

Comparative Study of Trans Radial versus Trans Femoral Route in Acute Stemi

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Date of Submission: 23-11-2019

Date of Acceptance: 07-12-2019

I. Introduction

Percutaneous coronary intervention is carried out via a catheter inserted into the arterial system from a femoral, brachial or radial artery. The transfemoral approach has dominated the growth of percutaneous coronary intervention over the past 3 decades, but more recently radial access has gained increasing popularity, mainly because of perceived advantages for patient safety.¹

Coronary artery disease has had high morbidity and mortality for a long time. To date percutaneous coronary angiography and percutaneous transluminal coronary angioplasty are standard diagnostic and therapeutic strategy for coronary artery disease respectively. The common femoral artery has long been the access site for doing coronary angiography and angioplasty. Femoral artery has been the preferred site of access because of the larger size and the larger diagnostic and angioplasty guiding catheters being used lately.²

The profile of balloons used is an additional factor for the same. The use of better coronary hardware and development of newer anticoagulants has significantly increased the spectrum for interventions. Vascular access site bleeding is one of the most feared complications particularly with the use of anticoagulants and platelet glycoprotein inhibitors. Percutaneous coronary intervention (PCI) can be performed by the following three routes: femoral, brachial or radial arteries. The vascular or bleeding risk associated with the femoral approach is reported upto 10% in some studies. Other complications include hematomas accompanied by significant blood loss, arterial pseudo aneurysms and arteriovenous fistulas.²

The transradial approach for coronary procedures is gaining fast acceptance. It was first introduced by Compeau in 1989 for diagnostic coronary angiography and it was subsequently improved upon by by Kiemenji and Laarman for percutaneous transluminal coronary angioplasty and stenting. The interest in the transradial approach is increasing due to decreased associated vascular complications, convenience for the patients, earlier discharge, shorter stay in the hospital and early ambulation.

Vascular complications are lesser in the transradial approach because of favourable anatomy, smaller size of the sheaths used and rapid hemostasis. The main complications for the approach are smaller radial artery that may not be accessed successfully and arterial occlusion post procedure. Radial artery is smaller in the Asian populations compared to West. Bleeding complications are lesser and easily controllable with the radial approach because of the easy compressibility of the radial artery. Another advantage is that no big nerves or veins are located in the vicinity of the artery making injury to such structures less likely. Also there are economic benefits to the approach as reflected by reduced hospital expenditures.²

Patients overwhelmingly prefer the transradial over the femoral approach. Although transradial approach has a lot of benefits, it has a longer learning curve for the operator making it more challenging. It also limits the devices which are used in interventions like temporary pacemakers, intra-aortic balloon pumps and larger devices for coronary interventions. Also it may not always be the best choice in some patients who may have an anomalous palmer arch not providing sufficient blood supply to the hand in case of occlusion of radial artery. Due to this reason several authors recommend assessment of adequacy of collateral blood flow from the ulnar artery using Allen's test before performing the procedure. Entry site failure is also one of the complications. Vascular access site preference is thus a choice in centers based on tradition and expertise.²

Hence, under the light of above mentioned data, we planned the present study to compare the efficacy of radial and femoral approach in primary angioplasty in Acute ST elevation myocardial infarction.

II. Aims & Objectives

1. To compare the efficacy of Transradial versus Transfemoral route for Primary angioplasty in acute ST segment elevation Myocardial Infarction

2. To compare the complications of Transradial versus Transfemoral route for Primary Angioplasty in acute ST segment elevation Myocardial Infarction

The present retrospective study was conducted in the department of Cardiology of Dr. D. Y. Patil Hospital, Navi Mumbai.

Sample size

100 patients with Acute ST elevation MI who presented to the emergency department of Dr. D. Y. Patil Hospital, Navi Mumbai and underwent primary PCI were selected for the present study as 'Cases'. Out of these 100 patients, 50 patients who underwent radial approach and 50 patients who underwent femoral approach were selected.

Ethical Clearance

Written ethical approval was taken from institutional ethical committee.

