COMPARISON OF TRANSRADIAL VERSUS TRANSFEMORAL ACCESS FOR PERCUTANEOUS CORONARY INTERVENTION IN A TERTIARY CARDIAC CARE FACILITY

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ABSTRACT

Objective: To compare the transfemoral and transradial access in term of safety and efficacy in patients undergoing percutaneous coronary interventions.

Study Design: Observational Study.

Place and Duration of Study: Rawalpindi Institute of Cardiology, Rawalpindi Pakistan, from Jan to Nov 2019.

Methodology: Patients undergoing percutaneous coronary intervention fulfilling the criteria for both transradial and transfemoral accesses were included in the study. Clinical data were obtained from patient's record while procedural and outcome data were obtained by observing the procedure and patients.

Results: Overall 584 patients were included. 461 patients were in radial group while 123 were in femoral group. Clinical and angiographic characteristics were similar between two groups of patients. Procedure failure was statistically similar between two groups; 1.6 vs. 4.3; p=0.16 for femoral and radial group respectively. Mean access time, procedural and fluoroscopy time was longer in radial group compared to femoral group; 2.7 ± 0.67 min vs. 11.0 ± 7.9, p=0.001, 68.0 ± 15.9 min vs. 76.1 ± 12.7 min, p=0.001, 24.7 ± 6.4 min vs. 28.8 ± 5.4 min, p=0.001 respectively. Mean amount of contrast used was higher in radial group compared to femoral group; 237.1 ± 4.7 ml vs. 248.4 ± 9.1ml, p=0.003. Access site complications were significantly higher in the femoral group as compared to radial group; 6(4.9) Vs 7(1.5), p=0.02. Non access site complications were similar between two groups; 2(1.6) vs. 11(2.4), p=0.61 for femoral and radial groups respectively.

Conclusion: In patients treated with percutaneous coronary intervention Transradial routeis associated with a reduced number of in comparison to Transfemoral route. It is also linked with lesser procedural related morbidity but with longer procedure and fluoroscopy time.

Keywords: Percutaneous coronary intervention, Transradial artery access, Transfemoral artery access.

INTRODUCTION

There are many management options to treat coronary artery disease one of them is Percutaneous coronary intervention (PCI). Use of PCI has been considered to reduce morbidity and mortality among such patients. With continual evolution of antithrombotic therapy and device technology, PCI is increa singly performed in a wider population of patients[1]. Transfemoral approach is one of the route of doing PCI. Although many advancements have been made in this regard still access site complications remain a matter of concern for the operators[2,3]. Although the anatomical course for this artery is deep yet bleeding and other vascular complications of around 3-7% have been reported in literature[4].

Transfemoral access has been associated with complications like hematomas pseudoaneurysm and arteriovenous fistulas which sometimes require surgical correction. Studies have shown the incidence of these to be around 2-4% with complexity of the lesion increasing the frequency of such complications[5,6]. Consequently, hospitalization duration, costs and periprocedural morbidity are increased.

Transradial approach after its introduction in 1989 has emerged as an attractive alternative to the femoral approach[7]. It has some advantages as compared to transfemoral route one of them being the decrease in vascular complications and better clinical results among young and elderly patients[8,9]. Moreover, decease chances of bleeding from access site, hematoma formation and along with that early mobility of the patient, shorter stay at hospital and reduced hospital financial burden are also described in literature[10]. Transradial access, to date, is still used in a small no of patients planned for routine PCI. A report by National Cardiovascular data registry has shown that TR PCI made up <1.5% of all procedures. The fear of procedural failures and Technical issues faced during transradial approach are considered to be the reason for under mining the use of this technique. However, there is a learning curve for transradial approach and it is associated with longer procedural and fluoroscopy times[1].

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Various international studies conducted in Europe and America have compared both of these techniques for angiography as well as for intervention [11,12]. However very few studies have been conducted on this subject in our local community. As Asian population, especially females tend to have small caliber radial artery due to small body habitus, it can make this technique even more challenging[21]. We looked to assess the different outcomes in terms of safety and efficacy between transfemoraland trans radial access in patients undergoing percutaneous coronary intervention for the management of coronary artery lesions in our local population.

