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Research Article

COMPARISON OF RADIATION EXPOSURE IN RADIAL AND FEMORAL VASCULAR APPROACH OF PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY –A CROSS SECTIONAL ANALYTICAL STUDY FROM A TERTIARY CARE CENTRE, KERALA

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A B S T R A C T

Introduction: Studies show there is no significant difference in the radiation exposure to the patient or to the operator when the percutaneous transluminal coronary angioplasty (PTCA) was done using radial and femoral artery approaches by a single operator.

Objectives: The objectives of the current study were (a)to compare the radiation exposure in single operator radial and femoral approach of PTCA (b)to estimate the radiation exposure in patients undergoing PTCA using Nano dot radiation measuring chipinstead of DAP meter (dosage area product).

Method: A cross sectional analytical study done in the cardiology department of a tertiary care institution for a period of 2 years .Patients with age >18 yrs, undergoing elective PCI, eligible for radial and femoral vascular approaches were included in the study after getting the informed consent. The radial and femoral vascular approaches were done by an experienced single operator. The sample size required for the study was 40 and collected data for a total of 40 patients. In a structured study proforma the clinical and procedure related data were collected. The data were entered in Microsoft excel and analysed in SPSS version 20.

Results: The mean age of the study participants in radial approach was 59.5 (9.8) years and that of femoral approach was 61.9 (7) years. The dosage area product for radial v/s femoral approach was 8351 $\pm$ 4164.7 v/s 8797.8$\pm$ 4254.3 cGy·cm^{2}with p value 0.52, patient exposure dose was 28.85$\pm$12.95 v/s 29.17$\pm$14.52 cGy with p value 0.95 and the operator exposure dose was 10.9$\pm$5.5 v/s 10.7$\pm$ 5.4 µSv with p value 0.35.

Conclusion: Our study showed that there wasno significant difference in radiation exposure to the operator or the patient during radial and femoral vascular approaches in a single operator PTCA.

INTRODUCTION

Cardiac catheterization and percutaneous coronary intervention undergoing through radial access vascular approach had shown beneficial outcomes in terms of reduced incidence of complications, better patient comfort and cost effectiveness compared to that of femoral access.[1] In a meta analysis of 24 randomised controlled trialscomparing the effectiveness of radial v/s femoral access done by Ferrante *et al* reported 29% reduction in all cause early mortality (in hospital+ 30 days mortality), 16% reduction in major adverse cardiovascular events and 47% reduction in the risk of major bleeding events.[2] The Radial v/s femoral access for coronary intervention (RIVAL) study revealed duration of fluoroscopy was higher in the radial access group (median 9.3[range 5.8–15] minutes) compared with that in the femoral access group (median 8.0 [range 4.5–13] minutes).[3] However, the authors did not directly measure radiation exposure. RAD-MATRIX(Minimizing Adverse Haemorrhagic Events by TRansradial Access Site and Systemic Implementation of angioX) and REVERE(Randomised Evaluation of Vascular Entry site and Radiation Exposure) trials have raised doubts about safety of radial approach and their data revealed radiation exposure was more to patient and operator in radial approach.[4,5] The results of some studies have shown radial approach is safer and no excess radiation exposure when compared with femoral approach.[6] So far, all studies have got a major potential limitation as multiple operator with variable experiences conducting the procedure and hence prolonged procedure time when done by a less experienced operator.[7,8,9] This limitation results in erroneous radiation exposure data to both the operator and patient. Due to these reasons more radiation exposure was noted in trans radial approach. We decided to eliminate this inter-operator bias by opting for a single expert operator. The aim of our study was to eliminate the inter-operator bias by opting for a single expert operator. The objectives of the study were (a) to compare the radiation exposure in single operator radial and femoral approach of

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PTCA (b)to estimate the radiation exposure in patients undergoing PTCA using Nano dot radiation measuring chip instead of DAP meter (dosage area product).

METHODS

A comparative cross sectional analytical study was performed. Based on fluoroscopy time of earlier study by Mattos *et al* [9] and with 95 % confidence and 80% power, the minimum sample size was found to be 20 in each group of radial and femoral vascular approaches of PTCA. Adult patients who were admitted under the operating cardiologist to undergo elective percutaneous coronary transluminal angioplasty were included in the study from the period between July 2016 to December 2017at Amrita Institute of medical sciences and research, Kochi. The inclusion criteria were age > 18 years, patients undergoing elective PTCA and eligible for both radial and femoral access. The exclusion criteria were complex anatomy of iliac vessels, aorta and radial artery with available information regarding the same prior to procedure, procedures which can be done preferably via femoral approach only and Chronic total occlusion (CTO). Cases for the procedure were analysed by another cardiologist so that they satisfy both the inclusion and exclusion criteria.