Inclusion criteria:

1. Patients with Acute ST elevation MI and underwent primary angioplasty.
2. Chest pain lasting more than 20 minutes
3. Diagnostic ECG changes with characteristic ECG alterations consisting of (in Absence of LVH and LBBB)
 - i. ST elevation:
New ST elevation at the J point in two contiguous leads with the cut-points:
 ≥ 0.1 mV in all leads other than leads V2–V3 where the following cut points apply. ≥ 0.2 mV in men ≥ 40 years; ≥ 0.25 mV in men < 40 years, or ≥ 0.15 mV in women.
4. Diagnostic rise in CK-MB and troponin i

Exclusion criteria:

1. Renal insufficiency (serum creatinine > 2.0 mg/dl)
2. Patients with severe sepsis, local site infection, previous contrast allergy, severe intrinsic/iatrogenic coagulopathy (INR > 2)
3. An abnormal modified Allen's test (For transradial route).
4. Peripheral vascular disease (Iliofemoral disease) (For transfemoral route).

Method of study :

- All the patients of Acute ST elevation MI fulfilling the inclusion and exclusion criteria were included in the present study.
- Data on detailed history and thorough physical examination of the patients was collected.
- Physical examination included
- height and weight measurement for calculating Body Mass Index.
- Blood pressure in the right upper limb in sitting position with appropriate size cuff.
- An ECG obtained at the time of presentation and serial ECG thereafter.
- Record of routine baseline investigations i.e. Hemoglobin (Hb), Total leucocyte count (TLC), Differential leucocyte count (DLC), peripheral blood film (PBF), Fasting/ Random blood sugar (FBS/RBS), lipid profile, Serum CK–MB, blood urea and serum creatinine was noted.
- The study population included patients who underwent primary PCI in DY Patil hospital. Further data was collected from the detailed records of the procedure.
- In these patients procedural anticoagulation was achieved with preliminary administration of an unfractionated heparin bolus at a dose of 70 UI/kg, supplemented during the procedure to maintain an activated clotting time of 250 s.
- The choice of additional periprocedural antithrombotic agents (e.g., glycoprotein IIb/IIIa inhibitors or bivalirudin) or different revascularization strategies (e.g., thrombectomy, direct stenting) was left to the operators according to the institution's standard procedure. Unless clinically contraindicated, all anticoagulants were discontinued at the end of the procedure, whereas glycoprotein IIb/IIIa inhibitor boluses were followed by a ≥ 12 -h infusion. All patients had been pre-treated with acetylsalicylic acid plus a loading dose of clopidogrel (300 to 600 mg) and were discharged on dual antiplatelet and Hmg CoA reductase inhibitors (atorvastatin 80mg) therapy for ≥ 12 months at the discretion of the operator and depending on the stent implanted.
- Before the procedure, bilateral femoral and radial pulses had been evaluated by a physician. In particular, Allen's test was performed twice on both hands to exclude insufficient ulnar collateral circulation; in case of an abnormal Allen's test result, further evaluation with pulse oximetry or plethysmography was not precluded but not encouraged to prevent consistent time delay. In patients presenting with cardiogenic shock, radial pulse and Allen's test were assessed after intra-aortic balloon positioning or specific pharmacological

treatment (i.e., inotropic drug administration); patients with persistent pulseless cardiogenic shock were excluded from the study.

- An Allen test indicating a well-functioning ulnar artery was necessary in order to consider a patient eligible for the transradial approach. The arm and forearm were extended and, after local anesthesia with 2% lidocaine, the radial artery was cannulated with a 19-gauge needle, through which a 0.022" guidewire was advanced and a 6F radial sheath (Terumo, Japan) was introduced over it. The use of vasodilating medical cocktail containing 5 mg dilzem , and 2mg nikorandil was given. Hemostasis was achieved with external compression either with TR band (Terumo, Japan) or with Radistop.
- For the transfemoral approach, after local anesthesia with 2% lidocaine, a 6F sheath was advanced over a 0.035" guidewire, using the Seldinger technique. The use of closure devices was on the operator's discretion. The patients were allowed to ambulate 1 h after intervention in the transradial group and after 12–24 h in the femoral group, unless indicated otherwise by their clinical condition.