METHODOLOGY

The study was carried out at Rawalpindi institute of Cardiology from January 2019 to November 2019 for a total period of 11 months. Casagrande, Pike & Smith calculator for sample size calculation and the aforementioned response distributions, the estimated sample size was 584 patients, 123 for transfemoral group and 461 for transradial group, purposive non probability sampling technique was used for enrollment patients' recruitment in the study. The study was approved by ethics review board of Rawalpindi Institute of Cardiology hospital and informed consent was taken from all the patients who underwent intervention.

Patients who have already undergone coronary angiography through any route and referred for percutaneous coronary intervention were reviewed for participation in the study. Patients who had a normal Allen's test and palpable femoral pulse were considered eligible for cardiac catherization by either route. These patients were randomly assigned by lottery method to either trans femoral or trans radial group in a 1:4 ratio. Patients who had the following conditions were excluded from the study; cardiogenic shock at the of arrival to catherisation laboratory, previous coronary artery bypass, pathologic Allen's test, Raynaud syndrome, femoral access problems, peripheral artery disease, aneurysm of the abdominal aorta, simultaneous right heart catheterization, use of temporary pacing, chronic renal failure (creatinine >2mg/dl) with the potential necessity of using the radial artery as a native fistula in the future, patients who were having arteriovenous fistula for hemodialysis. After recruitment in the study, demographic variables included age, gender, body mass index, coronary artery disease risk factors, diagnosis of stable angina, unstable angina, recent MI, history of previous PCI and echocardiographic ejection fraction were noted from patient clinical record.

We performed Allen's test by asking the patient to make a fist tightly followed by operator simultaneously occluding with his/her thumbs both radial and ulnar arteries of the same hand of the patient. After that, patient was asked to open the fisted hand and after confirming the palmar pallor, release of the ulnar artery was done. Abnormal test was defined as when >15 seconds passed before normal return of color appeared after it has been blanched.

We defined risk factors for coronary artery disease as below: Hypertension: patients who are on either antihypertensive medications or having blood pressure of >140/90mm Hg for nondiabetics and >130 /80 for diabetics had been documented in hospital record. Diabetes: patient with either fasting blood glucose of >126 mg/dl or are on oral antidiabetic medication or insulin.

Smoking

Use of cigarettes within the last 10 years. Hypercholesterolemia patients having total cholesterol of >200 mg/dl and/or LDL levels of >150 mg/dl.

Family History

First degree relative having either myocardial infarction or who had undergone revascularization of thecoronary artery before the age of 65 years in female and 55 years in male.

Access site was selected on operator's discretion. Crossover to another was allowed. For radial approach, Terumo or Boston scientific kits for vascular access were used while femoral access was obtained with Cordis femoral access kit. Vascular access time was taken as time from administration of local anesthetic agent to final wash out of sheath with normal saline. 6-F radial sheaths were used in case of radial access. to prevent radial artery spasm An additional 0.2 mg of nitroglycerine and 5,000 IU of unfractionated heparin (UFH) to avoid thrombus formation, were given through the sheath. 6-F sheath was taken for performing procedure through transfemoral route.

Sheaths were taken out immediately after transradial procedure along with manual compression followed by pressure bandage which was removed after 6 hours. For transfemoral access, the sheaths were removed after 6-h followed by bandage to the puncture site and patients were further restricted to bed rest for 6 hrs.

All the cardiologists who performed procedures had experience of performing of >100 angioplasties per year. Guiding catheters including judkin, EBU, Voda and Implantz were used to engage coronary arteries (Toshiba's Infinix-i system, (CAAS II QCA Research, version 2.0.1 software, Pie Medical Imaging, Maastricht, the Netherlandswas used to evaluate the lesions. Procedural success was defined was the decrease of residual stenosis of <30% with TIMI 3 flow post stenting.We also noted fluoroscopy time in minutes.

After taking required coronary angiographic views and decision for intervention, heparin or enoxaparin were used for anticoagulation. The dose of UF heparin was 10,000 IU while the dose of enoxaparin was 80mg in the sheath. Glycoprotein IIb/IIIa antagonists (Aggrastate) was given as and when required. All patients were given 600mg loading dose of clopidogrel and 300mg of aspirin at least 4-h before the procedure. For bare-metal stent 75-mg of clopidogrel and 100-mg of aspirin once a day was given for 4 weeks while they were given for 12 months in case of after drug-eluting stent.

