at which the stenosis disappears. The procedure is complemented by insertion of a metallic prosthesis (stent), which is introduced to the area of the lesion in a very similar manner to that of the balloon catheter. There are clinical circumstances in which the stent is placed in a stenotic coronary artery without pre-dilation of the lesion. Depending on the particular circumstances, two or more arteries, each with two or more lesions, may be treated in the same session.

Patients may be scheduled for a combined CA and PTCA procedure. This generally occurs when the patient’s history of non-invasive cardiac testing indicates a significant possibility of

coronary artery disease or if previous CA images are inadequate. A single combined procedure is planned and the patient is prepared to have an immediate PTCA procedure if indicated by the results of the CA procedure. In case CA result is negative, no further procedure is carried out [IAEA SRS 59].

5.3.3 Percutaneous cardiovascular intervention (PCI)

PCI is defined as any type of interventional procedure performed on the coronary arteries. These procedures may or may not include a partial or complete CA procedure performed in the same setting. Fluoroscopy is used to place the catheters and to monitor the procedure. There are regional, institutional and individual variations on the definition of what views comprise a standard study. Additional views are often required if the standard study provides insufficient information to reach a clinical decision. Thus, there is a range of variability in the images collected during the performance of this procedure. PCI procedures are highly tailored to the clinical condition of the individual patient. Within this category one finds procedures ranging from the simple treatment of a single discrete lesion to a complete endovascular reconstruction of the entire coronary artery system. If the diagnostic angiogram is positive, the PTCA is usually performed immediately. Such combined procedures require more exposure than a simple diagnostic study or a separate simple PTCA, but usually require less radiation than that needed to perform two independent simple procedures [IAEA SRS 59].

5.3.4 Performance evaluation of interventional radiology equipment

The variation of patient exposure and clinical image quality is a result of combination of performance of the imaging equipment, selection of its modes of operation, and the complexity of the procedure. PMMA (poly-methyl-meth-acrylate) phantom of thicknesses 30cm x 30cm x20 cm was used for performance evaluation of the IR system. The key dosimetric parameters

are patient entrance surface air kerma (K_e), related image quality parameters i.e. high contrast detectability, spatial resolution, low contrast detectability and automatic exposure control (AEC) system. Automatic dose rate control systems are designed to image tissue and materials such as stents and iodinated contrast media in specific clinical contexts. Air kerma rates are best measured by placing only the air kerma meter and an appropriate thickness of PMMA in the beam. Equipment performance evaluation included calibration of all available dosimetric displays (e.g. K_a, P_{ka}) and the accuracy of operational displays (e.g. kV, mA, time). The performance of the equipment was found to be well within the tolerance limits as per AERB quality assurance protocol.

5.3.5 Complexity index

With increasing awareness about the use of DRLs in the field, many studies are undertaken in various countries. Considering the challenges faced in classification of procedures, wide range of observed dose parameters and difficulty in arriving at some reference values for common interventional procedures, there implies a need to take into account another important factor of complexity index, which is measure of clinical complexity involved in the procedure. However, as the present study has been performed on a small scale and without much support of physicians to understand the clinical aspects of the individual procedure the complexity index was not considered in this study.

5.3.6 Effect of patient weight on the results

Entrance surface air kerma, K_e, depends on the patient thickness. This is particularly true when automatic exposure control (AEC) is used to keep the dose to the image receptor constant, which requires compensation for the larger attenuation of heavier patients. Fluoroscopic and cinefluorographic patient entrance air kerma rates are decided by automatic control devices,

which manage beam parameters such as kVp, mA, pulse width and added beam filtration. In this study standard sized patients were selected for data collection and weight dependent variation in the P_{ka} values has not been considered. Studies shows that more than 50 % patient normally lies within the normal range of weight. P_{ka} values vary to almost more than double as weight increases from 50 kg to greater than 100 kg [IAEA SRS 59].

5.3.7 Patient data and local DRL

The details of patient (age, gender), procedure (CA/PCI), exposure parameters [average kVp, fluoroscopy time (mins), frame rate (frames/sec), number of acquisitions], and system displayed dose quantities [P_{ka} (µGy-m^2) and K_a (mGy)] were recorded. The data of 572 patients (374 CA and 198 PCI) was recorded and analysed to calculate 75^{th} percentile values of P_{ka} and K_a. Both male and female patients were included in this study. The complexity index and variation of dose with the weight of the patients were not considered as most of the selected procedures are standard and patient weights were within the range of 65 to 85 Kg.

Usually, 75^{th} percentile of dose quantities is designated as DRL. Recently there are studies and discussion regarding use of 50^{th} and 90^{th} percentile for establishing DRLs. However, in the present study conventional value of 75^{th} percentile is used. The criteria for selection of the percentile is decided on the basis of stage of DRL implementation. For the institutions first time using DRLs, if 50^{th} percentile is established as DRL, it is likely that most of the procedures or IR facilities may not comply and optimization will be difficult. Contrarily, if 90^{th} percentile is established as DRL, almost all the facilities will be complying with the established values and identifying bad practices will be difficult and purpose of DRL establishment will be defeated. Compared to both of the above choices, 75^{th} percentile is found to have a balanced

approach, where the facilities/procedures exceeding the value should review for possible reduction of doses. Hence in this study 75th percentile is usedfor establishing DRL.

5.4 Results

The kVp values recorded were within 76 to 92 kVp. Frame rate of 15 frames/second was used. The statistics of recorded data of CA and PCI are given in Table 5.2 and Table 5.3 respectively. Data of 374 patients undergoing CA procedures were recorded from selected hospitals and mean, median, standard deviation and 75th percentile were evaluated.

Table 5.2Statistics of data for coronary angiography (CA) procedures

Parameters	Number of patient (N)	Mean	Median	Standard deviation (SD)	Range	75th percentile
Age (Years)	374	56.44	56	12.6	28 - 91	---
Fluoroscopy Time (Mins)	374	5.67	3.5	6.2	0.6- 31.4	---
Cumulative Air Kerma K_a(mGy)	374	500.11	425.85	314.27	35.2 - 1954	590
DAP P_{ka}(Gy.cm^2)	374	25.70	21.05	21.85	4.86 - 106.36	34.1

Table 5.3Statistics of data for percutaneous coronary interventions (PCI)

Parameters	Number of patient (N)	Mean	Median	Standard deviation (SD)	Range	75^{th} percentile
Age (Years)	198	58.01	58	12.04	28 - 91	----
Fluoroscopy Time (Mins)	198	17.42	14.9	11.25	2.13 - 66.8	----
Cumulative Air Kerma (mGy)	198	1654.14	1454	860.85	294 - 5162	1930
DAP $P_{ka}(Gy.cm^2)$	198	114.93	111.47	75.71	10.56 - 423.65	134

Table 5.4 presents the local diagnostic reference levels for coronary angiography and percutaneous coronary intervention procedures in terms of KAP and cumulative air kerma. As indicated earlier the DRL is 75^{th} percentile of the data recorded for a given procedure.

Table 5.4 Local diagnostic reference levels for coronary angiography and percutaneous coronary intervention procedures

Procedure	Coronary Angiography	Percutaneous Coronary Intervention
$P_{ka}(Gy.cm^2)$	34	134
$K_a(mGy)$	590	1930

Table 5.5 presents comparison of DRL values reported by several investigators. The DRL values estimated in this study are also shown in this table. A close observation of the data indicates that DRL values for CA and PCI procedures ranges from 21 to 102 Gy.cm^2 and 50 to 193 Gy.cm^2. The DRL values estimated in this study lies well within the DRL reported in the literature.

Table 5.5Comparison of diagnostic reference levels for coronary angiography and percutaneous coronary intervention procedures expressed in KAP values (Gy.cm^2)

Study	DRL for CA	DRL for PCI
Present study	34	134
Siiskonen et al.	35.5	87.2
Brindhaban et al.	42	135
Sentinel study	45	85
UK	29	50
Belgium	71.3	106
Ireland	42	84
Croatia	32	72
Switzerland	102	125
USA	83	193
Greece	53	129
France	38	80
Uniyal et al	21.1	107

5.5 Discussion

The variations in the radiation doses incurred during PCI are observed to be larger than the variation of doses incurred in the CA procedures. The reason for variation in the doses are due to clinical complexity involved in the procedure, number of stents implanted and skill of the medical practitioner. The data presented in this study were collected from a few hospitals in Mumbai. The present data can be considered as a representation of Mumbai region and the local DRLs presented in this work can be implemented in the city. However, median of these data may not be the representative of the practices in the country. There is a need of conducting country wide survey for establishing national DRLs.

During course of present study, it was noted that the important parameters affecting patient dose readings used for establishment of DRLs are, lacking of proper nomenclature and categorization of procedure, identifying clinical complexity of procedure, grouping the data based on Body mass index or patient weight, accuracy and consistency of dose display quantities and importantly skill of medical practitioner. The entire cardiology team need to be involved in generation of data, analysis, review and possible improvements in the procedure. The uncertainty because of KAP meter performance can be reduced by periodic calibration. In the present study, the observed variation was 20%. When setting local DRLs, each institute should reduce this uncertainty by correcting the values with appropriate calibration coefficient.

The DRL derived in this study for coronary angiography is comparable to the values reported by the earlier study in India and other countries, however the DRLs derived in this study for PCI appears to be higher than the values reported from the other countries. This may be because, the patient doses in interventional radiology procedures have not been studied comprehensively and guidance for clinical practitioner is not available. CA being simpler

procedure and standardized, patient doses are more or less optimized and hence DRLs are comparable with reported values. Introduction of flat panel technology and dose reduction features in the recent years also have affected the patient doses [Pantos et al., 2009].P_{ka}valuescan be used to estimate the effective dose for adult patients using conversion factor as 1 Gy.cm^2 (P_{ka}) yields 0.18 mSv effective dose [IAEA SRS 59].

