Research Article

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Safety, Efficacy, Feasibility of Trans Radial Approach Compared with Trans Femoral Approach in Patients Undergoing Coronary Catheterization

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ABSTRACT

Background: Percutaneous Coronary Intervention has been done traditionally through Trans femoral route. Trans Radial route is coming up in the practice. We compared Trans Radial with Trans femoral accesses for ease of operability, time of procedure, complications, and failure rates through a cross sectional study.

Objectives: To evaluate the safety, efficacy, feasibility and procedural variables in Trans radial approach compared with the Trans femoral Approach in patients undergoing coronary catheterization.

Methods: A total of 180 patients with both chronic and acute coronary syndromes were enrolled in this study, 140cases with Radial 28 of whom were crossed to Femoral access(hence 112 Radials with 108 Right Radial and 4 Left Radial)and 68 cases with Femoral access.

Results: Procedural time between Trans Radial and Trans femoral accesses were similar (17.39±10.33 vs19.68±16.62 minutes p 0.36) respectively while among Femoral crossover group was higher (33.50±20.30 minutes p0.01). Fluoroscopy time was (5.51±4.70 in Trans Radial Vs. 7.18 ±7.65 minutes in Trans femoral p 0.07) were similar in both groups. Post procedure access site complications seen in (9% in Trans Radial compared to 7.35% in Trans femoral P 0.048), Access site Hematoma being the most common one (6.25% in Trans Radial vs 4.4% in Trans femoral), Non-flow limiting dissections occurred in (0.89% in Trans Radial VS 1.4% Trans femoral), Radial artery perforation occurred in 1.78%, 1.4% of patients in Femoral group had Femoral artery perforation and had major bleeding.

Conclusion: The overall local complications were lower in Trans femoral access, except for major bleeding which is still a big concern. Both vascular Access techniques should not be considered opposite or mutually exclusive, but rather provide the Interventionist a wide spectrum of the therapeutic options.

Keywords: Trans Radial, Trans Femoral, Safety, Feasibility, Efficacy

Introduction

Cardiovascular diseases are among the most common causes of non-communicable disease deaths. It num¬bers at 17.7 million annually all over the world, particularly in low- middle income countries, it ranks first as a cause of disease-related death in Iraq [1-4]. Coronary artery disease has had high morbidity and mortality for a long time. To date percutaneous Coronary Artery angiography (CAG) and Percutaneous Coronary Intervention (PCI) are standard diagnostic and therapeutic strategies for coronary artery disease respectively [5].Trans femoral Approach (TFA) is considered as a classical one over Trans radial approach (TRA), because it has a large caliber that makes it easily accessible, multiple repetition of puncturing, less radiation time and less contrast usage. Bleeding is the most common complication of TFA and is associated with poor clinical outcomes. In the last two decades, TRA emerged as mostly being used for the interventional and diagnostic approach in cardiology [6-9]. Following the first report of radial CAG by Campeau in 1989 and radial PCI by Kiemeneij et al. in 1992, there is an increase in use of TRA because of lower access site bleeding, patient preference and satisfaction, early ambulation, reduced morbidity, and lower procedural cost over TFA around the world [10-12]. Although TRA has a lot of benefits, it has a longer learning curve for the operator making it more challenging. Devices which are used like temporary pacemakers, intra-aortic balloon pumps and larger devices for coronary interventions cannot be inserted through [13].in our locality the preferred vascular route access is being radial artery over the last 5-10 years.

Material and Method

Design: It is a cross sectional study, conducted in Slemani Cardiac Center hospital. The study was approved by the "Scientific and Ethical Committee" of KBMS in September

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2022. Informed written consent to participate in the study was provided by all participants.

