Proposal of reference levels for cardiac interventional procedures. An European Coordination Action

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Abstract. Interventional cardiology is a medical specialty widely known to deliver high radiation dose to patients, who may receive, in some complex cases, skin doses over the threshold for deterministic effects. Because several studies have demonstrated large variability in delivered doses, European SENTINEL consortium has carried out a patient dose survey to propose regional Reference Levels (RL) as a tool to reduce dose variability and aid in the optimisation of radiation protection. The survey, performed in cardiac centres from 9 European countries, investigated doses in selected cardiac procedures: coronary angiography (CA), percutaneous transluminal coronary angioplasty (PTCA) and electrophysiology, collecting data on near 2,000 procedures. All examined doses, air kerma area product (KAP) and cumulative dose (CD) at the Interventional Reference Point, or dose analogues, fluoroscopy time and number of acquired images, exhibit a large variability. The examinations have been pooled and RL assessed as the 75\textsuperscript{th} percentile of distributions. Proposed European RL for kerma-area product (KAP) are: 45, 85 and 35 Gycm\textsuperscript{2}, for fluoroscopy time: 6.5, 15.5 and 21 min, respectively for CA, PTCA and diagnostic electrophysiology procedures. Because equipment performance is one of the factors contributing to patient dose variability, RL for air kerma for fluoroscopy and image acquisition measured (in low dose modes) at the entrance of a 20 cm PMMA phantom, are also proposed: 13 Gy/min and 100 μGy/image respectively. The study confirms a large variability of patient doses across Europe and the need of a set of European RL as a tool for the optimisation of radiation protection for patients. The complexity of the procedures should be introduced in the future to refine RL in fluoroscopy guided procedures (SENTINEL EURATOM Research contract No. 012909).

KEYWORDS: interventional cardiology, patient dosimetry, reference level, equipment performance.

1. Introduction

Interventional cardiology is a medical specialty widely known to potentially deliver high radiation dose to patients, who may receive, in some complex cases, high organ doses and skin doses over the threshold for deterministic effects.

The radiation dose depends on a number of factors, including patient size, equipment, technique and type of examination. Large variation in patient dose, for the same type of X-ray examination, has been demonstrated in several studies \cite{1-5}. These variations are almost due to different complexity of the procedures, equipment performance, procedure protocols and patient body size.

By investigating patient dose, variations can be acknowledged, causes founded and the necessary adjustments can be implemented.

Reference Levels (RL) provide a framework to reduce this variability and assist in the optimisation process \cite{6-8}. For this reason, monitoring patient exposure in prolonged interventional procedures and comparison with RLs is a mandatory task in every quality assurance programme.

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2. Materials and methods

A European survey was conducted by the SENTINEL (Safety and Efficacy for New techniques and Imaging Using New Equipment to Support European Legislation) consortium to investigate doses in selected interventional cardiac procedures and to establish updated reference levels.

Cardiac procedures were divided into three main groups:
- coronary angiography (CA)
- percutaneous transluminal coronary angioplasty (PTCA)
- electrophysiology procedures, including diagnostic electrophysiology, pacemaker implantation (PM), defibrillator implantation (ICI) and radiofrequency cardiac ablation (RFCA).

The survey has involved 9 European partners of the SENTINEL consortium and near 2,000 interventional procedures have been examined (Table 1).

Table 1. Cardiac interventional procedures in the sample of patient dose survey.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No. of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary angiography (CA)</td>
<td>672</td>
</tr>
<tr>
<td>Percutaneous transluminal coronary angioplasty (PTCA)</td>
<td>662</td>
</tr>
<tr>
<td>Electrophysiology diagnostic procedure (EFP)</td>
<td>112</td>
</tr>
<tr>
<td>Pacemaker implantation (PM)</td>
<td>51</td>
</tr>
<tr>
<td>Radiofrequency cardiac ablation (RFCA)</td>
<td>337</td>
</tr>
</tbody>
</table>

Information, including the fluoroscopy time, number of frames, air kerma-area product (KAP), and, when available, the cumulative dose (CD) to Interventional Reference Point (IRP), were collected.

Accuracy of dose values provided by the various centres has been evaluated by a dosimetry intercomparison performed by the Lodz (Poland) partner.

Reference levels (RL) have been assessed adopting the procedure recommended in the EC Guideline 109 [8]; RL is assessed as the rounded value of the 75th percentile of the dose distribution.

