Patient doses in interventional cardiology procedures.

J. Domienik\textsuperscript{a}, S. Papierz\textsuperscript{a}, J. Jankowski\textsuperscript{a}, J. Z. Peruga\textsuperscript{b}

\textsuperscript{a}Nofer Institute of Occupational Medicine in Lodz, Radiation Protection Department, Lodz, Poland

\textsuperscript{b}II Chair and Department of Cardiology Medical University of Lodz, Poland

Abstract. In most countries of European Union legislation requires the determination of the total skin dose to patient resulting from interventional procedures to assess the risk of deterministic effect. To this end, various dose indicators like dose area product (DAP), cumulative dose (CD) and entrance dose at the patient plane (EFD) are used in clinical practice. The study aims at relating those dose indicators with doses ascribe to the most irradiated areas of the patient skin usually expressed in terms of local maximal skin dose (MSD). For the study the local MSD and related to their areas are investigated and compared for coronary angiography (CA) and intervention (PCI). Two methods implying radiographic films Kodak EDR2 and matrices of thermoluminescent dosimeters (TLDs) are applied for direct measurements of dose distribution for selected procedures. Both methods are compared.

Additionally, for patient dosimetry the following data: MSD, CD, EFD, fluoroscopy time (FT), number of acquired images, total DAP, fluoro-DAP and record-DAP were collected for randomly selected procedure. The statistical quantities like: median, 3\textsuperscript{rd} quartile, mean and standard deviation for all dosimetric parameters are determined. Preliminary study showed that the values of data collected for coronary procedures are in the ranges $0.7 – 27.3$ min for fluoroscopy time, $50 – 350$ Gy cm$^2$ for total DAP, $300 – 2000$ mGy for CD, $140 – 2000$ mGy for EFD and $100 – 1500$ mGy for local maximal skin dose. For interventions the ranges are, accordingly $3.0 – 43.6$ min, $25 – 450$ Gy cm$^2$, $270 – 6600$ mGy, $80 – 2600$ mGy and $80 – 1500$ mGy.

As a result of the study the correlations between dose indicators and local MSD are analyzed. The concentration of dose on irradiated films are going to be investigated in some detail as well.

Key words: cardiac procedure, local maximum skin dose, cumulative dose, dose – area product (DAP)

* 1. Background

Some radiation-induced skin injuries in patient may occur when doses received during cardiac intervention exceed threshold limits. Thus in order to avoid serious injuries the practical actions to control dose need to be implemented in clinical practice. The International Commission on Radiation Protection (ICRP) in Publication 85 recommends the evaluation of doses absorbed by patient in the area that receives maximum dose. The suggestion of ICRP is complied in legislation of most countries of European Union, also in Poland\textsuperscript{[1-4]}

A few methods has been proposed to measure local maximum skin dose from dose distribution. The most frequently discussed in scientific literature are large, self made, TL dosemeters arrays, large-area slow films or self-developing Gafchromic films. Although, the accuracy of large

* Presenting author, E-mail: jdom@imp.lodz.pl
film methods in determining local maximum skin dose might be good, at least theoretically, one has to take into account not only their suitability but also costs (which are rather considerable) and practicability (they are laborious) when planes to implement them in routine dosimetry. Due to the latter the measurements with films or TLD arrays are rather not likely to become preferable method to monitor the local maximum dose in hospitals\cite{5,6}. The availability of direct estimation/evaluation of local maximum dose from beam monitoring quantities is desirable for prevention of deterministic injuries. Depending on the angiography unit there are various beam monitoring quantities displayed by the system like dose-area product or and cumulative dose. Sometimes additional ionizing chamber is installed on X-ray tube for measurements of beam air kerma at the reference point distance, specified by operator. The correlation between the beam monitoring quantities and local maximum skin dose (MSD) will depend on the concentration of the dose which in turn depends on projection and collimator settings used by the operators as well as on the distance at which the beam monitoring quantity of interest is specified. Thus the relations between them defined in one hospital usually are not applicable in another one.

In this study we investigated the correlation between local MSD and beam monitoring quantities in two hemodynamic rooms in Poland. For local maximum skin dose measurements the method of large area films (Kodak EDR2), used also in other studies\cite{4,7-10} was applied.