Following data was collected: result of procedural success, reason of switching to alternative procedure site, duration of the procedure, fluoroscopy time and quantity of contrast used. Procedural time included time when patient entered the catheterisation lab till the the end of the procedure without taking into account time for hemostasis. Procedural failure was defined as either of the following was done: crossover to other site, combined endpoint of access site crossover, failed coronary engagement or failure of target vessel revascularization. Vascular access site complications like hematoma >5cm, access artery dissection, repair of vessel surgically, losing pulsations of radial artery and bleeding at puncture site, defined as a drop of 2g/dl hemoglobin level from baseline or requiring blood transfusion, were noted. Non-access site complications like coronary artery dissections, perforations, aortic dissection and hospital death were recorded.

Statistical Analysis

Numerical variables were expressed as mean ± SD. Categorical variables were presented as frequencies and percentages. Student-t test was used to compare quantitative variables between two groups while for categorical variables chi-square test was applied. p-value ≤0.05 was considered significant. For statistical analysis SPSS 25 was used.

RESULTS

Overall 1118 patients were screenedout of which 584 (52.2%) patients met eligibility criteria for entry in the study. Froty six patients were in the radial group while 123 patients were in the femoral group. Clinical characteristics of age, gender, body mass index (BMI), risk factors, clinical presentation, history of previous PCI and left ventricular ejection fraction (LVEF) were statistically similar between two groups of patients as shown in table-I.

Table-I: Clinical characteristics of the patients undergoing percutaneous coronary intervention via transradial ortrans femoral approach.

Clinical Characteristics		Femoral Group n=123	Radial Group n= 461	*p*-value
Age ± SD (years)		53.64 ± 10.8	53.9 ± 9.96	0.13
Gender	Male	93 (75.6)	342 (74.3)	0.42
	Female	30 (24.4)	119 (25.8)	0.42
Body Mass Index kg/m² ≥24.9		40 (32.5)	142 (30.8)	0.39
Risk factors	Diabetes	33 (26.8)	115 (24.9)	0.38
	Hypertension	75 (61.0)	297 (64.4)	0.27
	Hypercholesterolemia	39 (31.7)	152 (33.0)	0.44
	History of smoking	34 (27.6)	105 (22.8)	0.16
	Family history of CAD	20 (16.3)	73 (15.8)	0.50
Clinical Presentation	Recent MI	15 (12.2)	42 (9.1)	0.31
	NSTEMI/UA	27 (22.0)	125 (27.1)	0.44
	SA	85 (69.1)	317 (68.8)	0.51
Previous PCI		16 (13.0)	53 (11.5)	0.79
LV ejection fraction (%)		48.1 ± 9.6	49 ± 9.7	0.98

Angiographic characteristics including number of vessels diseased, number of stents deployed per patient, use of drug eluting stents, bare metal stents use, use of eftifibatide and anticoagulants given were similar between two groups of patients. It is shown in table-II.

Overall successful procedure was present more in the femoral group compared to radial group; 97.6% vs

Table-II: Angiographic data of patients undergoing percutaneous coronary intervention via transradial versus transfemoral approaches.

Angiographic and Procedural Characteristics		Femoral Group n=123	Radial Group n=461	*p*-value
No. of Vessels Disease	1-vessel disease	39 (31.7)	138 (29.9)	0.70
	2-vessel disease	32 (26)	111 (24.1)	0.80
	3-vessel disease	53 (43.1)	213 (46.2)	0.54
No. of Stents Deployed		1.82 ± 0.96	1.85 ± 1.04	0.79
Type of Stents	Drug-eluting stents	70	255	0.89
	Bare metal stents	75	243	0.73
Use of eftifiBatide/ Tirofiben		4 (3.3)	16 (3.5)	0.91
Anticoagulants	Heparin	52 (42.3)	175 (38.0)	0.38
	Enoxaparin	71 (57.7)	285 (61.8)	0.41

Table-III: Outcome data of patients undergoing through percutaneous coronary intervention via transradial versus transfemoral approaches.