It appears that although these arevery common procedures all over the world many of the procedures are not expected to result in the skin injury. Further for optimization of the radiation dose, every institute need to establish the local DRLs for common procedures and review the radiation dose by comparing among various practitioners for improving safety culture. For interventional procedures it is important to understand that the reference levels are never meant for individual patients and are to be applied with flexibility to allow higher exposures if these are indicated by clinical judgment.

The reference levels suggested in this study as 75th percentile of P_{ka} values can be used by the institute for initial comparison of patient dose for optimization and can review the same after analysis of sufficient number of procedures. It is seen that the median values of P_{ka} i.e. 21 Gy-cm^2 for CA and 111 Gy-cm^2 for PCI are below the respective reference levels. Which implies the acceptability of the procedures in the selected institutions.

5.6 Conclusions

The results of the present study provided useful statistical data for CA and PCI procedures. However, the boundary between pure interventions and interventions involving some diagnostic runs is not easy to define in clinical practice. The 75th percentile of the dose distributions reported here provides a reasonable set of initial values. Table 5.4 presents suggested reference levels.

Individual facility should compare their mean values against these reference levels for standard procedures only. Investigation will be required if the facility's values are too high or too low compromising intension of the procedure. Reference levels are expected to change over time. They may decrease if equipment becomes more dose rate efficient or if clinical devices and techniques become more proficient. However, guidance levels may increase if the average clinical complexity of procedures increases. Very low patient exposure is not desirable if the clinical purpose of the procedure is compromised. For CA and PCI, too low a dose may indicate an incomplete procedure, inadequate image quality, low complexity or excellent technical settings.

Based on the data analysis, an initial PCI reference level of 135 $Gy \cdot cm^2$ and CA reference level of 34 $Gy \cdot cm^2$ is proposed. Action levels also should be established for Centres with mean values of procedures below the action levels should investigate the quality of their procedures and above the action levels procedures should be investigated for optimization. Till date there are no DRLs established for these procedures in India and this study could be used as an interim yardstick for other cardiac interventional labs in India until a large national study could be performed.

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Chapter 6

Investigation of skin reactions in complex interventional radiology procedures

6.1 Introduction

The use of fluoroscopically guided interventional radiology (IR) procedures are rapidly increasing as it helps in avoiding complicated invasive surgery and reduce hospitalization time [Pantos et al., 2009]. Nevertheless, as the complexity of the interventional radiology procedures increases, so do procedure time and concomitant cumulative skin dose, and therefore, the risk of skin injury [McCabe et al., 2011]. Radiation-induced skin damage has been recognized as a rare complication of fluoroscopically guided interventional procedures [Valentin et al., 2000]. The radiation doses in the complex procedures often exceed the threshold values for skin reactions in single or multiple procedures. Single procedure peak skin doses of the order of several tens of Gy have also occurred during IR procedure as reported earlier [Koenig, et al., 2001, Balter et al., 2014]. Manifestations of radiation injury to the skin range from mild erythema at low doses to dermal necrosis or chronic ulceration at very high doses [Koenig,et al., 2001]. Radiation skin reactions are not 'burns'; but they occur as a result of damage to the basal cell layer of the skin and the resultant imbalance between the normal production of cells in this layer and the destruction of cells at the skin surface [Khanna et al., 2013]. Erythema occurs as a result of capillary dilatation and resultant increased vascularity in the dermis [Khanna et al., 2013]. The exposure of the subdermal lymphatics as a result of loss of the superficial epithelium leads to moist desquamation, or after higher doses, skin necrosis

[Khanna et al., 2013]. It is essential that any damage is minimized, as far as possible, by ensuring that interventions are based upon best practice and supported by evidence based guidelines [Porock et al., 2001].

During any interventional procedure, the dose delivered to the patient is distributed over different areas of the skin based on beam directions used in the procedure and hence skin reactions are not observed in general. However, complex IR procedures may deliver doses which exceed the tissue reaction threshold to some areas of skin, causing skin injuries. Therefore, monitoring of patient doses in real-time would be helpful in predicting the occurrence of any tissue reactions. Thresholds for the nature and severity of radiation injury and period of its manifestation vary from patient to patient [Balter and Miller, 2014]. Patient related factors that increase susceptibility to radiation injury include auto immune and connective tissue disorders, hyperthyroidism, diabetes mellitus and compromised skin integrity among others [Miller et al., 2010]. National Council on Radiation Protection and Measurements (NCRP) recommends follow-up of patients who undergo IR procedures in which cumulative air kerma at reference point (K_{ref}) exceeds 5Gy in order to detect clinically relevant skin reactions (NCRP Report, 2010). The International Electrotechnical Commission (IEC) defines K_{ref}as the air kerma accumulated at patient entrance reference point which lies on the central axis of the beam, 15cm on the x-ray tube side of isocenter for isocentric IR equipment [IEC, 2010; Miller et al., 2010]. In this study, a comparative analysis was carried out for 6 patients who underwent complex IR procedures where K_{ref}exceeded 5Gy, to monitor the occurrence of skin reactions, if any. To the best of our knowledge, follow up studies of patients who received doses with potential to cause skin reactions in interventional radiology procedures are scarce. The objective of this study was to (i) compare the radiation induced skin

reactions, if any on 6 patients who underwent complex IR procedures and received K_{ref}above 5Gy, and (ii) experimentally validate the onset of skin reaction in one case and estimate probable causes of such reactions.

6.2 Materials and methods

6.2.1 Patient case studies

In the present study, comparative analysis of onset of skin injury was carried out for 6 patients (hereafter referred to as Patients #1 to #6) who underwent complex IR procedures. The complexity of procedures is considered based on time of exposure (fluoroscopy/ cine acquisition) and resultant radiation dose delivered. Out of six, five IR procedures were carried out by the same interventional radiologist. Two patients (#1 and #2) reported with suspected radiation-induced skin injury. Patient#1 developed skin reactions on the right mid forearm and gluteal region one month after embolization procedure for treatment of pelvic arteriovenous malformation (AVM). Dose records of patient #1 were not available in the system. The total fluoroscopy time for this patient was 90 minutes; and total skin dose was estimated to be approximately 8 Gy. The skin reactions were reported by the patient after a month of the procedure. Skin biopsy test and successive investigations carried out by the hospital showed that the patient has developed chronic radiation dermatitis (RD). Patient #2 reported skin reddening and desquamation within 24 hours of the ventricular pacemaker implantation procedure. The total procedure time was 101 minutes and the cumulative air kerma recorded in the IR system was5.7 Gy. This dose was delivered from three different angulations of the C-Arm, namely postero-anterior (PA), 30^0 left anterior oblique (LAO) and 20^0 right anterior oblique (RAO). In this case, skin reactions were visible in the various areas of the patient skin, not consistent with the irradiated area. Patient #3 to Patient #6 who underwent complex IR

procedures and received K_{ref}exceeding 5 Gy were followed up for a period of 2 years after the procedure to check for occurrence of skin reactions.

6.2.2 Estimation of peak skin dose

Anthropomorphic phantom and radiochromic film

The skin reactions in case of patient #2 were not concurring with the skin areas subjected to radiation exposure. Anthropomorphic phantom based experimental simulation was performed to estimate the peak skin dose and identify the skin areas which might have received dose above the skin reaction threshold. The dosimetric measurements were carried out on C-arm mount monoplane digital angiography unit (Artis Zee, Siemens, Germany) which was used for conducting the clinical procedure on patient #2. An anthropomorphic thorax phantom (Alderson Lung/Chest Phantom RS-320, Radiology Support Devices, USA) which extends from the neck to below the diaphragm was used. The phantom is moulded about a male skeleton, corresponding to the external body size of a patient, 5 feet and 9 inches (175 cm) tall and weighing 162 lbs (73.5 kg). The materials in the phantom cavity are equivalent to natural bone and soft tissues. Lungs are fixed in the inflated state and are moulded to conform to the pleural cavities of the phantom. The pulmonary arteries are injected with a blood equivalent plastic to simulate patient anatomy.

Gafchromic XR-RV3 dosimetry film (Ashland Inc. Covington, Kentucky, USA) was used to record and measure patient skin dose during interventional procedure. The film was calibrated in terms of air kerma in the range of 15 to1000 cGy using 80 kV x-ray beam with 3mm Al filtration. During calibration film samples were placed on 20 cm X 20 cm X 30 cm Perspex

phantom to simulate patient-equivalent backscattering conditions [McCabe et al., 2011]. The irradiated film samples were scanned using Epson Expression 10000 XL flatbed scanner.

6.2.3 Experimental set up

The performance of the IR equipment was tested using a calibrated multi-O-meter (UnforsRaySafe AB, Sweden) before conducting the experiment. The table top dose rate of the IR equipment was measured and verified with system displayed data. Based on the dose report of patient#2 stored in the IR system and inputs of the interventional cardiologist who performed the procedure, phantom exposures were carried out. The phantom was placed on the patient table reproducing the patient position for IR procedure. Gafchromic XR-RV3films are available in standard size of 14”x17”. A single sheet of film was cut into two sections, each of size 7”x 8.5” for better conformity to the phantom contours and was placed adjacent to each other on the anterior side of the chest. Film sections of size 7” x 8.5” were placed on lateral sides of the phantom and a single film sheet of size 14”x17” was placed on the posterior side. The phantom was irradiated using same angulations as in the case of patient #2and cumulative air kerma values delivered in each angulation was matched as closely as possible to the values recorded in the patient dose report. The irradiated films were scanned after 48 hours and peak skin doses were determined using the calibration curve.

6.3 Results

Table 6.1 shows the patient age, type of interventional procedure, total fluoroscopy time and cumulative air kerma at reference point of the 6 patients included in the present study. Patient #1 developed radiation dermatitis which initially presented as mild form of skin damage and

eventually became ulcer within a period of four months after the embolization procedure (Fig. 6.1).

