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Clinical Study of Radial Versus Femoral Artery Approach for Percutaneous Transluminal Coronary Angioplasty

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Abstract

Introduction: Coronary catheterization is usually performed via the transfemoral approach. Transradial access may offer some advantages in comparison with transfemoral access especially under conditions of aggressive anticoagulation and antiplatelet treatment. *Methods:* Between January 2013 and March 2014, a total of 200 patients undergoing Percutaneous Transluminal Coronary Angioplasty were selected with 100 patients each intransradial or transfemoral arteryapproach. Patients with an abnormal Allen's test, simultaneous right heart catheterization, chronic renal insufficiency, or known difficulties with the radial or femoral access were excluded. *Results:* Mean age of presentation in radial arm was 57years and in femoral arm was 54.8years. 90% patients were male and 10% female in radial arm(male; female ratio 9:1) and 82% male and 18% female in femoral arm(male; female ratio 8.2:1.8). Clinical presentation in both groups were similar. The number of patients presenting with ACS were 66% in radial arm and 69% in femoral arm. 57% patients in radial arm and 52% in femoral arm were either overweight or obese. Conventional risk factor profile was similar in both groups. All patients of femoral group and 99% patients of radial group underwent successful procedure and one patient in radial group had cross over to femoral access. More number of stents were used in femoral arm than radial arm (131 vs116 $p<0.3$) but the difference was statistically insignificant. *Conclusion:* Radial approach to percutaneous transluminal coronary angioplasty is a safe, feasible and effective technique and yields clinical results comparable to femoral approach. Radial approach virtually abolishes access site bleeding complications. However technical challenges may impose crossover to another approach.

Keywords: Radial Approach; Femoral Approach; Percutaneous Transluminal Coronary Angioplasty.

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Introduction

Percutaneous coronary intervention (PCI) is an integral partof treatment for ischemic heart disease. Coupled withevidence-based pharmacological strategies, the use of PCIin appropriate patients reduces morbidity and mortalityacross the spectrum of risk [1]. Continual evolution ofantithrombotic therapy and device technology has resultedin the application of PCI to a wider population of patients [2]. Procedural success rates are high and ischemic complicationsrelatively rare [3]. So, attention has turned toperiprocedural bleeding complications [4]. There is evidence tosuggest that post-PCI bleeding is associated withan adverse prognosis [5]. Many clinical trials are evaluating newer pharmacological strategies to reduce thisrisk [6,7]. But absolute reductions in bleeding risk were modest across most studies.

A growing body ofevidence suggests that a procedural strategy— using the transradial rather than the transfemoral approach for PCI—is associated with comparatively larger reductions in bleeding complications than those achieved with any anticoagulantstrategy. However transradial approach requires higher skill and training and has inherent issues like larger learning curve, radial spasm etc. Complications related to transradial approach are more common during initial phase of learning curve. In the present study, clinical evaluation with respect to procedural variables and complications of radial versus femoral artery approach was done in our institute during the time when radial approach for percutaneous coronary intervention was increasing applied.

Methods

Study Design and Protocol

This is a single center, observational clinical comparative study. In this study, total 200 patients were evaluated, who underwent percutaneous transluminal coronary angioplasty in Sri Jayadeva Institute of Cardiovascular Sciences and Research, Bengaluru, India, between January 2013 and March 2014. Total of 100 patients who underwent radial artery approach and 100 patients who underwent femoral artery approach were considered for study. All patients underwent thorough clinical examination, 12 lead ECG, routine biochemical examination and 2-D Echocardiography. For those patients who had coronary angiogram before, coronary angiogram was reviewed. The decision to take up the patient for radial or femoral approach was left to the primary operator. In the radial group, 6Fterumo radial arterial sheaths were used. Initially 5000 units of heparin was given for all patients followed by Cocktail injection of 100 microgram of nitroglycerine, 5mg of diltiazem and 20 mg of lidocaine to prevent radial artery spasm. Repeat doses of heparin were given depending on measured ACT (Activated Clotting Time) which was maintained above 300seconds. Sheath was removed within 30 minutes of procedure. In femoral group, 7F femoral arterial sheaths were used. Heparin dosage was similar to radial group. Sheaths were removed after 4 hours of procedure if aPTT (activated partial thromboplastin time) less than 60 seconds. Procedural details were collected including procedure duration, fluoroscopy time, amount of contrast used and complications during the procedure. Patients were reexamined clinically after the procedure and before discharge to look for any access related complications.

