Volume 23, No 1 | International Journal of Radiation Research, January 2025

Estimation of peak skin dose in cardiac interventional procedure using radiation dose structured report-an indirect method

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► ***Original article***

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Received: June 2023
Final revised: January 2024
Accepted: February 2024

Int. J. Radiat. Res., January 2025; 23(1): 141-146

DOI: 10.61186/ijrr.23.1.141

Keywords: *Interventional radiology, radiation dose, cardiologist, patient, follow up.*

ABSTRACT

Background: The purpose of this study is to estimate PSD indirectly using a Radiation Dose Structured Report (RDSR) from Cath lab interventional procedures. The estimated dose was then compared with direct measurements using films. ***Materials and Methods:*** Information on radiation exposure and dosage associated with a specific interventional radiology procedure is provided in the RDSR document. The RDSR produced by the machine was verified using slab phantom, Gafchromic XRV3 film, and Ray Safe X2 detector. The PSD is estimated by adding the intensely projected beam dose in acquisition mode with the fluoroscopic dose percentage obtained from the RDSR. During the procedure, Gafchromic films were used to measure PSD directly. Then, the estimated PSD was compared with the measured PSD. ***Result:*** The PSDmes and PSDcal in this study showed an average difference of 0.12 Gy (8%). The Wilcoxon Signed-Rank test has a p-value of 0.08 and the Spearman's rank correlation coefficient (rs) of 0.97 indicates a very strong positive correlation between the two variables. ***Conclusion:*** The Statistical analysis shows that the estimation of PSD using RDSR is reliable for monitoring the patient. This method may help the cardiologist to follow up of the patients to give extra care to skin reactions. A safe standard work practice will certainly monitor the prevention of undesirable consequences of radiation.

INTRODUCTION

The risk of skin damage is considered more important in Cath-lab interventional procedures than in any other radiological investigation [1]. The complexity of the procedure and the cardiologist's expertise are significant factors in procedural time and an undue prolongation of the procedure. The prolonged radiation exposure increases the dose to the patient and to all members of the Cath-Lab team. The data published by the American Heart Association in 2021 showed that more than one million Cath-Lab procedures are done every year [2]. A total of 4,38,351 percutaneous interventional procedures were carried out in 12 months in 2018 according to national interventional data published in 2020 [3]. During Cath-Lab procedures, the major part of the radiation is contributed to the skin dose of the patient. It induces severe skin reactions [4] such as erythema, epilation, dry and moist desquamation, dermal atrophy, etc.[5]. Coronary angiography (CAG) [6] and percutaneous transluminal coronary angioplasty (PTCA) [7] were the most frequently performed cath lab procedures. There is a higher chance of skin reactions with longer exposure times in PTCA operations. Cardiologists, Cath lab technicians, and staff nurses are the most common members of cath lab teams. Similar to radiologists, physicists, and radiographers, these specialists do not have the necessary background in radiation safety. Therefore, there may still be a risk of overexposure to the patient and occupational exposure to the staff [8]. Many researchers are trying to find out the Peak skin dose (PSD) using various techniques [9, 10]. For direct dose measurements, Thermo luminescent dosimeter (TLD) [11, 12] and Gafchromic films [13] are commonly employed; different dose-verifying software [14–16] and dosimeters are developed for real-time dose monitoring. All these methods are costly and require specific skills to manage and evaluate the dose [17].

This study estimated the PSD from the radiation dose structured report (RDSR) and verified the dose with a directly measured dose using Gafchromic films. This is a new approach to peak skin dose measurement and the main advantage of this method was no need for any additional dose-measuring instruments or special software for PSD calculation. The cardiologist or the cath lab technologist can

[DOI: 10.61186/ijrr.23.1.141]

easily calculate the PSD from machine-generated RDSR after each procedure.

MATERIALS AND METHOD

The study was conducted in our cath lab room equipped with the Siemens Artis dFC Cath-Lab unit. This is a floor-mounted type unit with a 20cm² Flat panel detector manufactured by Siemens Medical Solutions USA. The treatment table is made up of low-attenuating carbon fiber material. The tabletop is free -floating with a customizable tableside control module and can rotate up to 120°. A calibrated RaySafe X2 detector with its base unit was used to measure the dose for film calibration. RaySafe X2 detectors are specially designed dosimeters for diagnostic QA (Quality Assurance). The system was manufactured by Unfors RaySafe AB, Sweden and marketed in India through Fluke Technologies Pvt. Ltd, India. It can measure the dose ranges from 1nGy to 999Gy with 5% uncertainty.

