A dosimetric trial for the clinical follow-up of potential skin injuries on patients undergoing interventional cardiology procedures

Vano E (1,2), Aviles P (1,2), Prieto C (2), Fernandez JM (1,2), Guibelalde E (1), Galvan C (1,3), Sabate M (4), Villacastin J (4)

(1) Radiology Department. Complutense University. 28040 Madrid. <eliseov@med.ucm.es>
(2) San Carlos University Hospital. Medical Physics Service. 28040 Madrid.
(3) San Carlos University Hospital. Radiotherapy Service. 28040 Madrid.
(4) San Carlos University Hospital. Cardiovascular Institute. 28040 Madrid.

Abstract

A methodology for the evaluation of skin dose distribution and peak skin dose (PSD) on patients undergoing interventional cardiology (IC) procedures has been developed as part of the European DIMOND programme. A protocol for the clinical follow up when a certain dose threshold was exceeded has been established. Application to a sample of 191 patients undergoing IC procedures was carried out. The procedures included in the trial were radio-frequency (RF) cardiac ablations (16%), intra-coronary brachytherapy (ICB) (47%), percutaneous transluminal coronary angioplasty (PTCA) (18%) and coronary-angiography (CA) (19%). The clinical follow up was initiated when PSD exceeded 3Gy or if it is recommended by other medical circumstances (e.g. previous procedures, special skin radiosensitivity, etc). DAP values of 200 Gy cm² were proposed in the protocol to trigger a more detailed skin dose investigation. This analysis allows determining whether the PSD has reached the value of 3 Gy. From all the patients included in this trial, 16% (7% for RF, 7% for ICB and 2% for PTCA) have shown skin doses higher or equal to 1.5 Gy. Excluding the case of ICB procedures (all interventions were followed with TLDs and slow therapy films), the percentages are not absolute values since they depend on the number of procedures included in the trial. Despite the complexity of some of the interventional procedures included in the trial, no skin injuries were found in any of the patients followed until now. A strict quality assurance programme including a periodic dosimetric evaluation of the X-ray systems have probably contributed to this finding.

Introduction

The U.S. Food & Drug Administration (FDA) published in 1994 an alert on serious X ray induced skin injuries to patients during fluoroscopically guided procedures [1]. Later, the World Health Organization (WHO) in its publication “Efficacy and radiation safety in interventional radiology” (2000) [2], recommends that “patients should be asked to report any skin tissue problems occurring in the irradiated area after interventional procedures”. This advice is amplified in a specific report of the International Commission on Radiological Protection (ICRP) on “Avoidance of radiation injuries from medical interventional procedures” [3], which recommends that “for patients whose estimated skin dose is 3 Gy or greater, the interventionist should arrange for the patient to be reviewed between 10 and 14 days after the procedure. The purpose of this review is to identify skin effects (mainly erythema), which, depending on its timing, may be predictive of more serious and chronic damage”. The concern about the radiological protection of patients has also been stated in a specialised cardiology journal [4].

The patient’s personal physician should be informed about the possibility of ionising radiation effects, along with the usual details of the procedure. It is therefore recommended that each centre
performing interventional radiology (IR) establishes a protocol for identifying patients who have had previous procedures. The skin dose for these earlier procedures should be evaluated if enough data are available.

A protocol for the clinical follow-up of potential skin injuries on patients undergoing interventional procedures has been established and accepted by the corresponding quality assurance committee at the San Carlos University Hospital in Madrid. The protocol includes a methodology for the evaluation of skin dose distribution and PSD on patients undergoing complex interventional procedures. It has been promoted as part of the European DIMOND programme [5]. Application to a sample of 191 patients undergoing IC procedures is presented.

Material and methods

Candidates for the clinical follow up of possible radiation effects were patients undergoing IR procedures selected according to the complexity of the procedure to be carried out and the number of previous interventional procedures (when available) performed in the patient under study. The procedures included in the trial for IC were: RF cardiac catheter ablations, ICB, PTCA and some complex coronary angiography.

Details about previous interventional procedures are collected (if available) [6] and information on relevant pathological processes (previous diseases especially those affecting skin radiosensitivity such as connective diseases, diabetes, xeroderma pigmentosum, porphyria etc) are also considered when deterministic effects are anticipated or observed.

In addition to all the relevant demographic data of the patients and information on the anatomical region exposed, the identification of the X-ray system used, the staff in charge and the details of the procedure are included in a data base.

A photograph of the patient back is taken (with a white paper as colour reference) before the procedure takes place to compare with later images taken during the clinical follow up.

The fluoroscopy time, the total number of acquired images and the dose area product values for fluoroscopy and cine or image acquisition are recorded as relevant dosimetric parameters together with details of possible additional dosimetric controls for skin dose evaluation (slow therapy films or radiochromic films, termoluminiscenct dosimeters (TLD), etc).

