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Original Article

Efficacy of RADPAD protection drape in reducing radiation exposure in the catheterization laboratory—First Indian study

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ABSTRACT

Background: Occupational radiation exposureis a growing problem due to increasing number and complexity of interventional procedures.The RADPAD is a lead-free sterile drape containing bismuth and barium that reduces scatter radiation during fluoroscopic procedures. We aimed to study the radiation exposure reduction to operators with the use of RADPAD and also measureradiation doses in different angiographic projections.

Methods: 65 randomly selected patients undergoing elective complex percutaneous coronary intervention (PCI) procedures from January 2017 to 2017 were randomized in a 1:1 pattern with or without the RADPAD. Primary endpoint was the ratio of operator received dose in mrem to total radiation in Gyat the end of the procedure which was designated ''Relative operator exposure'', with or without RADPAD.

Results: Despite similar fluoroscopy times (20.4 ± 9.4 min with RADPAD vs. 19.4 ± 9.2 min without RADPAD, $P = 0.871$) and total radiation dose (3.4 ± 4.3 Gy with RADPAD vs. 2.3 ± 1.4 Gy, $P = 0.198$), the relative operator exposure was significantly less with RADPAD (1.39 ± 0.95) as compared to no RADPAD group (2.27 ± 1.4) ($p = 0.004$) amounting to a 39% reduction. Additionally mean radiation dose per shoot of recorded Left anterior oblique (LAO) oriented projections was 34.4 ± 15.7mGyvs 24.9 ± 12.9 mGy for a non LAO oriented projection. ($p < 0.001$).

Conclusion: RADPAD significantly reduces radiation exposure to the primary operator during prolonged complex PCI procedures. Further, amongst all views, LAO views have significantly higher emitted radiation as compared to Non LAO views and need more radiation protection.

1. Introduction

Ionizing radiation remains an integral part of all percutaneous coronary interventions (PCI). For operators, as well as technical staff members employed in a cardiac catheterization suite, chronic exposure to low-dose radiation confers a small but definitive stochastic risk for developing malignant diseases, skin damage, or eye problems.[1–3] In any given PCI procedure, the total radiation dose is usually determined by the procedural duration, the duration of fluoroscopy and numbers of cine runs taken.[4] Longer procedures involving chronic total occlusions (CTO) intervention, bifurcation lesions, and multi vessel PCI often result in higher radiation exposure.[5] The settings used for image acquisition also add to the total radiation dose which can vary between operators. However, the different radiation protection precautions as taken by an individual operator could help limit the operator received dose.

RADPAD (Worldwide innovations & technologies, Inc., Kansas City, Kansas) is a radiation protection drape, which is available as a sterile surgical drape containing bismuth and barium as radiation protection materials and it is advocated to be placed appropriately on the patient in between the image intensifier and the operator, so as to reduce the scatter radiation. It has been shown to reduce radiation exposure in routine PCI procedures, pacemaker & device implantations such as cardiac resynchronization therapy and also fluoroscopically guided electro physiologic procedures,[6,7] but still its use in daily practice is not very common and no data is available from the Indian subcontinent.

Thus, the aim of this study was to evaluate the efficacy of RADPAD drapes in reducing radiation dose in our catheterisation laboratory (cath lab) during complex therapeutic PCI procedures and thus to reiterate the need for its routine use if found beneficial.

Abbreviations: CTO, chronic total occlusion; Gy, grey; LAO, left anterior oblique; LM, left main artery; PCI, percutaneous coronary intervention; rem, roentgen equivalent man; cath lab, catheterisation laboratory.

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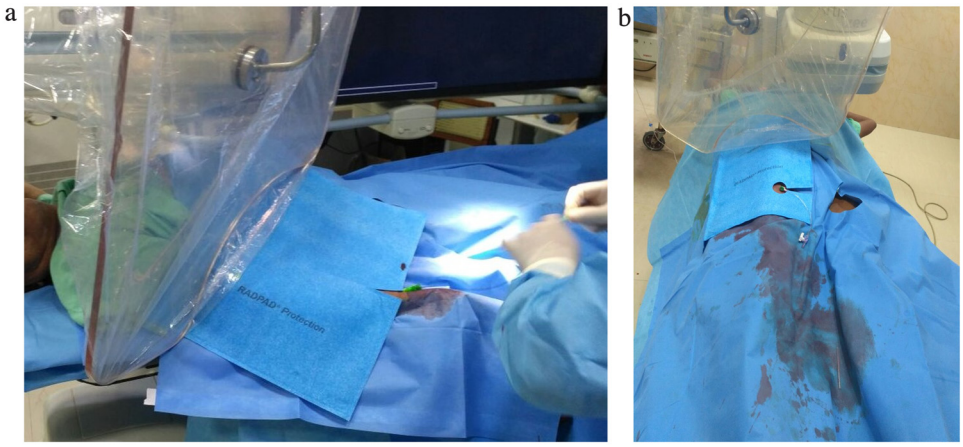