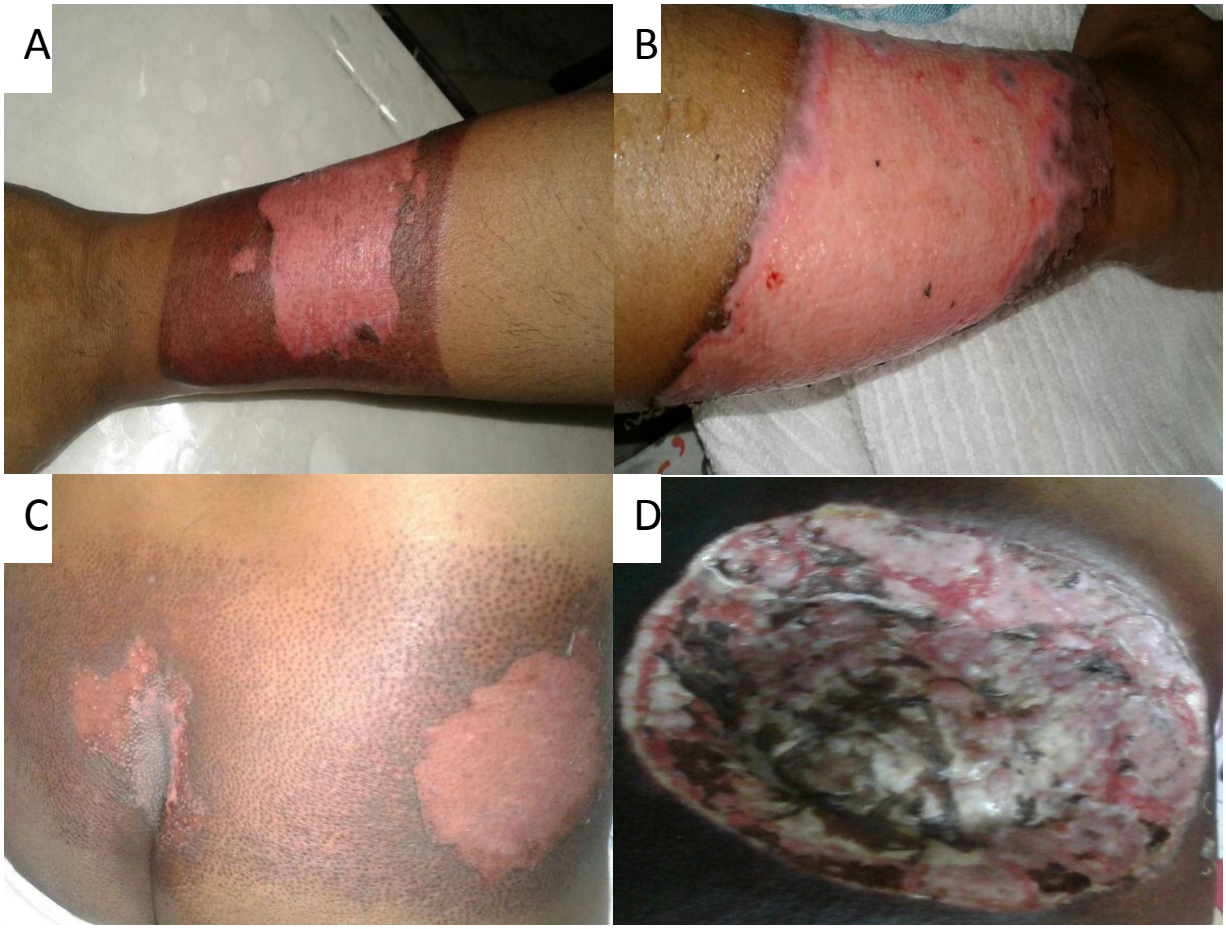

Figure 6.1 Skin reactions in patient #1 who underwent embolization procedure for pelvic AVM. (A) Skin reaction on right arm after a month of the IR procedure (B) Skin reaction in the right arm progresses (C) Skin reactions in the posterior and right lateral gluteal region (D) Skin reactions in the right gluteal region progresses to a non-healing ulcer

Exposure parameters of experimental simulation performed to estimate the peak skin dose and identify the skin areas which received maximum skin dose in case of patient #2 are presented

in Table 6.2. The analysis of exposed Gafchromic films showed that the lower right area of the back where radiation fields from all the three angles overlapped received maximum dose.The value of peak skin dose measured by Gafchromic film was 5.8 Gy. Even though this dose is higher than the threshold dose for skin reactions, no specific injuries were observed in the area of skin which received maximum dose. Reddening and peeling of skin of patient #2 were not specific to the area of radiation exposure but were noticed in other parts of the body. Patient #2also had predisposed skin condition. Patient #3 to patient #6 did not report any skin reactions after the procedure (followed up for 2 years).

Table 6.1Details of patients and interventional radiology procedures

Patient	Age	Procedure	Total fluoroscopy time (Minutes)	No. of cine acquisitions	Total cumulative air kerma (Gy)
Patient 1	55	Pelvic arterial embolization	90	--	*8
Patient 2	72	Ventricular Pacemaker Implantation	100.8	18	5.7
Patient 3	24	Uterine artery embolisation	36.6	38	5.2
Patient 4	58	Left Colic artery embolisation	36.7	27	7.1
Patient 5	52	Endovascular embolization	34.3	24	5.4
Patient 6	65	Fenestrated Endovascular Aortic Repair	322.9	60	19.9

* Estimated skin exposure

Table 6.2Operating parameters and recorded cumulative air kerma in anthropomorphic phantom study performed to determine peak skin dose in case of patient #2

Projection	Fluoroscopy		Cine acquisition		Cumulative air kerma (mGy)
	kV	mA	kV	mA	
PA	65	4	81	178	3990
LAO	68	3.8	85	130	684
RAO	70	3.6	87	116	1026

6.4 Discussion

Fluoroscopically guided interventional procedures are associated with a risk of radiation injury to the skin. Many a times, complex procedures require long fluoroscopy times which may cause significant increase inpatient skin dose. The skin dose in such cases might exceed the threshold limits for skin reactions. The threshold dose for transient skin erythema is 2 Gy[Miller et al., 2003]. In the present study, 6 patients who received dose exceeding this threshold limit were followed up for a period of 2 years after the completion of IR procedure. These cases were selected to compare the radiation induced skin reactions, if any, in these patients. Out of six, only two patients reported suspected radiation induced skin injury. The skin injury of patient #1 was diagnosed as chronic RD through biopsy test. The initial symptom of skin injury in the case of patient #1waserythema in the upper mid line and right lateral gluteal region. The right arm of patient #1 was also exposed during the procedure to radiation and skin reactions were observed on the arm as well (Fig. 6.1). The radiation induced erythema in the right gluteal region progressed to a non-healing ulcer and hence skin grafting had to be performed. The initial skin grafting was unsuccessful and hence the patient underwent repeated

skin grafting. The skin reaction on patient arm could have been avoided, if it was placed out of the primary beam.

Patient #2 reported with reddening and peeling off skin in areas exposed to radiation as well as unexposed areas within 24 hours of the IR procedure. An anthropomorphic phantom based study was performed to simulate the exposures performed in the case of patient #2.The results of the experimental study using phantom and XR-RV3 Gafchromic films enabled to identify the area exposed to maximum radiation dose due to overlapping fields. Reported skin condition of patient #2 was not consistent with areas exposed to radiation during the procedure. The dermatological tests confirmed that the patient has epidermal necrolysis. Hence in the case of patient #2 it was concluded that the skin reactions were not radiation induced. Patient #3 to patient #6 received entrance skin dose in the range of 5.2 Gy to 19.9 Gy and there was no reportable radiation induced skin reaction. In the case of patient #6, cumulative air kerma value was much higher compared to other patients included in the study. However, no skin reactions were observed in this patient. This may be attributed to the distribution of radiation dose in different areas of the body without overlapping the separate radiation fields, thus reducing peak skin dose [Balteret al., 2014].

The comparative analysis of 6 patients proves that the effect of radiation on patients undergoing complex fluoroscopically guided interventional radiology procedures delivering doses exceeding the threshold values for skin reactions is widely varying. The follow up study in patients who received doses exceeding the threshold for skin reactions indicates that factors other than radiation dose play a significant role in manifestation of radiation induced injuries. Obesity, diabetes, nicotine abuse, compromised skin integrity, skin type, autoimmune/connective tissue disease, hyperthyroidism and certain drugs are among many factors which affect the expression and severity of the radiation injuries [Jaschkeet al., 2017].

Individual differences in radiosensitivity exist in human populations, which could be caused by nucleotide variants of DNA repair genes [Matsuuraet al., 2016]. As radiation produces DNA damage, patients with impaired cellular DNA repair capabilities are at increased risk. Patients suffering from ataxia teleangiectasia, a rare autosomal-recessive disorder resulting from mutations in both copies of ATM(ataxia teleangiectasia mutated) gene, are predisposed to develop severe cutaneous complications after radiation exposure. It has been suggested that many patients with serious and unanticipated radiation injuries may be heterozygous for the ATM gene or possess some other ATM abnormality [Balter et al., 2010]. ATM heterozygocity occurs in approximately 1% of the general population [Balter et al., 2010; Hymes et al., 2006].

The present study had a few limitations. In the absence of dose records for patient #1, estimate of entrance skin dose was made from system technique factors, exposure rate during fluoroscopy and total fluoroscopy time. Cumulative air kerma values were used as surrogate for patient entrance surface dose for all the other cases. Since cumulative air kerma does not include corrections for scatter contribution, C-arm angulations, rotation or table movements, it may overestimate the skin dose. The exact cause of radiation injury induction in one patient out of 6 patients who received similar values of radiation dose could not be verified.