For direct patient dose measurements, Gafchromic XR-RV3 films [18] are used, which is considered to be the gold standard [19] for estimating PSD. Gafchromic XR-RV3 films are designed for skin dose measurements in the radiological interventional procedure. It has four layers –The yellow polyester layer, a pressure-sensitive adhesive layer, an active layer, and a white polyester layer. The total thickness of the film is 231 microns. The film size used in this study was 14"×17", sufficient to cover the exposed area using different projections. The film was analysed using Image J software version 1.53S by Wayne Rasband and Contributors, NIH, USA. It is a Java-based image processing program [20, 21]. It is a public-domain image processing and analysis program. The calibration of the film was done at the Patient Entrance Reference point (PER), which was formerly known as the interventional reference point [22]. The RaySafe X2 detector was placed at the PER point and exposed the detector with fixed exposure factors to find out the dose. Then replace the detector with the film and repeat the exposure with the same exposure factors to record the same dose on the film. Then repeat the process with various exposure times to get different doses. Thus eight films were exposed in different known doses (0.25,0.5,0.75,1,2,3,4 and 5 Gy) and one unexposed film (background correction) of the same batch was used to create the calibration curve using the Rodbard function in Image J software (Fig-1). The Rodbard function is available in ImageJ software with four fitting coefficients [23, 24].

Verification of radiation dose structured report (RDSR)

A comprehensive document that provides information on radiation exposure and dose-related to a particular interventional radiology procedure is called a Radiation dose structured report. The RDSR was generated from the machine after the end of each interventional procedure. To verify the RDSR from the machine, a standard RDSR was created by exposing the machine to a 20 cm thick slab phantom in a Coronary Angio setting and evaluating the percentage of variation of RDSR from the measured dose. The measurement was done using Gafchromic XR RV3 film, which was placed at the level of PER point. The slab phantom was placed above the film to simulate the patient. The exposure time was adjusted in steps of one second, ranging from one to six seconds. On each exposure, the exposure area on the film was changed to avoid the overlap of the field on the film. Thus, six fields with different levels of blackness (optical density) were formed on the film depending on the dose exposed. The RDSR from the machine was generated after these procedures. The optical density on the exposed film was converted to dose using Image J software. Finally, calculated the dose variation by comparing the Total Dose (TD-R) in the Radiation dose structured report from the machine with the Total Dose (TD-Mes) measured using film. This value is used as a correction factor for calculating PSD.

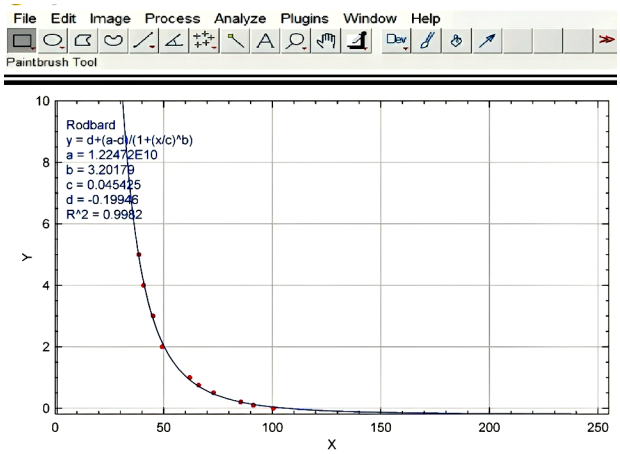

Figure 1. Shows the Image J program toolbar and Calibration curve generated with the Rodbard function using measured dose.

Direct measurement of PSD

Gafchromic XR RV3 films of size 14"×17" are used to measure the skin dose for each patient. Due to the high cost of the Gafchromic XR RV3 film and its unavailability, direct dose measurement was limited to 30 selected patients. The patient inclusion criteria were (i) Percutaneous transluminal coronary angioplasty (PTCA)/Coronary Angiogram (CAG) procedure and (ii) the average chest thickness becoming 25±2 cm (table 1). The PSD measurement was done by fixing the film on the back side of the patient's chest. During the procedure, X-rays are passed through the film and the patient's body and fall on a flat detector (FD), forming the image. The dose of the X-rays passing through the films creates corresponding blackness (optical density) on the film. These films were stored for 24 hours and then

[DOI: 10.61186/ijrr.23.1.141]

scanned with an Epson 12000XL flatbed scanner [25, 26]. The blackness on the film (Optical density) was converted to dose using the Image J software.