Outcome Data		FemoralGroup n=123	Radial Group n=461	*p*-value
Procedure success 120 (97.6) 432 (93.7) 0.01				
Procedure Failure 3 (2.4) 29 (6.3) 0.24				
	Puncture failure	-	20 (4.3)	0.04
	Radial artery loop		4	
	Tortuous femoral/ sub-clavian artery	2 (1.6)	4 (0.87)	0.46
	Failed catheterization of coronary arteries	-	2 (0.4)	0.46
	Severe radial artery spasm		7 (0.7)	
	Difficulty in engagement of guide	-	7 (0.7)	0.46
	Poor guide support	1 (0.81)	6 (1.3)	0.34
Mean access time (min)		2.7 ± 0.67	11.0 ± 7.9	0.001
Mean procedural time, min		68.0 ± 15.9	76.1 ± 12.7	0.001
Mean fluoroscopy time, min		24.7 ± 6.4	28.8 ± 5.4	0.001
Mean contrast amount, ml		237.1 ± 4.7	248.4 ± 9.1	0.003
Access-related complications		6 (4.9)	7 (1.5)	0.02
	Hematoma >5 cm	4 (3.3)	-	0.01
	Bleeding from access site	5 (4.1)	-	0.01
	Dissection	3 (2.4)	2 (0.4)	0.03
	Access site surgery/intervention	2 (1.6)	-	0.006
	Absent radial pulse at hospital discharge		32 (7)	
Nonaccess site complication		2 (1.6)	11 (2.4)	0.61
	Coronary dissection	1 (0.8)	3 (0.7)	0.85
	Coronary perforation	-	1 (0.2)	0.61
	Death during hospital stay	1 (0.8)	3 (0.7)	0.85
	Aortic dissection	-	2 (0.4)	0.46

93.7%, p=0.01. Procedure failure was statistically similar between two groups: 1.6 vs 4.3; p=0.16 for femoral and radial group respectively. The main cause of procedural failure in the femoral group was tortuous course of iliac arteries while main causes in the radial group were puncture failure, tortuous radial arteries course, tortuous subclavian arteries, radial artery spasm and poor guiding catheter support. was longer in radial group patients showed increased mean time to access as compared to femoral group; 2.7 ± 0.67 min Vs 11 ± 7.9, p=0.001. Mean procedural time was also longer in radial group as compared to femoral group; 68.0 ± 15.9 min Vs 76.1 ± 12.7min, p=0.001. Mean fluoroscopy time was also longer in transradial group as compared to transfemoral group; 24.7 ± 6.4 min Vs 28.8 ± 5.4 min, p=0.001. Mean amount of contrast used was higher in radial group as compared to femoral group; 237.1 ± 4.7 ml Vs 248.4 ± 9.1ml, p=0.003.

Access related complications were significantly higher in the femoral group as compared to radial group; 6 (4.9) vs 7 (1.5), p=0.02. Among these access related complications, hematoma >5cm 4 (3.3%), access artery dissection 5 (4.1%), access site surgery or intervention and bleeding 2 (1.6%) were only seen in femoral group patients. Impalpable or absent radial pulse at hospital discharge was present in 32 (7%) of patients in the radial group. Nonaccess site complications which included coronary dissection, coronary perforation, aortic dissection and hospital death were similar between two groups; 2 (1.6) vs 11 (2.4), p=0.61 for femoral and radial groups respectively. It has been shown in table-III.

DISCUSSION

This study demonstrated that use of transradial-site for percutaneous coronary intervention is highly safe, feasible and effective as compared to transfemoral access. The most important advantage is reduction in access site complications while the most important drawbacks are lower success rate, increase procedural and fluoroscopy time.

Procedural success was significantly higher in patients when femoral route was used (97.6 Vs 93.7; p=0.01). It is similar to other studies in which higher success rate for transfemoral access has been described. In study by Brueck *et al*, procedural success for the transfemoral access was significantly higher as compared to transradial access (99.8 vs. 96.5%; p=0.001)[13]. In our study, although rate of procedure failure was numerically higher in transradial group (3.2% vs. 6.3%; p=0.24), but it did meet statistical significance. Agostoni *et al.* also observed similar findings in which they showed rate of failure of 7.2% in transradial group vs 2.4% in transfemoral group (p<0.001)[2,14]. In other study by Louvard et al, procedural failure for the transradial access group was 10% in the first 50 cases, 3-4% after other 500 cases, whereas it stabilizes at <1% only after 1,000 procedures[15]. Due to progressive advancement as well as increase in the expertise of the interventionists, a trend towards high success and lower failure is emerging in transradial PCI. The main cause of procedural failure in our study was failure to puncture the radial artery. Other causes included tortuous radial artery, tortuous subclavian artery, radial artery spasm, guiding catheter unable to hook coronary sinus ostium and poor guide support. Puncture failure of the radial artery has been described as the main cause of procedural failure by other studies as well[13]. We observed that the procedural time in the transradial group was 76 ± 12 minutes as compared to 68 ± 15 minutes for the transfemoral group; p=0.001. Bhat *et al* showed that procedural time for transradial and transfemoral groups were 29 ± 11.3 min and 27.3 ± 12.4; p=0.03 respectively[12]. In our study this time period did not include the time interval required for hemostasis, which may exceed 15 min after transfemoral access. The time required for hemostasis using transradial route is markedly shorter because manual compression is needed for short time and bandage could be applied immediately after the procedure. Therefore, procedural time does not constitute a strong rationale for the transfemoral approach, especially for experienced operators. The main cause for long procedural time is long access time needed for transradial route as compared to transfemoral route; 11.0 ± 7.9 min vs 2.7 ± 0.65 min, p=0.001.

