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Comparison of Radial vs Femoral Approaches in Terms of Coronary Intervention in Native Coronaries

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Abstract

Background: Percutaneous coronary interventions has been performed through traditionally through transfemoral route.In the current scenario, transradial are evolving in the routing clinical practice.

Aim: To compare the compared radial versus femoral routes for procedure time, radiation parameters, Fluoroscopy time, contrast amount required and access site complications.

Methods: This was a hospital based single center randomized comparative interventional study conducted on 230 patients who underwent PCI. Out of 230 patients, radial access (n=48) and femoral access (n=182). The route of intervention were compared for procedure time, radiation dose, fluoroscopy time, amount of contrast used and complications.

Results: The procedure time in femoral group was higher as compared to radical group (76.48 ±43.80 vs 44.33 ±37.91mins; p<0.001). The dose of radiation was significantly higher in femoral group as compared to the radial group (2062.99±1948.03 vs 917.00±664.78 mGY; p<0.001). Further, the amount of contrast used was significantly higher is significantly higher in femoral group as compared to the radial group (205.93 ±83.47 vs 157.31± 67.31; p<0.001) and was statistically significant. The overall access site complications were higher in femoral than radial group.

Conclusion: The present study concludes that radial approach was found to be safer alternative to femoral approach for coronary interventions with lesser radiation exposure, lesser vascular complications and reduced risk of contract induced nephropathy due to lesser contrast usage.

Keywords: Radial approach; Femoral approach; Radiation; Contrast; Access site; Procedure time.

Introduction

The cardiovascular diseases (CVDs) is one of the leading cause of mortality in India. The shift in this epidemiology is mainly due to rampant elevation of CVDs prevalence and its associated risk factors among the Indian population. In 2016, the estimated prevalence of CVDs in India is estimated to be 54.5 million.[1] One-fourth of mortality among the Indian population is predominantly due to CVD, with ischemic heart disease and stroke accounts for >80% of the burden One in 4 deaths in India are now because of CVDs with ischemic heart disease and stroke responsible for >80% of this burden.1 Currently, percutaneous coronary angiography (PCA) and percutaneous transluminal coronary angioplasty (PTCA) are widely used diagnostic and therapeutic strategy for coronary artery disease respectively.[2] During the past, femoral artery is the major and mostly preferred access site for performing coronary angiography due to its larger size. Percutaneous coronary intervention (PCI) can be performed by major three routes such as femoral, brachial or radial arteries. In femoral access, there is a high chance of vascular complications with or without bleeding events. The

more prevalent vascular complications post femoral PCI encompasses groin hematomas, formation of arterial pseudoaneurysms, and arteriovenous fistulae.[3] Thus the bleeding events is highly variable and previous reports shows an incidence between 1–5% and the rate is comparatively higher in PCI patients as that of the diagnostic catheterization.[4-6] The use of new sheaths, guiding catheters and wires are feasible by radial access for for coronary interventions and also offers better patient compatibility. Further, radial access elicits easy artery compression and earlier patient mobilization[7] and even reduces the hospital stay.[8] This lead to more interventions carried out using radial access and most of the operators are comfortable with the PCI performed using radial access. However, many operators opined that femoral access is easier and faster but it imposes significant complication among the patient population. However, in other instance, the radical access delivers more complication for the operators but offers less post-administration procedural complications.[9] The purpose of this study was to assess procedure time, radiation parameters, contrast amount required and access site complications between the femoral and radial approaches during percutaneous coronary interventions.

Materials and Methods

This was a hospital based single center Randomized Comparative Interventional study which included 230 patients who underwent PCI at Vydehi institute of Medical Sciences and Research Centre during the period between January 2018 to June 2019.

Inclusion Criteria

All Patients more than 18 years of age admitted in CCU for coronary interventions.

Exclusion criteria

Patients with sepsis, bleeding diathesis, severe thrombocytopenia, decompensated heart failure, active bleeding especially gastro-intestinal bleeding, post CABG and acute myocardial infraction were excluded from the study.