The exclusion criteria were: contraindication to eitherradial or femoral vascular access (e.g., abnormal Allen's test or known severe peripheral vascular disease),simultaneous right heart catheterization, chronic renal insufficiency, recent stroke (within 4 weeks), anticoagulant therapy assumption with an international normalized ratio >2, or other severe bleeding diathesis.

Statistical Analysis

The Statistical software namely, MedCalc 13.1.2.0, was used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc. Comparison of proportions was carried out in the present study. Results on continuous measurements are presented on Mean andresults on categorical measurements are presented in Number (%).

Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups. Chi-square has been used to find the significance of study parameters on categorical scale between two or more groups. A p value ≤ 0.05 was considered significant.

Results

A total of 200 patients were evaluated in this study with 100 patients in the radial arm and 100 patients in the femoral arm. The clinical presentation of patients in both subgroups was similar as shown in Table 1. The number of STEMI patients in radial arm was 50 and femoral arm was 57.

Average age of patients in the radial arm was 57 years and in the femoral arm it was 54.8years. Age groups in both the arm was as shown in table 2. There was no statistically significant difference between both groups across all age groups.

There were significantly higher number of male patients in each group with 90 male patients in radial arm and 82 male patients in femoral arm and 10 female patients in radial arm and 18 female patients in femoral arm as shown in Table 3 .

Nearly half of patients in both subgroups were overweight and 6% patients in radial arm and 5% patients in femoral arm were obese as in Table 4.

Risk factor profile in both radial and femoral arms were as in Table 5. Radial arm had more patients with diabetes and dyslipidaemia.

Table 1: Presentation of patients studied

	Radial Approach	Femoral Approach	P value
ASWMI	1	0	1.0
AWMI	26	27	1.0
IW+PWMI	2	5	0.44
IW+RVMI	4	4	0.71
IWMI	17	17	0.85
LWMI	0	2	0.47
PLWMI	0	1	1.0
ILWMI	0	1	1.0
EA	34	31	0.76
UA	5	1	0.21
NSTEMI	11	11	0.82

Table 2: Age distribution of patients studied

Age range	Radial	Femoral	P value
31-40	3	8	0.21
41-50	30	25	0.52
51-60	33	37	0.66
>60	34	30	0.64

Table 3: Gender distribution

Gender	Radial	Femoral	P value
Male	90	82	0.15
Female	10	18	0.15
Male:Female Ratio	9:1	8.2:1	-
P value	<0.0001	<0.0001	-

Table 4: Body mass index

	Radial Approach	Femoral Approach	P value
<20	0	4	0.13
20-25	43	44	1.0
25-30	51	47	0.67
>30	6	5	1.0

Table 5: Risk factor profie

Risk Factors	Radial Approach	Femoral Approach	P value
Hypertension	45	41	0.66
Diabetes	46	33	0.08
Dyslipidemia	29	18	0.09
Smoking	17	13	0.55
Family History	9	9	0.8

Table 6: Past history of IHD

Past h/o IHD	Radial arm	Femoral arm	P value
NONE	90	91	1.0
PCI	6	5	1.0
CABG	1	3	0.61
ACS	3	1	0.61

There were 10 patients with significant past history of IHD in radial arm and 9 patients in femoral arm as in table 6. There were 6 patients with previous PCI in radial arm and 5 patients in femoral arm. There were 3 patients of previous CABG in femoral arm and one patient in radial arm. There were three patients with previous ACS in radial arm and one in femoral arm who were on medical management.

With respect to coronary artery involvement, both radial and femoral groups patients were comparable as in Table 7

More DES were used in both radial arm and femoral arm than BMS and the number of BMS and DES stents were comparable in each group as shown in Table 8.