Procedure: Enrolled patients where those whom have been admitted in both hospitals, either as a case of acute coronary syndrome (ACS) or as an elective case. Diagnostic CAG done as a part of their diagnostic procedure and some underwent subsequent PCI. Patients with lack of informed consent, severe sepsis, access site infection, previous contrast allergy, coagulopathy (International normalized ratio > 2) were excluded from the study. Exclusion Criteria for TFA was the same as TRA and included peripheral vascular disease including (Ilio-femoral disease). The choices between TFA or TRA was Operator's preference, or difficulties related to the Radial access that made the Operator to change the access site to Femoral, with right Radial approach being the preferred one. TFA was done for patients with absent right Radial pulse, instant or previous Radial cannulation failure, failure of previous Radial approach other than cannulation failure and with coronary artery bypass grafts (CABG). For the Radial approach, the wrist was sterilized and draped. Hyperextension over an arm board was done, skin over the puncture site sterilized and anesthetized with (2 mlxylocaine5%), Radial artery access gained using the trans-radial kit (Prelude, Merit Medical company) which is a 21-gauge needle, 0.018guide-wire, and a short (7cm long) sheath using Seldinger technique. after sheath insertion, 200μg nitroglycerin and 5000 IU un-fractionated heparin (UFH) was injected into the Radial artery. For TFA the groin was sterilized, draped and the site was punctured after anesthetizing the skin with 10 ml of 1%Xylocaine.For diagnostic CAG, the following catheters were used:6F or 5F Tiger (TIG) catheter (Terumo, Japan company) or 6FUltimate catheter (Merit Medical company) to cannulate both left and right coronary arteries or Judkin's left (JL 6/3.5 and6/4) and Judkin's right (JR 6/4 and 6/3.5) catheters to cannulate the left and right coronary artery respectively. For patients with PCI, Judkin's guiding catheters (JL6/3.5 and JR 6/4) and extra back-up (EBU) guiding catheter (6/3.5) were used for coronary engagement. All patients were loaded with dual antiplatelet drugs (300 mg aspirin and 300 mg clopidogrel for elective PCI, or 300 mg aspirin and 180 mg Ticagrelor for patients with ACS). UFH (70-100 IU/kg) used as a standard anti coagulation. A drug eluting stent (DES) ("Xience", Abbott Vascular or "Resolute", Medtronic companies) were used whenever stenting is required. Radial sheath was removed immediately after the procedure and compression done for 2 hours with radial compression device (TR band; Terumo) using the "patent hemostasis" protocol proximal to puncture site. TR band was inflated with 15–20 mL of air. Radial artery patency was checked at least once every 15 minutes by observing the color and temperature of the hand; it was removed 2 hours after the sheath removal. Light pressure bandage was applied at the end of the procedure. femoral sheath was removed directly after the procedure if no anticoagulation is used and kept in place for 4 hours in contrary, manual compression was done until satisfactory hemostasis had been achieved followed by placement of compressive bandage with dynaplast for 6 hours.

According to the Arterial Access, we categorized the patients in to 4 groups, (TRA, TFA, crossover to Right Femoral Artery and Left distal Radial accesses).

Crossover to Femoral or left distal Radial accesses was defined as failure to cannulate through right radial route and classified into the following four subgroups:

1. Puncture failure (inability to canulate radial Artery)
2. Radial and Brachial failure (severe spasm, tortuosity, loopsor other anomalies)
3. Epiaortic failure (severesubclavian or aortic tortuosity).
4. Coronary cannulation failure

Procedural duration was defined as time between the first needle skin contacts to removal of last catheter. Total fluoroscopy time and the amount of contrast were recorded. Most of the elective PCI patients were discharged on the same day provided that no complications occurred in the first 6 hours after the procedure. Patients with primary PCI were discharged after 24-48 hours when they were stable. The site of Radial and Femoral punctures was examined before discharge.

Statistical Evaluation: Statistical analyses were performed using the SPSS 21.0 (SPSS Inc., Chicago, Illinois). Continuous variables were expressed as mean ± standard deviation (SD), Categorical variables as numbers (n.) and percentages. Independent t-test was used for comparing group means for continuous variables, and Pearson's chi square was used to determine correlation between nominal variables. A p value of ≤ 0.05 was set to be statistically significant. Binary logistic regression analysis was used to identify predictors (OR) of radial approach abandonment.

Results

Between August 2021 to February 2022, a total of 180 patients with both chronic coronary syndrome (CCS) and ACS were enrolled in this study at Slemani Cardiac Center Hospital .140 cases with Radial access, 28 of whom were crossed to Femoral access (hence 112 Radial with 108 Right radial and 4 Left Radial) and 68 cases with Femoral access as shown in (table 2). The baseline characteristics of the patients were relatively similar in both groups (Table 1). The mean (and SD) Age of the patients with Radial access was 59.38±9.55 years and those assigned to Femoral access was 58.94±11.46 years, with 104(57.78%) being male and 76(42.22%) being female patients.

Table 1: Baseline Characteristics

Characteristic	Radial access n=112 (108 RR+4 LR).	Femoral access n=68	p-value
Age year (mean±SD)	59.38±9.55	58.94±11.46	0.087
Gender **Male** **Female**	 68(60.7%) 44(39.3%)	 36(53%) 32(47%)	0.3
HTN	57(51%)	32(47%)	0.64
DM	34(30%)	19(28%)	0.8
Dyslipidemia	15(13%)	12(17.6%)	0.52
Smoking	16%)	4(5.9%)	0.1
HF	2(1.8%)	1(1.5%)	0.87
CKD	5(4.5%)	3(4.4%)	0.9
Presentation: **ACS** **CCS**	 17(15%) 95(85%)	 4(5.9%) 64(94.1%)	