2. Materials and methods

The hemodynamic room I was equipped with GE Innova 2000 with digital flat panel imaging detector, frame acquisition rate 15 or 30 frames per second and four field sizes available, whereas in the hemodynamic room II measurements were performed with Philips Integris 3000 X-ray system (Philips Medical Systems) with a conventional image intensifier, frame acquisition rate 12,5 and 25 frames per second and three field sizes available. Both units have an undercouch X-ray tube configuration and work under automatic exposure control. The units performance was checked both according to the typical QA/QC tests described in the reference\cite{11} as well as for the purpose of present presented study according to the following method\cite{12}. The dose rates were measured, at the distance of 60 cm from focus to the entrance surface of the patient simulated with 20 cm of PMMA phantom and the image intensifier place in the distance of 5 cm from the patient. The dose rates measured in room I were 13.2 mGy.min\(^{-1}\) and 32.6 mGy.min\(^{-1}\) for two modes low and normal, respectively; the one measured in room II for low fluoro mode was 26.8 mGy.min\(^{-1}\) (which is about two times higher). The entrance dose per image measured, for the same geometry and for routinely used acquisition rate (15 frames per second in room I and 12.5 frames per second in room 2), was equal 116 µGy per image in room I and 153 µGy per image in room II, respectively. Furthermore, the system in room I is provided with a dose area product meter DIAMENTOR M4-KDK [PTW-FREIBURG] with additional function allowing to measure the beam air kerma, while the unit in room II was equipped with KAP – meter (Doseguard 100, RTI Electronics AB).

The data were monitored for two cardiac procedures: diagnostic coronary angiography (CA) and percutaneous coronary intervention (PCI). The procedures were performed by 8 specialists from hemodynamic room I and 3 specialists from hemodynamic room II. Altogether in the survey 162 cardiac procedures were randomly collected. In more detail: 106 procedures in room I (52 CA procedures and 54 PCI procedures) and 56 examinations in room II (29 CA procedures and 27 PCI procedures).

The statistical data concerning dosimetric parameters like:
- fluorscopy time (FT),
- total number of images,
- DAP-dose area product, EFD-entrance dose in the patient plane measured at the distance of 55cm from the meter (internal flat ionization chamber DIAMENTOR M4-KDK mounted directly to the light beam diaphragm housing), cumulative dose CD (calculated by the system on the basis of the algorithm using the physical exposure parameters, filtration and geometry of the X-ray beam) and maximal skin dose MSD assessed with the use of Kodak EDR2 films were determined for the randomly selected patients.
The Kodak EDR2 films were calibrated in the dose ranged from 100 mGy to 1250 mGy. In order to determine the exact response of the film to the fluoroscopy beam qualities close to those used in clinical condition the dose calibration was performed for the ISO W-80 spectrum (80kV, 0.5 mmCu). The calibration performed in Secondary Standard Laboratory of Nofer Institute of Occupational Medicine in Lodz was carried out with respect to the surface air kerma. The contribution from backscatter radiation from the patient was included by placing the calibrated films in front of 20 cm PMMA phantom. The film were processed manually with the developer at the temperature 20.0°±0.5°, the processing conditions were under sensitometric quality control according to the internal protocols of the Laboratory. The model of polynomial film characteristic curve was applied. The fitting curve with correlation coefficient $R^2=0.999$ is presented on the Figure 1.

![Figure 1. Kodak film calibration curve](image)

Simultaneously with Kodak films the self-made TLD arrays were also used as optional measurement method for dose assessment in the nonlinear part of film characteristic curve. The values of quotient $q=\text{MSD}_{\text{film}}/\text{MSD}_{\text{TLD}}$ (were $\text{MSD}_{\text{film}}$ and $\text{MSD}_{\text{TLD}}$ are the values of maximal doses measured with film and TLD, respectively) lie in the interval 0.83 to 1.17 for the $\text{MSD}_{\text{film}}$ up to 1500 mGy.

One of the main tasks of the study was to define the dose indicator that would approximate most closely patient maximal skin dose (MSD). In other words the purpose was to allow the operator to monitor the maximal skin dose (MSD) received by the patient and to assess the probability of deterministic effects. To this end, the statistical analysis for the correlation between dose indications like DAP, CD or EFD and actual MSD received by the patient was performed.