Fig. 1. Pictorial presentation of application of RADPAD in radial (1a) and femoral (1b) access.

2. Method

Sixty five randomly selected patients due to undergo complex coronary interventional procedures were enrolled and were randomized in 1:1 pattern to "with RADPAD" or "without RADPAD" use. The study was conducted from 1st January 2017 to 30th June 2017. Complex procedures included multi vessel PCI, bifurcation PCI, left main PCI and CTO interventions. The PCI procedures were carried out by a single operator at a single centre using uniform image acquisition protocols and standard radiation protection precautions in all cases. All procedures were done on Siemens® Artis zee machine, images were acquired at frame rate of 7.5 frames/s in fluoro mode and 10 frames/s in cine mode. Majority of the procedures were done at magnification of 16 cm diagonal field of view (600 × 600 pixels). The standard shielding equipment used included, a lead coat, a thyroid shield and a lead shield suspended from the ceiling between the image intensifier and operator as a part of standard protocol, in both the groups. The RADPAD group had the pad placed during the procedure on the exposed surface in addition as per instructions for use.

For all cases involving right radial arterial access, the RADPAD was positioned superior and medial to the sheath insertion point and immediately below the lead shield suspended from the ceiling in between the image intensifier and operator (Fig. 1a). For cases involving femoral arterial access the RADPAD was positioned superior to the sheath insertion point and immediately below the lead shield suspended from the ceiling between the image intensifier and operator (Fig. 1b). The distance between the image intensifier and the operator varied from 60 to 70 cm in postero-anterior (PA) view.

As a part of uniformity in protocol the dosimeter was placed on the upper part of left side of chest of the primary operator in all cases and under the lead apron. It was reset to zero at the beginning of each procedure and the total exposure to physician was recorded (in mrem) at the end of the procedure. Fluoroscopy times and the total radiation dose as given by the machine (in Gy) was collected for each case. The numbers of cine runs and the angles left anterior oblique (LAO)/non LAO and cranial/caudal were also recorded as a part of secondary analysis.

Primary endpoint of study was the ratio of operator received dose in mrem to total radiation in Gy as given be the machine at the end of the procedure which was designated the relative operator exposure, with or without RADPAD.

3. Statistics

All the variables are shown in mean ± standard deviation. Student's independent *t* test was used to compare mean values of different parameters of radiation exposure. Scatter plot analysis and linear regression slopes of individual exposed dose relative to total radiation dose were performed. Comparison between the slopes was made using analysis of covariance to assess for statistical significance. A p value < 0.05 was accepted as statistically significant. A SPSS® 20.0 version was used for data analysis.

4. Results

Data was collected from all 65 patients included in the study. Baseline characteristics of patients in the two groups are shown in Table 1. Most cases were male [59 out of 65(90.7%)], with the mean age of 57.8 ± 11.3 years. The different types of PCI procedure performed were similar in the 2 groups. PCI was performed via radial artery access in all cases except 8, in which femoral route was used additionally for contralateral injection. Overall, the cases had a mean fluoroscopy time of 19.61 ± 9.3 min and a mean total

Table 1
Comparison of baseline clinical and procedural characteristics in groups with and without RADPAD use.