Radial Approach

Modified Allen test was done to determine collateral circulation is present from ulnar artery in case thrombosis occurs in radial artery. The hand was elevated and the patient was asked to clench their fist for about 30 seconds. Pressure was applied over the ulnar and the radial arteries so as to occlude both of them. Still elevated, the hand was then opened. It should appear blanched (pallor may be observed at the finger nails). Ulnar pressure was released while radial pressure is maintained, and the color should return within 5 to 15 seconds. If color returns as described, Allen's test was considered to be normal. If color fails to return, the test was considered abnormal and it suggests that the ulnar artery supply to the hand was not sufficient, indicating it was unsafe to cannulate. After confirming, patency of Collateral circulation to hand, the wrist was prepped and draped with a femoral access groin drape. 1 mg of midazolam was given before starting procedure. Radial artery was then punctured using 23G needle and 0.032" guide wire(Radiofocus-terumo Corp.) was be inserted. Following which a 6F introducer sheath was inserted. After sheath replacement, cocktail containing 5mg diltiazem, and 100 IU/kg unfractionated heparin was injected. After procedure, Radial sheath was removed and compression applied till adequate homeostasis was achieved.

Femoral approach

Groin was prepped and draped. The femoral artery puncture site localized and punctured and a spurt of pulsatile blood was seen and then a J tipped guide wire was advanced gently into the artery. After the guide wire was positioned in the iliac artery, needle is removed with firm hand pressure applied over the puncture site with the last 3 fingers to control bleeding, and the first 2 fingers pinching the guide wire to secure it while the sheath is placed over the wire. this followed by advancing the sheath-dilator assembly with a rotatory motion while holding the guide wire straight and stable. The dilator and guide wire together were then removed. Blood was then aspirated and sheath is flushed through the side arm with heparinized saline. At the end of procedure ACT was measured and sheath was removed after ACT was less than 180 seconds. Manual compression was performed until satisfactory hemostasis had been achieved and followed by placement of compressive bandage for 6 hours. The leg was immobilized for 12 hours.

Outcome measures

The following outcomes were measure during the study,

Procedure time which was defined as time between first needle skin prick for obtaining access till removal of last catheter. The amount of contrast used were also measured.

The following radiation parameters such as dose area Product (DAP), which reflects both the dose and the area of radiation administered to the patients and expresses as mGy cm^2. Fluoroscopy time (FT) which reflects the length of time the patient and operator are exposed to radiation and expressed in minutes. Then cumulative air kerma–measured in milligray(mGy) administered from the angiography system were also measured.

Access site complications such as vascular complications was defined as death caused by vascular complications, vascular repair, major vascular bleeding (>3 g hemoglobin decrease because of access site bleeding or retroperitoneal bleeding) requiring blood transfusion, vessel occlusion, or loss of distal pulse. Minor vascular complications was defined as any of the following: hematoma <10 cm, artery spasm.

Data Analysis

All data were expressed as mean ± standard deviation of the mean. Descriptive statistics was used to analyse the demographics details. Comparison between radial and femoral approach was done by one-way ANOVA. In all cases, $p < .05$ was considered as significant. Data analysis was performed using SPSS V22.0 (SPSS Inc., Chicago, Illinois).

Results

In this study, 230 patients were recruited and out of these 48 subjects were assigned to radial group and 182 subjects were assigned to femoral group.

Table 1 shows the demographic characters of the subjects such as age , gender, BMI and smoking status, disease status and biochemical levels in radial and femoral group.

In the present study, for coronary invention the left anterior descending artery were widely used in both the groups (Femoral - 58.7% and Radial - 62.5%; p=0.74), followed by right coronary artery (46.2% vs 31.2%; p=0.07), left circumflex artery (33.5% vs 25%; p=0.29) and it was statistically non-significant. However, multi-vessel coronary interventions was significantly higher in femoral access group as compared to the radial access group (32.4% vs 16.7%; p=0.03).

Table 1: Baseline characteristic of the patients.