3. Results

The typical values of the following parameters: fluoroscopy time, the number of acquired images, MSD, and beam monitoring quantities like DAP, CD and EFD are given in Table 1.
Table 1. Dosimetric parameters for monitored procedures.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Parameter</th>
<th>FT (min)</th>
<th>No. of images</th>
<th>DAP (Gy.cm$^2$)</th>
<th>EFD (mGy)</th>
<th>CD (mGy)</th>
<th>MSD (mGy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>Min:</td>
<td>0.7</td>
<td>222</td>
<td>20</td>
<td>121</td>
<td>295</td>
<td>105</td>
</tr>
<tr>
<td></td>
<td>Max:</td>
<td>27.3</td>
<td>1 128</td>
<td>317</td>
<td>1 768</td>
<td>4 689</td>
<td>1 507</td>
</tr>
<tr>
<td></td>
<td>Median:</td>
<td>3.4</td>
<td>484</td>
<td>59</td>
<td>308</td>
<td>908</td>
<td>298</td>
</tr>
<tr>
<td>Room 1</td>
<td>3$^{rd}$ quartile</td>
<td>5.4</td>
<td>583</td>
<td>78</td>
<td>434</td>
<td>1 192</td>
<td>373</td>
</tr>
<tr>
<td></td>
<td>Min:</td>
<td>2.3</td>
<td>116</td>
<td>17</td>
<td>68</td>
<td>267</td>
<td>84</td>
</tr>
<tr>
<td></td>
<td>Max:</td>
<td>43.6</td>
<td>2 502</td>
<td>425</td>
<td>2 279</td>
<td>6 524</td>
<td>1 555</td>
</tr>
<tr>
<td></td>
<td>Median:</td>
<td>8.9</td>
<td>877</td>
<td>120</td>
<td>700</td>
<td>1 891</td>
<td>831</td>
</tr>
<tr>
<td></td>
<td>3$^{rd}$ quartile</td>
<td>18.3</td>
<td>1 082</td>
<td>209</td>
<td>1 256</td>
<td>3 503</td>
<td>1 322</td>
</tr>
<tr>
<td>PCI</td>
<td>Min:</td>
<td>1.2</td>
<td>174</td>
<td>16</td>
<td>-</td>
<td>-</td>
<td>43</td>
</tr>
<tr>
<td></td>
<td>Max:</td>
<td>18.9</td>
<td>538</td>
<td>204</td>
<td>-</td>
<td>-</td>
<td>850</td>
</tr>
<tr>
<td></td>
<td>Median:</td>
<td>2.5</td>
<td>3 23</td>
<td>39</td>
<td>-</td>
<td>-</td>
<td>155</td>
</tr>
<tr>
<td>Room 2</td>
<td>3$^{rd}$ quartile</td>
<td>5.5</td>
<td>381</td>
<td>69</td>
<td>-</td>
<td>-</td>
<td>289</td>
</tr>
<tr>
<td></td>
<td>Min:</td>
<td>2.1</td>
<td>209</td>
<td>24</td>
<td>-</td>
<td>-</td>
<td>71</td>
</tr>
<tr>
<td></td>
<td>Max:</td>
<td>21.1</td>
<td>615</td>
<td>279</td>
<td>-</td>
<td>-</td>
<td>1 356</td>
</tr>
<tr>
<td></td>
<td>Median:</td>
<td>6.7</td>
<td>377</td>
<td>63</td>
<td>-</td>
<td>-</td>
<td>383</td>
</tr>
<tr>
<td></td>
<td>3$^{rd}$ quartile</td>
<td>12.1</td>
<td>4 47</td>
<td>100</td>
<td>-</td>
<td>-</td>
<td>353</td>
</tr>
</tbody>
</table>

The first, general and rather obvious, conclusion is that all investigated parameters take significantly higher values for more complex, therapeutic procedures; this is true in both rooms. However, significant differences are observed. In general, all parameters are higher in room 1 when medians are compared. The effect of relatively poor dosimetric performance of the unit in room 2 (higher than in room 1 dose rates provided by AEC system) is reduced probably due to the operators techniques employing shorter FT and lower number of acquired images. As a result, the MSD and DAP values are lower in room 2 when compared with room 1.

The present study allowed to determine the reference levels (RL) defined as 3$^{rd}$ quartile. The RLs for selected dose indicators are compared with those determined in the framework of SENTINEL project$^{[13]}$. The comparison is presented in Table 2.
Table 2. Reference levels for DAP, FT and no. of images defined in room 1 and room 2.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>DAP (Gy.cm²)</th>
<th>FT (mGy)</th>
<th>No. of images</th>
<th>CD (mGy)</th>
<th>Entrance surface air kerma rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sentinel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CA</td>
<td>45</td>
<td>6.5</td>
<td>700</td>
<td>650</td>
<td></td>
</tr>
<tr>
<td>PCI</td>
<td>85</td>
<td>15.5</td>
<td>1000</td>
<td>1500</td>
<td>Fluoroscopy low: 13.0 mGy.min⁻¹</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Image acquisition: 100 µGy per image</td>
</tr>
<tr>
<td>room 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CA</td>
<td>78</td>
<td>5.4</td>
<td>583</td>
<td>1192</td>
<td>Fluoroscopy low: 13.2 mGy.min⁻¹</td>
</tr>
<tr>
<td>PCI</td>
<td>209</td>
<td>18.3</td>
<td>1082</td>
<td>3503</td>
<td>Image acquisition: 116 µGy per image</td>
</tr>
<tr>
<td>room 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CA</td>
<td>69</td>
<td>5.5</td>
<td>381</td>
<td>-</td>
<td>Fluoroscopy low: 26.8 mGy.min⁻¹</td>
</tr>
<tr>
<td>PCI</td>
<td>100</td>
<td>12.0</td>
<td>447</td>
<td>-</td>
<td>Image acquisition: 153 µGy per image</td>
</tr>
</tbody>
</table>

One notes that the DAP reference levels are in our case higher than those recommended in European project, both for diagnostic and therapeutic procedures. The discrepancies might be as much as by the factor 2.5 (c.f. Table 2, room 1). Moreover, the FT and No. of images are lower in both rooms, except RLs for therapeutic procedures in room 1. This fact would indicate rather not satisfying collimation technique presented by operators and the necessity for further training; nevertheless, the optimization of the unit performance would be also desirable.

