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Comparative Study of Radiation Exposure of Patients undergoing Transradial and Transfemoral Coronary Angiogram and Percutaneous Coronary Intervention

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Abstract

Introduction: *Coronary artery disease (CAD) is now the leading cause of death worldwide. Percutaneous coronary interventions (PCIs) are an important group of technologies for the diagnosis and treatment of patients with CAD. PCI is usually performed using the transfemoral (TF) approach but the transradial (TR) approach has been increasingly used as an alternative to TF approach due to less vascular complications, earlier ambulation and improved patient comfort. Accurate assessment of radiation exposure during PCI is paramount important as radiation has many short and long term hazards. TR and TF route has distinct advantages and disadvantages. But in respect of radiation exposure of patients there are controversial evidence between TR and TF approach.* ***Objective:*** *To compare the radiation Exposure in patients with percutaneous coronary intervention by TR and TF approach.* ***Materials and Methods:*** *This prospective observational comparative study was conducted in the National Institute of Cardiovascular Diseases, Dhaka, from June 2015 to May 2016. A total of 200 patients were selected and categorized into two groups (Group I= Trans radial, n =100) and (Group II = Trans femoral, n= 100). Again divided into subgroups (group Ia, trans radial CAG = 70, group IIa, trans radial PCI =30) and (group IIa, trans femoral CAG =70, group IIb, trans femoral PCI = 30). Then different outcome variables were evaluated and compared.* ***Results:*** *Patient demographics were the same in both groups. Fluoroscopy time during TR and TFCAG and PCI was (4.4.±1.6 min vs 4.1±3.9 min, p=0.61) and (11.7±1.3 min vs 11.1±1.5 min, p=0.13) respectively. Regarding radiation dose during TR and TF coronary angiogram, Dose area product(DAP) were (2732±1195.5 mGym²vs 2434±488.0 mGym², p=0.07&) and Air Kerma (AK) were (307.6 ±112.2 mGy vs 283.7±48.5 mGy, p=.10) with statistically no significant difference of radiation dose (DAP and AK) between two groups. Utilization of Contrast volume during TR and TF angiogram (64.8±8.9 vs 68.2±7.5, p=0.01) were less in trans radial group. Also Utilization of Contrast volume in TR-PCI and TF- PCI (168.0±13.0 vs 177.7±19.9 ml ,p=0.03) were less in trans radial PCI.* ***Conclusion:*** *The basis of the results, no significant differences were found in patient of radiation dose in both TR and TF group. Furthermore utilization of contrast volume was lower in trans-radial CAG and PCI. Trans radial CAG and PCI can be performed with the same safety as for the trans femoral approach.*

Key words: *Radiation Exposure, TR-PCI, TF-PCI.*

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Introduction:

Coronary artery disease is the Global Burden of Disease & remains a major cause of health loss for all regions of the world[1]. As a result of an epidemiological transition from communicable to non-communicable diseases for last few decades, cardiovascular diseases (CVD) are being considered as an important cause of mortality and morbidity in many developing countries including Bangladesh[2]. There are many risk factors associated with coronary heart disease. Diabetes mellitus (DM), hypertension (HTN), obesity, smoking, high density lipoproteins and triglycerides levels have been found to have a greater impact on coronary heart disease[3].

In patients with obstructive coronary artery disease (CAD), percutaneous coronary intervention (PCI) and CABG surgery are both treatment options[4]. With the advent of increasing facility of catheterization procedures and increased burden of coronary artery disease, frequency of performing cardiac catheterization procedures is increased significantly. Percutaneous coronary intervention (PCI) is the standard treatment for ischemic heart disease. Coupled with

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evidence-based pharmacological strategies, the use of PCI in appropriate patients reduces morbidity and mortality across the spectrum of risk[5]. Continual evolution of antithrombotic therapy and device technology has resulted in the application of PCI to a wider population of patients[6]. Procedural success rates are high and ischemic complications relatively rare after percutaneous coronary intervention[7].

Till now the transfemoral approach (TFA) has traditionally been the preferred access site for percutaneous coronary interventions (PCIs) and coronary angiograms (CAGs). In 1989, the radial route was first introduced, and since then, the number of procedures performed by the radial route increased as the technique evolved with improvement in catheter design and with interventional cardiologists' experience[8]. However, vascular access site complications such as bleeding, hematoma, arteriovenous fistula or pseudoaneurysm are quite common after procedures through TFA[9]. Transradial approach (TRA) is an attractive options for same-day or outpatient procedure. This approach results in improved time to ambulation, additional comfort to patients, shorter hospitalization duration[10], lower hospital expenses and improve clinical outcomes. But there is controversy over the amount of radiation dose that received by the patient in TRA compared to TFA approach[11].

