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Paper

Patient skin dose measurement and risk of deterministic effect during fluoroscopy cardiac procedures

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Abstract

This study aimed at assessing patient's peak skin doses (PSD) during fluoroscopy cardiac procedures and proposed a look up table to enhance patient's dose management. Perspex phantom and thermoluminescent dosemeters (TLD) were irradiated for different dose levels with X-ray equipment (Philips Azurion 7). It was found that PSD measures were higher than the kerma at the interventional reference point [K (IRP)] reported with factors 1.55, 1.75 and 2.88 for anterior posterior (AP0°), left anterior oblique (LAO45°) and right anterior oblique (RAO45°), respectively. The equations describing the correlation between the PSD measured kerma area product and cumulative air kerma were found with *R*-square values of 0.98 and 0.99, respectively. The statistical analysis shows a strong linear correlation between PSD and K (IRP) (*P*-value = 0.05). It was also found that 27% of the patients population considered in this work, received a skin dose higher than the threshold of deterministic effect of 2 Gy and a look up table with the equation of fitness were proposed to be implemented in the facility for K (IRP) higher than 500 mGy.

Introduction

Since the past decades, the introduction of more sophisticated equipment in fluoroscopy guided intervention has contributed to the growing number and complexity of procedures. However, complex procedures are the causes of substantial radiation dose to patients which can lead to deterministic effects (hair loss, epilation, skin burn, etc.). Many studies have reported radiation-induced deterministic effects in patients undergoing fluoroscopy interventional procedures,[1–7] highlighting the need to enhance patient dosimetry as the number increases over the years. In recent years, great efforts have been made to advance radiation protection and optimize the dose administered to patients during fluoroscopy interventional procedures in the technical and organizational measures and international regulations.

It is shown in literature that radiation inducing risk can be appropriately managed by a real-time evaluation of patient radiation dose.[8, 7] Modern fluoroscopy system manufacturers display the fluoroscopic time (FT), kerma area product (KAP) and air kerma at the interventional reference point K (IRP), which can serve as indicators of stochastic risk and deterministic risk respectively.[8,10–12] Additionally, an alert has been established in that equipment at specific thresholds which are K (IRP) greater than 2 Gy, the fluoroscopy time greater than 5 minutes and the KAP greater than 200 Gy.m^2.

However, all of these metrics are limited to assess patient's peak skin dose (PSD) as they do not account for radiation absorption in tissue, radiation backscatter, geometry and table attenuation, all of which directly affect the entrance skin dose.[13] The National Council

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on Radiation Protection and Measurements (NCRP) suggested the use of effective dose to evaluate the possibilities of stochastic effect on exposed patients and PSD as a relevant quantity to evaluate the potential for deterministic effect of the skin.[14] The International Commission of Radiation Protection (ICRP) recommended the assessment of PSD of patients during those procedures to improve patients follow-up.[15] In the literature, there are different methods to determine the PSD. This includes TLDs, OSL, dosimetry film and calculation techniques.[15–18]

Nowadays, several dose mapping software are available for assessing the PSD during or after the examination in the developed world such as Dose Tracking System (Toshiba, Tokyo, Japan), Dose Map (General Electric, Fairfield, USA) and em.dose (esprimed SAS, Villejuif, France).[17–20] Unfortunately, the system available in most developing countries does not have an incorporated PSD Map software. In an attempt to comply with the international regulations, this study aims to measure the PSD in order to propose a look up table that will contribute to patient radiation dose management after the procedure. This is a preliminary study and first in its kind in the region and will serve as a baseline for more detailed procedure.

Methodology

The Cath-Lab is equipped with an undercouch Philips Azurion 7 M20 Medical Systems manufactured in March 2021 in Germany. The X-ray tube model MRC 2000407 with serial number (SN: 173965) and the nominal X-tube voltage is 125 kV and filtration of 2.5 Al/75. An approval letter was obtained from the institutional review board of the facility before any data collection.

Quality control test

Standard quality control measurements of peak tube voltage (kVp) accuracy, collimation accuracy, current-time product (mAs) linearity, half value layer (HVL), reproducibility test (tube voltage, exposure time and exposure), collimation and beam alignment test were performed on the Philips Azurion 7 system prior to the data collection. These tests were performed using a calibrated dose quantity kit manufactured by Radcal in order to assess whether the machine output is performing self consistently. The calculated deviations for each test were compared with the national standard acceptable deviations.