Procedural characteristics are shown in (Table 2).in the Radial access group, 64 patients (57%) underwent diagnostic CAG, 42

patients (37.5%) CAG& PCI and 6 patients (5.35%) underwent PCI, and the Femoral access group 36 (53%) had diagnostic CAG, 20(30%) CAG & PCI, and 12 (17%) patients underwent PCI. The number of cases with crossover from Radial to Femoral access was 24, and 4 cases to left Radial in patients assigned to radial access. Among the crossover groups the main reason was Radio brachial failure in 14 patients (50%) mostly due to Radial artery spasm and Radial artery loop. puncture failure (35.7%) mostly in those who had previous radial artery punctures followed by Epi-aortic failure (7.1%) and (7.1%) for difficult catheter engagement. The mean fluoroscopy time was not significantly different between the two access sites which was 5.51±4.70 for Radial and 7.18 ±7.65 for femoral group (p-value 0.07), the same is applicable for total contrast volume used 88.88±59.25 vs 99.71±73 p-value 0.28. The mean time spent in the procedures was not significantly different in Femoral compared to Radial groups, 19.68 ±16.62 vs 17.39±10.33 p-value 0.36 respectively, however those who had femoral crossover had a statistically significant longer time 33.50±20.30 minutes (p-value 0.01).

Table 2: Procedural Characteristics

Procedural Characteristic	Radial access n=112(108 RR+4 LR)	Femoral access n=68	p-value
Procedure(n.) (%) **Diagnostic CAG** **CAG&PCI** **PCI**	 64(57%) 42(37.5%) 6(5.35%)	 36(53%) 20(30%) 12(17%)	0.026
Fluoroscopy time(mint) mean±SD	5.51±4.70	7.18 ±7.65	0.07
Duration (mint) mean±SD	17.39±10.33	19.68±16.62 (Femoral) 33.50±20.30 (Crossover toFemoral).	0.36 between Femoral and Radial 0.01 among 3 groups
Contrast(ml) mean±SD	88.88±59.25	99.71±73	0.28
Access site Complications: **Hematoma** **Major bleeding** **Dissection** **Perforation**	10(9%) 7 0 1 2	5(7.35%) 3 1 1 0	 0.048

Table (3) shows causes and numbers of prior attempts among patients who crossed to Femoral or left Radial.

Table 3: Crossover to Femoral or Left Radial

Variable	Cross to Femoral n=24	Cross to Left Radial n=4	
Causes: **Puncture Failure** **Radiobrachial failure** **Epiaortic Aortic failure** **Coronary canulationfailure**	 8 13 2 2	 2 1 0 0	
Puncture Failure(n=10) **1st Radial attempt** **2nd Radial attempt** **3rd Radial attempt**	 2 5 1	 0 2 0	 p-value <0.01

A model of binary logistic regression analysis was run to identify predictors of Radial abandonment to Femoral access, in our study however male Gender and prior Radial attempt were associated with increased risk of Radial failure (OR 3.91, CI :1.39-10.96, P-value 0.01) and (OR 2.71, CI 1.543.99, P-VALUE 0.038) respectively as shown in table 4.

Table 4: Predictors of Radial Access Failure

Variable	B	S.E.	Sig.	Exp(B) (OR)	95% C.I. for EXP(B)	
					Lower	Upper
Male Gender	1.364	0.526	0.01	3.912	1.395	10.968
HF	-0.815	1.349	0.546	0.443	0.031	6.226
DM	-0.066	0.491	0.893	0.936	0.358	2.45
Dyslipidemia	1.728	1.08	0.11	5.627	0.678	46.702
Smoking	-25.324	40193.115	0.999	0.0001	0	
CKD	0.244	1.186	0.837	1.276	0.125	13.051
HTN	0.198	0.489	0.685	1.219	0.468	3.179
PCI	-0.804	0.761	0.29	0.447	0.101	1.987
CAG&PCI	-0.586	0.683	0.391	0.557	0.146	2.124
Age	0.009	0.024	0.719	1.009	0.962	1.058
2nd radial attemt	1.13	0.43	0.038	2.71	1.549	3.991

B: Coefficient for constant (intercept)
S.E: Standard of error
Exp(B): Exponentiation of B coefficient (Odd Ratio).
CI: Confidence interval

Discussion

TRA for cardiac catheterization is an appealing alternative to TFA for both diagnostic and therapeutic purposes though it requires a steep learning curve initially. Because of the Radial artery anatomy, there are technical challenges to overcome. In our study the overall success rate for CAG and PCI through TRA was 80%, which is lower than other studies like in Agostoni et al which was 92.7%, while we had 100% success in femoral access which is as near as to the Brueck et al which was 99.8% [14,15]. This may be related to our low sample size compared to the other studies and our Operator higher experience with Femoral access.