Parameters		Femoral approach (n=182)	Radial approach (n=48)	P-value
Age (Years)		56.79±8.97	55.29±10.30	0.65
Gender				
Male		165 (90.7%)	42 (87.5%)	0.59
Female		17 (9.3%)	6 (12.5)	
BMI (Kg/cm2)		23.95±3.47	23.29±3.48	0.25
Disease Status				
CAD	Yes	131 (72%)	41 (85.4%)	0.06
	No	51 (28%)	7 (14.6%)	
Hypertension	Yes	67 (37.8%)	21 (43.8%)	0.41
	No	115 (63.2%)	27 (56.2)	
Diabetes	Yes	62 (34.1%)	18 (37.5%)	0.73
	No	120 (65.9%)	30 (62.5%)	
Smoking Status	Yes	108 (59.3%)	26 (54.2%)	0.52
	No	74 (40.7)	22 (45.8%)	
Biochemical Levels				
Haemoglobin (%)		13.03±1.66	13.18±1.93	0.61
TLC (× 109 cells/ liter)		9.20±2.51	9.29±3.12	0.83
Platelet count (X 109 /liter)		213.33±113.07	198.56±75.68	0.39
Random Blood Sugar (mg/dl)		132.54±65.77	124.81±53.01	0.45
Prothrombin time (Secs)		13±7.83	12.06±0.92	0.41
INR		1.09±0.13	1.05±0.09	0.09
Blood Urea (mg/ dl)		23.81±8.32	23.79±7.87	0.99
Sr. Creatinine (mg/dl)		1.10±1.94	0.95±0.21	0.59

The data were represented as mean± standard deviation. INR: International Normalized Ratio.

In this study, the radiation dose represented as Cumulative Air Kerma [CAK] milligray [mGy] (CAK [mGy]) was significantly higher in femoral approach as compared to the radial approach (2062.99±1948.03 vs 917.00±664.78 mGy; p <0.001). Further, the total amount of radiation delivered, represented as dose area product (DAP) mGy cm^2 was significantly higher in femoral approach as compered to the radial approach (112995.44±70187.22 vs 61137.98±98431.83 mGy cm^2; p<0.001). The fluorography time was significantly higher in femoral approach as compered to the radial approach (24.84 ±17.05 vs 13.54±11.53 mins; p<0.001). The data were shown in Table 2.

The coronary intervention procedure time was significantly higher in femoral approach as compared to the radial approach (76.48±43.80 vs 44.33±37.91; p<0.001). Further, the contrast used were significantly higher in femoral approach as compared to the radial approach (205.93 ±83.47 vs

157.31±67.31; p<0.001). The results were shown in Table 3.

Table 2: Comparison of Radiation parameters between radial and femoral group.

Radiation Parameters	Femoral approach (n=182)	Radial approach (n=48)	P-value
Radiation dose (mGy)	2062.99±1948.03	917.00± 664.78	<0.001
Total amount of radiation (mGy cm^2)	112995.44 ±70187.22	61137.98 ± 98431.83	<0.001
Fluorography time (mins)	24.84 ±17.05	13.54± 11.53	<0.001

The data were expressed as mean ± standard deviation.

Table 3: Comparison of procedure time and contrast volume between radial and femoral group.

Parameters	Femoral approach (n=182)	Radial approach (n=48)	P-value
Procedure Time (mins)	76.48±43.80	44.33±37.91	<0.001
Contrast volume (ml)	205.93 ±83.47	157.31±67.31	<0.001

The data were expressed as mean ± standard deviation.

The overall access site complications was significantly higher in femoral approach as compared to radial group (67.5% vs 27%; p<0.001). The minor complications such as hematoma < 3cm (15.9% vs 0% ; p=0.000) and ecchymosis (50.5% vs 8.3%; p<0.001) were higher in femoral approach as that of the radial approach and it was found to be statistically significant. In our study, none of the patients developed major complications such as vascular repair, major vascular bleeding, blood transfusion, vessel occlusion, loss of distal pulse. However, one patient in both femoral and radial approach developed hematoma > 3cm. Nil access site complications were significantly higher in radial approach as that of the femoral approach (72.9% vs 32.4%; p<0.001). The data were displayed in Table 4.

Table 4: Comparison of complications between radial and femoral approach.