The radiation exposure during fluoroscopy-guided procedures became a topic of concern as the number of procedures increased during the years. In Publication of the International Commission on Radiological Protection (ICRP), the risks of radiation exposure from fluoroscopy guided procedures are described. The ICRP reported an increase of radiation induced injuries to patient's skin (deterministic effect) as well as the risk to develop radiation induced cancers (stochastic effect). Deterministic effects occur with increasing severity as the dose of radiation rises, leads to temporary or permanent sterility, cataract, lung fibrosis and permanent neurological deficit. Stochastic effects occur with increasing probability due to the increased dose of radiation and repeated intervention also increasing the chance. Leukaemia may arise after an interval of around 2-5 years and solid tumours after an interval of about 10-20 years[12]. Roguin et al (2012) reported that radiation exposure during PCI is associated with radiation-induced injuries. With an increasing number of complex and repeated PCI, radiation-induced hazards are currently a major concern in fluroscopy guided procedure mainly due to risk of cancer induction[13].

Over the years, contradictory results were reported on the radiation exposure of patients from procedures performed by the radial route. Some studies showed a significant increase in radiation dose for radial compared to femoral approaches. Other studies showed no differences between two approaches[14]. Usman et al demonstrate that radial route for cardiac catheterization procedures is associated with longer fluoroscopy time leading to increased radiation exposure[15]. In another study no differences were found in patient's radiation dose in both transfemoral and transradial group and transradial route might be a good substitute route[11].Shah et al.,(2013) showed that transradial approach is associated with higher radiation exposure when compared with transfemoral approach[16].While this controversay continues, very few studies have compared the radiation exposure with radial versus femoral approach throughout the world. The aim of the study was to compare radiation exposure of patients during coronary angiogram and PCI accessed by the radial and femoral route.

Materials and Methods:

This case control study was conducted in Department This prospective observational comparative study was conducted in Department of cardiology National Institute of Cardiovascular Diseases (NICVD), Dhaka, from April 2016 to March 2017, to assess the radiation exposure and Fluoroscopy time between transradial and transfemoral coronary angiogram and PCI. Patient's undergone coronary angiogram & percutaneous Coronary Intervention (PCI) who were hemodynamically stable were included in this study. Total 200 patients were selected and allocated into two groups on the basis of procedural approach during coronary angiogram and PCI. The group I was consisting of 100 patients who underwent transradial approach and the group II comprised of 100 patients who underwent tranfemoral approach. Again divided into subgroups (group Ia, transradial CAG, n =70, group IIa, trans radial PCI, n =30) and (group IIa, trans femoral CAG, n =70, group IIb, trans femoral PCI, n = 30). Informed written consent was taken from each patient before enrollment. Meticulous history was taken and detailed clinical examination was done and recorded in pre designed structured pro forma. Demographic data, e.g., age, sex, occupation, BMI and different risk factor profile was evaluated.

Cardiac procedure: CAG and PCI will be done according to standard protocol. A detailed explanation was provided to the patient regarding the nature of the procedure, its potential risk and benefits. Even if radial access was planned, both femoral access sites were also be prepared. Premedication was done by giving a loading dose of 300 mg of Aspirin, Clopidogrel 300 mg, 40 mg of Atorvastatin and 5 mg of tab. Diazepam. Armrest was provided with the table, so that the patients arm was in abduction. A 500ml plastic sachet of normal saline was placed on the armrest beneath the wrist to elevate the wrist. The hand was then fixed in hyperextension with adhesive tape, prepared in a sterile fashion and the draped positioned. The course of the artery was palpated and 1-2 ml of 2% injection lignocaine subcutaneously infiltrated, 2-3 cm proximal to the flexor crease of the wrist. Then the radial artery was fixed with the index and middle finger of the left hand and the radial artery was punctured with puncture needle at 30-45° angles. A soft 0.025-inch straight guide-wire was advanced through the needle, and a 6-F, 17-cm radial sheath was be placed. Spasmolytic cocktail made up of injection verapamil of 2.5 to 5mg in 10 ml normal saline with or without 100 microgram nitroglycerine was introduced through side channel of vascular access sheath to reduce the spasm of the radial artery. Along with that 10,000 unit of conventional injection heparin regardless of the weight of the patient, was administered during PCI to keep activated clotting time (ACT) values between 250-300 s. Over a 0.032 inch exchange wire the JR-6F/JL-6/AL-2/TR5 catheter was advanced to the ascending aorta using fluoroscopic guidance. The PCI was performed with 6-F (7-F if need) traditional guide catheters used for TF (Dehghani P et al., 2009) or radial guide catheter. Where difficulty encountered in advancing the wire in the arm due to loops or other anatomic variants, a hydrophilic (Terumo) wire had tried to solve the problem. When difficulty was encountered in advancing the wire from the subclavian artery to the ascending aorta, the patients asked to take a deep breath. The radial artery sheath was removed immediately after completion of TR-PCI, and haemostasis was achieved by application of an adjustable plastic clamp (TR-Band) on the radial artery. The clamp was gradually released over 2 to 3 h while monitoring for access site bleeding or hematoma. The clamp was be removed after satisfactory access site haemostasis had been achieved. PCI through transfemoral approaches done by standard method. Haemostasis was achieved over 2 to 3 hrs with monitoring of ACT for access site bleeding or hematoma by manual pressure over femoral artery. Duplex study done when clinically suspected any vascular complication. After completion of CAG and PCI, radiation exposure dose, fluoroscopy time recorded from monitor and contrast volume used in procedure was noted in data sheet.