Variable	With RADPAD n = 35(%)	Without RADPAD n = 30(%)	p value
Age (years)	59.0 ± 9.5	55.9 ± 13.5	0.289
Male sex	32(49.2%)	27(41.5%)	0.843
Diabetes	17(26.1%)	12(18.5%)	0.658
Hypertension	22(33.8%)	13(20.0%)	0.185
Clinical Presentation			
Acute coronary syndrome	8(12.3%)	9(13.8%)	0.711
Chronic stable angina	27(41.5%)	21(32.3%)	
Procedural Characteristics			
Multi vessel disease	11(16.9%)	9(13.8)	0.901
Left Main stenting	2(3.0%)	3(4.6)	0.857
Bifurcation	7(10.8%)	5(7.7)	0.980
CTO	10(15.4%)	7(12.3)	0.844
Single vessel	5(7.7%)	6(9.2)	0.742
Approach			
Radial	31(47.7)	26(40.0)	0.815
Femoral	4(6.1)	4(6.1)	
Fluoroscopy time (min)	20.4 ± 9.4	19.4 ± 9.2	0.871
Total radiation exposure (Gy)	3.4 ± 4.3	2.3 ± 1.4	0.198
Operator received dose (mrem)	4. 0 ± 3.5	5.9 ± 6.4	0.124

Abbreviation: CTO = Chronic total occlusion.

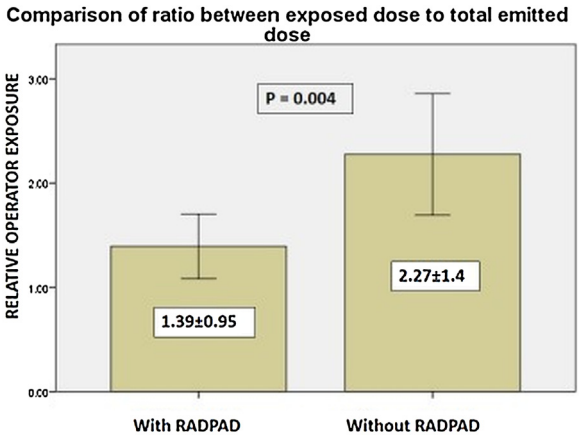

Fig. 2. Comparison of ratio between operator received dose (mrem) to total radiation dose (Gy) between study groups.

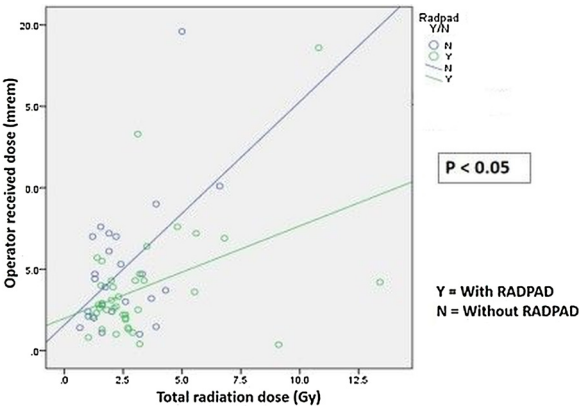

Fig. 3. Scatter plot analysis of total radiation dose (Gy) vs operator received dose (mrem) between both groups.

radiation dose of 2.99 ± 3.5 Gy. There was no difference in the RADPAD cohort and no-RADPAD cohort in fluoroscopy time and radiation dose.

The operator received dose (in mrem) studied as proportion of the total radiation dose (in Gy) in individual case is shown in Fig. 2. The proportion was 1.39 ± 0.95 in RADPAD group vs. 2.27 ± 1.4 in no-RADPAD group ($p < 0.05$) which amounted to about 39% reduction in operator received dose with RADPAD.

Fig. 3 shows a plot of total radiation dose to individual physician exposure (operator received dose) in each individual case with or without RADPAD with a difference between the two lines being significant with p value of 0.04. (Analysis of covariance F = 4.32).

Radiation emitted per cine shot in mGy in LAO vs non-LAO oriented views depicting significantly higher emitted radiation in LAO (34.4 ± 15.7) as compared to non LAO (24.9 ± 12.9) oriented views ($p < 0.001$) (Fig. 4). There was no significant difference in mean radiation dose in cranial vs. caudal oriented views (Table 2).

5. Discussion

Minimizing radiation exposure both to patients and operating personnel in the cath labs remains an important part of interventional cardiologist's role in the lab. In addition to standard radiation protection equipment, various image acquisition settings need to be programmed to minimize radiation, such as performing fluoroscopy imaging at a lowest available pulse rate, minimizing

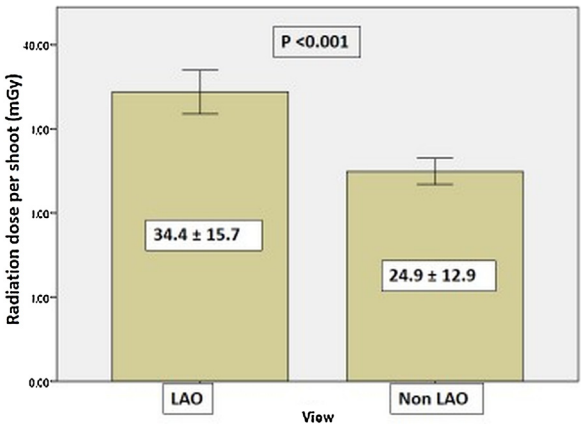

Fig. 4. Comparison of radiation dose per shoot (mGy) in LAO vs. Non LAO views.