Intervention

All interventions were performed for both approaches using 6F guiding catheters, according to the medical standards and the routine use of drug eluting stents.

STATISTICAL ANALYSIS:

- All the results were analyzed by SPSS software version 17.0.
- Chi-square test and Mann- Whitney U test were used for assessment of level of significance.
- P- value of less than 0.05 was taken as significant.
- The present study was conducted in the department of Cardiology of Dr. D. Y. Patil Hospital, Navi Mumbai. 100 patients with AMI who presented to the emergency department of Dr. D. Y. Patil Hospital, Navi Mumbai and underwent Primary Angioplasty were selected for the present study as ‘Cases’. Out of these 100 patients, 50 patients were of radial approach and 50 patients were of femoral approach. Following observations were made:

Table 1: Age-wise distribution of patients

Age group (years)	Transradial group		Transfemoral group	
	Number of patients	Percentage	Number of patients	Percentage
Less than 50	6	12	4	8
50 to 60	20	40	20	40
More than 60	24	48	26	52
Mean age ±SD	60.4±7.49		61.4±7.21	

Graph 1: Age-wise distribution of patients

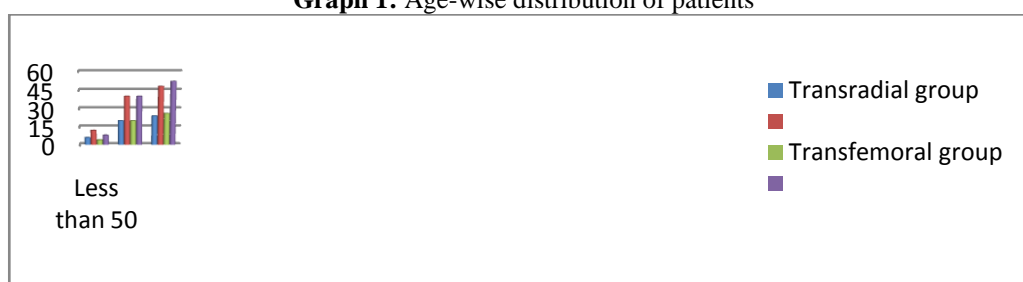


Table 1 and **Graph 1** show the age-wise distribution of patients of the present study. Among the Transradial group, 6 patients (12 percent), 20 patients (40 percent) and 24 patients (48 percent) belonged to the age group of less than 50 years, 50 to 60 years and more than 60 years respectively. Among the Transfemoral group, 4 patients (8 percent), 20 patients (40 percent) and 26 patients (52 percent) belonged to the age group of less than 50 years, 50 to 60 years and more than 60 years respectively. Mean age of the patients of the Transradial group and Transfemoral group was 60.4 years and 61.4 years respectively.

Table 2: Gender-wise distribution of patients

Gender	Transradial group		Transfemoral group	
	Number of patients	Percentage	Number of patients	Percentage
Males	36	72	34	68
Females	14	28	16	32
Total	50	100	50	100

Graph 2: Gender-wise distribution of patients

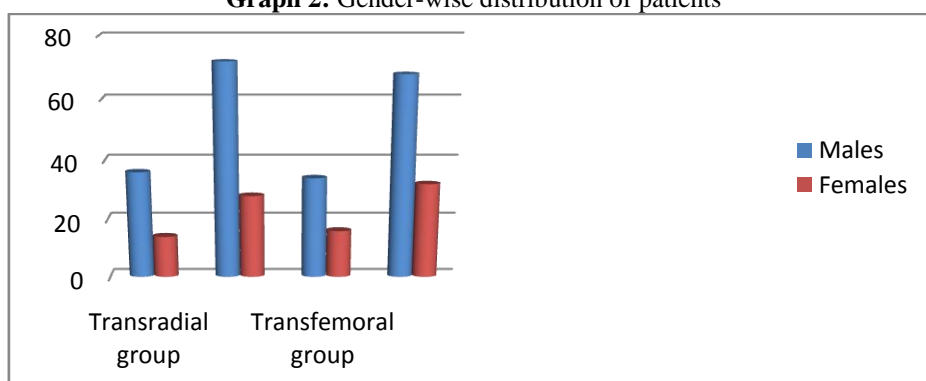


Table 2 and **Graph 2** show the gender-wise distribution of patients. There were 36 males (72 percent) and 14 females (28 percent) in the Transradial group, while there were 34 males (68 percent) and 16 females (32 percent) in the Transfemoral group respectively.