6.5 Conclusion

The present study of comparison of onset of skin reactions if any, of 6 patients who underwent complex IR procedures, concludes that individual-specific factors play a significant role in the onset/occurrence of skin reactions. Therefore an intensive assessment and analysis of intrinsic and extrinsic factors related to radiation sensitivity of patients prior to complex IR procedures

may help in preventing radiation induced skin injuries. The study also emphasize the significance of patient positioning during IR procedures so that extraneous body parts like arms would not be exposed in primary x-ray beam. Method of in-phantom dose measurement simulating the clinical conditions may be used in investigation of skin injury cases reported after complex interventional radiology procedure to identify the skin areas exposed and determine the dose delivered.

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Chapter 7

Estimation of occupational doses in interventional radiology practice

7.1 Introduction

Monitoring of occupational doses in the radiology facilities has become important after the introduction of fluoroscopy. The advancement in the technology has brought the better-quality images and invention of cinefluorography made it possible to use the x-ray equipment for guiding the catheter in the vascular and non-vascular interventional procedures. The medical professionals performing the IR procedures and assisting staff are required to be in the close vicinity of the patient (source of scattered radiation) during the procedure. Increasing clinical complexity of procedures may require longer fluoroscopic duration, leading to increased exposure to the patient as well as to the medical professionals associated with the procedure. Health benefits of these procedures to patients are extensive and undisputable; however, recurrent exposure to significantly high radiation doses of associated medical professionals is a matter of concern. The knowledge about various dose reduction features and radiation levels at various locations around the equipment in the different modes of equipment operation and beam angulations is necessary to reduce the occupational doses. Radiation protection measures are therefore necessary for all individuals who work in the interventional fluoroscopy suite. This includes interventional radiologist, technologists, nurses, and anaesthesiologists (who may be in the radiation environment only occasionally). All of these individuals may be considered as radiation workers, depending on their level of exposure likely to be incurred and regulatory

requirements. Monitoring of radiation doses to radiation workers is necessary and they should also be advised to use protection tools and accessories.

Fluoroscopically guided interventional procedures are performed in large numbers in India. There are around 1700 licensed IR facilities performing about 50,000 procedures annually as per data of the year 2017 taken from website of 'The Indian Society of Vascular & Interventional Radiology (ISVIR)' i.e. www.isvir.org. The radiation dose received by interventional radiologists may vary by a large magnitude for the same type of clinical case with different patients. Recently, there has been particular concern regarding occupational dose to the lens of the eye for interventional radiologists [Addendum to ICRP 103].

There are various methods of monitoring or estimating the radiation doses to occupational workers. Use of personnel monitoring devices is the most common technique. However, systematic and regular use of personnel monitoring badges is necessary otherwise estimation of the actual dose received will be difficult. Also, many of the physicians are associated as consultants to more than one institute and adding up of doses from all the institutions is difficult unless the physicians themselves inform it to regulatory body or use the same personnel monitoring badge all the time.

In the present work, for studying the trend of occupational doses to the personnel working in the IR facility Thermo-Luminescent Dosimetry (TLD) badges were distributed in the five institutions. It was requested to radiation professionals in the department to use TLD badges regularly and record the respective workload in terms of patient procedure details for a period of four months. However, due to lack of awareness and training of professionals, data collected was not of the appropriate scientific significance. Hence the TLD doses could not be correlated with the workload and respective personnel dose could not be estimated.

Later, an alternate method was used to estimate the radiation doses to the personnel working in IR, using radiation protection survey data and workload (number of patients and KAP values/procedure) of the particular medical professional in terms of procedures conducted. An examination protocol is generated in the IR equipment after every procedure which gives the details of operating potential, fluoroscopy time, number of cine runs, cumulative air kerma and KAP delivered from various angles during the procedure. Every angulation leads to different dose levels at medical professional's position in the IR room. The dose delivered from a particular angle decides weightage of that dose in the total dose received during the selected procedure. For estimating the dose per procedure, the survey readings of simulation and KAP delivered in various angulations from the exam protocol generated by the system was used. This method can also be used for the investigation of excessive exposures received by the radiation workers (for verification of personnel monitoring badge reading) retrospectively.

There are many uncertainties involved in the estimation of personnel doses in this method as practically there may be different positions of the personnel (compared to the positions used during radiation survey) , period of presence (full time or partial) and use of protective accessories are the variables compared to direct personnel dosimetry using individual monitoring badges. Similarly, NCRP Report 122 discuss about the uncertainties in the effective dose estimation using personnel monitoring badges owing to use of various formulas and its inaccuracies in the standardization. In this method the badges are calibrated with standard sized phantom which also needs correction while applying for individuals considering the variations in the weight, height etc. However, considering all the above practical limitations, there has to be some method to be used for estimation of occupational doses for improving the safety and ensuring the compliance to regulatory limits. In this study, an attempt was made to provide the gross idea about the order of doses received by the individuals working in the IR facilities.

The objectives of this work were (i) Estimation of doses for all in-room personnel using radiation levels and Optically Stimulated Luminescent dosimeters (OSLDs), (ii) Comparison of occupational doses measured by OSLDs and simulation experiment and (iii) Investigation of the contribution of fluoroscopy and cine radiographic mode of exposure using irradiation time and dose rates.

Luminescence is a phenomenon of emission of light by certain class of materials. Among the various categories of luminescence, thermo luminescence (TL) and optically stimulated luminescence (OSL) are the ones in which emission of light takes place during stimulation of an irradiated material through thermal and optical means respectively. OSL is relatively new technique for radiation dosimetry that was originally developed for geological / archaeological dating [Huntley et al. 1985]. Over several decades TL is being practiced as an established method for radiation dosimetry. However, of late, in the international scenario OSL based dosimety is being increasingly adopted in various branches of radiation dosimetry which includes personnel and environmental monitoring, medical dosimetry etc. The reason for this being several advantageous features of OSL over TL technique like fast and multiple readouts, absence (no) of thermal quenching, high sensitivity and dose re-estimation in a simple manner. OSL dosimetry thus is a viable alternative to the existing TL dosimetry program. [BARC Newsletter BARC newsletter founder's day special issue 2015].

7.2 Material and methods

The x-ray systems used in the study are given in Table 7.1.

Table 7.1 Details of interventional radiology equipment used for survey measurements

Sr. No.	Model
Hospital -1	Artis Zee FMSIR, Siemens Ltd., Germany
Hospital -2	Intus, Philips Healthcare, Netherlands
Hospital -3	Artis Zee, Siemens Ltd., Germany

Performance verification of interventional radiology equipment was carried out using standard protocols prior to conducting an extensive radiation survey of the IR facility. A tissue equivalent phantom was used to simulate the patient. A stand with lead apron was placed at the primary operator's (medical practitioner) location. Two pairs of OSLDs were fixed inside and above the apron at the chest level as shown in Fig. 7.1. Typical examination protocols of coronary angiography (CA) and percutaneous transluminal coronary angioplasty (PTCA) were analysed from all the three hospitals and various beam angles used in these procedures were noted. The primary operator (cardiologist), assisting physician, technologists and anaesthesiologists' positions were decided with the guidance of IR staff and setting of IR facility. Distance to all these locations was measured and noted. Radiation levels at above positions were measured from the phantom (source of scattered radiation) for fluoroscopy and cineradiography mode at all the locations using Xi survey meter (Raysafe AB, Sweden). The built-in protective accessories of the IR equipment i.e. couch hanging lead rubber flaps and ceiling suspended lead glass was in place during the radiation level measurements. Personnel protective accessories i.e. lead apron and thyroid collar were used for primary operators' position. At all other locations, survey meter readings were recorded without protective

accessories. These readings were corrected using apron transmission factor. The OSLD measured dose values and personnel doses estimated by radiation survey at primary operators' position were compared.

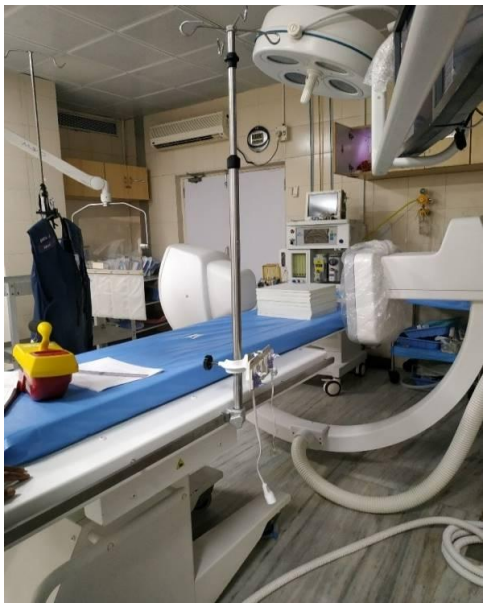

Fig 7.1 Positioning of lead apron with stand for estimation of dose to medical practitioner.

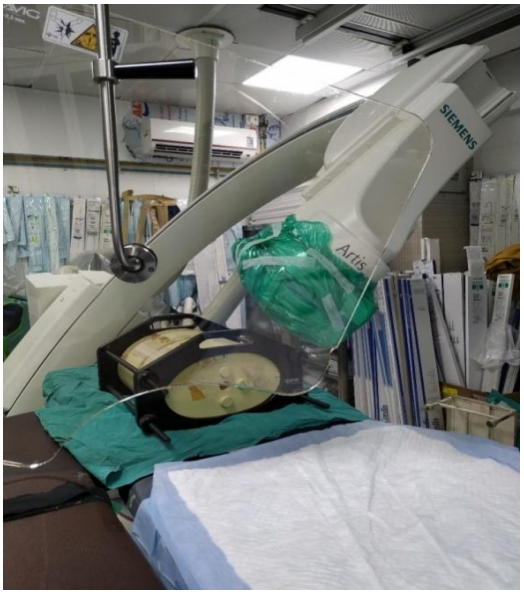

Fig. 7.2 Simulation experiment with phantom for radiation survey

7.3 Results and discussion

The average radiation levels at various locations in the IR facility in fluoroscopy mode and cineradiography mode are given in Table 7.2 and Table 7.3 respectively. It is observed from the data in these tables that the radiation levels in fluoroscopy mode are considerably lower than the radiation levels during cineradiography mode. Hence, small reduction in number of cine images/time can make the considerable difference in the doses incurred compared to curtailing of fluoroscopy time. Thus, the same should be used to extract as much information as possible.