Studies have reported that both fluoroscopic time and dose of radiation exposure are deemed to be higher in transradial access[12]. In our study fluoroscopic time was also longer in the transradial group as compared to transfemoral group. Although we didn't look at the dose area product (DAP) of the operators, but according to Brasselet *et al,* radiation exposure is considered to be high in case of the transradial route[16]. These findings can be linked with both technical difficulties as well as having the position of the operatornear to the X-ray tube. This can be hazardous to the health of the operators and is a matter of concern which needs further research and develop strategies to mitigate the risk.

In case of transfemoral access, obesity, female gender and old age are risk factors for access site complications[6]. These are also more frequent whenever an aggressive antiplatelet and/or antithrombotic treatment is needed. Consequently, transfemoral intervention in acute myocardial infarction carries a high risk of bleeding complications ranging from 2.5-23%[17,18]. This increase risk of complications can be reduced by adopting transradial access. In our study, access site complications were significantly lower in transradial route as compared to transfemoral route; 4.9% vs 1.5%, p=0.02. This fact has been described by other investigators as well[13]. Since radial artery follows asuperficial course it is easily compressible and hemostasis can be managed simply by using bandage.

Transradial route is used only in selected patients. It should be deferred in abnormal Allen's test[13,25]. It is reported to be abnormal in 6.4-27% of the patients undergoing coronary angiography[19]. In our study, the main reason for becoming ineligible to be enrolled into the study groups was having abnormal Allen's test (22.7%). Transradial approach can be used in rare instances e.g where proceeding through transfemoral approach confers a higher risk of complications like in cases of severe peripheral arterial disease, abdominal aortic aneurysm etc[13].

The loss of radial artery pulse with no ischemia in hand after coronary interventions is a well known fact. It ranges from 0-9% in various studies[20]. Using doppler ultrasound assessment, the post-procedural absence of a radial flow was detected in 9%, subsequently decreasing to 3-6% in follow-up[21,22]. The occurrence of radial artery occlusion is a rare event, particularly if the vessel is not overstretched (sheath size ≤6-F), intra-arterial heparin is administered without neutralization by protamine at the end of the procedure, the sheath is removed immediately after the procedure and the bandage is removed as soon as hemostasis is achieved. Radial artery occlusion after the transradial approach is directly related to the ratio between the sheath and artery size[23]. Therefore, smaller guiding catheters are potentially advantageous leading to less arterial spasm, pain, and post-procedural vessel occlusion. Furthermore, this canulated radial artery can be used for future catherization and coronary artery bypass surgery as pointed out by various investigators[24]. In our study, we observe absent radial pulse in 7%of patients at hospital discharge.

Transradial access for coronary interventions is as safe as transfemoral access from the stand point of non access site complications. In study by Hibbert *et al,* non access site complications were similar for both radial and femoral routes; 4.5% vs 2.4%, p=0.86[25]. In this study, these were also similar for transradial and transfemoral access groups; 2.4% vs 1.6%, p=0.61.

LIMITATION OF STUDY

The following limitations should be kept in mind while interpreting the results of this study. First, frequency of small hematomas was not taken into account. Second, patency of radial artery post procedure was not evaluated; this might have led to underestimation of radial occlusion. Thirdly the results could not be generalized due to selected population group. Finally, dose of heparin was 10,000-IU instead of the weight base regimen which can decrease access site bleeding and hematoma.

CONCLUSION

Transradial route for percutaneous coronary intervention can be considered safe, feasible and effective. It reduces access site complications as compared to transfemoral route. However it is associated with longer access time, increased procedural failure rates, longer procedural and fluoroscopy time and excessive radiation exposure when compared to transfemoral route.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

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