Table 3: Presence of CVD risk factors

CVD risk factors	Transradial group		Transfemoral group	
	Number of patients	Percentage	Number of patients	Percentage
Smoking	14	28	16	32
Dyslipidemia	16	32	18	36
Diabetes	16	32	16	32
Hypertension	20	40	22	44
Family history of CAD	12	24	10	20

Graph 3: Presence of CVD risk factors

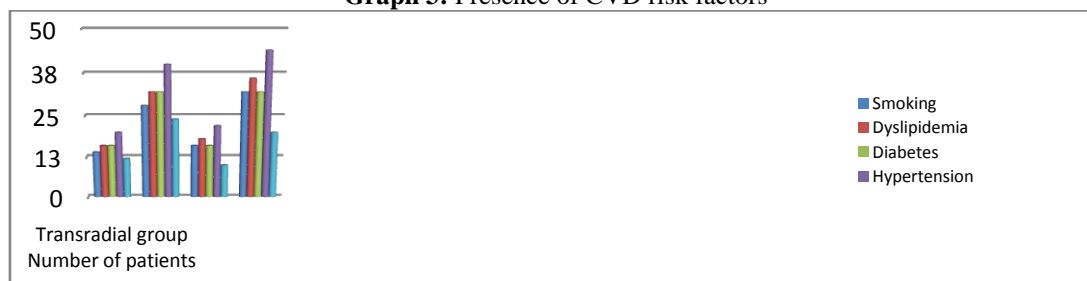


Table 3 and **Graph 3** show the distribution of patients according to different of CVD risk factors. Smoking habit was present in 14 patients (28 percent) and 16 patients (32 percent) of the Transradial group and Transfemoral group respectively. Dyslipidemia was present in 16 patients (32 percent) and 18 patients (36 percent) of the Transradial group and Transfemoral group respectively. Diabetes mellitus was present in 16 patients (32 percent) each of the Transradial group and Transfemoral group respectively. Hypertension was present in 20 patients (40 percent) and 22 patients (44 percent) of the Transradial group and Transfemoral group respectively. Positive family history of CAD was present in 12 patients (24 percent) and 10 patients (20 percent) of the Transradial group and Transfemoral group respectively.

Table 4: Distribution of patients according to severity of the disease

Severity	Transradial group		Transfemoral group	
	Number of patients	Percentage	Number of patients	Percentage
0-vessel	2	4	4	8
1-vessel	24	48	22	44
2-vessel	16	32	18	36
3-vessel	8	16	6	12
Total	50	100	50	100

Graph 4: Distribution of patients according to severity of the disease

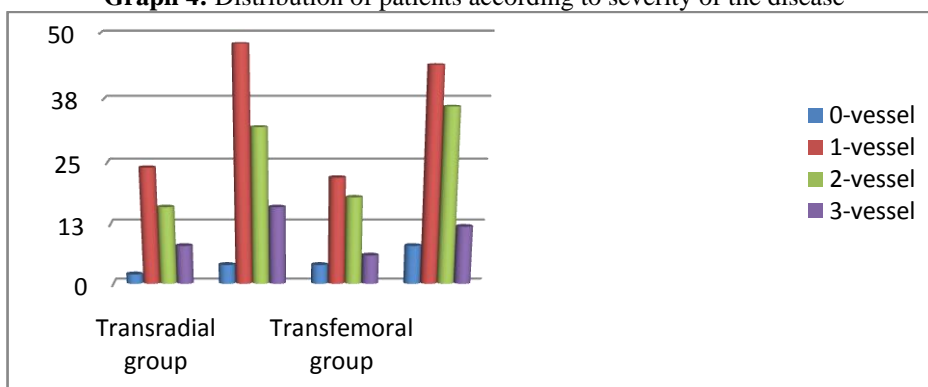


Table 4 and **Graph 4** show the distribution of patients according to severity of the disease. 1-vessel disease was the most commonly seen found to be present in 24 patients (48 percent) of the Transradial group and 22 patients (44 percent) of the Transfemoral group.