Table7.2 Radiation levels at various locations for different C-Arm angulations in fluoroscopy mode

	Radiation level in mSv/hr (fluoroscopy mode)			
Angulations used during procedures	Primary operator (50-70 cm from phantom)	Assistant physician (1.3 m from phantom)	Technologist (2m from phantom	Anaesthesiologists (3 m from phantom)
AP $0^{0,}$ Cranial 30	0.6	0.112	0.010	0.240
LAO 50, Cranial 25	0.7	0.28	0.021	0.7
LAO 40, Caudal 40	1.2	0.32	0.042	0.68
RAO 30, Cranial 30	0.62	0.3	0.23	0.45
RAO 30, Caudal 30	0.85	0.32	0.049	0.56
LAO 30, Cranial 30	0.9	0.39	0.035	0.6
RAO 30, Cranial 0	0.340	0.178	0.011	0.200
Lateral 90 (Right)	0.9	0.75	0.157	--
Lateral 90 (Left)	3.5	2.0	0.25	--
Average dose rate	1.06	0.51	0.089	0.49

Table 7.3 Radiation levels at various locations for different C-Arm angulations in cine radiography mode

	Radiation level in mSv/hr (Cine radiography mode)			
Angulations used during procedures	Primary operator (50-70 cm from phantom)	Assistant physician (1.2 m from phantom)	Technologist (2m from phantom	Anaesthesiologists (1.5 m from phantom)
AP $0^{0,}$ Cranial 30	1.39	0.380	0.032	0.7
LAO 50, Cranial 25	2.6	1.15	0.068	2.6
LAO 40, Caudal 40	3.2	1.41	0.120	2.2
RAO 30, Cranial 30	1.6	0.95	0.074	1.65
RAO 30, Caudal 30	1.73	1.4	0.122	1.75
LAO 30, Cranial 30	2.5	1.64	0.100	2.2
RAO 30, Cranial 0	0.75	0.55	0.036	0.56
Lateral 90 (Right)	3.1	2.0	0.5	3.0
Lateral 90 (Left)	11	5.8	0.590	6.0
Average	3.09	1.69	0.18	2.29

By knowing the information about fluoroscopic time, fluoroscopic KAP, cine radiographic time and cineradiographic KAP, the average dose per procedure can be calculated using instantaneous dose rates. A typical analysis of CA and PTCA protocols is given in Table 7.4.

Table 7.4Kerma area product distribution in fluoroscopy and cine radiography mode for CA and PTCA procedures

	Fluoroscopy mode	Cine radiography mode	Total KAP
Coronary angiography	1243 (3.2 min)	3264 (0.65 min)	4507 (3.85 min)
percutaneous transluminal coronary angioplasty	4262 (20.4 min)	2800 (1.2 min)	7062 (21.6 min)

These values along with radiation survey data (radiation levels) given in Table 7.2 and Table 7.3 are used for dose estimation, an example of the same is given below:

(Measured dose rate-fluoro) x (Fluoroscopy time) + (Measured dose rate-Cine) x (Cine time)

[1.06mSv/hr x 0.053 hr] + [3.09 mSv/hr x 0.010 hr] = 0.05618 + 0.0309 = 0.087 mSv/procedure

The estimated effective doses /procedure for typical procedure protocols of CA and PTCA are given in Table 7.5.

Table 7.5 The effective doses /procedure for typical procedure protocols of CA and PTCA

Personnel	CA	PTCA
Cardiologist	20 µSv/procedure	32 µSv/procedure
Assisting physician	16	22
Technologist	8	10
Anaesthesiologist	--	--

Table 7.5 shows that the estimated mean effective dose per procedure to the primary operator is 20 µSv (ranges from 8 to 40 µSv) for CA procedure and 32 µSv (ranges from 14 to 54 µSv) for PTCA procedure (calculated using sample of 12 procedures each).

The personnel radiation doses using OSLDs was measured and found to be 6.8 mSv/year for interventional cardiologist. The estimated personnel dose by radiation survey-based assessment was found to be 7.5 mSv. The OSLD readings were extrapolated for the similar workload that was used for dose estimation by radiation survey method. The results by both the methods were in close compliance; this indicates the reliability of dose estimation by radiation survey-based assessment in the absence of direct personnel dosimetry.

The studies performed in the field of invasive cardiovascular procedures over the past 2 decades have revealed that there is an increased exposure to both patients and to medical personnel. Between 1987 and 2006, exposure to medical radiation increased from 0.6 mSv per year to 4 mSv per year [National Council on Radiation Protection and Measurements, 2009]. Patient exposure during an interventional cardiology procedure averages 8 to 10 mSv, with some complex procedures using substantially greater doses. Interventional

operators receive an average effective dose of 1.2 μSv per procedure for femoral access and 2.3 μSv for radial access. Consequently, a busy interventional cardiologist performing 300 procedures a year with 80% radial access may accumulate 0.6 mSv occupational exposure in a year. Over a 30-year career, an operator would incur an exposure of 18 mSv [Taisei et at. 2017].

The results for this study were found to be on higher side of the published values. The eye lens doses measured for primary operator without lead glasses was found to be 16 μSv per procedure in the present study. The estimated annual effective dose for a busy interventional cardiologist was found to be considerably lower than the recommended occupational dose limit of 20 mSv/year, averaged over 5 consecutive years and 30 mSv in any single year as prescribed by the AERB.

7.3.1 Protective accessories transmission

Protective apron of 0.5 mm Pb equivalence attenuates almost 90-95 % of scattered radiation for 80 – 100 kVp x-rays. Leaded glass (eye wear) attenuates the dose to the operator's eye by approximately 80-90%. Combining various types of shielding (i.e., couch-suspended drapes, ceiling-suspended screens, aprons, leaded glasses, and thyroid collar) results in a dramatic dose reduction for the operator.

Murphy et al. [1993] found a transmission factor of 3% for lead aprons of 0.3 mm in the primary beam of 80 kVp. Vano et al. [2006] found a fraction transmitted through 0.25 mm lead aprons between 3.3% at 70 kVp and 5.7% at 80 kVp. Christodoulou et al. [2003] reported about transmission fraction ranged from 4.3% up to 10% through lead aprons of 0.25 mm at a tube potential of 70 kVp.

The minimum thickness recommended by the IAEA [IAEA-PRTM-5, 2004] for lead aprons of radiologists performing interventional procedures is 0.35 mm. In the present study the doses were measured with 0.5 mm Pb equivalent apron with transmission factor of 10 %.

Niklason et al. [1994] measured doses under lead aprons of 0.25 and 0.5 mm. The average annual dose under the lead apron reported by Niklason et al. was 0.88 mSv, while in the present study the average annual dose was 10 mSv for primary operator (medical practitioner). Results reported by Williams et al. [1997], the differences in doses were probably caused by the variation in thickness of the lead aprons worn by the radiologists and relative positions inside the IR room.

Efstathios et al. [2003] published the values of fluoroscopy and cine contributions to the radiation doses of the patient and operator and found to be 66% of total KAP during CA procedures is attributable to digital cine that contributes only 23% of the total exposure time. Regarding PTCA, the contribution of digital cine is 43% to KAP and 9% to total irradiation time, respectively. Thus, minor changes in digital cine time may result in substantial reduction of the radiation received by the patient as well as operator.

7.4 Conclusions

The study of estimation of occupational doses by means of radiation survey and using OSLDs has similar results. The annual doses estimated for primary operator (medical professional) and other staffs of IR facility are well within the annual dose limit for occupational workers as prescribed by AERB. The positions in which interventional operators stand relative to the x-ray beam are largely determined by the procedures performed. Cardiologists carrying out CA and PTCA procedures need to stand closer to the area being imaged when introducing catheters via the radial artery route than when they use a femoral access route. As a result, operators will

tend to receive higher doses for radial access procedures. However, the radial route may have advantages for patient management that outweigh the higher dose to the operator. In interventional radiology, femoral access is used for the majority of procedures, but for percutaneous procedures such as biliary stent or drainage, the operator will need to stand closer to the region being imaged, so the scatter dose will be proportionately higher than that for other procedures. All these factors contribute to the variations in dose between different studies. [Martin et al., 2011]

Regular monitoring of organ doses is generally impractical; hence protection can be provided more readily, use of built is safety accessories would help to maintain the doses as low as reasonably practicable (ALARP) is a better option. Regarding radiation exposure, coronary intervention is considered a quite safe procedure for both patients and personnel working in IR facility while ensuring the use of appropriate protective accessories and training of the operators.

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Chapter 8

Establishment of national radiation protection programme

8.1 Introduction

Radiation safety is the concern of all health care providers who particularly works in the field of interventional radiology, whether for diagnostic purposes or therapeutic procedures. In recent years there is an increasing awareness in the public for limiting patient radiation in such procedures. Likewise, medical professionals involved in the procedure are at risk for radiation compounded by long procedures and multiyear careers using radiation procedures as part of occupational exposure [Gautam et al., 2016].

