



Original Article

Minimizing scattered radiation dose in cardiac catheterization laboratory during interventional procedures using lead free drape – MILD study



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ABSTRACT

Objective: RADPAD is a lead-free sterile drape that reduces scattered radiation during fluoroscopic procedures. We aimed to study the effect of using RADPAD on primary operator (PO) and secondary operator (SO) during coronary angiography (CAG) as well as percutaneous coronary intervention (PCI). **Methods:** 137 patients undergoing elective CAG and PCI were randomized in a 1:1 pattern with or without the RADPAD. The ratio of PO received dose in mrem to total Air Kerma (AK) in mGy, Dose Area Product (DAP) in mGycm² and Cine Adjusted Screening Time (CAST) in minute, at the end of the procedure with or without RADPAD were measured and designated as dose relative to AK, DAP and CAST. The exposure ratios were compared for both cohorts.

Results: There was no significant difference in CAST, DAP and AK between the two patient cohorts. PO radiation dose relative to CAST was 0.15 ± 0.18 mrem/min for RADPAD cohort and 0.43 ± 0.31 mrem/min for No RADPAD cohort ($p < 0.00001$). PO dose relative to DAP was 0.00042 ± 0.00049 mrem/mGycm² for RADPAD cohort and 0.0011 ± 0.0013 mrem/mGycm² for No RADPAD cohort ($p = 0.000014$). PO dose relative to AK was 0.0030 ± 0.0037 mrem/mGy for RADPAD cohort and 0.0071 ± 0.0049 mrem/mGy for No RADPAD cohort ($p < 0.00001$). All PO doses relative to CAST, DAP and AK were significantly reduced in the RADPAD cohort compared to the No RADPAD cohort. Similar findings were observed for the SO also.

Conclusion: RADPAD significantly reduces radiation exposure to both PO and SO during CAG and PCI. © 2022 Published by Elsevier, a division of RELX India, Pvt. Ltd on behalf of Cardiological Society of India. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

1. Introduction

Radiation safety is an area of utmost concern for all health care providers who have an association with X-ray-based imaging during the routine diagnostic or therapeutic procedures. Interventional radiologists and cardiologists who receive excessive exposure to ionizing radiation are at risk of developing severe occupational hazards such as cancer, cataract, skin injuries, and tumor.^{1–5} In a cardiac catheterization laboratory (Cath lab) not only the health-care provider such as primary operator or the support staff but also the patient undergoing the procedure are exposed to significant dose of radiation. Both Fluoroscopy and Cine Angiography (Cine) are responsible for generating radiation in a Cath lab. While

Fluoroscopy accounts for 40% of the total radiation exposure, Cine is responsible for causing 60% of the total radiation exposure.⁶ In a study on radiation-induced cataracts, it was found that 52% of interventional cardiologists had posterior subcapsular cataracts, citing radiation as the cause.² The lens of the eye is a region of particular involvement, and several studies have shown an increased incidence of cataracts among the workforce of the Cath lab.^{2,7,8} This may be attributed to the compounding effect of multi-year career in radiation environment as well as exposure to prolonged interventional procedures.⁹

According to the recent data of the National Interventional Council of Cardiological Society of India (CSI–NIC), a total of 4.38 lakh percutaneous coronary interventions (PCIs) were performed in the year 2018 across 709 cardiac centers. This data corresponds to a growth of 13.14% in the number of procedures during one-year period as compared to the year 2017.¹⁰ Due to the increasing number of interventional coronary and endovascular procedures

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with fluoroscopy along with the corresponding high annual radiation dose for interventionists, additional dose-protecting measures are desirable. 'RADPAD' is a newly introduced radiation protection drape in India (Worldwide Innovations Technologies, Inc., Kansas City, Kansas) that contains Bismuth and Antimony. It is an ecofriendly Bismuth-based, lead-free drape to be placed appropriately on the patient (Fig. 1) between the primary X-ray beam and the operator which has been shown to reduce scatter radiation exposure of the primary operator (PO).^{11–15} However, there is no study that has assessed the effect of radiation protection drape on secondary operator (SO). There are only a few studies which have assessed its efficacy in PO.