Direct measurement

Calibrated lithium fluoride Thermoluminescent dosemeters (TLDs) were used with an acrylic polymethylmethacrylate (PMMA) phantom with dimensions $25 \times 25 \times 20$ cm. The TLDs were calibrated in terms of shallow dose equivalent Hp (0.07) and deep dose Hp (10) before they were used. The values of Hp (0.07) were considered as the skin dose in this study. A total number of sixty (60) TLDs were used for the study. For each set of measurements, an array of nine (09) TLDs were placed between the phantom and the patient table to measure the skin doses. The average value and the standard deviation of each measuring set were calculated. The first study was performed varying the field size and the phantom thickness in order to assess the impact of those parameters on the skin dose during image acquisition (five series of 30 images) and five (05) minutes of fluoroscopy mode at the AP 0^{o} position of the tube. The TLDs were placed at the edge of the irradiated field size defined on a plane sheet and some images were taken before the irradiation for more precision. The second part of the study consisted in measuring the skin dose corresponding to a specific K (IRP) reported on the console only in cine mode. The K (IRP) and the KAP were recorded for each set. The TLDs were read 14 hours after exposure and the calibration factors were automatically applied to the readings. The highest dose of each set was chosen to represent the PSD.

Dose calculation

Air Kerma calibration factor

The allowable tolerance for the displayed K (IRP) or kerma-area product (KAP) on interventional C-arm fluoroscopy is ±25% according to the International Electro-technical Commission (IEC) and the United States Food and Drug Administration (USFDA) requirements. Large deviations in the accuracy of the displayed K (IRP) are therefore possible.[9, 13] The RADCAL ion chamber was set on the direct beam at 80 cm from the source without a patient table and pad. The ion chamber was irradiated using a collimator opening in such a way that the field size was 10×10 cm^2 at the level of the ion chamber. An attenuator of 5 mm Cu was placed on the image receptor and the low and medium fluoroscopy mode was selected. The irradiation was long enough (50 mGy) and three measurements were taken for each mode and the mean values were calculated. The K (IRP), KAP were recorded from the console and the measured air kerma from the ion chamber was also recorded. The measured KAP was estimated from the measured air kerma using equation 1.

$$\mathrm{KAP} = \left[\text{measured } K_{a,r}\right] \times \text{Field size} \qquad (1)$$

The measured air kerma was first corrected for distance difference between the measurement point and

the IRP using the equation 2.

$$\text{Measured Air Kerma}_{\text{RPAK}} = \text{Measured Air Kerma}_{\text{SDD}} \left[{}^{\text{SDD}}\!/_{\text{SAD}-15} \right]^2 \quad (2)$$

where SDD is the source to detector distance and SAD is the source to axis distance which is at 15 cm from the IRP. The air kerma correction factor is calculated based on equation 3.

$$\text{Correction factor} = {}^{\text{Measured air kerma}}\!/_{\text{Console air kerma}} \quad (3)$$

Peak skin dose calculation

The peak skin dose was determined by irradiating a PMMA phantom and the correction factors for physical dependencies were applied to the corrected air kerma. The corresponding physical factors applied are: irradiation geometry, conversion of K (IRP) to absorbed skin dose, scattered radiation and tabletop and pad. Skin absorbed dose is then derived using equation 4 below[20]:

$$D_{\text{skin}} = AK_{\text{corr}} \times K_{\text{isq}} \times K_{BS} \times K_f \times K_{(T+P)} \quad (4)$$

AK_{corr} is the value of the K (IRP) read on the console corrected with the factor obtained with equation 3.

$K_{\text{isq}} = \left(\frac{d_{\text{IRP}}}{d}\right)^2$ is the correction for source to skin distance where d_{IRP} is the distance from the focal spot to the interventional reference point (15 cm from the isocenter) and d represents the source-to-skin distance which is derived from table position. K_{BS} is the backscatter factor, $k_{(T+P)}$ is the correction factor for tabletop and pad attenuation and k_f is the conversion factor of K (IRP) measured in air to the dose in soft tissue or PMMA phantom.