Table 1. Shows the patient's characteristics.

Variable	Content	Value
Age	Mean (Min, Max)	57 (30,73)
Gender	Male, Female	23,7
Chest size (cm)	Mean (Min, Max)	25 (22.5,27)
Procedure	Angioplasty Angiography	25 5

Indirect measurement of PSD

In this section, a new method has been used to estimate the PSD. The PSD be indirectly calculated using the Radiation Dose Structured Report [27] from the machine (figure 2). The total dose in a Cath-Lab interventional procedure is the sum of all doses when the machine is operated in Acquisition mode as well as Fluoroscopic mode. The first process in this calculation is to determine the proportion of fluoroscopic doses in the total dose. Then identify the Intensely Projected Beam Dose (IPBD) in the acquisition mode. This was obtained by the summation of the dose from each projection separately in the acquisition mode. Then the sum of IPBD and a percentage of Fluoroscopic doses give the estimated PSD. This value may be corrected using the correction factor explained in the 'Verification of RDSR' section to get a more accurate PSD (PSD_{cal}). The measured data are given in table 2.

The step-by-step calculation process in equation (1) to (5):

Total Dose (TD) = Acquisition Dose (AD) + Fluoroscopic Dose (FD) (1)

Percentage of FD in TD, (FD %) = FD/TD × 100 (2)

Intensely projected Beam Dose (IPBD) = Maximum projected beam dose in Acquisition Mode.

Fluoro Contribution in Peak skin dose, PSD_{FC} = FD × FD% (3)

$PSD = IPBD + PSD_{FC}$ (4)

$PSD_{Cal} = PSD - CF$ (5)

CF –Correction factor explained in the section "Verification of RDSR".

Statistical validation

The data collected were in Microsoft Excel. The test of normality is done using the Shapiro–Wilk test. The correlation of PSD measured using film (PSD_{mes}) and PSD_{Cal} was analysed using the Wilcoxon Signed-Rank test and Spearman's rank correlation coefficient (r_s). The Bland and Altman plot was used to assess the clinical concordance and the potential bias between PSD assessments. BA plot method[28] is used to analyse the presence of a systematic difference between the two measurements. If the data points in the plot are very close to the zero line, it indicates a good agreement between the two methods.

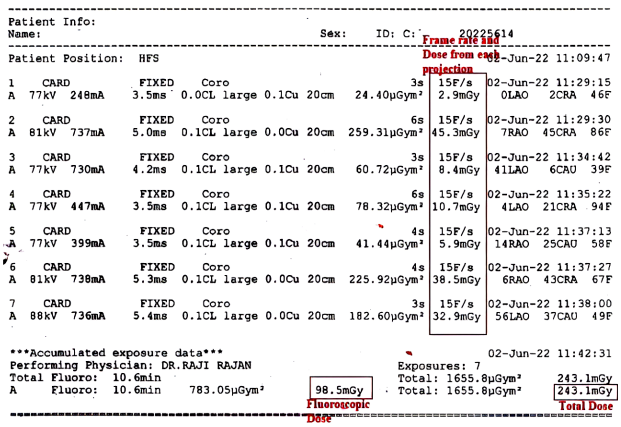

Figure 2. Shows a sample RDSR from Siemens Artis-dFC Cath-Lab unit.

RESULTS

The film was calibrated with Image J software using the rodbard function, and the calibration curve was generated. The difference between the total dose measured using film (TD-Mes) and the total dose from RDSR (TD-R) was calculated. The TD-R was 0.942Gy, the TD-Mes were 1.042Gy and the variation between the two is 10.6% (0.1Gy). Figure 3 shows the values of TD-Mes versus TD-R. The acquisition doses in the RDSR were tabulated in an Excel sheet and the dose from each projection was separately added to find out the Intensely Projected Beam Dose (IPBD). The average percentage of fluoroscopic dose in the total dose from whole patient data was 59%, which is a comparable value with other literature data [29]. The mean and standard deviation of the differences in doses from PSD_{Mes} and PSD_{Cal} values are given in table 3. Percentage variation from the measured dose has a minimum value of -18.34 and a maximum value of 33.80. The 50th percentile of this result is 11% and the 75th percentile is 20.51%, i.e. 50% of values lie within 11% variation and 75% of values lie within 20.51% variation.