We aimed to study the effect of using radiation protection drape (RADPAD), on PO and SO during coronary angiography (CAG) as well as PCI. The primary objective of this study was to compare the dose exposure ratio of PO dose to Cine Adjusted Screening Time (CAST), Air Kerma (AK), and Dose Area Product (DAP) in the RADPAD versus No RADPAD cohorts in order to evaluate the effect of this drape in reducing scatter radiation dose exposure to PO. The secondary objective was to do a similar comparison for SO.

2. Methods

From March 2021 to May 2021, 137 consecutive patients (RADPAD Cohort –77 patients and No RADPAD cohort 60 patients) planned for undergoing CAG and PCI were enrolled in the study. The procedures involved were CAG, Single/multi-vessel PCI, complex PCI of chronic total occlusion (CTO), rotablation, and Imaging/physiology modalities such as intravascular ultrasound (IVUS), fractional flow reserve (FFR) and optical coherence tomography (OCT). Permission was obtained from the Scientific Review Committee before the start of the study (SRC 101/2020). The study was conducted according to the ethical principles stated in the latest version of Helsinki Declaration, and the applicable guidelines for good clinical practice (GCP). Patients were randomly assigned to RADPAD or No RADPAD cohort in a 1:1 pattern to undergo the procedure with or without the RADPAD in-situ. Patients with weight <50 kg and >90 kg were excluded from the study. Hybrid procedures and procedures requiring a change of operator (during the procedure), were also excluded from the study.

The PCI procedures were carried out by two interventional cardiologists with background in performing high-volume complex PCI procedures. During the PCI procedures, all the standard measures for scatter radiation protection were used as per the existing protocol of the Cath lab. Standard shielding equipment was used including a lead apron, thyroid shield, in addition to a lead shield suspended from the ceiling between the image intensifier and operator. Both operators had a fair understanding of radiation safety measures and were familiar with the optimal placement of the RADPAD drape. All the procedures were performed in Siemens Cath Lab (Model Artis Zee Biplane). All procedures were performed

at 15 frames per second (FPS) for both Fluoroscopy and Cinemode, as per the standard practice. The procedures performed in the two groups were similar and the angulations of the picture tube were similar. For cases involving right radial artery access, the RADPAD was positioned cranial and medial to the sheath insertion point, on the forearm, immediately below the lead shield suspended from the ceiling between the image intensifier and operator (Fig. 1A). For cases involving right femoral artery access, the RADPAD was positioned cranial to the sheath insertion point, just above the groin, below the lead shield suspended from the ceiling between the image intensifier and the operator (Fig. 1B). For cases involving left femoral artery access, where the operator was standing on the right side of the patient, the RADPAD was positioned on the right side (not on the left side) in the same way as for right femoral access below the lead shield suspended from the ceiling between the image intensifier and the operator (Fig. 1B). The underlying principle is to place the drape between the primary beam and the PO, ensuring that the drape does not appear in the fluoroscopy image during the procedure.

In order to standardize the study in every case, the dosimeter was placed on the chest (clipped on the lead apron pocket) of the PO and the SO/allied staff. Dosimetric measurements were obtained using a personal dosimeter MYDOSE mini PDM127 (Hitachi Aloka Medical Ltd. Japan), placed on the left side of the chest outside the lead apron (Fig. 1C). The dosimetry was commenced at the start of the procedure. The operator received dose for PO and SO was recorded from the dosimeter immediately at the end of the PCI. Screening Time (STs), AKs, count of acquisitions (CineCount) and DAPs for the individual procedures were recorded from the console display at the end of the procedure, which was then computed to the relative operator exposure, with or without RADPAD. To consider the factor of increased radiation exposure on account of Cine, which emits approximately 15 times¹⁶ more radiation than fluoroscopy (non- Cinescreening), we derived CAST, using average Cine duration (observed to be of 4 s), the factor of 15 and number of Cine acquisition, in the calculation of both primary and secondary objectives.

Statistical analysis for categorical variables were summarized by the arithmetic mean, standard deviation (SD), median, and minimum and maximum value. The student's independent *t*-test was used to compare mean values of different parameters of radiation exposure in the two groups. Scatterplot analysis of dose relative to Screening Time, DAP and AK were performed. A *p*-value of less than 0.05 was considered statistically significant. Statistical analysis was performed using SPSS version 27 (IBM, New York, USA).