Estimation of radiation dose and fluoroscopy time:

The radiation exposure of patients undergone CAG and PCI were measured using dose area product (DAP) meters and Air Kirma (AK). The DAP is expressed in $mGym^2$ or μGym^2. The DAP and AK was integrated in the X-ray systems. The X-ray systems provided direct feedback of the radiation exposure on the monitor of the systems. The radiation exposure from fluoroscopy mode and cine mode as well as the total radiation exposure displayed on the monitor of the X-ray systems and recorded from monitor. Moreover, the fluoroscopy time (in minutes) displayed on the monitor and recorded fluoroscopy time. All the information were recorded in data collection sheet. Statistical analysis of the data was done using statistical processing software (SPSS) and Microsoft. Quantitative data expressed as mean and standard deviation and qualitative data as frequency and percentage. Comparison was done by tabulation and graphical presentation in the form of tables, pie chart, graphs, bar diagrams, histogram & charts etc.

Results & Observation:

The findings of the study obtained from the data analysis were presented. Results and observations are given below:

Table I: Demographic characteristics of the patients (n=200)

Variables	Group I (n =100)	Group II (n =100)	Total (n=200)	p value
Age in years				
Mean ± SD)	51.2±10.0	52.9±10.8	52.0±10.4	0.243
Range (min – max)	(32 – 73)	(35 – 72)	(32 – 74)	
Gender				
Male	83 (83%)	85 (85%)	168 (84%)	0.701
Female	17 (17%)	15 (15%)	32 (16%)	
BMI (kg/m^2)				
Mean ± SD	25.21±4.20	25.25±3.28	25.23±3.75	0.175

The age distributions revealed that mean age was found 51.2±10 years in Group I and 52.9± 10.8 years in Group II. The mean age difference was insignificant (p=0.243) between two groups in unpaired t-test. The mean age of the total population was 52.0±10.4 years. Out of 200 patients, 168 (84%) patients were male and 32 (16%) patients were female. Male and female patient's ratio was 5.25:1. In group I, there were 83 (83%) male and 17 (17%) female patients and in group II, male and female patients were 85 (85%) and 15 (15%) respectively. Male patients were predominant in both study groups. The mean BMI of group I and group II were 25.21±4.20 vs. 25.25±3.28kg/m2. The difference of mean BMI was statistically insignificant (p=0.175)

Table II: Evaluation of clinical parameters between two groups (n = 200)

Clinical parameters	Group I (n= 100) Mean± SD	Group II (n= 100) Mean± SD	P value
Pulse /min	78.3±5.6	80.6±7.8	0.105
Systolic Blood pressure (mmHg)	126.6±16.6	129.3±16.6	0.254
Diastolic Blood pressure (mmHg)	79.0±8.8	79.5±9.2	0.695

Table II shows clinical parameters. Mean pulse rate was found 78.3±5.6/min in group I and 80.6±7.8/min in group II which was statistically insignificant (p=0.10).The mean systolic blood pressure was 126.6±16.6 mmHg in group I and 129.3±16.6 mmHg in group II. The mean diastolic blood pressure was 79.0±8.8 mmHg in group I and 79.5±9.2 mmHg in group II. Difference of systolic and diastolic blood pressure was not significant statistically (p=0.25, p=0.69).