The audit of skin dose for a given patient was typically carried out using 7 calibrated TLDs (TLD-100 LiF: Mg, Ti, Harshaw-Bicron Chemical Company, Newbury, OH, USA) which were attached to a slow therapy film (EDR2, Eastman Kodak Co, Rochester, N.Y., USA) placed under the patient in close contact with his or her back, and the density of the film [7]. The square cross sectional size of a TLD was 3.2 x 3.2 mm² and the thickness was 0.9 mm. The small dimension of a TLD compared to the dimension of a typical X-ray field (60-100 cm²) and the area likely covered when varying the X-ray beam projection can lead to the underestimation of the PSD if the dosimeters are not in the position of the most irradiated area. To improve the efficiency of the estimations, the positioning of crystals was decided according to previous experimental studies of the distribution of the X-ray tube projections on the film depending on the type of the interventional procedure.

In some complex cases and when a high concentration of X-ray exposures have been performed in the same area of the skin, a retrospective analysis of the skin dose distribution or map can be done using the information contained in the DICOM header of the cine angiographic series [8].
The DAP is measured for all the patients undergoing interventional procedures in our centre. DAP trigger levels have been agreed for a further dosimetric investigation on a case by case basis. This investigation involves the numerical analysis of the slow therapy film or radiochromic film; activation of the process for the immediate reading of the TLD’s or an analysis of the DICOM header to obtain the skin dose map. The initial trigger levels agreed for IC have been 200 Gy cm\(^2\) for RF cardiac ablation and ICB procedures. In these cases, the radiation fields are usually more concentrated in a region of the skin (see fig. 1) and 300 Gy cm\(^2\) for other IC cases. These trigger levels refer to cumulative skin doses (CSD) of 3.7 and 5.6 Gy with a typical radiation field area of 70 cm\(^2\) used in our centre and assuming a backscatter factor of 1.3. PSD values are usually quite lower than CSD.

The DAP during the procedure (trigger levels) and the film density were considered to decide whether the clinical follow up of the patients could be necessary. This clinical follow up is initiated when PSD could exceed 3Gy or if other medical circumstances (e.g. previous procedures, special skin radiosensitivity, etc) recommend doing it. In this case, the time between the interventional procedure and the full dosimetric evaluation has been minimised to allow the clinical follow up on time.

Every slow film will be processed and digitised the same or the next day of the procedure. The image of the radiation pattern on the slow film will be analysed by the physicist in charge. If the person that examines the film verifies that TLD positioning agrees with the maximum exposure region and suspects that doses could overcome the level of 2-3 Gy (Kodak EDR-2 films are usually saturated at 1.5 Gy for X rays used in diagnostic radiology [7]) then he/she will contact the person in charge of the TLD reading process in order to read the detectors in 24-48 hours.

2-8 days after the procedure [3] the patient should be scheduled with a specialist (could be a radiotherapist or a dermatologist) if skin dose is expected to be 3 Gy or higher.

In our follow-up protocol, the patient is informed by the cardiologist of all potential risks of radiation exposures and possible skin changes that may appear after a complex IR procedure. The patient is advised to contact a specialist of the Cardiovascular Institute if he or she realises some skin changes in his/her back after the procedure.

A sample of 191 patients undergoing IC procedures was followed with TLDs and slow therapy films. The procedures included in the trial were RF cardiac ablations (16%), ICB (47%), PTCA (18%) and CA (19%). The sample of RF cardiac ablations, PTCA’s and CA’s has been selected based on the expected complexity of the procedure determined by the cardiologist in charge of the intervention.

**Results**

From all the patients included in this trial (see table 1), 16% (7% for RF, 7% for ICB and 2% for PTCA) have shown skin doses higher or equal to 1.5 Gy. Excluding the case of ICB procedures (all interventions were followed with TLDs and slow films), the percentages are not absolute values since they depend on the number of procedures included in the trial, and in this case, the sample of patients has not been randomised.
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cases followed</th>
<th>Cases with PSD&gt;1.5 Gy</th>
<th>Percentage</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF cardiac ablation</td>
<td>31</td>
<td>13</td>
<td>42%</td>
<td>Not all the cases were followed. Results are relative</td>
</tr>
<tr>
<td>ICB</td>
<td>90</td>
<td>12</td>
<td>13%</td>
<td>All the cases were followed. Results are absolute</td>
</tr>
<tr>
<td>PTCA</td>
<td>35</td>
<td>3</td>
<td>9%</td>
<td>Not all the cases were followed. Results are relative</td>
</tr>
<tr>
<td>CA</td>
<td>35</td>
<td>0</td>
<td>-</td>
<td>Not all the cases were followed. Results are relative</td>
</tr>
</tbody>
</table>

Table 1. Cases included in the trial and peak skin doses higher than 1.5 Gy

Fig. 1: Examples of skin dose distributions for: a) coronary angiography, b) intra coronary brachytherapy and c) cardiac ablation (Kodak EDR-2 slow film used). Note the radiation fields overlapping in cases b and c.
Conclusions

Despite the complexity of some of the interventional procedures included in the trial, no skin injuries were found in any of the patients followed until now. A strict quality assurance programme including the periodic dosimetric evaluation of the X ray systems and several training sessions on radiological protection organised by the Cardiovascular Institute have probably contributed to this finding.

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References