Over the years, there have been various equipment modifications. The initial focus was to improve image quality by increasing radiation intensity however, now a greater focus is on limiting patient exposure in theprolonged procedures. The modern fluoroscopic x-ray equipment are able to provide excellent image quality with lower x-ray exposure. However, despite these improvements, radiation remains a risk for associated medical personnel and patient. By understanding the probable effects of radiation in this practice, a comprehensive radiation protection programme is required to be implemented in the country. The studies undertaken in the present thesis were targeted to identify the gap areas of regulations in the IR practice to improve the radiation safety status of patient as well as associated medical professionals.

8.2 Regulations in India for interventional radiology practice

In India there is a regulatory framework for ensuring overall radiation safety in the field of diagnostic radiology. The practice specific requirements are given in AERB safety code on 'Radiation Safety in the manufacture, supply and use of medical diagnostic x-ray equipment'. The license for operation is issued based on verification of compliance with the safety requirements. The overall radiation safety in the field comprises of (i) built in safety of equipment and (ii) operational safety requirements to be followed while operating the equipment. The regulations are focused to ensure built-in safety in the use of IR equipment. However operational safety is the responsibility of the employer and associated medical personnel in the IR facility. The mandatory requirements that are verified prior to issuance of License are, design approval of IR equipment (type approval), layout approval ofIR facility, satisfactory acceptance test reports, availability of radiological safety officer (RSO), qualified operator, medical professional and personnel monitoring service (TLD badges) to all the radiation professionals. Additionally, there is a requirement of conducting periodic quality assurance and submitting safety status report to AERB annually. The facilities are also subjected to regulatory inspections for verification of compliance to regulations. Further for introducing the specific patient safety requirements by means of optimization of procedures, AERB has made it mandatory to provide kerma area product (KAP) meter and protective accessories during supply and installation of the IR equipment. Presently there are around 1700 IR equipment licensed by AERB.

As per present regulatory framework, there is no direct concern for the patient radiation doses being the part of medical exposure. This is the responsibility of the Licensee to ensure all the planned procedures are justified and optimized for individual patient doses. However, in most

of the facilities, licensee is not aware about this requirement and there is no confidence that the operational safety requirements are followed even in the Licensed IR facilities.

During the studies for patient dose monitoring (system displayed KAP and cumulative dose), skin dose measurements, quality assurance, incidence analysis and occupational dose estimation, certain important observations are noted. These observations are consolidated and revisions are proposed in the existing regulatory requirements for improvement in the radiation safety culturein the IR practice. The following sections enumerate the specific operator and personnel approaches to minimize overall radiation risk. A review of these preventive strategies is important to re-emphasize the personnel responsibilities for radiation protection.

8.3 Management responsibilities

Management is responsible for providing an appropriate level of resources, such as staff, facilities, and equipment, to ensure that radiation dose is adequately controlled. Facilities and equipment includes shielding, radiation monitoring instruments, protective clothing etc. Quality assurance is an essential component of any monitoring program, management should ensure provision and facility for the same. Occupational doses should be analysed by each department; high doses and outliers should be investigated for corrective and preventive measures. Protective aprons should be examined fluoroscopically every year and inspected visually on a daily or weekly basis for damage and defects. Standardized methods for acceptance testing of protective aprons should be followed as there is wide variation in actual attenuation values of aprons. Local safety committee should be responsible for above responsibilities. A radiation protection program should be prepared and implemented in all the IR facilities.

8.4 Probable radiation effects to the medical professionals

Interventional cardiologists/radiologist and cardiac catheterization laboratory personnel are repeatedly exposed to ionizing radiation in the course of their duties. In addition to cardiologists, in today's practice many other medical professionals such as echo-cardiographers, cardiac surgeons, and anaesthesiologists are frequently close to the x-ray field. Therefore, minimizing radiation exposure is of utmost importance.

Significant radiation exposure has the potential to impact the health and well-being of the medical professionals associated in the IR facility.Thebiological effects of radiation exposure are described in terms of stochastic and deterministic effects.

The stochastic effect is the non-threshold biological effect of radiation that is possible at any lowest doses and even due to natural background to a population of persons. The probability of occurrence is proportional to the dose and its severity is independent of the dose. Developing malignancy due to radiation exposure is a stochastic risk.

The deterministic effect is a dose-dependent direct health effect of radiation for which a threshold exists. The threshold values of various deterministic effects depend on tissue sensitivity. Developing a skin burn as a result of a prolonged case is a deterministic effect.

Typically, in the occupational workers (primary operator) the data published for evidences of brain tumors, cataracts (specifically posterior sub capsular), thyroid disorders, cardiovascularеffects, and reproductive system effects[Gautam et. al, 2016].

Patients undergoing IR procedures are at higher risk for all the above effects. Radiation-induced hair loss and injuries of the skin and subcutaneous tissues are collectively termed

"tissue reactions" (deterministic effects) and are rare complications of prolonged fluoroscopic procedures. Tissue reactions may be graded based on its severity and complications. The most probable tissue reactions are the skin reactions in the region of higher exposures in the complex and prolonged procedures.

8.5 Probability of skin injury

The highest radiation dose to the skin occurs at the point of entry of the x-ray beam and that becomes the likely area for skin injury. If the beam is entering through the posterior surface (back of the patient), the entry port on the back will become the most likely area for radiation injury when the radiation dose to skin exceeds the dose threshold for skin injury. The radiation intensity is typically 2 to 3 times higher for lateral and oblique views as compared to anteroposterior (AP) and posteroanterior (PA) views. Breast tissue in the beam will increase the thickness of the imaged part of the patient's body and will lead to an increase in exposure parameters (kV, mA) and beam intensity. Thus, one should avoid breast as the point of entry for the x-ray beam. On the other hand, the intensity of the exit beam is only about 1% of the intensity of the entrance beam. Directing the beam from the posterior surface rather than the anterior, whenever feasible and if it does not interfere with clinical purposes, will reduce the chances of breast skin injury during interventions in the chest region.

8.6 Monitoring radiation exposure

Radiation dose or exposure to the patient is usually described in terms of the following parameters:

1. **Fluoroscopic time (min):** This is the time during a procedure that fluoroscopy is used but does not include cine acquisition imaging. Therefore, considered alone, it underestimates the total radiation dose received.
2. **Cumulative air kerma (Gy):** The cumulative air kerma is a measure of radiation dose delivered to air at the interventional reference point (15 cm from the isocenter in the direction of the focal spot). This measurement has been closely associated with deterministic skin effects.
3. **Dose-area product ($Gy.cm^2$):** This is the cumulative sum of the instantaneous air kerma and the x-ray field area. This monitors the patient dose burden and is a good indicator of stochastic effects.

8.7 Notification and reference levels

Notification levels are intended to make the operator aware, during the procedure, of the cumulative radiation used. This is proposed at cumulative dose of 3 Gy. The substantial radiation dose level is a trigger level for certain processes and follow-up measures and happens at 5 Gy. It is not an indicator of a tissue reaction or a predictor of the risk of a stochastic effect but is intended to alert providers to the possibility of a tissue reaction.

In case a patient receives radiation substantially higher that the notification level, same should be documented in the respective clinical case file. Patient and relatives should be counselled for probable radiation effects and follow up should be carried out based on expected tissue reactions. If a tissue reaction is identified, the patient should be referred to an appropriate doctor for management.

Every IR facility should establish local DRLs for commonly performed procedures. These DRLs should be periodically reviewed and compared with regional or national DRLs for possible improvements and minimizing patient doses, Periodic workshops, seminars and training programs should be organized by professional associations for mutual communications and betterment of the practice.

8.8 Minimizing x-ray exposure

For every justified IR examination, radiation doses to patient as well as operators should be "as low as reasonably achievable". The level of protection should be the best under the prevailing circumstances, maximizing the margin of benefit over harm. Imaging requirements depend on the specific patient and the specific procedure. Moreover, all the modern imaging equipment are capable of producing much better image quality than adequate image quality at the cost of additional radiation dose without additional clinical benefit. Lowering of doses significantly may lead to loss of clinical information expected in the procedure. Hence the presence of medical professional (Doctor) is very much important for optimization of patient doses by defining the adequate image quality. The common dose reduction strategies to minimize the radiation exposure are discussed in this chapter.

8.8.1 Precautions to minimize exposure to patient and operator

- Utilize radiation only when imaging is necessary. Avoid allowing the "heavy foot," to step on the fluoroscopy pedal while not looking at the image.
- Minimize use of cine radiography. "Fluoro-save" has a <10% radiation exposure of cineangiography.

- Minimize use of steep angles of x-ray beam. The left anterior oblique (LAO) cranial angulation has the highest degree of scatter exposure to the operator.
- Minimize use of magnification modes. Most modern systems have software magnification algorithms that allow for magnification without additional radiation. In modern machines, there is a "Live Zoom" feature without significant degradation of the image.
- Minimize frame rate of fluoroscopy and cine. Ensure that complex/long cases are performed on the 7.5 frames/sec fluoroscopy setting. A reduction of the fluoroscopic pulse rate from 15 frames/sec to 7.5 frames/sec with a fluoroscopic mode to low dose reduces the radiation exposure by 67%.
- Keep the image detector close to the patient (low subject-image distance).
- Utilize collimation to the fullest extent possible. In a room with a peripheral-compatible large flat panel detector, ensure that this is collimated to the field of view adequate for coronary procedures. Modern system has feature of virtual collimation that suggests the possible collimation of the area based on intensity pattern.
- Monitor radiation dose in real time to assess the patient's risk/benefit ratio during the procedure.

8.8.2 Precautions to Specifically Minimize Exposure to Operator

- Use and maintain appropriate protective lead garments. Consideration should be given to ceiling suspension or floor-mounted personal radiation shielding for enhancing radiation protection.

- Maximize distance of operator from x-ray source and patient.
- Keep above-table (hanging) and below-table shields in optimal position at all times. A larger ceiling-mounted shield with attached lamellae, used in combination with a drape, decreased exposure to the operator by half.
- Keep all body parts out of the field of view at all times.
- Use personnel monitoring device (TLD badges) regularly. If possible, use eye dose monitors.