The study was approved by institutional Ethics Committee and conforms to ethical principles of the Declaration of Helsinki.
In a structured study proforma the clinical and procedure related data such as age, sex, weight, height, status on chronic illness like Diabetes mellitus, Hypertension and Dyslipidemia, number of cardiac vessels involved, number and type of cardiac lesions, number of stents deployed, bifurcation stenting and crossover to another approach if any. The data were collected by the principal investigator under the guidance of the interventional cardiologist. The collected data were entered in Microsoft excel and analysed in SPSS version 20.

Procedure details

Standard operator radioprotection was ensured using a lead apron, a thyroid lead collar, lower body X-ray curtain fixed on the angiographic table and an upper mobile leaded glass suspended from the ceiling. The imaging equipment used in this case is a Siemens Artis Zee which is powered by a Polydoros 100 kW high frequency multipulse generator. The X-ray tube is a Megalix Cat plus 125/40/90 and is dual focus (0.4 and 0.8 mm). This machine was calibrated under the supervision of radiation physics and safety department by Siemens engineer prior starting the study. Radiation data like Fluoroscopy time in minutes, Air kerma in centigray (cGy), Dose area product (DAP) in µGy·cm2 were obtained from Cath machine radiation examination protocol. Operator distance from Isocentre (in inches), operator radiation exposure in micro Sievert and patient's skin entry dose in cGy were recorded.Operator distance from Isocentre was measured while starting each patient studyand Operator distance was fixed throughout during each study. Operator radiation exposure measured by Intech IDA-110A pocket dosimeter placed inside lead apron (left shirt pocket) of the operator. Intech pocket dosimeter uses Intech DMS software package(10).Patient's skin entry dose recorded directly by placing Nano dot (a new Nano dot for every patient and the nanodotdosimeter is based on the OSL (Optically Stimulated Luminescence) technology (11). Nano dots were placed in the field of operation (Thoracic T5/T6 left paraspinal region).

Statistical analysis

The continuous variables are presented as Mean ± SD and categorical variables as percentages. Continuous variables are compared using Student's't' test/*Wilcoxon rank-sum test* depending upon the distribution of the variable. Categorical variables are compared with Chi square test/ Fisher's exact test.

RESULTS

The mean age of the study participants in radial approach was 59.5 (9.8) years and that of femoral approach was 61.9 (7) years. The proportion of males were more in both groups (80% in radial v/s 75% in femoral). The major risk factors were diabetes mellitus (75%), hypertension (65%) and dyslipidemia (57.5%).

Table 1 Baseline Characteristics and clinical profile of the patients in the Radial v/s Femoral vascular approaches of PTCA

Variables	Radial	Femoral	P value
Age (years) (Mean ,SD)	59.5 (9.8)	61.9 (7)	0.39
Sex			
Male v/s Female (%)	80 % v/s 20%	75% v/s 25%	0.71
BMI	27.86 ± 2.55	26.9±3.09	0.31
Risk factors			
Diabetes mellitus	15 (75)	15 (75)	0.72
Hypertension	13 (65)	13 (65)	0.99
Dyslipidemia	13 (65)	10 (50)	0.34
No:of vessels with disease			
SVD	10 (50)	9 (45)	
DVD	8 (40)	9 (45)	0.76
TVD	2 (10)	2 (10)	
Number of flow limiting lesions			
1	10(50)	14(70)	
2	9 (45)	3(15)	
3	1 (5)	3(15)	0.20
Type of lesions (complexity)			
A and B1 (less complex)	10 (20)	25(5)	
B2 and C (more complex)	16 (80)	14(70)	0.71
No:of stents deployed			
1	13(65)	15(75)	
2	6(30)	2(10)	
3	1(5)	3(15)	0.49

Table 2 Comparison of radiation exposure data among radial and femoral vascular approaches

Radiation data	Radial	Femoral	P value
Fluoroscopy time(min)	14.25 +/- 6.07	13.2+/-4.7	0.47
Dosage area Product (u*Gym2)	8351 +/- 4164.7	8797.8+/-4254.3	0.52
Air kerma(cGy)	192 +/- 93.7	197+/-100.0	0.52
Patient exposure(cGy)	28.85 +/-12.95	29.17+/-14.52	0.95
Operator exposure(µSv)	10.9 +/- 5.5	10.7 +/- 5.4	0.35
Operator distance(inch)	17.3+/- 1.95	19.1+/-2.6	0.19