2. Results and discussion

2.1 Coronary angiography procedures

Examined dose or dose analogues data exhibit a large variability. In figures 1 mean and median values of fluoroscopy time (FT) and KAP, respectively, are reported for CA procedures.

Figure 1. Fluoroscopy time and air kerma-area product of CA procedures in the 9 participating centres.
Figure 2. Frequency distribution of fluoroscopy time and air kerma-area product for CA procedures.

The examinations have been pooled and frequency distribution of fluoroscopy time, number of frames and KAP derived together with the associated reference levels. Reference levels have been assessed as the rounded values of the 75th percentile of distributions.

Figures 2 report the histograms for FT and KAP values of all CA procedures evaluated in this study.

2.2 PTCA procedures

In figures 5 and 6 histograms for FT and KAP, respectively, for PTCA procedures are reported.

Figure 3. Frequency distribution of fluoroscopy time air kerma-area product for PTCA procedures in participating cardiac centres.
2.3 Electrophysiology procedures

Frequency distribution histograms approximate a log-normal shape in all cases. This result represents the effects of differences between patient sizes and procedure protocols as well as technical differences between equipment.

Reasons arise from the variety of different type of radiofrequency cardiac ablations performed to treat different arrhythmias: atrial fibrillation, atrial flutter, nodal tachycardia, ventricular tachycardia and WPW. Important differences in procedure protocols bring to different mean FT and KAP values.

In figure 4 the frequency distribution of FT for RFCA procedures is reported and it is possible to recognise the distribution has not a log-normal shape.

Figure 5 reports data from an electrophysiology laboratory (Udine Hospital, Italy) where information on type of RFCA has been collected. It is possible to recognise that treatment for atrial fibrillation is the procedure that requires the highest fluoroscopy time (median value of 45 min) and, consequently, the highest KAP (median value 35 Gycm²).

Figure 4. Frequency distribution of fluoroscopy time for electrophysiological procedures.

![Figure 4](image1)

Figure 5. FT and KAP of different types of RFCA procedures

![Figure 5](image2)

From the data of electrophysiology collected in the Udine hospital, it emerges the impossibility to pool all RFCA data together.

On the other side, the data available for each single procedure are insufficient to treat them separately. Consequently, from this survey, it is not possible to assess reference levels (DRLs) for RFCA procedures.
2.4 Reference Levels

In table 2 the assessed reference levels are reported for fluoroscopy time, air kerma-area product, cumulative dose (CD) at IRP, effective dose (calculated as \( E = 0.18 \times \text{KAP} \)) and No. of cine images.

Because equipment performance and equipment set up by the maintenance service is one of the factors contributing to patient dose variability, the entrance surface air kerma for fluoroscopy and image acquisition, measured at the entrance of a 20 cm PMMA phantom, are also introduced in the set of proposed reference levels.

The present set of reference levels proposed for coronary angiography and angioplasty are lower compared to those assessed in 2004 by the DIMOND group (CA: KAP=57; PTCA: KAP=94 Gy cm\(^2\)) [7]. The main difference derives from the lower number of cine images that had influenced the KAP.

Table 2. SENTINEL Reference Levels for interventional cardiac procedures.

<table>
<thead>
<tr>
<th>Dose or dose analogue</th>
<th>Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>KAP (Gy cm(^2))</td>
<td>CA</td>
</tr>
<tr>
<td>Effective dose (mSv)</td>
<td>45</td>
</tr>
<tr>
<td>CD at IRP (mGy)</td>
<td>650</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>6.5</td>
</tr>
<tr>
<td>No. of cine images</td>
<td>700</td>
</tr>
<tr>
<td>Entrance surface air kerma rate (for 20 cm PMMA)</td>
<td>Fluoro low: 13 mGy/min</td>
</tr>
</tbody>
</table>

Regarding the RL for the cumulative dose at IRP, it will be necessary to evaluate the impact of this quantity in the optimisation process of patient exposure and, mainly, in the prevention of deterministic injuries from radiation to the skin. In fact, it is well known that CD is better correlated to the maximum (or peak) skin dose than the KAP.

3. Conclusion

The SENTINEL survey performed on interventional cardiology in a sample of European centres demonstrates the presence of a large variability in the entrance surface air kerma rates for both, fluoroscopy and image acquisition modes. For the first time, reference levels for this quantities is proposed in the set of quantities to be used in the process of optimisation of patient exposure.

The SENTINEL reference levels proposed allow also an estimation of the effective dose, calculated from the KAP reference value, and the cumulative dose at the IRP, quantity today displayed in the interventional room by the new equipment.

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REFERENCES