Table 5: Comparison of procedural parameters in between the two study groups

Procedural parameter	Transradial group	Transfemoral group	p-value
Access time (minutes)	6.6	4.2	0.02 (Significant)
Fluoroscopy time (minutes)	6.5	5.6	0.04 (Significant)
Procedural time (minutes)	29.2	26.5	0.01 (Significant)
Cross-over to femoral (patients)	1	-	-

Graph 5: Comparison of procedural parameters in between the two study groups

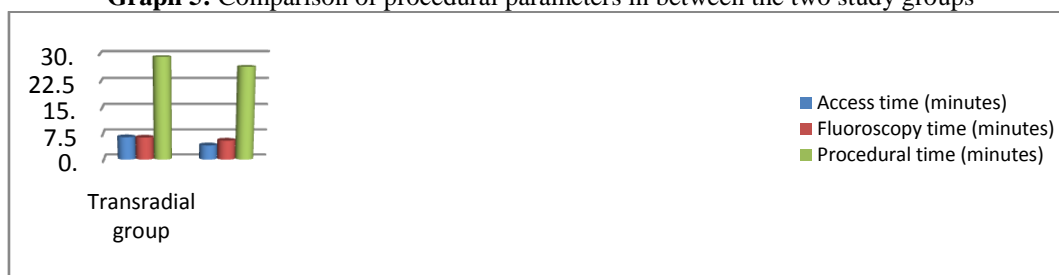


Table 5 and **Graph 5** show the comparison of procedural parameters in between the two study groups.

Mean access time among the subjects of Transradial group and Transfemoral group was found to be 6.6 minutes and 4.2 minutes respectively. Mean fluoroscopy time among the patients of the Transradial group and Transfemoral group was found to be 6.5 minutes and 5.6 minutes respectively. Mean procedural time among the patients of the Transradial group and Transfemoral group was found to be 29.2 minutes and 26.5 minutes respectively. Significant results were obtained while comparing the mean Access time, mean fluoroscopy time and mean procedural time among the subjects of both the study groups. Cross-over to femoral approach was seen in 1 patient of the Transradial group.

Table 6: Comparison of mean hospital stay in between the two study groups

Parameter	Transradial group	Transfemoral group	p-value
Mean hospital stay (days)	3.3	4.5	0.04 (Significant)