3. Results

A total of 137 patients were included in the study. There were 102 (74.45%) men and 35 (25.55%) women. Baseline patient characteristics for the two cohorts are presented in Table 1. There was



Fig. 1. RADPAD drape placement: Radial drape placement (A); femoral drape placement (B); dosimeter placement (C).

Table 1
Demographic data of the study cohorts.

Variable	RADPAD (n = 77)	No RADPAD (n = 60)
Men/Women	56/21	46/14
Age (years)	58.81 ± 10.61	58.85 ± 10.29
Weight (kg)	67.19 ± 9.18	67.68 ± 9.47
Access site		
Radial	42 (54.55%)	44 (73%)
Femoral	30 (38.96%)	14 (23%)
Both	5 (6.49%)	2 (4%)
Procedure Type		
CAG	37 (42%)	25 (41.7%)
PCI Single/Multi-vessel	40 (58%)	35 (51.3%)

Data represented as numbers, mean ± SD.

no statistical difference between the baseline patient characteristics among the study cohorts. Patients were predominantly males in both the cohorts with a mean age of 58 years. This finding reflects the general trend of increased prevalence of coronary artery disease in men as compared to women in this age group. The different types of PCI procedures performed were similar in the two cohorts. PCI was performed by radial or femoral artery access in all cases with a ‘radial first’ approach. The procedural radiation data of the two cohorts are presented in Table 2. Overall, the mean CAST, mean DAP, and mean AK were similar in the two cohorts. Fig. 2 represents a scatter plot of PO dose to CAST (Fig. 2A), PO dose to DAP (Fig. 2B), and PO dose to AK (Fig. 2C) in each individual case with or without RADPAD with a difference between the two groups being significant (p-value ≤ 0.00001) as shown in all the 3 plots. The positive association between the independent (DAP, CAST and AK) as well as dependent variable (PO dose) is evident from the graph. However, PO dose relative to CAST, DAP, and AK in the RADPAD cohort was significantly less (PO dose/DAP-62%, PO dose/

AK-52%, PO dose/CAST -65%) as compared to the NoRADPAD cohort (Fig. 3).

While the primary objective of the study was to evaluate the dose reduction to PO, the effect of RADPAD on SO was also evaluated in 124 patients out of 137 patients. The mean dose exposure for SO in the No RADPAD cohort was 6.15 mrem as compared to 12.44 mrem for the PO. In the RADPAD cohort, the mean dose for SO and PO were 1.48 mrem and 4.54 mrem respectively. In both RADPAD and No RADPAD cohorts, we observed that SO had significantly less radiation exposure compared to PO. This finding can directly be attributed to the fact that SO is farther away from the primary beam compared to PO. Also, for SO, exposure dose relative to DAP, CAST and AK were significantly lower in the RADPAD cohort as compared to the No RADPAD cohort (Fig. 4) and the relative reduction of dose for the SO in the RADPAD cohort was higher as compared to the PO (10–19% higher absolute reduction of radiation to SO).

4. Discussion

In India, there is a paucity of data on radiation exposure in Cath lab. The present study is a relatively large, prospective randomized Indian study to evaluate the efficacy of radiation protection drape -RADPAD in reducing the radiation exposure to both PO and SO in the Cath lab. This is the first study that has investigated the benefit of radiation protection drape even to the SO. Although the radiation exposure to SO is almost half as that of PO, the cumulative effect of radiation exposure to SO can have similar adverse effects as that of PO.^{11,17} The first guidelines for radiation safety in cardiac Cath lab were published in 1992 by the Society of Cardiovascular Angiography and Interventions (SCAI).¹⁸ However, there has been no change in the radiation doses to PO during the last twenty years.¹⁹ In a study that evaluated the radiation exposure of the operator and assistant during CAG and PCI procedures on 1090 patients, it was

Table 2
Procedural radiation data of the study cohorts.