Table and pad factor

In order to avoid the scattered radiation from the table and pad, the ion chamber was placed at 5 cm on top of patient (or phantom) entrance surface with the tabletop and pad in their normal position during an FGI procedure. The phantom was irradiated for a field size of 10 × 10 cm^2 at the interventional reference point. Therefore, the correction factor of the distance from focus to IRP and focus to patient skin distance was considered as 1. The K (IRP) without the tabletop was calculated from the K (IRP) corrected with the factor found in equation 5 applying the inverse square law for distance correction.

$$AK_{\text{without},TP} = AK_{\text{corr}} \left(\text{IRP}/d_{\text{source to table}}\right)^2 \quad (5)$$

The correction factor was found by calculating the ratio between the measurements and the value found without the tabletop and pad as shown in equation 6.

$$K_{T+P} = {}^{AK_{\text{with}}}\!/_{AK_{\text{without}}} \quad (6)$$

The table and pad attenuation factor found in this study without added filtration was between 0.65 and 0.70 in function of the field size.

f-factor

The f-factor is the conversion factor from exposure, or K (IRP), to absorbed dose in PMMA or soft tissue. The f-factor calculated using equation 7 below from the data provided by NIST is 1.05[21]. According to the International Commission on Radiation Units and Measurements (ICRU) data for soft tissues, the f-factor value at 80 keV of 1.06 is commonly employed for diagnostic and interventional radiology X-ray beams[22].

$$f - \text{factor} = \frac{\left(\mu/\rho\right)_{\text{PMMA}}}{\left(\mu/\rho\right)_{\text{air}}} \quad (7)$$

Backscatter factor

The backscatter factor is the ratio of the dose at the entrance surface of the phantom or patient, to the dose at the same point in air without the phantom. It can be measured with an ionization chamber or be calculated using Monte Carlo methods. Many studies have shown that the backscatter factor depends on the primary beam quality expressed in terms of HVL and kV, the field size of the beam at the entrance of the phantom, the thickness and the material composition of the phantom and the source to skin distance[23–26]. According to AAPM TG 357, the most used work for backscatter factors was provided by Petoussi-Henss *et al.* for ICRU soft tissues for a range of diagnostic quality X-ray beams for entrance field sizes from 10 × 10 to 25 × 25 cm^2 [27]. Therefore, the backscatter factor for this study was adopted from the table provided by Petoussi-Hens *et al.* For PMMA phantom at different energies, field size and focus to surface distance (FSD). The factor of 1.53 which correspond to a beam at

Table 1. Air kerma and mean ESD function of field size and thickness in fluoroscopy and image mode.

Field size	Thickness	KV	mA	Air kerma (mGy)		KAP (Gy.cm^2)		Total air kerma (mGy)	Mean ESD ± STD (mSv)
				Fluoro/Minute	Dose/Image	Fluoro/Minute	Dose/Image		
10 × 10	10	55	3	3.6	0.02	0.39	0.004	21	27.47 ± 0.62
	15	61	5.4	9.4	0.05	0.74	0.004	54.5	65.14 ± 5.35
	20	67	9	21.4	0.14	1.72	0.011	128	145.55 ± 8.96
15 × 15	10	55	3	4	0.02	0.74	0.004	23	27.3 ± 0.68
	15	61	5.4	9.4	0.05	1.92	0.01	54.5	73.53 ± 3.61
	20	67	9	21.6	0.14	4.26	0.026	224	171.6 ± 5.75

80 keV, a field size of 10 × 10 cm^2 and FSD equal to 50 cm was considered.

Data analysis

The calculated PSD were compared to PSD measured using TLDs. The correlations between the cumulative K (IRP) reported at the console and the PSDs found were analyzed. K (IRP), KAP and fluoroscopy time were collected from real procedures (only procedures with K (IRP) higher than 300 mGy were selected). The results obtained from the correlation in this study and previous findings were applied to the K (IRP) from real procedures for comparison purpose[8, 28]. The corresponding deviations were calculated using equation 8 below and box plot was performed using excel features. A look up table was proposed for use in the Cath-Lab to facilitate patient dose management after prolonged procedures.

$$\text{Deviation} = \frac{\text{PSD}_{\text{calculated}} - \text{PSD}_{\text{measured}}}{\text{PSD}_{\text{measured}}} \times 100 \quad (8)$$