8.8.3 Precautions to specifically minimize exposure to patient

- Keep table height as high as comfortably possible for the operator.
- Every 30 minutes, vary the imaging beam angle to minimize exposure to any specific skin area
- Minimizing steep LAO and anteroposterior cranial angles
- Keep the patient's extremities out of the beam.

8.9 Outcomes of the study

During the course of studies, there were two cases reported for excessive exposures to the patient leading to severe skin reactions. Investigation of the same and follow up of patients revealed that there is a pressing need for patient dose monitoring and follow up of patients exceeding the threshold values. It was evident that, neither patient nor medical professionals are aware about the probable effects of radiation. There may be a greater number of un-reported injuries in the field which are not addressed appropriately. While investigating these cases it was noted that the patient dose monitoring and recording system was not enabled in the IR equipment, although that was one of the renowned institutes in the country. Similar observation was repeated while carrying out the study for DRL establishment. This reveals that

verification of implementation status of the patient dose data recording requirements is necessary, the same has been recommended to be added in the inspection checklist of IR facilities. Sample audits also can be conducted periodically in different regions of the country.

During the course of data collection and analysis, it was observed that the range of P_{ka} (KAP) values of similar procedures is very high. There are many parameters responsible for this observed variation: The higher values were due to clinical complexity or untrained (fresher) medical professionals performing the procedure (lack of experience). It was also observed that even a small guidance of experienced professionals could simplify the procedure and reduce the overall fluoroscopy ON time. Hence it is suggested that the presence of at least one experienced medical professional is desirable when new entrants in the field are carrying out the procedures.

Contrarily, very small procedures were the result of improper accessories, rescheduling of patient due to lack of clinical management (routine medication was not ensured), un availability of required accessories(appropriate size of stents, catheters, balloons etc.), which lead to abrupt end of the procedures without desired clinical output. Patient needs to be rescheduled for the same procedure and the incomplete procedure results in total unnecessary radiation dose to the patient and operator. It is recommended to follow a pre-procedural checklist to ensure the correctness of the procedure for every patient.

It was observed that, the similar procedures carried out in the same institute, with the same equipment and similar clinical complexity also leads to a considerable variation in the radiation doses owing to different medical professionals with varying expertise and protocols followed. The establishment of DRLs may help in comparing and optimizing such procedures.

The patient registry maintained in the IR facility is not the part of clinical case file of the patient. The patient data recorded by technologists is not verified by the concerned medical professional. There observed a large variation in the recording of procedure details. This makes the authentication of data further more difficult to group and analyse. It is recommended to prepare a standard list of procedures and should be made available in the dropdown for selection. Similarly the radiation dose quantities displayed on the monitor should be practitioner friendly i.e easy to understand. On the live screen during procedure only relevant information for knowing the doses should be displayed.

Estimation of occupational doses was a useful exercise and found to be beneficial for investigation of excessive exposure cases in the IR practice. Although the use of personnel monitoring badges was not sincerely followed at many institutions and actual dose measurement was not possible in the absence of factual data, study provided adequate confidence that the annual occupational doses in this field are within the regulatory limits with the assumption that all the required protective accessories are available and used.

Practically, there exist a gap between the technical knowledge required for optimization of IR procedures considering QA, radiation safety and technological aspects and the available IR team of medical professional, IR technologist and nursing staff. Hence it is recommended that a medical physicist should be available in the IR department.

8.10 Conclusion

A national radiation protection program is an essential part of the quality management for the catheterization laboratory. This requires coordinated and collaborative effort involving physicians, staff, medical physicists, and hospital administration. Interventional cardiologists

are an essential part of this process and need to ensure the best possible outcomes for themselves and for the patients. The national radiation protection program identifies the responsibilities of the stakeholders of the practice i.e IR facility, supplier and regulatory body.

The programme should comprise the following:

- Licensing of IR equipment and facility – IR management and Regulatory body
- Radiation safety training based certification to be mandatory for every personnel to work in IR facility - IR management and Regulatory body
- Improved wall hanging or floor-mounted personal shielding and robotic cardiac catheterization laboratories need to become a standard of care –Supplier and IR management
- Acceptance testing and patient specific tailoring of protocols – Supplier, medical physicist and medical professionals.
- Ensuring periodic quality assurance and patient dose monitoring – Medical physicist
- Counselling of patient undergoing complex IR procedure for post procedure care – Medical professionals and patient relatives.
- Establishing and periodic review of Diagnostic Reference Levels (DRLs) – Associations, medical physicist, medical professionals and regulatory body.
- Periodic audits for ensuring implementation of DRLs – Regulatory body and associations.

The collaborative efforts of all the above professionals are necessary for success of radiation protection program in the country. Further, skill of the medical practitioner, knowledge about

the equipment and inclination towards radiation safety are the key parameters for minimizing radiation exposure to the patient and the operators.

Further, this study clearly indicates that there is a need to establish national DRL in IR where AERB can play an important role by encouraging the interest groups to take up the assignment and come forward with recommendations for common IR procedures. In addition, AERB may also insist the institutions to implement the recommendations of the interest groups which is the favour of patient as well as occupational workers.

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Chapter 9

Summary and Conclusion

9.1 Introduction

This chapter summarizes the work undertaken in this thesis. This includes the aim and objectives of the present work, an overview of international scenario in this field and various methodology and experiments performed towards achieving desired results. The discussion on the results and observations brings out the comparison among the procedures and practices followed. The practice of interventional radiology has increasedmulti-fold in numbers and its applications during last few decades. The exponential growth in the number of procedures also brought the radiation safety concerns for the healthcare professional associated with the use of such equipment. The patients are also at relatively higher risk of developing malignancy and in certain complex procedures there is a probability of skin reactions. There is a concern of developing cataract for the medical professionals with heavy workload of performing IR procedure. Studies are also being performed to analyse any such effects due to use of radiation. Organ dose measurement for radiation professionals and patients is currently being undertaken in this field.

Obviously known reasons for such higher doses are (i) clinical complexity (ii) longer procedure and x-ray beam on time, and (iii) medical professionals are required to stand near the patient and to the source of radiation. Lack of awareness about radiation safety measures is also an important parameter for the reported higher doses in these procedures. Moreover, many professionals other than interventional radiologists such as cardiologists and neurologists, who do not have adequate knowledge about radiation safety, are also involved in the use of these

equipment. Hence, the radiation safety measures for patients as well as medical professionals are not followed in many of the facilities. In India, as on date, there are limited studies conducted in this area, however many people are now showing interest to initiate such studies for improving radiation safety of patients.

The aim of the study was to carry out a comprehensive assessment of the practice to understand the various factors (technological, technical, administrative and operational) that contributes to the higher doses and possible measures for reduction of patient and professionals doses. The actual study of the practice needs a large sample size considering geographical distribution of facilities, number of facilities, type of IR equipment (make, model, and technology), number of patient's data collection, operational safety status in practice, administrative measures in place and importantly compliance to the local regulations. This need involvement of many professionals and longer time to verify the compliance, analysis of data and generating the results, this was not possible with the limitations of time, manpower and access to various facilities. Hence, a small-scale study was designed and performed to cover all the aspects with sample of representative number of facilities.

Literature survey helped to understand the current practice of imaging modalities, relative concern of radiation doses and various dose measurement quantities used in different modalities. There are number of quantities defined for this purpose such as absorbed dose, equivalent dose, effective dose and patient specific doses are expressed using special quantities such as skin entrance dose, mean glandular dose, dose length product, computed tomography dose index and dose area product depending on dose delivering technique, tissue involved and

other parameters. Further the quantities used for establishing DRLs and their units for measurements are described.

As pre-requisite to carry out any studies, performance verification of IR equipment is necessary. Studies were carried out to verify the performance status of IR equipment and to review their adequacy in the light of increased radiation safety concerns. The performance status of 39 IR equipment of different make and model in Mumbai, Pune and Coimbatore from 24 institutions were verified as per established QA protocol, the same protocol is followed by Atomic Energy Regulatory Board (AERB), Mumbai for verifying type approval testing of interventional radiology equipment. Additional tests for accuracy and consistency of KAP meters were also performed. On the basis of the data acquired in this study, the QA protocol has been revised by incorporating the additional tests for improving the patient and operator safety. The recommendations for additional requirements with supportive data will be provided to national regulatory authority for consideration in revising regulation in the IR practice.

Skin dose measurements were carried out using Gafchromic XR-RV3 film. Films were calibrated and used for peak skin dose measurements in the coronary angiography and percutaneous coronary intervention. Sixty-four interventional cardiology procedures were evaluated for skin dose measurements. The details of patient and procedure were recorded with film number including Kerma Area Product (P_{ka}) and Cumulative air kerma (K_a). The peak skin dose measured for CA and PCI ranges from 48.2 to 740 mGy and 84 to 1242 mGy respectively, which are significantly below the threshold for skin injury and within the internationally published values. It was observed that the peak skin entrance dose (PSED) is least correlated with fluoroscopy time (FT). The correlation of PSED with K_a and P_{ka} shows

that either of these quantities can be used for proposing DRLs for interventional cardiology procedures.