Procedural data	RADPAD (n = 77)	No RADPAD (n = 60)	p value
CAST (Minute)	35.66 (4.82–182)	32.33.62 (6.82–92.57)	0.24
DAP (mGycm ²)	13253 (1881–75992)	14290 (1146–52948)	0.33
AK (mGy)	2019 (251–11449)	2253 (173–8556)	0.25
PO Dose (mrem)	4.53 (0.4–36.6)	12.44 (1.1–76.9)	0.00001*
PO Dose/DAP (mrem/mGycm ²)	0.00042 ± 0.00049	0.0011 ± 0.0013	0.000014*
PO Dose/AK (mrem/mGy)	0.0030 ± 0.0037	0.0071 ± 0.0049	<0.00001*
PO Dose/CAST (mrem/minute)	0.15 ± 0.18	0.43 ± 0.31	<0.00001*
SO Dose (mrem)	1.48 (0–15.8)	6.15 (0.2–64.7)	0.00012*
SO Dose/DAP (mrem/mGycm ²)	0.0001 ± 0.0001	0.0004 ± 0.0006	<0.00001*
SO Dose/AK (mrem/mGy)	0.0007 ± 0.0008	0.003 ± 0.003	<0.00001*
SO Dose/CAST (mrem/minute)	0.04 ± 0.06	0.18 ± 0.20	<0.00001*

Data represented as numbers, mean ± SD, or mean (range), * Significant value.

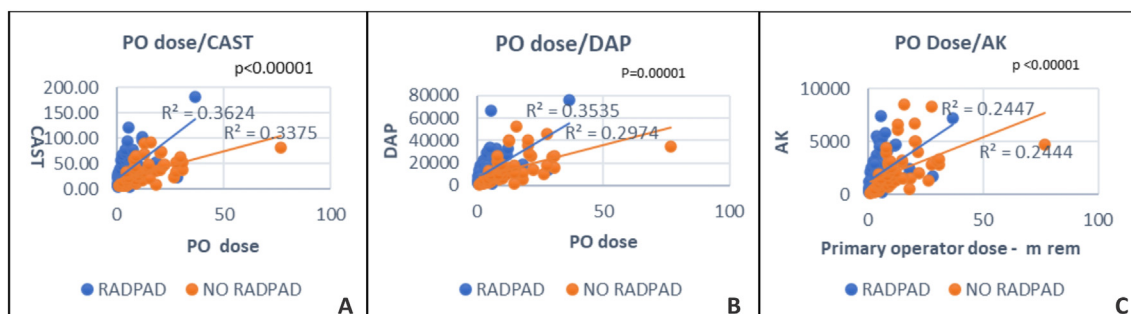


Fig. 2. Scatter Plot Analysis of PO Dose/CAST (A), PO dose/DAP(B) and PO Dose/AK (C).

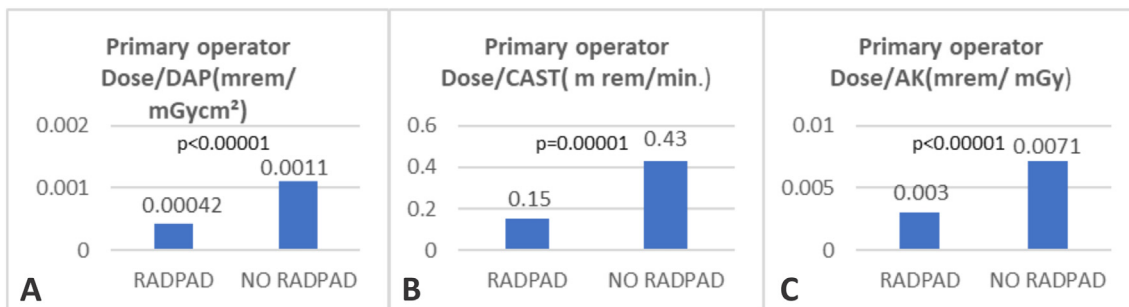


Fig. 3. PO Dose Relative to DAP, CAST and AK Comparison- RADPAD versus No RADPAD cohorts.