Table 2
Comparison of mean radiation per cine shot in mGy in cranial and caudally oriented projections.

	Number of views	Mean ± SD radiation (mGy)	p value
Cranial projections	162	27.3 ± 15.4	p = 0.76
Caudal projections	146	29.7 ± 14.6	

the number and duration of cine runs, minimizing the cine frame rate, minimizing image size amplification, maximum collimation so that only areas of interest and only during PCI remain exposed. In a study, Mark Pitney et al.[8] show that LAO views are the highest source of radiation during coronary angioplasty. In our study we have also found that LAO oriented projections are associated with higher amount of radiation emitted as compared to rest of the views. So use of LAO views should be minimized to reduce the radiation exposure. Use of RADPAD in the procedures particularly requiring LAO oriented views can help to reduce the operator radiation exposure the most. Although these techniques are helpful, they are not universally possible in all cases when complex PCI is performed.

In CTO cases the risk of radiation exposure increases exponentially. Relatively long cine runs are often required to adequately visualize collateral circulation during PCI for CTO. Furthermore, multiple orthogonal imaging of the target artery is required during the wiring of CTOs.

It is therefore clear that complex PCI will become more prevalent in the coming decades. Thus the importance of any adjuvant devices that reduce radiation exposure to primary operators during complex PCI is well recognised and it is thus essential that such devices be validated.

In initial studies Ertel et al.[9] had demonstrated up to 72% reduction to operator dose using a lead free drape in simulated cardiac cath lab model operating from radial route.

The first in man use of such lead free radiation protection drape is reported by Politi el al.[10] in 2012. In their randomized study of 60 patients undergoing diagnostic coronary angiograms and they demonstrated up to 34% reduction in operator dose with use of such radiation protection drape. In a study of 60 patients by Kherad et al.[11] it was recently demonstrated that the operator dose was reduced by up to 59% using RADPAD while performing routine diagnostic coronary angiography procedures.

In our study of 65 patients, we observed that the ratio between the operator received dose to total radiation dose was 1,39 for RADPAD and 2,27 for no-RADPAD groups. This states a near 39% reduction of operator received dose with use of this novel

radiation protection drape. Hence our study also translated a similar reduction in operator dose in complex PCI. The cases involved in our study were clearly complex with the mean exposure time of 19.61 ± 9.31 min and a mean total dose exposure of 2.99 ± 3.47 Gy. Therefore, our study clearly demonstrates that the use of the RADPAD reduces radiation exposure to primary operators during complex PCI with long radiation exposure. Murphy et al.[12] also did a similar study of 60 patients, undergoing complex PCI with or without RADPAD drape in situ, which showed a reduction of radiation exposure to primary operators with the use of RADPAD.

6. Limitations

It is also worth noting that the strength of the study may have been improved if the no-RADPAD group had a "sham" drape in place during their procedures. It could be argued that the presence of the RADPAD drape made the operator more aware of radiation safety and that this may have altered dosimetry readings in this cohort.

There may also be some concern that the 2 groups in the study may not have been ideally matched. However, the cases were randomly chosen to be performed with or without the RADPAD, and the differences in fluoroscopy time and total radiation dose were not statistically significant. Furthermore, with the variation in coronary anatomy, coronary disease, and body habitus that exists in patients, a true control-matched study is not realistic in a real-world environment. We could also have additionally applied radiation dosimeters to the secondary operators & nurses to have additional data of scattered radiation to them also.

7. Conclusion

The RADPAD significantly reduces radiation exposure to primary operators during prolonged, complex PCI cases. Further LAO views have significantly higher emitted radiation as compared to non LAO views. There is no significant difference in emitted radiation in cranial vs caudal oriented views.

With near 39% reduction of operator dose, we would recommend uniform use of the radiation protection pad as a standard for all interventional procedures especially in complex PCI.

Conflict of interest

None.

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