One of the main objectives of the paper was to verify whether there exists some beam monitoring quantity (from those available in hemodynamic room) which would allow the operator to control MSD in order to indicate, in reliable way, the possible overexposure. To this end, the analysis of the correlations between actual MSD and dose indicators (DAP, CD, EFD) was performed. Although, a similar analyses can be found in literature[4,6,9,10] the need for further study is justified by the fact that in general the results depend on the facility where the measurements are performed.

On Figures 2-7 the comparison between MSD and DAP, EFD, CD are presented for CA and PCI procedures in room 1.

Figure 2. Correlation between MSD and DAP values for CA procedures in room 1.
Figure 3. Correlation between MSD and CD values for CA procedures in room 1.

![Graph showing correlation between MSD and CD values for CA procedures in room 1.](image)

y = 0.3608x  
$R^2 = 0.7875$

Figure 4. Correlation between MSD and EFD for CA procedures in room 1.

![Graph showing correlation between MSD and EFD values for CA procedures in room 1.](image)

y = 0.0481x  
$R^2 = 0.2021$

Figure 5. Correlation between MSD and DAP values for PCI procedures in room 1.

![Graph showing correlation between MSD and DAP values for PCI procedures in room 1.](image)

y = 0.9682x  
$R^2 = 0.7925$
Some general remarks are in order. First the correlation is much better for diagnostic procedures. This can be explained by the fact that, typically, the latter are simpler and standardized procedures contrary to more complex and individual therapeutic ones. Secondly, in room 1 the best correlation for CA procedures was found for DAP values. Third, even in the case of diagnostic procedures the reliability of the estimation of MSD by dosimetric quantities can be put in doubt. In fact, if one relied on experimental points above the correlation line one would underestimate the actual dose obtained by the patient. The rate of underestimation may be as much as one third of actual MSD (c.f. Figure 2, 4). Indeed, let us take into account the points (1017,1475) and (1768,1507); we see that, in spite of large difference in EFD, the corresponding MSD values are roughly equal. This might suggest that the correlation coefficient $R^2=0.79$ is not sufficient to provide safe estimation of MSD. In addition, as far as Figure 2 and Figure 3 are concerned, it is seen that the gauging of MSD with the help of DAP or CD values is not one to one which is not comfortable from practical point of view. However, this might be improved by introducing the appropriate trigger level\textsuperscript{[9,10,14]}, here the trigger level for DAP readings indicating the MSD equal to 2 Gy- the threshold for deterministic injury (main erythema)\textsuperscript{[14]}- would be 40200 cGy.cm\textsuperscript{2}.

Looking at the Figures 5, 6 and 7 representing the correlations for therapeutic procedures, one realizes that the situation is even worse. The correlation coefficients are low and most of the points lie above the line which implies that in most cases the MSD are underestimated. Data collected in room 2,
Figures 8 and 9 illustrate low correlation between DAP - value and MSD for CA ($R^2 = 0.59$) and relatively good for PCI procedures ($R^2 = 0.80$) which is quite opposite to the relations in room 1.

Figure 8. Correlation between MSD and DAP for CA procedures in room 2.

Figure 9. Correlation between MSD and DAP for PCI procedures in room 2.

This confirms the fact that for every facility the individual study of correlations between the system beam monitoring quantities and MSD is needed.

The appropriate DAP-reading trigger level for therapeutic procedures in room 2 for the above proposed MSD would be 346 Gy.cm$^2$.

4. Discussion

The need for optimization of unit performance and staff training in radiation protection, including the collimation techniques, were ascertained. The results of our paper seem to support the point of view presented by the number of authors like Vano E. at al[4], S van de Putte[6] and Morell at al[8] who states in their papers that the dose – area product can not predict the maximum skin dose in reliable way. In our study we extended the analysis to other dosimetric quantities beyond DAP like cumulative dose or entrance dose at the patient plane showing that neither of them is satisfactory as the estimation of MSD on the level which could be accepted from the point of view of patient safety. There are too many factors which can influence the relations between the MSD and beam monitoring quantities making them rather complicated. However, the better correlations of DAP and MSD obtained in our study justify the statement that DAP (as registered in both hospitals) can still serve, when dealt with
sufficient care, as rough, preliminary, estimation of the risk experienced by the patient. The results allowed to propose trigger level for DAP readings for coronary angiography and percutaneous coronary intervention, respectively in room 1 and room 2.

5. References