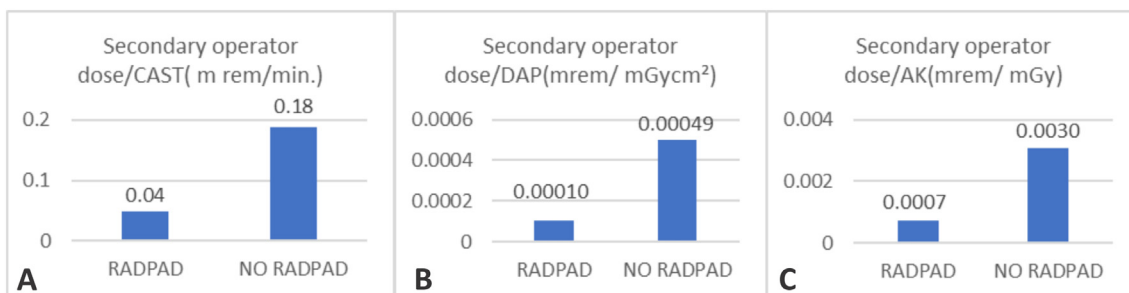


Fig. 4. SO Dose Relative to CAST, DAP and AK in RADPAD versus No RADPAD cohorts.

found that the average effective dose of operator was 3.4 times greater during PCI than during CAG.²⁰

Even though significant efforts to reduce the scatter radiations emitted by fluoroscopy/Cineangiography equipment have been made in the recent years, the expected reduction in the radiation dose to the operator has been neutralized due to the increased complexity of the procedures being undertaken in recent years. A previous study has reported that the operator is exposed to a higher radiation dose in radial access as compared to the femoral approach.²⁰ As the radial access is increasing, the use of radiation reduction measures seems beneficial for patients as well as PO and SO.²¹ Due to the ineffectiveness of the traditional methods, there is a compelling need for alternative shielding techniques in order to reduce the radiation exposure to the operators.

In our study, it was observed that the dose of radiation to PO was reduced by 64% by using RADPAD (4.53 versus 12.44 mrem). This observation is consistent with the findings of two previous studies that have reported a reduction of 41–59%.^{12,22} In a double-blind trial of 766 consecutive coronary procedures (CAG and PCI), the use of RADPAD was associated with 20% reduction in relative operator exposure as compared to standard treatment (p = 0.01) and a 44% relative exposure reduction as compared to a sham shield (p < 0.001).²³ In another randomized controlled trial, the use of RADPAD resulted in dose reductions of 49% and 55% respectively on the hand and chest of the interventionalist and 48% on the chest of the theatre nurse.²⁴ These observations are consistent with the findings of our study. In our study, PO dose/DAP was reduced by 62%. One previous study from Europe has reported a reduction of PO dose/DAP by 48%.¹² PO dose/AK was reduced by 58% by using RADPAD in the present study whereas a study from India, reported a reduction of 39% for the PO dose/AK.¹⁵ Our study reports a reduction in the PO dose/CAST by 65% that has not been analyzed in any other study to the best of our knowledge. The finding of our study that RADPAD drape significantly reduces radiation exposure to PO is consistent with previously published reports.^{12–15,22}

It is well-known that SO is exposed to the lower dose of radiation as compared to the PO due to the distance from the primary beam and the source. Our study also assessed the dose exposure relation between PO and SO and the protective effect of this drape on SO. To the best of our knowledge, our study is the first to specifically evaluate the effect of RADPAD lead-free drape on SO. We observed that for SO also, dose exposure relative to CAST, AK and DAP were significantly (74%, 76% and 79%) lower in RADPAD cohort as compared to the No RADPAD cohort. However, the efficacy of this lead-free drape must be taken into consideration as an added benefit of best practices in the Cath lab. These include performing fluoroscopy imaging at the lowest acceptable pulse rate, minimizing the number and duration of Cine runs, minimizing the Cine frame rate, minimizing image size amplification, maximum collimation, and very importantly periodic checking of the imaging system by competent technical personnel in order to avoid over emission of radiations from the system.

5. Strengths and limitations

This was a randomized study of radiation protection drape along with the use of all other radiation protection measures in cardiac Cath lab. The study included both angiography and angioplasties of varying complexities and the protection provided by the drape was noticed in all the interventional procedures. A relatively small number of patients in each group may be regarded as a limitation but the high quantum of protection provided by the drape clearly offsets the limitation of relatively small sample size. We did not use any sham drape.

6. Conclusion

Our study reports data on the effect of using radiation protection drape during the routine clinical practice. The radiation protection drape RADPAD significantly reduces radiation exposure to the primary and secondary operators while performing CAG as well as PCI.

The use of the radiation protection drape seems justified in all Cath lab interventional procedures.

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Declaration of competing interest

The authors declare that they have no conflict of interest.

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