Graph 6: Comparison of mean hospital stay in between the two study groups

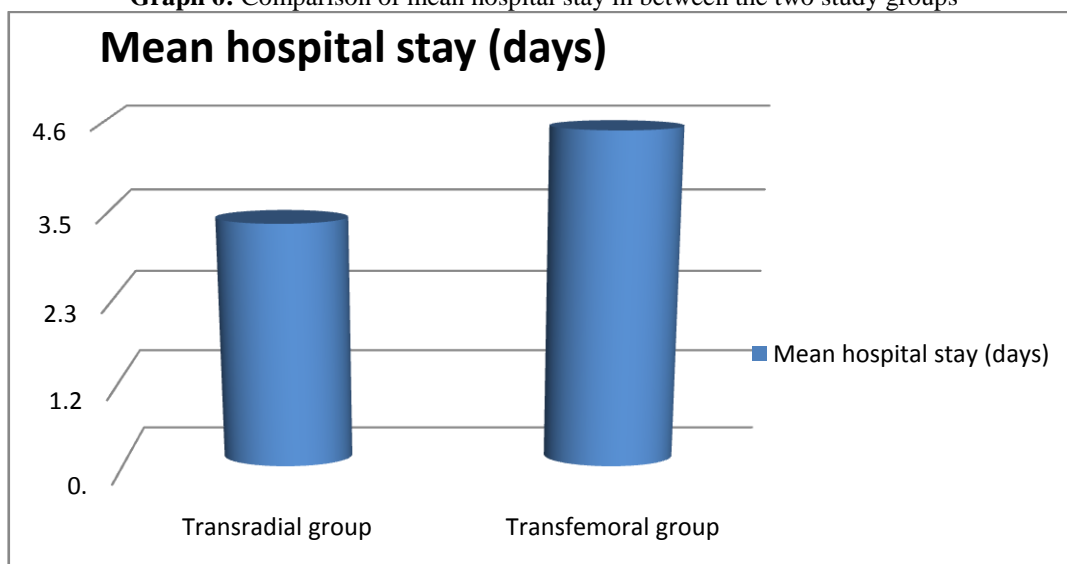


Table 6 and **Graph 6** show the comparison of mean hospital stay in between the two study groups. Mean hospital stay among the subjects of the Transradial group was found to be 3.3 days, and was found to be significantly lower than that of the subjects of the Transfemoral group, in which the mean hospital stay was found to be 4.5 days.

Table 7: Comparison of complications in between the two study groups

Complications	Transradial group		Transfemoral group		p- value
	Number of patients	Percentage	Number of patients	Percentage	
Major Hematoma	0	0	1	2	0.04 (Significant)
Minor Hematoma	0	0	5	10	0.00 (Significant)
Bleeding complications	1	2	5	10	0.01 (Significant)
Thrombophlebitis	4	8	8	16	0.03 (Significant)
Ecchymosis	6	12	10	20	0.01 (Significant)
Pseudo aneurysm	0	0	2	4	0.01 (Significant)
Loss of radial artery	4	8	0	0	0.04 (Significant)

Graph 7: Comparison of complications in between the two study groups

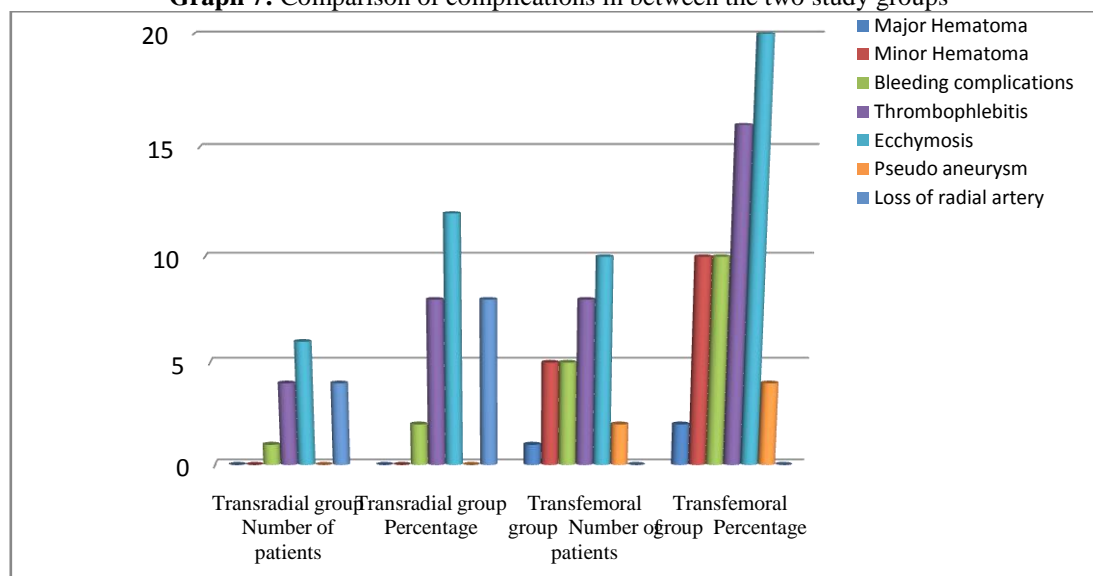


Table 7 and **Graph 7** show the comparison of complications in between the two study groups. Significantly higher incidence of complications was seen among the patients of the Transfemoral group in comparison to the patients of the Transradial group.