Mean procedure duration was 39.5min in radial arm and 35.16min in femoral arm and was not statistically significant (p value 0.99)

Mean fluorotime as 12.91 minutes in radial approach and 12.15 minutes in femoral arm and difference was not statistically significant with p value of 0.22

Amount of contrast used was 160.3ml in radial arm and 155.5ml in femoral arm and the difference was not statistically significant with p value of 0.18

Various complications seen in radial and femoral art are compared in Table 12. There were 9 cases of radial spasm, 3 cases of haematoma,1 case with minor bleeding, and 4 cases of absent radial pulse at discharge in radial arm. There was one case in which radial artery could not be canulated and access cross over was done to femoral approach and completed succesfully. There were 8 cases of small hematoma and 2 cases of minor bleeding in femoral group. Even though the number of bleeding and hematoma complications were more in femoral group they were statistically not significant. There was one case of slow flow and one case of coronary artery dissection in radial arm. There were no complications of peripheral vascular occlusion, pseudoaneurysm, cerebrovascular accident, arrhythmia and left ventricular failure.

Among cases of periprocedural bleeding and hematoma, one case of bleeding in radial arm was in ACS and in femoral arm one case of bleeding in ACS and one in non-ACS. There were 2 cases of hematoma in ACS and one in non-ACS in the radial group while there were 7 cases of hematoma in ACS and one case in non-ACS in femoral group.

Table 7: Coronary artery involvement

	Radial Approach	Femoral Approach	P value
LMCA	1	2	1.0
LAD	59	65	0.46
LCX	29	35	0.44
RCA	53	44	0.25

Table 8: Types and number of stents used

Type of stent	Radial Approach		Femoral Approach		P value
BMS	23	-	36	-	-
BMS1	-	20	-	27	0.31
BMS2	-	3	-	9	0.13
DES	93	-	95	-	-
DES1	-	81	-	73	0.23
DES2	-	12	-	22	0.09
P value	<0.001	-	-	<0.001	

Table 9: Mean procedure duration

	Radial Aproach	Femoral Approach	P value
Mean Procedure Duration (Min)	39.5	35.16	0.99

Table 10: Mean fluoro time

	Radial Approach	Femoral Approach	P value
Fluoro Time (MIN)	12.91	12.15	0.22

Table 11: Amount of contrast used

	Radial Approach	Femoral Approach	P value
Quantity of Contrast (ml)	160.3	155.5	0.18

Table 12: Complications

	Radial Approach	Femoral Approach	P value
Access Cross Over	1	0	1.0
Bleeding	1	2	1.0
Hematoma	3	8	0.21
Spasm	9	0	0.06
PV Occlusion	0	0	-
Absent Radial Pulse	4	0	0.12
Slow Flow	1	0	1.0
Dissection	1	0	1.0
Pseudoaneurysm	0	0	-
CVA	0	0	-
Arrhythmia	0	0	-
LVF	0	0	-

Discussion

Transfemoral approach to cardiac catheterization has dominated the explosive growth of invasive cardiology in past decades. But transradial access appeared as early as in 1948, Radner [8] published one of the first descriptions of transradial central arterial catheterization. Despite this, limitations of contemporary equipment resulted in a shift to larger vessels such asthe brachial, carotid, and femoral systems for most catheter-based procedures. In the late 1970s, percutaneous coronary angioplasty was introduced using predominantly 9-F guiding catheters [9]. First successful transradial angiography reported fromCanada in 1989 by Campeau L et al [10], Kiemeneij and Laarman [11] firstreported on the transradial approach for coronary stentingin 1993. Subsequently many small studies observed reductions in periprocedural bleedingand improvements in patient comfort with thisapproach, but thetransradial approach generally remained a technically more demanding approach. As experience with the transradial approach grew, thelack of severe access-site complications when compared withthe transfemoral approach was repeatedly demonstrated insmall observational studies. A "learning curve" for developingproficiency in transradial procedures was noted [12], cost-effectiveness was demonstrated [13,14], and smallsingle-center or limited multicenter randomized comparisonsto femoral (with or without vascular closure devices)and brachial approaches [15,16] showed the superiority oftransradial procedures with respect to vascular access sitecomplications, speed of post-procedural recovery, and patientpreference. The safety of transradial PCI in patientstherapeutically anticoagulated with warfarin [17] was described.