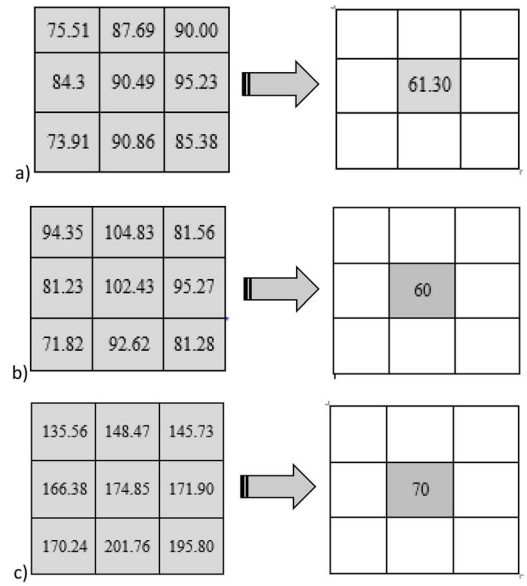

Figure 1. Measured skin dose (mSv) against the air kerma (mGy) at different tube angulations (a) AP 0° (b) LAO 45° and (c) RAO 45°.

Results

The QC tests performed on the under-couch tube were found comparable with the national acceptable criteria. The impact of factors such as field size, and the thickness of the phantom on the K (IRP), KAP and mean skin dose are presented in Table 1.

The estimated air kerma correction factor without any additional filtration were 1.18 and 1.2 for 10 × 10 cm^2 and 15 × 15 cm^2 field sizes respectively. The error of 0.2% was within the 35% recommended by international regulations.[12, 16, 28] The estimated mean table and pad attenuation factor was 0.65.

Peak skin dose represents the highest skin dose that would be reasonably expected to observe by assuming that the entire radiation dose is directed through the same skin area while the tube angulation is not taken into account. In reality, the conversion factors applied represent a conservative scenario. Figure 1 presents the reality between the reported K (IRP) on the console without correction against the directly measured skin dose for different tube angulation in cine acquisition mode.

Figure 1 shows that the Peak Skin Doses (PSD) for each orientation of the gantry are 95.23, 104.83 and 201.76 mSv for AP 0°, LAO 45° and RAO 45° respectively. These PSD correspond to a non-corrected air kerma reported on the console (cumulative doses) of 61.30, 60 and 70 mGy respectively. This shows that PSD are higher than the air kerma read on the console with factors 1.55, 1.75 and 2.88 for AP 0°, LAO 45° and RAO 45°, respectively. Meaning the K (IRP) reported on the console underestimate patient dose, therefore cannot be considered as such unless a factor is applied to it.

Figures 2 and 3 present the correlation between KAP and PSD, air kerma (measured and estimated) and PSD respectively. From the analysis, the equations that can

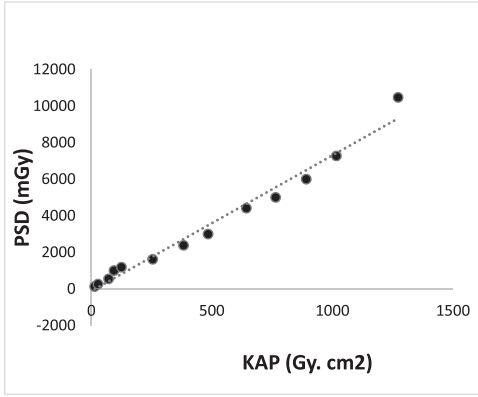

Figure 2. Relationship between the estimated PSD using Stecker *et al.* 2009 formula and the recorded KAP from the console.

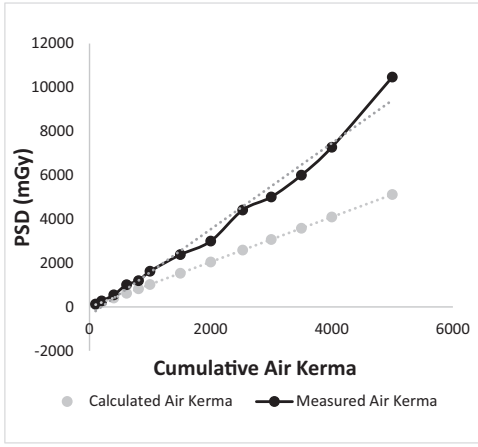

Figure 3. Relationship between the directly measured PSD using TLDs. The calculated PSD using the formula provided in equation 4 and cumulative air kerma recorded from the console.