Table III. Comparison of different procedural variables during transradial CAG (TR-CAG) with transfemoral CAG (TF-CAG) (n=140)

Variables	Group Ia (TR-CAG, n=70)	Group IIa (TF-CAG, n=70)	P value
Fluoroscopy time (FT) in min mean±SD	4.4±1.6	4.1±3.9	0.618

Table III. Comparison of different procedural variables during transradial CAG (TR-CAG) with transfemoral CAG (TF-CAG) (n=140)

Variables	Group Ia (TR-CAG, n=70)	Group IIa (TF-CAG, n=70)	P value
Radiation unit (mean±SD)			
Dose area product (DAP, µGym^2 or mGym^2)	2732±1195.5	2434±488.0	0.078
Air Kirma (AK, mGy)	307.6±112.2	283.7±48.5	0.107
Contrast volume (ml) mean±SD	64.8±8.9	68.2±7.5	0.011[s]

The above table III demonstrates that mean Fluoroscopy time (FT) during transradial and trans femoral CAG were (4.4±1.6 vs. 4.1±3.9 min) with no statistical difference (p=0.618). Mean dose area product (DAP) during TR –CAG and TF-CAG were (2732±1195.5 vs. 2434±488.0 µGym^2) with no statistical difference (p=0.078). Mean Air Kimma (AK) during TR-CAG and TF -CAG were (307.6±112.2 vs. 283.7±48.5 mGy) with no statistical difference (p=0.10). Mean contrast volume was observed greater in transfemoral CAG than transradial CAG (68.2±7.5 vs. 64.8±8.9ml) with statistically significant difference (p=0.01).

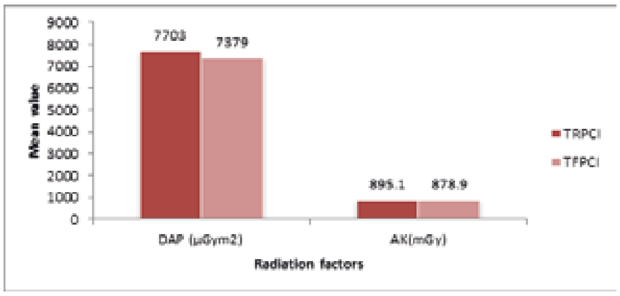

Figure 1: Comparison of Radiation dose between TR –PCI (RCA, single stent, type A lesion, n=30) and TF-PCI (RCA, single stent, type A lesion, n=30)

The figure 1 describes that mean dose area product (DAP) during trans radial and trans femoral PCI were (7703 ± 1247.6 vs. 7379 ± 631.9 µGym^2) with no statistical difference (p=0.21). On the contrary, mean Air Kirma (AK) during trans radial and trans femoral PCI were (895.1±142.4 vs. 878.9±87.9 mGy) with no statistical difference (p=0.60).

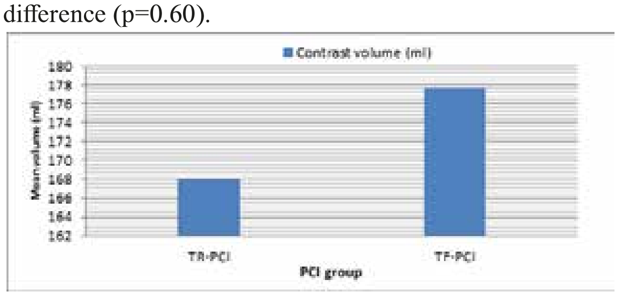

Figure 2: Comparison of contrast volume during PCI with TRA (RCA, single stent, type A lesion, n= 30) and TFA approach (RCA, single stent, type A lesion, n= 30)

The above table describes that Mean contrast volume used greater in transfemoral PCI than trans radial PCI (177.7±19.9 vs. 168.0±13.0ml) with statistically significant difference (p=0.03)

Discussion:

The main objective of the study was to assess radiation exposure of patients undergoing transradial and transfemoral coronary angiogram and percutaneous coronary intervention. In the current study the mean age of group I was 51.2± 10 years and group II was 52.9± 10.8 years. The mean age was almost similar between two groups. The sex incidence of the present study was observed that male were 83 (83%) and 85(85%) and female were 17 (17%) and 15 (15%) in the group I and II respectively. No statistically significant differences were found in between groups. The clinical parameters like Pulse and BP were observed almost identical in both groups of patients.