Access Failure

Radial artery access has been associated with a greater access crossover rate, which was reported to be 4% to 7% in various studies [16-18]. Louvard et al reported the crossover from TRA to TFA in 8.9%, while in our study the rate was 20% (85.7% to Right Femoral and 14.3% to Left Radial) [19]. In our study the most common cause for Femoral cross over was Radio brachial failure (50%) cases with spasm being the most common cause despite intra arterial nitrates, followed by Radial loop, Radial artery perforation and dissection and this is near to the Brueck et al results, Puncture failure being second most common cause (35.7%) [18]. being male and having previous radial artery access was risk factors, with 25% of patients had previous Radial artery canulation with p value of 0.01,7% of the patients had tortuosity of the subclavian artery and aorta and same number of patients had difficulty in coronary artery cannulations. This may be due to improper selection of suitable radial cases, inaccurate puncture techniques, coarse maneuvers of catheters, and improper methods for dealing with tortuous Epi-aortic anatomy. Radial artery is a small vessel, it is pronator spasm. Wrist pain at puncture site is an important factor leading to radial spasm and puncture failure. As puncture is the gateway of radial access, it should be near perfect. Also, improvements in device technology and increase in expertise should narrow the gap of access site crossover from the earlier period of TRA to the modern era.

Procedural Duration

In our study the mean procedural time was (17.39±10.33) minutes for TRA and (19.68±16.62) minutes for TFA, although the procedure time was higher in TFA but this was statistically on-significant (p value of 0.36) and this matches with Louvard et al and santosh et al studies [19,20]. Which reported the procedural duration (from first puncture attempt to removal of last catheter) without any significant differences between the Femoral and Right Radial approaches. While the Femoral cross over group had significantly higher procedural time (33.50±20.30) minutes with p value of 0.01. While the procedure time was more in TRA group compared to TFA group confirmed by Saleem Kassman et al. and Ferdinand Kiemeneij et al [21,22].

Fluoroscopy Time and Contrast Volume

Fluoroscopy time in our study for both Radial and Femoral approaches was not significantly different (5.51±4.70 vs 7.18 ±7.65 minutes respectively, P =0.07). This result matches with those of santosh et al and Osama et al [20,23]. Louvard et al reported that fluoroscopy time was longer in TRA than TFA (4.5 ±3.7 versus 6.0 ± 4.4 minutes $p< 0.05$) for CAG which sometimes becomes more demanding and longer in elderly patients because of the frequent presence of specific vascular abnormalities, calcification, or arterial loops [24]. Plourde et al in their meta-analysis reported that TRA was associated with a small but significant increase in fluoroscopy time for CAG which narrows down over time, the clinical significance of this small increase is uncertain and is unlikely to outweigh the clinical benefits of TRA [25].

Contrast utilization during the CAG and PCI was lower in Radial (88.88±59.25 ml) femoral (99.71±73 ml) respectively, but this was statically non-significant P = 0.28, this matches the results of santosh et al and Louvard et al that reported the volume of contrast was similar in Radial and Femoral approaches for CAG [20,24]. While Contrast utilization during the CAG procedure was significantly lower in the Radial than the femoral approach in Osama et al and Kabir et al. [26].

Entry Site Complications

In our study the overall local complications were lower in Tran's femoral group than trans racial group (7.35% vs 9.0% p value 0.048), Access site complications are considerably more frequent whenever an aggressive anti platelet and/or antithrombotic treatment is needed. Consequently, trans femoral intervention carries a risk of bleeding complications ranging from 2.5%to 23% that matches our study [27-29]. In the Femoral group we had 3 patients with groin hematoma <10 cm that required no specific treatment, one patient with non-flow limiting Femoral artery dissection and one patient developed severe external and subcutaneous bleeding that required 6 pints of blood transfusion and underwent operation for femoral artery repair, stayed 3 days in ICU and 3 days in ward. While the risk of local complications in Radial group was higher, 7 patients had local hematoma< 5 cm, all managed with bandaging, 2 patients had radial artery perforations managed conservatively and one patient had non flow limiting dissection. Although the local complication was higher in Radial group but no patient developed major bleeding and all elective radial cases were discharged same day. This matches with Jang JS et al. Hibbert B et al. and Jolly Setal studies [30-32].

Conclusion

In our study in addition to that TRA was not superior to TFA in so many characteristics like (contrast volume and fluoroscopy time), yet another conclusion to be mentioned that the TRA is limited by significant higher rates of procedural failure, either due to Operator factors like in puncture failure, or patient or anatomical factors like (being male, repeated punctures, Radio brachial failure and Aortic arch geometry that may affect Catheter advancement and Engagement).moreover the overall local complications were lower in TFA, except for major bleeding which is still a concern in Femoral access. Now we concluded that both vascular Access techniques should not be considered opposite or mutually exclusive, but rather provide the Interventionist a wide spectrum of the therapeutic options, with the choice based on logical risk to benefit ratio judgment.

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