be used to predict the PSD from KAP or air kerma are presented in equations 9, 10 and 11.

$$\mathrm{PSD}_1\ (\mathrm{mGy}) = 7.44\ \mathrm{KAP}\ \left(\mathrm{Gy.cm}^2\right) - 115.99\ \left(R^2 = 0.98\right) \quad (9)$$

$$\mathrm{Measured\ PSD}_2\ (\mathrm{mGy}) = 1.96\ K_{a,r}\ \ (\mathrm{mGy}) - 383.57\ \left(R^2 = 0.98\right) \quad (10)$$

$$\mathrm{Estimated\ PSD}_3\ (\mathrm{mGy}) = 0.94\ K_{a,r}\ \ (\mathrm{mGy})\ \left(R^2 = 1\right) \quad (11)$$

Stecker *et al.* in 2009, in order to evaluate the risk of deterministic effect proposed equations that can be used to estimate the PSD after procedure from K (IRP) higher than 500 mGy and KAP higher than

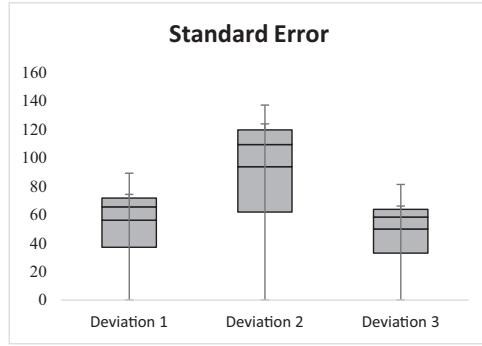

Figure 4. Boxplot of the standard errors between the measured PSD with the TLDs and deviation 1: estimated PSD using equation 4, deviation 2: the estimated PSD using Stecker *et al.* (2009), deviation 3: the estimated PSD using Dickinson *et al.* (2014).

50 Gy.cm^2. In the same perspective, Dickinson *et al.* in 2014 proposed a look up table for patient's entrance surface dose estimated based on calculation from the cumulative K (IRP) starting at 1000 mGy.[8, 28] The PSD equations estimated from the previous figures were used to calculate the PSD in real procedures based on the collected sample data and a comparison study between the results obtained from different methods are presented in Table 2. Figure 4 is an illustration of the standard errors estimated from the results estimated from equations in relation with the measured values. This results in proposing the look up table from the radiation protection point of view which is presented in Table 3.

Discussions

Interventional cardiology are long and complex procedures involving high radiation dose that sometime can reach the threshold of deterministic effect. The most recent equipment (c-arm) has incorporated commercial dose mapping software, but because of the high cost of such equipment, most in Africa report only the fluoroscopy time, KAP and cumulative K (IRP). In this study for the first time, we have evaluated the PSD from the reported metrics using two different methods: direct measurements using TLDs and calculation methods using conversion factors for left coronary diagnostic and interventional procedures. From the measurements, the correction factor for K (IRP) was 1.2 and the table and pad attenuation factor were found to be 0.65. The equation describing the correlation between the PSD measured and the KAP, PSD measured and estimated with the cumulative K (IRP) was found with R-square values of 0.98, 0.98 and 1 respectively, meaning that those metrics are highly correlated and fit. The corresponding equations of fitness were derived and applied to the values obtained

Table 2. Calculated and measured PSD applied to real cases compared with previous study.

AK (mGy)	KAP (Gy.cm^2)	PSD from air kerma (Gy)			
		This study measured	This study estimated	Stecker *et al.* 2008[8]	Dickinson *et al.* 2014[29]
324	19.4	0.25	0.30	0.37	0.28
382	38.0	0.37	0.36	0.40	0.33
413	39.4	0.43	0.39	0.42	0.36
526	89.5	0.65	0.49	0.48	0.46
723	27.3	1.03	0.68	0.58	0.64
760	70.4	1.11	0.71	0.60	0.67
966	159	1.51	0.91	0.70	0.86
1100	45.3	1.77	1.03	0.77	0.98
2436	251	4.391	2.29	1.46	2.18
7360	442	14.04	6.92	3.98	6.61
8895	1966	17.05	8.36	4.77	7.99

Table 3. Look up table with measured PSD, tissue reactions and approximate time of onset.