In this study regarding the mean fluoroscopy time in trans radial and trans femoral coronary angiogram, it was 4.4±1.6 min and 4.1± 3.9 min in the group Ia and group IIa respectively with the statistically no differences (p=0.61). It resembling a study done by Tayeh and Ettori[17] where showed no significant difference of fluoroscopy time in transradial CAG and trans femoral CAG. In Present study finding regarding fluoroscopy time is consistent with the studies done by Tarighatnia A et al., (2016)[11], Barbosa et al., (2014)[18], Weaver et al., (2010)[19], there is no significant difference.

The mean fluoroscopy time in present study regarding trans radial and trans femoral PCI, mean fluoroscopy time was 11.7 ± 1.3 min in group Ia and 11.1 ± 1.5 min in group IIa with statistically insignificant difference (p= 0.13). Current study finding regarding fluoroscopy time during PCI is consistent with the studies done by Tarighatnia A et al., (2016)[11], Weaver et al., (2010)[19].

In present study regarding radiation exposure in trans radial and trans femoral coronary angiogram, mean dose area product (DAP) was (2732±1195.5 mGym^2 and 2434±488 mGym^2, p=0.07) Air Kirma (AK) was (307.6 ± 112.2 and 283.7 ± 48.5, p=0.10) in group Ia and group IIa respectively with statistically no significant difference. It resembling a stydy done by Tarighatnia A, et al., (2016)[11] showed no significant difference of DAP in trans radial and trans femoral angiogram (1732.55 vs 1949.71, p=.17) and also no significant difference of Air Kirma in trans radial and trans femoral route (233.88 vs 210.78, p=0.9). Georges JL, et al[20] demonstrated radial route associated with lower radiation exposure in comparison to femoral route (p<.001). The Learning curve, the experience and the high volume centres for radial access have been underlined as key factors in radiation dose reduction[20]. Jolly S, et al[21] showed median DAP was not different between radial and femoral angiogram. Kuipers et al[22] showed radial route was associated with lower radiation exposure in compare to femoral route. Lower radiation dose in radial approach in above studies might be due to intervention done in high volume radial centers by experienced operators[11]. But following studies contradict the result of present studies. Shah B et al[16] revealed that radial route was associated with higher radiation exposure in compare to femoral angiogram (DAP was 19649 vs 15395, p=.02). The main reasons for the possible higher radiation dose during trans radial access are probably related to the more complicated catheter manipulation requiring prolonged fluoroscopy time and to more unfavourable operator position, closer to X –ray source, especially for less skilled operators. These difficulties are easily overcome by increasing the radial competence[20].

Regarding radiation exposure in this study during trans radial and trans femoral PCI, mean dose area product (DAP) were (7703 ± 1247.6 $mGym^2$ and 7379 ±631.9 $mGym^2$,) and Air kirma were (895.1 ± 142.4 mGy and 878..9 ± 87.9 mGy, p= .60) in group Ib and group IIb respectively with statistically no significant difference. It resembling a study done by Tarighatnia A, et al[11] showed no significant difference of DAP in trans radial and trans femoral PCI (3907.96 ± 249.7 vs 4643.58±221.4, p=.02) and also no significant difference of Air Kirma in trans radial and trans femoral PCI (619.85± 40.44 vs 702.19± 35.87 , p=0.12). Georges J., et al[20] revealed that radial route associated with lower radiation exposure in comparison to femoral route (p<.001). Jolly S, et al[21] demonstrates median DAP was not different between radial and femoral route. Kuipers, et al.[22] showed that radial route was associated with lower radiation exposure in compare to femoral route. Radiation exposure is higher in radial route in comparison to femoral route but differences present only in lower volume centers and less experienced operator. There is no significant difference in radiation exposure in radial vs femoral route if it is done in high volume center by experienced operator.

But following studies contradict the result of present studies. Shah B, et al[16] showed that radial route was associated with higher radiation exposure in compare to femoral route. Radial route for cardiac catheterization procedures is associated with longer fluoroscopy time leading to increased radiation exposure[15]. The discrepancy regarding radiation exposure dose between trans radial and trans femoral PCI studies could be explained by differences in the imaging system used, the operator`s skill and the characteristics of angiography[11].

Conclusion:

In this study no significant differences were found in patients radiation dose in both radial and femoral group regarding coronary angiogram and PCI. Furthermore utilization of contrast volume was lower in trans radial coronary angiogram and PCI. So we can conclude that trans radial angiogram and PCI can be performed with the same safety as for the trans femoral approach. The operator`s experience plays a major role in the success rate. These results are obtained in an experienced center in the trans radial approach and conclusions might look different in catheter laboratory with lower experience in this approach. So, transradial approach is an attractive alternative to conventional transfemoral approach.

Conflict of Interest: None.

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