The present study was conducted in the department of Cardiology of Dr. D. Y. Patil Hospital, Navi Mumbai. 100 patients with acute ST Elevation myocardial infarction who underwent Primary Angioplasty were selected for the study. Out of these 100 patients, 50 patients were of radial approach and 50 patients were of femoral approach.

DEMOGRAPHIC DATA

Mean age of the patients of the Transradial group and Transfemoral group was 60.4 years and 61.4 years respectively. There were 36 males (72 percent) and 14 females (28 percent) in the Transradial group, while there were 34 males (68 percent) and 16 females (32 percent) in the Transfemoral group respectively. Our results were in concordance with the results obtained by Bhat FA et al, Romagnoli E et al and Tewari S et al, who also reported similar age-wise distribution of patients and male preponderance in their respective studies.^{3,4,5} This reiterates the fact that age is an important risk factor for CAD.

PROCEDURAL TIME

Mean access time among the subjects of Transradial group and Transfemoral group was found to be 6.6 minutes and 4.2 minutes respectively. Mean fluoroscopy time among the patients of the Transradial group and Transfemoral group was found to be 6.5 minutes and 5.6 minutes respectively. Mean procedural time among the patients of the Transradial group and Transfemoral group was found to be 29.2 minutes and 26.5 minutes respectively. Significant results were obtained while comparing the mean Access time, mean fluoroscopy time and mean procedural time among the subjects of both the study groups. Our results were in concordance with the results obtained in the past literature, where similar findings have been reported.⁴⁻⁶

In one study conducted by Bhat FA et al, authors reported that the access time was more with the transradial approach compared to transfemoral approach (6.0 ± 1.8 min versus 4.2 ± 0.70 min, p value of <0.0001). The total procedure time was also more in transradial approach group compared to transfemoral approach group (29 ± 11.3 min versus 27.3 ± 12.4 min, p value of 0.03). Similarly the total fluoroscopic time was more in transradial approach compared to transfemoral approach (6.4 ± 2.9 min versus 6.0 ± 2.5 min p value 0.015).³

Similar results were found in the study conducted by Saleem Kassman et al. Ferdinand Kiemeneij et al. also showed similar results in relation to procedure time and fluoroscopic time. Our results in terms of access time in two approaches were similar to the results shown in the study by Veli Vefali et al. and to a meta-analysis on 12 trials.^{7,8,9,10}

The higher time requirements for the procedure in transradial group is usually due to radial artery spasm (can be prevented by using vasodilators), presence of tortuous subclavian arteries in many patients (causing obstacles in advancing the catheters), abnormal radial artery anatomy and operator dependent. In our study crossover from radial to femoral approach was required in 4% patients. Saleem Kassman et al.⁸ in their study had crossover from radial to femoral route required in up to 4% as well. Similarly Ferdinand Kiemeneij et al.⁷ in their study found that access failure was more common with transradial procedure. The failed attempts in transradial group are usually due to radial artery puncture failure, radial artery spasm, the size of the catheter used, type of procedure being done (diagnostic vs. therapeutic, which also affects the size of catheter used), tortuosity of the innominate trunk, dilatation of the ascending aorta, lusoria artery and inability to track the catheter in the left main coronary artery. Procedural success has also been shown to be higher in trans-femoral PCI in an updated report from the US national cardiovascular data registry as well. In the RIVAL trial, radial and femoral approaches were both found to be safe and effective for PCI but lower rate of local vascular complications were seen in the radial approach.¹¹

MEAN HOSPITAL STAY

Mean hospital stay among the subjects of the Transradial group was found to be 3.3 days, and was found to be significantly lower than that of the subjects of the Transfemoral group, in which the mean hospital stay was found to be 4.5 days. Our results were in concordance with the results obtained by Bhat FA et al, who also reported similar range of hospital stay among patients of their study group.³

In their study, Bhat FA et al observed that the hospital stay was less in transradial approach group compared to transfemoral group (3.6 ± 1.3 days versus 4.0 ± 1.1 days, $p = 0.009$) and it was statistically significant. Our results were also consistent with the study by Vefali et al. and Ferdinand Kie and also with the updated report from the US national cardiovascular data registry.^{9,11}