Look up table with measured PSD					
Air kerma (mGy)	Measured PSD (Gy)	Tissue reactions & approximate time of onset			
		Prompt (<2 wk)	Early (2–8 wk)	Midterm (6–52 wk)	Long term (>40 wk)
610	1.01	No observable effects expected	No observable effects expected	No observable effects expected	No observable effects expected
810	1.19				
1000	1.63				
1500	2.38				
2000	2.99	Transient erythema	Epilation	Recovery from hair loss	No observable results expected
2500	4.52				
3000	5.01				
3500	6.01				
4000	7.28				
5000	10.47	Transient erythema	Erythema, epilation	Recovery; at higher doses, prolonged erythema; permanent partial epilation	Recovery; at higher doses, dermal atrophy or induration
6000	11.38				
7000	13.34				
8000	15.30				
9000	17.26				
10 000	19.32				

from the real procedures. This study was applied to selected patients in the institution who were irradiated with a cumulative K (IRP) higher than 300 mGy. The results of this study shows that the direct measured PSD was higher than the calculated PSD with a mean deviation of 28.6±23.04%. Dickinson *et al.* in 2014 proposed a look up table based on calculation methods and Stecker *et al.* in 2009 proposed equations to estimate the PSD from radiation dose reported from the information system after procedures. The measured PSD in this study was found higher than the PSD obtained when proposed methods by Dickinson *et al.*[29] and Stecker *et al.* in literature were applied with mean deviations equal to 33.21±20.50% and 34.73±38.41%, respectively. But the calculated PSD found in this study is comparable to the one found by Dickinson *et al.* and Stecker *et al.* This can be attributed to the fact that it is based on the same methodology of calculation.

The high difference of the measured values from the calculations (Figure 4) can be explained by the fact that the radiation beam distribution is non uniform and is different at specific points on the same skin irradiated area (Figure 1). While the calculation method is based on the reported cumulative K (IRP) at a specific point on the beam (IRP) which may not be the point of highest dose, the measurement is performed on the whole irradiated area and the highest dose is chosen as PSD. Therefore, calculation methods can underestimate the PSD. It can be concluded that the best and more accurate method to evaluate the PSD is the direct measurement using TLDs or gafchromic films, etc. This method also presents some disadvantages in the sense that it is expensive and difficult to implement in practice. Therefore, this study concluded by proposing a look up table (Table 3) based on TLD measurement on the radiation protection point of view. This will facilitate the conversion of cumulative K (IRP)

or KAP reported on the system after each procedure into PSD in order to facilitate patient dose management after every procedure and judge the implementation of direct follow-up in case of long and complex procedures. Additionally, the equation of fitness (equation 8) was proposed to be used by the facilities for doses higher than 500 mGy. Overall, 27% of recorded patients received skin doses higher than the threshold of deterministic effects and are likely to develop transient erythema, epilation, etc. Therefore, more practices for dose optimization must be applied in the corresponding center.

This study did not take into account the uncertainties of measurements during the correction factors estimations as proposed by Jonas Andersson *et al.* 2021 in the summary of a joint report by AAPM TG357 and EFOMP.[27] Additionally, a deep study of the determination of those factors taking in account the variation of filtrations, field of view and other factors affecting patient dose is yet to be carried out. The estimation of the PSD does not take into account the tube angulation during real procedures, further studies taking into account the tube angulation are highly encouraged.

Conclusion

PSDs during fluoroscopy cardiac procedures using an acrylic PMMA phantom of dimensions 25 × 25 × 20 cm with TLDs were evaluated. From the reported metrics, the mean [range] of fluoroscopy time, KAP and K (IRP) were 21.44 [2.2–165] minutes, 2171.36 [324–8895] Gy.cm^2, respectively for left coronary diagnostic and interventional procedures. It was found that measured PSDs were higher than the K (IRP) read on the console with factors 1.55, 1.75 and 2.88 for AP0°, LAO45° and RAO45°, respectively. Additionally, the measured PSD in this study was found higher than the PSD obtained when proposed methods by Dickinson *et al.* 2014 and Stecker *et al.* 2009 in literature were applied with mean deviations equal to 33.21±20.50% and 34.73±38.41%, respectively. It was also found that 27% of the patient's population considered in this work. Therefore, a look up table was proposed based on TLD measurement on the radiation protection point of view for implementation in order to contribute to the patient dose optimization and facilitate patient management after procedures.

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