The main focus of issue when comparing the transradial with the traditional transfemoralroute for PCI include comparisonsof procedural success, fluoroscopy times, and bleeding/vascular complications.

In a systematicoverview of 12 randomized trials (n=3,224) comparingradial and femoral approaches for diagnostic (7 studies) andinterventional (5 studies) procedures, Agostoniet al [18] reported significantly higher rates of procedural failure fortransradial access. When compared with earlierstudies included in the analysis, more recent trialsdemonstrate no differences in procedural failures betweentreatment strategies, likely reflecting advances in both techniqueand technologies, including vasodilator pharmacologyand hydrophilic catheters. In present study there was only one patient with access failure in radial arm in which cross over was done to femoral arm.

The largest observational study to compare radial and femoral approaches useddata from the National Cardiovascular Data Registry (593,094 procedures; 606 institutions) [19]. Radialapproaches represented a modest proportion (1.32%) of casevolume. Procedural success did not differ between access methods. In contrast, asystematic overview by Jollyet al [20] (23 trials;7,000 patients) found that the radial approach was associated witha trend toward a higher rate of inability to cross the lesion with a wire, balloon, or stent, compared with the femoral approach.

Brasselet et al [21] noted that among 420 patients undergoing diagnostic coronary angiographyand percutaneous revascularization, proceduralduration and fluoroscopic time were significantly longer forradial compared with femoral procedures, corresponding tosignificantly higher radiation exposure for operators andpatients, but there was significant variabilityamong operators. In the meta-analysis by Agostoni et al. [18], fluoroscopy time was significantly lower in the femoralcohort (7.8 min vs. 8.9 min, $p< 0.001$) . InNational Cardiovascular Data

Registry, radial PCI had longer fluoroscopy time (13.5 min vs. 11.3 min, p<0.01), but there was no significant difference in totalvolume of contrast used [19]. In the present study, in radial versus femoral groups procedure duration (39.5 vs 35.16, p=0.99), fluorotime (12.91 vs 12.15, p=0.22) and amount of contrast (160.3 vs 155.5ml, p=0.18) used were marginally more in radial arm but was not statistically significant. One more point of importance is that even though procedure duration is more in radial group, significant additional time is required in femoral group to obtain homeostasis in femoral group for sheath removal after procedure.

Increasing experience with thetransradial approach is associated with decreased rates ofprocedure failure. Spaulding C et al noted an annualprocedural volume >80 transradial cases correlated withsignificant reductions in access failure, sheath insertiontime, and overall procedural time [22].

Similarly, other trials demonstrate an initial difference in proceduraltime between radial and femoral cases that resolved by trial completion as operator experience improved [12,16,18,23].

Jolly et al [20] demonstrated that among operators whopreferred the radial route, there was no significant differencein successful lesion crossing (p=0.44); among less experienced operators, there was a strong trend toward higher failure rates (p < 0.07).

Bleeding complicationsafter PCI are most commonly related to vascular access site and are associated with an increased risk of post-PCI morbidity and mortality [4,5,24,25].

In the National Cardiovascular Data Registry, the radial approach was associated witha significant reduction in bleeding complications that wasmore pronounced in certain high-risk subgroups, such aswomen and patients with acute coronary syndromes (ACS) [19].

These findings are consistent with those of other studies evaluating the safety of a radial approach regardingsignificantly reduced bleeding events, especially amongACS patients [26], those receiving more potent antithrombotic agents [27], and elderly patients [28].

Jolly et al [20] found that the transradial approach was associated with a 73% reduction in major bleeding compared with the transfemoral approach. In the present study one case of bleeding in radial arm was in ACS and in femoral arm one case of bleeding in ACS and one in non-ACS. There were 2 cases of hematoma in ACS and one in non-ACS in the radial group while in femoral there were 7 cases of hematoma in ACS and one case in non-ACS suggesting low periprocedural bleeding complications in radial groups especially in ACS situations. Even though the number of cases with local bleeding and hematoma were more in femoral group than radial group, the difference was not statistically significant.

When vascular complications do occur after transradial PCI, they consist mainly of early and late radial artery occlusion [29]. Rarely, instances of radial artery eversion orperforation [30], chronic regional pain syndrome [31], and forearm hematoma or compartment syndrome [32] havebeen described. In present study there were 4(4%) cases with absent pulse without any signs of forearm ischemia at discharge in radial group.