COMPLICATIONS

Common complications observed in the present study included hematoma formation, bleeding complications, thrombophlebitis and ecchymosis. Significantly higher incidence of complications was seen among the patients of the Transfemoral group in comparison to the patients of the Transradial group. Our results were in concordance with the results obtained by Bhat FA et al and Romagnoli E1 who also reported significantly high-

er incidence of complications in patients of the Transfemoral group in comparison to the patients of the Transradial group.^{3,4}

R. Choussat et al¹² in their study found that access site bleeding was seen in 7.4% in transfemoral [TFA] group where as none had hematoma formation in transradial [TRA] group [$p = 0.04$]. Agostoni et al¹³ in their study found that TRA was associated with a significantly lower rate of complication, even at the cost of higher rate of procedure failure. Similarly Kassman et al. in their study found that radial access was associated with low rate of access site related major bleeding ($p = 0.04$).⁸ Vefali et al. in their study found that only minor complications were seen during transradial approach most commonly being pain ecchymosis. 5.4% developed hematoma at the access site in the transfemoral group and the results of our study were comparable with the above study. Bleeding complications were also significantly higher in the updated report from the US national cardiovascular data registry.^{9,10}

Major trials conducted for comparison of the two procedures showed similar conclusions. In the RIFLE-STEACS trial; a multicentre, randomized, parallel-group study, it was found that radial access in patients with ST-segment elevation acute coronary syndrome was associated with significant clinical benefits, in terms of both lower morbidity and cardiac mortality. Thus, it should become the recommended approach in these patients, provided adequate operator and centre expertise is present.⁴

Hemorrhagic complications constitute an important risk factor for a worse outcome in ST-Elevation Acute Coronary Syndrome. Due to the strict correlation among bleeding, ischemic events, and mortality, more attention has been recently paid to the reduction of all avoidable iatrogenic hemorrhagic complications.^{14,15,16}

Several bleeding risk score models have been developed to define the patient risk profile and facilitate a personalized decision-making process, but the urgency of care and the unavoidable need to minimize ischemic risk often limit the applicability of standardized treatment, especially in terms of antithrombotic regimens.¹⁷⁻¹⁹

In this context, use of the transradial approach for acute patients undergoing early invasive treatment has undoubtedly a key role in the prevention of access site-related bleeding, accounting for as many as 40% of all causes of bleeding in acute coronary syndrome patients. Several studies have strongly emphasized the possible link between the decrease in major vascular complications and improved outcome associated with the transradial approach, especially in patients with ST-Elevation Acute Coronary Syndrome (STEACS). Nonetheless, the currently available evidence in this context is limited by the small number of patients and/or the observational study design. More recently, the Radial Versus Femoral Access for Coronary Intervention study and a post hoc analysis of the HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) trial showing improved event-free survival in patients undergoing primary Percutaneous coronary intervention by the transradial approach raised the question about the best vascular access in acute patients.^{14,15,20,21}

This study emphasizes on the use of radial access in patients with ST-segment elevation acute coronary syndrome as this approach is associated with significant clinical benefits. Thus, it should become the recommended approach in these patients, provided adequate operator and centre expertise is present.

The present study was conducted in the department of Cardiology of Dr. D. Y. Patil Hospital, Navi Mumbai. 100 patients with Acute ST elevation MI who presented to the emergency department of Dr. D. Y. Patil Hospital, Navi Mumbai and underwent Primary Angioplasty were selected for the present study. Out of these 100 patients, 50 patients were of radial approach and 50 patients were of femoral approach.

Under the light of above obtained results, following conclusion could be drawn:

- i. Both Transfemoral and Transradial approaches are feasible for performing primary angioplasty.
- ii. Bleeding complications are more in patients undergoing transfemoral intervention.
- iii. Loss of radial pulse is seen in few patients with radial intervention which are largely inconsequential because of collaterals from ulnar artery.
- iv. Transradial route is preferable for primary angioplasty, when feasible.

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Dr Rohit Kumar. "Comparative Study of Trans Radial versus Trans Femoral Route in Acute Stemi." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, vol. 18, no. 12, 2019, pp 61-69.