In the subgroup comparison between radial and femoral approach there was no statistically significant difference in the age, sex and BMI scores (p value 0.39, 0.71 and 3.34 respectively). The distribution of participants with chronic illness namely Diabetes Mellitus, Hypertension and Dyslipidemia in the radial and femoral approach also did not show statistically significant difference (p value 0.72, 0.99 and 0.34 respectively). The distribution of participants in terms of number of vessels with disease and number of flow limiting lesions also did not differ significantly (p 0.76 and 0.20 respectively). There was no statistically significant difference found while comparing the type of lesions and the number of

stents placed between the radial and femoral approach participants (p value 0.71 and 0.49 respectively).

The dosage area product for radial v/s femoral approach was 8351 ± 4164.7 v/s 8797.8± 4254.3 cGy·cm^2 with p value 0.52, patient exposure dose among the two groups was 28.85±12.95 v/s 29.17±14.52 cGy with p value 0.95 and the operator exposure dose in two groups was 10.9±5.5 v/s 10.7± 5.4 µSv with p value 0.35. So in the dosage area product and radiation exposure comparison parameters also there was no statistical significance between the radial and femoral vascular approaches of PTCA.

DISCUSSION

The present study was conducted to compare the dosage area product and radiation exposure for the operator and patient while performing PTCA through two different vascular approaches such as radial artery approach and femoral artery approach. The study also provides detailed information regarding major risk factors for CAD among the two groups of patients, the severity of disease in terms of single vessel, double vessel and triple vessels involved, about the severity of flow limiting lesions, type of flow limiting lesions and number of stents deployed. All these parameters were similar in two groups and didn't show any statistical significance. When the dosage area and radiation exposure were compared, there was no statistical significance between the two vascular approach groups.

In the present study the mean age of the participants in the radial approach was 59.5 (9.8) years and that of femoral approach was 61.9 (7) years. The mean age between the two categories didn't vary significantly (p value 0.39). The similar observations were seen in a study done in 1187 patients of intensive medical service unit in Canada.[10]Conversely, it was also observed that younger patients have undergone more radial approach procedures than older individuals.[11]

Males were predominantly more in the two groups and the difference between male female proportions was not statistically significant between the two groups (80% v/s 20% in radial approach and 75% v/s 25% in femoral approach, p value 0.71). The same pattern was observed in several similar studies.[12,13,14]Similarly the BMI also didn't show any statistically significant difference among the two groups (27.86±2.55 v/s 26.9±3.09 with p value 0.31). George *et al* study showed younger and obese individuals were done radial approach PTCA more than that of femoral approach PTCA.[12]

The major risk factors identified in the study were diabetes mellitus, hypertension and dyslipidemia. There were equal proportions of patients with diabetes mellitus (75%) and hypertension (65%) in the radial and femoral group. In the radial group dyslipidemia patients were more (65% v/s 50%). All these risk factors didn't show any statistical difference between the two groups. Similar results were observed in many other studies.[13,14]

In our study the fluoroscopy time in minutes between the two groups were 14.25±6.07 and 13.2± 4.7 with p value 0.47.Mattos *et al* and Kin *et al* study showed fluoroscopy time was higher for patients undergoing femoral approach than compared to radial artery approach.[9, 13]

The operator radiation exposure and patient radiation exposure among the two groups in the current study were 10.9 ±5.5 v/s 10.7±5.4 µSv with p value 0.35 and 28.85±12.95 v/s 29.17±14.52 cGy with p value 0.95 respectively. The dosage area product for radial v/s femoral approach was 8351 ± 4164.7 v/s 8797.8± 4254.3 cGy·cm^2 with p value 0.52. The air kerma between the two groups were 192±93.7 and 197±100 cGy with p value 0.52.