As an important tool of patient dose optimization, the need for establishment of DRLs especially for IR practice was reviewed. The requirement for DRL was emerged based on the surveys of dose estimates from different studies, which showed the substantial variations in the doses between some of the healthcare facilities for same examination and similar patient group which indicate the need for standardization of dose and reduction in the dose variations without compromising the clinical purpose of each examination. In this work the major part of the study was to establish local DRLs for coronary angiography and percutaneous coronary intervention. The details of patient, procedure, exposure parameters and system displayed dose quantities were recorded. The data (age, sex, fluoroscopy time, KAP, cumulative doses) of 572 patients (374 CA and 198 PCI) were recorded, analysed and 75th percentile [0.75 (n-1)]thvalues of P_{ka} and K_a were suggested as local DRLs. The median values of P_{ka} and K_a for CA procedure were 14 Gy.cm^2 and 430 mGy respectively. The median values of P_{ka} and K_a for PCI procedure were 79 Gy.cm^2 and 994 mGy .respectively. Proposed DRL values are given in the table below

Procedure	**P_{ka} (Gy.cm^2)**	**K_a(mGy)**
Coronary angiography	34	590
Percutaneous coronary intervention	134	1900

There were two cases of skin injury reported to AERB during the course of the study. These cases were investigated for confirming the cause of injuries. Further, a study was conducted to

compare the radiation induced skin reactions on patients who underwent complex interventional radiology procedures and received cumulative air kerma (K_a) above 5 Gy. Six patients who underwent complex IR procedures and received K_a exceeding 5 Gy were followed up for a period of two years after the procedure to check for occurrence of skin reactions. Out of six patients, one patient reported with severe skin injury after a period of one month of IR procedure while another patient reported skin injury within 24 hours after the IR procedure. The remaining four patients did not show any visible skin injury/reactions followed up for a period of two years after IR procedure. Reddening and peeling of patient skin reported within 24 hours of the IR procedure were not concurring with exposed skin areas and this was validated by the in-phantom dosimetry studies.

This study indicates that individual-specific factors play a significant role in the onset/occurrence of skin reactions. Therefore, an intensive assessment and analysis of intrinsic and extrinsic factors related to radiation sensitivity of patients prior to complex IR procedures may help in preventing radiation induced skin injuries.

Although patient dose is a part of medical exposure and there is no regulatory limit, patient dosimetry is carried out owing to higher potential of deterministic effects in these procedures. However, assessment of occupational doses to radiation workers is necessary particularly in this practice, as this is the only diagnostic imaging modality that can cause deterministic effects like cataract to the radiation workers. The study has been carried out for estimation of occupational doses received during the interventional radiology procedures. This study was aimed at (i) Estimation of doses for all in-room personnel using radiation levels and OSL dosimeters, (ii) Comparison of occupational doses measured by OSLDs and simulation experiment for estimation of doses, and (iii) Investigation of the contribution of fluoroscopy

and cine radiographic mode using irradiation time and dose rates. Radiation levels were measured for fluoroscopy and cineradiography mode at all the indicated locations. The readings were corrected for apron attenuation factor. The mean estimated effective dose per procedure to the primary operator is 20 µSv (ranges from 8 to 40 µSv) for CA procedure and 32 µSv (ranges from 14 to 54 µSv) for PCI procedure. The estimated annual effective dose for a busy interventional cardiologist from this study is found to be considerably lower than the recommended occupational dose limit of 20 mSv/year, averaged over 5 consecutive years and 30 mSv in any single year given by the AERB.

The findings of all the above work were consolidated and reproduced to propose a comprehensive national radiation protection program. The existing regulatory framework for interventional radiology practice in the country was reviewed in the light of outcomes of the above described studies. The recommendations are proposed to fill regulatory gaps and to establish an effective radiation protection program. Responsibilities of all the stakeholders are identified and enlisted in the proposed radiation protection program.

9.2 Conclusions

The thesis concludes with the salient features of proposed national radiation protection program, which is an essential part of the quality management for the catheterization laboratory. The effective implementation of the national radiation protection program requires coordinated and collaborative effort involving physicians, staff of interventional radiology department, medical physicists, hospital administration and regulatory body. Interventional medical professional (cardiologist/radiologist/neurologist) are an essential part of this process and need to ensure the best possible outcomes for operators and patients.

Organizing country wide training programs on radiation safety is essential on priority for the medical practitioners working in the field of interventional radiology. Understanding the quantities and units for patient and professional dosimetry is important for radiation protection to interpret the dose information displayed on the IR equipment control console.

In India, interventional radiologists are normally associated with more than one IR facility as consultant, personnel doses should be properly monitored to review the total doses received by them in respective monitoring periods for any excessive exposure. Eye dosimetry should be carried out proactively by interventional physicians as sample study to provide basis for making regulations for implementation of latest ICRP recommendation regarding revised dose limits for eye.

Patient dose optimization tool, i.e. establishment and implementation of local DRLs as first step, should be initiated by every interventional radiology facility. Such data should be verified during periodic regulatory inspections. Taking in to account all the discussed measures for improving radiation safety in the practice, the skill of the medical practitioner, knowledge about the equipment and inclination towards radiation safety are the key parameters for minimizing radiation exposure to the patient and the operators.

9.3 Future scope of work

The present study was a sample consisting of all the stages required to enhance overall radiation safety status of patient and staff of interventional radiology facility. However, the data collection, analysis and results were limited to smaller number of facilities compared to the actual data required for representation of a country. The effective study of the practice needs a large sample size considering geographical distribution of facilities, number of

facilities, type of IR equipment (make, model, technology), number of patient's data collection, operational safety status, administrative measures in place and importantly compliance to the local regulations. This need involvement of many professionals and longer time to verify the compliance, analysis of data and generating the results, this was not possible with the limitations of time, manpower and access to various facilities. Hence, there is a scope of large-scale studies for establishment of national DRLs involving good representation of number of facilities all over the country for different types of procedures. This data can be generated in the form of national dose registry of IR patients.

Organ dose measurements for patient as well as operators is one of the important area of studies. But such studies are limited to a few countries in the world and is required to be taken up in India to understand the specific risk to the organs receiving higher radiation during the procedure. There are already some studies published on eye lens, hands, feet and finger dosimetry.

Further, work on standardization of clinical examination protocols by developing the data bank on common procedures is required to be developed. That will help the new practitioners to follow standard protocols for ensuring optimized procedures and expected to reduce the overall fluoroscopy time and number of cine runs.

Another area of research in this field is development of user-friendly protective accessories and dosimeters for various applications. This would help the interventional radiology staff to comply with the safety requirements such as lead free aprons and flexible shields.

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LIST OF FIGURES

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LIST OF TABLES

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Thesis Highlight

Name of the Student: Mrs. Arti Kulkarni
Name of the CI: Tata Memorial Centre, Mumbai **Enrolment No.:** HLTH 09 2012 04001
Thesis Title: Dosimetric and Quality Assurance Studies in High Dose Diagnostic Imaging Modalities to Establish National Radiation Protection Programme
Discipline: Medical and Health Sciences **Sub-Area of Discipline:** IR - QA and dosimetry

Date of viva voce: 27th August 2020

Interventional Radiology is one of the advanced modality used for fluoroscopically guided interventional procedures. Thesis comprises of the dosimetric and quality assurance studies carried out on interventional radiology system which has direct impact in optimizing the radiation dose to patients as well as associated medical professionals. These minimally invasive procedures are used as an alternative to conventional surgery, resulting in reduced patient morbidity and mortality. However, radiation doses to patients from fluoroscopically guided interventional procedures may be high enough to cause skin injuries and increased probability of developing cancer/heart diseases in future years. There is also a risk to staff members of deterministic effects such as cataract formation. Hence the practice demands attention towards optimization of radiation doses to both patient as well as operator. Under this thesis work, dosimetric studies of the patient were carried out for two common cardiology procedures (i) Coronary angiography (CA), and (ii) the percutaneous transluminal coronary angioplasty (PTCA).

Gafchromic XRRV-3 film was used to measure peak skin doses. Film was calibrated with semiconductor based dosimeter on an X-ray equipment. Additionally, patient doses displayed on the system in terms of Dose Area Product (DAP) and Air Kerma values are recorded and analyzed to propose local DRLs for above selected procedures. Results were compared with internationally published values.

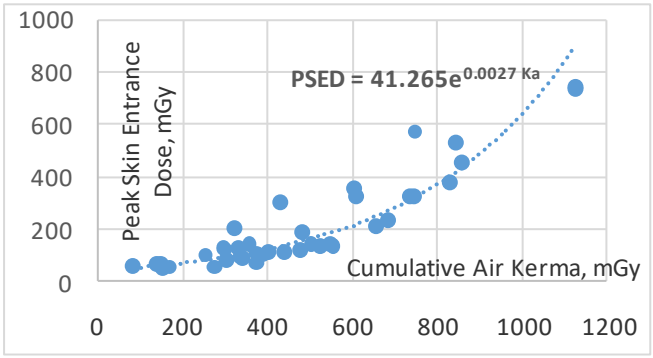

Figure 1: *Correlation between Cumulative air kerma (Ka) and measured peak skin entrance dose (PSED) using XR-RV3 film for CA procedures.*

Occupational doses for the medical professionals. Who are required to be in close association with patient during procedure were estimated using radiation protection survey and protocols used for CA and PTCA procedures. The study of estimation of occupational doses by means of radiation survey and using OSLDs has similar results. The annual doses estimated for primary and other staffs of IR facility are well within the annual dose limit for occupational workers as prescribed by AERB. A comprehensive QA of IR facility reveled the need of revising protocols for inclusion of verification of patient dose monitoring and recording system. Based on all the above studies a comprehensive National Radiation Protection Program is proposed to be implemented by the regulatory body in our country for improving the radiation safety in the field of interventional radiology.

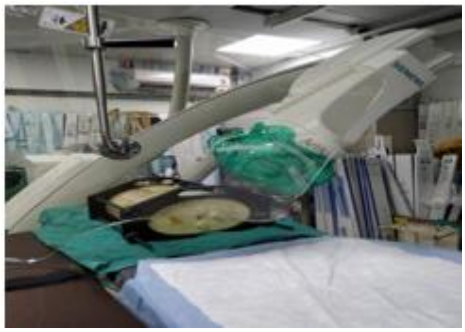

Figure 2: Simulation experiment with phantom for radiation survey