Complications		Femoral approach (n=182)	Radial approach (n=48)	P-value
Overall Complications		123 (67.5%)	12 (27%)	<0.001
Minor Complications				
Hematoma <3cm	Yes	29 (15.9%)	0	<0.001
	No	153 (84.1%)	48(100%)	
Ecchymosis	Yes	92 (50.5%)	4 (8.3%)	<0.001
	No	90 (49.5%)	44 (91.7%)	
Major Complications				
Hematoma <3cm	Yes	1 (0.5%)	1 (2.1%)	0.38
	No	181 (99.5%)	47 (97.9%)	
No Complications	Yes	59 (32.4%)	35 (72.9%)	<0.001
	No	123 (67.6%)	13 (27.1%)	

In this study, there was no significance difference in the duration of hospital stay between the radial and femoral approach (5.19±1.42 vs 4.97±1.29 days; p=0.317). The data were shown in Fig 1.

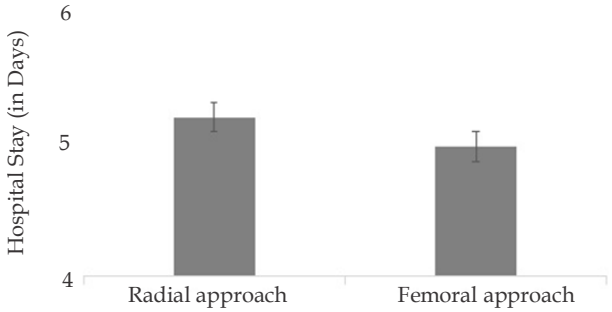

Fig 1: Hospital stay in the present study.

Discussion

Ischemic Heart disease (IHD) is one of the major cause of mortality among the Indian population with a prevalence of 3–4% in rural areas and 8–10% in urban areas based on the previous population based cross sectional surveys.[10] The disease progression and the development of acute events in CAD patients are the leading causes of morbidity and mortality. The aim of this work was to demonstrate the benefits of the radial approach in comparison to the femoral approach for patients with coronary interventions. The end result was to look for the procedure time, radiation parameters, and contrast amount, access site complication between the two approaches respectively.

In our study, the mean age of patients in femoral group and radial group was found to be 56.79±8.97 vs 55.29±10.30 years and it was found to non significant. Similar to our report in a study dine by Bhat et al . there was no significant difference in the age of the patients between the femoral and radial group.[11]

In our study the mean procedure time in femoral group was significantly higher as compared to the radial group (76.48±43.80 vs 44.33±37.91 mins; p<0.001). The increased procedure time for femoral approach might be due to the complex procedure involved during PCI. However, in FERARI study there was no significant difference in the procedure time between the femoral and radial group (45 vs 46.0 mins; p=0.363). In contrast the study conducted

by Bhat et al showed that the procedure time was significantly higher in radial group as compared to the femoral group [29 ± 11.3vs 27.3 ± 12.4 mins, p= 0.03].[11]

In our study contrast usage was more in femoral group when compared to radial group. This was in accordance to study by authors Bernat et al who found contrast usage was less in radial group.[12,13]

In our study. radiation exposure was considerably higher in femoral group than Radial group. The Fluoro Time, DAP, CAK were significantly higher in femoral group than Radial group. This might be due to enhanced multi vessel stenting and complex coronary anatomy. de Mattos et al showed that the in hands of expert operator, radiation exposure was less in transradial.[14] In contrast,Tarighatnia et al in there study found no differences between radial and femoral groups in patients undergoing coronary interventions.[15]

In our study the access site complications were higher in femoral group than radial group. The minor complications were significantly higher in femoral than radial group. Brueck et al. Showed lower complication rate in radial group as compared to the femoral group which is in line with the present study.[16] Further, the FARMI trial also showed lower vascular complications in radial access as compared to the femoral access which is in accordance with the present study.[17]

Limitations

The present study was performed on interventions in native coronary only and interventions in STEMI, post CABG patients were excluded. Complex coronary interventions were only done through femoral approach owing to familiarity by operators. The sample size in radial group was small as radial interventions were started recently. All the coronary intervention in Radial group was performed by a single expert operator.

Conclusion

Coronary artery disease is a major global health problem with an increasing trend. The present study shows that the radial approach to be a safer alternative to femoral approach for coronary interventions with lesser radiation exposure, lesser vascular complications, and reduced risk of contrast induced nephropathy due to lesser contrast usage.

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Conflict of Interest: None to Declare.

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