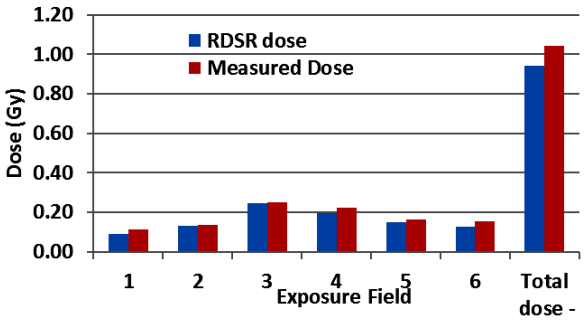

Figure 3. Shows the comparison between doses measured using film and the dose from RDSR.

Shapiro–Wilk test was done on PSD_{Mes} and PSD_{Cal} values. In both cases, the P-value is less than 0.01 which indicates that the values deviate from normality (table 4). Hence, the non-parametric test

[DOI: 10.61186/ijrr.23.1.141]

namely the Wilcoxon signed-rank test was used to test the difference in the doses from PSD_{Mes} and PSD_{Cal} values. The p-value is 0.271 in the Wilcoxon Signed-Rank test showing the difference between the two methods is non-significant and Spearman's rank correlation coefficient (rs) is 0.982 which means a strong positive association between the two variables.

Table 2. Shows the type of procedure and measured values.

Patient	Procedure	TD From RDSR (Gy)	DAP $Gycm^2$	PSD_{MES} Gy	PSD_{CAL} Gy
A	PTCA	4.608	230.56	2.347	2.768
B	PTCA	2.986	157.44	1.19	1.372
C	PTCA	1.022	51.215	0.597	0.494
D	CAG	0.329	19.875	0.28	0.19
E	PTCA	3.383	171.53	3.166	2.555
F	PTCA	0.961	53.92	0.676	0.598
G	PTCA	2.021	110.58	1.722	1.396
H	PTCA	1.323	64.269	0.719	0.721
I	PTCA	2.556	108.96	1.547	1.603
J	PTCA	3.048	129.88	2.035	1.623
K	CAG	0.363	21.434	0.361	0.239
L	CAG	0.181	11.62	0.169	0.133
M	CAG	0.504	29.518	0.277	0.217
N	PTCA	2.229	110.76	1.19	1.073
O	PTCA	1.633	89.807	0.676	0.8
P	PTCA	0.937	49.269	0.597	0.519
Q	CAG	0.243	16.558	0.127	0.111
R	PTCA	1.398	61.652	0.597	0.669
S	PTCA	1.105	57.54	0.867	0.662
T	PTCA	2.937	141.54	1.19	1.245
A	PTCA	2.935	164.32	2.75	3.059
B	PTCA	4.417	245.89	3.408	3.918
C	PTCA	4.918	278.97	2.98	3.446
D	PTCA	2.526	137.28	2.311	1.75
E	PTCA	3.86	224.89	1.082	1.217
F	PTCA	1.36	72.73	0.935	0.718
G	PTCA	4.953	234.94	1.826	1.635
H	PTCA	5.324	338.91	3.211	2.888
I	PTCA	1.978	125.37	1.005	1.106
J	PTCA	2.32	139.31	1.08	0.872

Table 3. Shows the descriptive statistics regarding the calculated and measured PSD.

Variables	Minimum	Maximum	Mean	Std. Deviation	Percentile		Interquartile range IQR
					50^{th}	75^{th}	
PSD_{Cal}	0.11	3.92	1.3199	1.040	1.090	1.664	1.09
PSD_{Mes}	0.13	3.41	1.3639	0.988	1.081	2.104	1.51
Difference	-0.51	0.61	0.0440	0.268	0.069	0.206	0.31
% of variation from measured dose	-18.34	33.80	6.8683	16.476	11.00	20.51	31.95

Table 4. Shows the Result of Normality Test between PSD cal and PSD mes.

Variables	Shapiro-Wilk test		
	Statistic	Degrees of freedom (df)	P-value
PSD_{Cal}	0.891	30	0.005
PSD_{mes}	0.901	30	0.009

The level of agreement between the two methods was also done by using Lin's concordance coefficient and it was calculated as 0.98 with a 95 % confidence interval [0.959; 0.990] and p<0.001 which showed a substantial concordance between the doses measured from the two methods that were further confirmed by the Bland–Altman plot (figure 4).