In the study by Kiemeneij Fet al [29] and Benit et al [41] the incidence of radial artery occlusion without any evidence of ischemia was reported to vary from 0 to 9%. Post-PCI radialartery occlusion may be reduced by using smaller diametercatheters and anticoagulation, and by avoiding prolongedhigh-pressure compression of the radial artery after arterialsheath removal.

In the PRESTO ACS [26] vascularsub study, the radial approach was associated with a significant decrease in bleeding complications compared with the femoral approach during hospitalization (0.7% vs. 2.4%; p <0.05), as well as a significant reduction in 1-year death or recurrent infarction (5.5% vs. 9.9%; p <0.05). Among procedural and clinical outcomes datacollected for 38,872 PCI patients (radial approach, 20.5%) included in the British Columbia Cardiac Registry, radial access for PCI was associated with a lower rateof bleeding complications and subsequent significantly lower post-procedural blood transfusion (1.4% vs. 2.8%, p <0.01) and a significant decrease in 30-day and 1-year mortality compared with femoral access [33]. In contrast, Jolly et al [20]. found no significant association between the radial approach and reduced 1-year mortality. Larger randomized controlled trials are needed for studying long term outcome with radial approach.

Transfemoral access site complications are also associated with increased length of hospital stay and costs [19,34,35]. In a small randomized study of 142 patients undergoing PCI for ACS, post-procedural LOS was reduced by approximately 1.5 days and total hospital charges were decreased from $23,389 to $20,476 with transradial access [37].

Although data strongly support use of the transradialapproach as the default method for

coronary intervention, there are also several limitations of thistechnique. Theselimitations includepatient issues (previous coronary artery bypass grafting,challenging forearm and chest arterial anatomy), technicalissues (e.g., limitation in the size of the guide catheter thatcan be used, increased procedure times andradiation exposure especially in early part of learning curve), and lack of largemulticenter randomized data on efficacy and safety.

Patient-specific factors include difficultiesin accessing the radial artery, traversing the radial/brachial/subclavian arterial anatomy, achieving adequateguiding catheter support, and performing transradial catheterizationand PCI using the left radial artery in patientswho have undergone previous coronary artery bypass grafting [38]. All of these challenges can increase procedure timeand radiation exposure to both operator and patient, but canbe addressed with adequate operator experience [12]. Theselimitations are offset by the advantages offered to patient.

Unresolved issues related to transradialPCI include the true incidence ofradial artery occlusion and its clinical sequelae, re-accessof the radial artery for repeat procedures, the durability ofpreviously accessed radial arteries as conduits for coronaryartery bypass grafting, the utility of the Allen test inpreventing complications related to vascular compromiseafter transradial PCI, the true learning curve for transradialPCI including the rate of crossover to the transfemoralapproach, the effect of the transradial approach on bleedingand "hard" clinical outcomes such as death or post procedural stroke, the influence of transradial PCI on costs,the safety of same-day discharge after transradial PCI.

Another important contribution possible with wider applicationof transradial PCI is the study and potentialapplication of higher doses of antithrombotics. Antithromboticdoses are often determined byexamining complications that occur across a range of dosesexplored. The upper limit of dosing for anticoagulants and parenteral antiplatelet agents commonly used in PCI is determined by bleeding complications, manyof which occur at the vascular access site. The substantial reduction in access-sitebleeding afforded by the transradial approach may allowhigher doses to be used clinical practice. Some studies havealso demonstrated an association between higher heparindoses and reduced ischemic events [39].

The transradial approachmay allow a wider therapeutic index for anticoagulantssuch as unfractionated heparin—preserving ischemic reductionwith higher doses while minimizing the penalty of increasedbleeding [40].

Conclusion

The findings of present study show that radial approach for PCI is safe, feasible and effective with similar results to those of femoral approach. The procedure duration, fluoroscopy time and amount of contrast used were only insignificantly more in patients with radial approach. The periprocedural bleeding complications were significantly less with radial approach. Both vascular access techniques should not be considered mutually exclusive but provide the interventionalist with wider therapeutic options.

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