Establishing the Greek National Reference Levels for Interventional Cardiology procedures

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• The frequency of Interventional Cardiology (IC) procedures has seen significant growth over the past decade.
• The extended use of these procedures raises various radiation protection issues, as they result in high radiation dose to the patient as well as to the medical personnel.
• Specifically, the dose to the patients’ skin can, in some cases, even exceed the threshold of tissue reactions.
• As a consequence, optimisation of radiation protection on IC procedures is of great importance.

Vliestra et al. (2004)
Introduction

- Directive 97/43/EURATOM introduced the concept of Diagnostic Reference Levels as a tool for optimisation for typical examinations.
- They are defined as dose levels in medical radiodiagnostic practices to patients of standard-sized groups or standard phantoms.
- Although IC procedures can hardly be standardized because of the variations of patients’ anatomy and pathology, the adoption of Reference Levels (RLs) for these procedures seems feasible and has been investigated in the literature.
- The establishment of RLs in image guided interventional procedures at a national level is required in the recent revision of the BSS*.

The purpose of this speech is to present the results of a national survey that was performed in Greece for the establishment of national RLs for the most common IC procedures.
Methods

• Two types of Reference Levels were set, as suggested in the literature*:
  – RLS related to the performance of the X-ray systems used in IC,
  – RLS related to the clinical procedures.

• For this purpose, the study included collection and analysis of clinical data as well as measurements related to the performance of the X-ray systems used in IC.

Measurements related to the performance of the X-ray systems

- The performance of 30 systems used in IC was evaluated in respect to the following parameters:
  - Phantom entrance dose rate during fluoroscopy
  - Phantom entrance dose rate and dose per frame during CINE
  - Air kerma-area product (P<sub>KA</sub>) accuracy
  - Image quality [Low Contrast Sensitivity (LCS) and High Contrast Resolution (HCR)]

<table>
<thead>
<tr>
<th>Model</th>
<th>Type of detector</th>
<th>Number of systems</th>
</tr>
</thead>
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<tr>
<td>Siemens Multistar</td>
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<td>1</td>
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</table>
Measurements related to the performance of the X-ray systems

Dose measurements*

• Typical PA projection

• Measurements were performed without magnification (20-25 cm FoV) and with magnification to 15-17 cm FoV.

• All exposure parameters (fluoroscopy and CINE mode, pulse and frame rate, filtration etc.) during the measurements were those that are used in typical clinical cases on each system.

• The accuracy of the $P_{KA}$ meters was evaluated using the beam area method (i.e. by measuring the air kerma and the field area at the plane of measurement) without the presence of the patient table (free-in-air).

RLs related to the clinical procedures

- The total fluoroscopy time and the PKA of a total of 5250 IC procedures from 26 hospitals were recorded and analyzed.

- Classification of procedures:
  - i) diagnostic Coronary Angiography (CA),
  - ii) Percutaneous Coronary Intervention (PCI): any therapeutic procedure (with or without a diagnostic component),
  - iii) Pacemaker Implantation (PMI),
  - iv) Radiofrequency Cardiac Ablation (RFCA).

RLs related to the clinical procedures

• The $P_{KA}$ meter accuracy that was assessed during the systems’ performance evaluation, was used in order to investigate factors to the collected data.

• The minimum sample size for each procedure was 30 patients per hospital.

• For each type of procedure, the mean fluoroscopy time and $P_{KA}$ values were calculated for each hospital.

• The rounded 3rd quartile of the mean values was set as the RL for each procedure.*

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Results – Systems’ measurements

Fluoroscopy - Phantom entrance dose rate

Each letter on the horizontal axis represents a specific system model.
Results – Systems’ measurements

CINE - Phantom entrance dose per frame

Each letter on the horizontal axis represents a specific system model.
Results – Systems’ measurements

• The accuracy of all $P_{KA}$ meters lied within the ± 35% tolerance*

• Eight systems presented inaccuracies greater than the estimated uncertainty of the $P_{KA}$ measurement (6.4%). A respective correction factor was applied to the clinical $P_{KA}$ data that was collected from these systems.

• Flat Detector systems presented better high contrast resolution against those with Image Intensifiers (mean values were 2.4 lp/mm and 1.5 lp/mm respectively). No significant differences were observed for the rest of the measured parameters.

Results – Clinical data

PCI and RFCA were the procedures with the highest mean values (112.0 mGy cm$^2$ and 98.3 mGy cm$^2$ respectively).

PCI - Mean DAP values per center
Results – Clinical data

RFCA - Mean DAP values per center

6.25 pps fluoroscopy (provides adequate image quality for RFCA)
### Suggested national RLs

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Fluoroscopy time (min)</th>
<th>( P_{KA} ) (Gycm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary Angiography</td>
<td>6</td>
<td>53</td>
</tr>
<tr>
<td>Percutaneous Coronary Intervention</td>
<td>18</td>
<td>129</td>
</tr>
<tr>
<td>Pacemaker Implantation</td>
<td>7</td>
<td>36</td>
</tr>
<tr>
<td>Radiofrequency Cardiac Ablation</td>
<td>40</td>
<td>146</td>
</tr>
</tbody>
</table>

- Fluoroscopic phantom entrance surface dose rate: 29 mGy/min (20-25 cm FoV)
- Image acquisition phantom entrance surface dose per frame: 0.23 mGy/fr (20-25 cm FoV)

### Other studies

Discussion

• The wide range of the dose rate and dose per frame values of the systems that were evaluated, represent differences not only in the systems’ dosimetric performance, but also in the protocols used by the operating staff during the clinical work.

• Optimisation by changing the systems’ settings used during the clinical practice seems feasible in some cases.

• Scaling of the RLs according to the complexity of the procedures was not feasible during the present study (no such information was available in the collected data).

• Each individual facility should compare its own values against the suggested RLs, after applying an adjustment for complexity to the local data.
Procedure complexity

• PTCA
  
  \[
  CI = No.\,ve.\,\text{No.\,Bif}^3
  \]
  
  – (a)
  
  – (b)
  
  – (c)


• PMI: type of device
  
  Conventional or biventricular

• RFCA: type of treated arrhythmia

Discussion

- Future re-evaluation of the suggested RLs should take into account
  - The complexity of the procedures
  - The number of acquired frames per procedure
  - The patient’s morphometric characteristics (e.g. Body Mass Index)

More information:

Thank you...

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