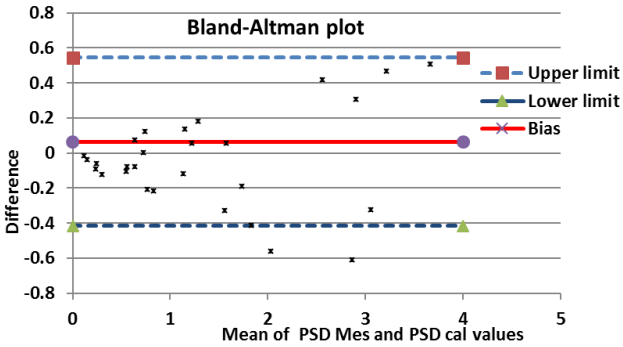

Figure 4. Shows the level of agreement in doses from PSDMes and PSDCal values using the Bland -Altman plot.

DISCUSSION

Radiology professionals still find it difficult to estimate radiation dose directly during complicated clinical procedures; in these cases, indirect measurements of dose are significant [30]. The accuracy of estimation PSD mainly depends on the dosimetric quantities reported in the RDSR(14). Therefore, it is important for the study that the reported value and measured value be verified in accordance with the requirements [31]. Obtaining a precise value during PSD estimate is not necessary, according to an article by Balter *et al*. By entering the estimated value in the dose bands [32] (0–2, 2–5, 5–10, 10–15, and >15 Gy), one can nevertheless access the radiation consequences. The statistical analysis shows that the above method is reliable in estimating the PSD for monitoring the patients. Skin damage, hair loss, and cataracts are examples of deterministic effects of radiation that vary depending on radiation dose and are evaluated using peak skin dose [33]. The estimation of PSD may help the doctors to follow up [34] with the patients to give extra care to avoid skin reactions. Doctors can accurately determine the degree of radiation exposure to a patient's skin surface by tracking and recording the peak skin dose. Long-term patient follow-up and monitoring are necessary to identify any possible late effects of radiation exposure which depends on this information. In this method, what one needs is only some basic knowledge about the RDSR generated by the machine. All other methods [35] require unique expertise for that device's usage, whether it may be TLD, OSDL, MOSFET etc. In this method, the priori and a posteriori models [36] are not necessary for the calculation of PSD. A slight modification of the format of the RDSR will help them to estimate PSD easily. It is suggested that the manufacturers to modify the RDSR format with some small changes. The cumulative dose from Right Anterior Oblique –Cranial (RAO-CRA), Right Anterior Oblique –Caudal (RAO-CAU), Left Anterior Oblique –Cranial (LAO-CRA), and Left Anteri-

[DOI: 10.61186/ijrr.23.1.141]

or Oblique –Caudal (LAO-CAU) (ignore the small variations in angle) may give separately in addition to the common parameters like total dose, Dose Area Product (DAP), Total time, etc. Thus cath lab technologist or doctor can easily calculate the PSD and record the dose. In future, this study may have the potential to compare the calculated PSD with different dose mapping software offered by various vendors.

Limitations of this study

- There were limited sample sizes utilized in this study's calculations, and just one alternative method was used for verification.
- This was a single-centered study so the mode of operations in Fluoroscopic and acquisition modes of various institutions and their work practice were not included.
- The RDSR used in this study was from our Siemens Cath-Lab unit. Other models may have different RDSR formats.

CONCLUSION

Throughout radiological operations, all patients get a small but inevitable dosage of radiation. This study provides a less expensive method of alternate dose measurement technique and makes available the easiest way for each member of the Cath lab team to estimate the PSD. This will help to optimise the radiation dose in Cath-Lab and help the patients to warn off the undue dose. To sum up, this will certainly improve the quality of life of patients and enhance the fine work practice of the staff. Comprehending the correlation between peak skin dose and other dose-related parameters, like the dose-area product, will aid future research in anticipating and handling radiation-related issues more effectively, as well as in maximizing radiation safety precautions during cath lab procedures.

ACKNOWLEDGEMENTS

We thank all the cardiologists, Cath-lab technologists, Staff nurses and other supporting staff in the Department of Cardiology, General Hospital Ernakulam for supporting the study.

***Funding*:** Nil

Conflicts of Interest: The authors declare no conflict of interest.

***Ethical consideration*:** The whole study was carried out with the approval of the institution's ethical committee (IEC/2020/29). All the procedures were performed according to the current standard of care and after receiving the patient's informed consent.

***Author contribution*:** Conceptualization, methodology, validation, writing -original draft, and editing, S.S.N.; Supervision, S.K.G. & S.N.S.; Formal analysis, writing-review, K.T.T.; All authors have read and agreed to the submitted version of the manuscript.

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[DOI: 10.61186/ijrr.23.1.141]