In a multicentric study done in France, it was observed that radial approach had lower radiation exposure to patient than femoral approach.[11]In a similar study in France, where the kerma-area product was compared, it was observed that radial approach was causing less radiation exposure to patients than femoral approach.[12]In a study conducted to assess radiation exposure among operators administering radiation to 289 patients undergoing per cutaneous coronary intervention procedures, it was found that operators were exposed more to radiation in femoral artery approach compared to radial artery approach. In the study it was also found that in the femoral artery approach, the operator gets 3.8 times more radiation exposure than the assistant operator. Also the fluoroscopy time was higher for patients undergoing femoral approach than compared to radial artery approach. It was also observed that as the distance from the source of radiation is more, reduced radiation exposure was seen in the operators.[13]In a study conducted in Turkey, where Percutaneous Coronary Intervention (PCI) procedures were done in stable angina subjects, dose-area product, reference air Kerma and fluoroscopy time were found to be more in those who had undergone radial approach compared to femoral approach. In the same study, it was observed that among Acute Coronary Syndrome patients too, the dose-area product, reference air Kerma and fluoroscopy time were more in those patients who have undergone radial approach compared to the femoral approach.[14] After adjusting for the age factor, the radial approach was found to induce an increase in radiation exposure. Radial approach was found to cause an average increase of 5.3% in dose-area product, 7.4% in reference air Kerma, and 3.7% in fluoroscopy time. Among the stable angina subjects and among Acute Coronary Syndrome patients, the mean age was higher among those undergoing femoral approach.[14]The mean age was marginally more among femoral approach participants in the present study too though the difference was not significant. Though in the present study, there was no significant difference observed in the radiation exposure between femoral and radial approach.

Coronary angiography (CAG) and percutaneous coronary intervention procedures were compared in a randomised study conducted in US. Fluoroscopy time, patient air kerma radiation exposure and operator exposure was observed to be significantly more in the radial approach compared to femoral approach among participants undergoing coronary angiography. However, among those undergoing percutaneous coronary intervention, the difference in exposure and fluoroscopy time was not found to be significant.[15]In a study involving 1696 individuals undergoing Coronary Angiogram with or without PCI, conducted by experienced operators, radial approach was found to have higher dose-area product and fluoroscopy time, which is a measure of patient exposure used in the study. This was significantly higher when compared to those undergoing coronary angiogram procedure done using femoral approach.[16] Contrary to the above findings,

in a study conducted at Italy where 1396 procedures were evaluated, the exposure for the patient measured in terms of dose-area product was significantly higher in femoral approach compared to radial approach. The fluoroscopy time was also found to be higher in femoral approach participants. However, after adjusting for possible confounding factors, both in the procedure and clinically, the different approaches were not found to be a predictor capable of independently causing radiation exposure.[9]

In a study conducted in Poland, radiation exposure and fluoroscopy time was between radial approach and femoral approach was not found to be significantly differ. In the study it was also observed that older patients in radial approach needed more procedural time when compared to femoral approach.[17]However, in a observation among patients undergoing PCI, no difference in radiation exposure measured using doe-area product and fluoroscopy time did not differ between those undergoing radial approach or femoral approach. The authors also observed no significant difference in use of contrasting agent used among radial and femoral approach participants.[18] Comparison of data of 3973 participants undergoing either radial or femoral approach in CAG or PCI, fetched the results that radiation exposure to the patients did not vary significantly between the two groups. This comparison was made after the procedural complexity was adjusted for the analysis between the two approaches. Observed radiation exposure among radial approach was not found to be higher than that of a expected radiation exposure model which was made on the basis of radiation exposure data of femoral approach subjects.[19]In a study done in Australia among 381 participants, however, radial approach was found to have increased fluoroscopy time and radiation exposure than femoral approach.[20]

Most of the studies have measured the radiation exposure indirectly using dose-area product or reference air kerma. Direct measurement of radiation exposure was done in the present study using nano dot measuring chip. This will definitely provide a more reliable data compared to those studies in which radiation measure was done using indirect methods.

The operator distance in the present study was 17.3$\pm$1.95 in radial approach and 19.1$\pm$2.6 in femoral approach with p value 0.19.Previous studies have proved that factors that could increase the procedural time for the approaches for coronary angiogram and PTCA could be the age of the patient and the severity of the cardiac disease which ultimately influence the radiation exposure to the patient.[14,15,16]Fluoroscopy time and distance from the radiation source could influence the exposure to the operator and assistant and it can have greater impact on exposure than the site of insertion.[13,18,19]

CONCLUSION

In our study, it was observed that there was no significant difference in the radiation exposure to the patient or to the operator when the percutaneous transluminal coronary angioplasty was done using radial and femoral artery approaches by a single operator.

Limitations of the study

1. The study sample was too small for subgroup analysis. As it was a single operator study to eliminate interoperator bias, acquiring large sample satisfying inclusion and exclusion criteria was difficult. However, we need a larger sample to confirm these findings.
2. Coronary artery anatomy and coronary lesions differ for every patient. Hence there is a difference in sequence and duration of cineangiography acquisitions during coronary intervention procedure, potentially causing procedural heterogeneity. Standardized acquisition duration and sequence of views of the coronary arterial system may further clarify these differences.

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