SAFETY, EFFICACY AND FEASIBILITY OF TRANS RADIAL APPROACH IN COMPARISON WITH TRANSFEMORAL APPROACH IN PATIENTS UNDERGOING CORONARY CATHETERIZATION

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ABSTRACT

Background

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

Objectives

To assess the efficacy, feasibility, safety and procedural variables in Trans radial approach compared with the Transfemoral Approach in patients undergoing coronary artery catheterization.

Patients and Methods

A total of 180 patients with both chronic and acute coronary syndromes were enrolled in this study, one hundred forty 140 cases 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 Transfemoral accesses were similar (17.39±10.33 vs 19.68±16.62 minutes P-value 0.36) respectively while among Femoral crossover group was higher (33.50±20.30 minutes P-value 0.01). The Fluoroscopy time was (5.51±4.70 in Trans Radial Vs. 7.18 ±7.65 minutes in Transfemoral P-value 0.07) were similar in both groups. Post procedure access site complications seen in (9% in Trans Radial compared to 7.35% in Transfemoral, P-value 0.048), Access site Hematoma being the most common one (6.25% in Trans Radial vs 4.4% in Transfemoral), Non-flow limiting dissections occurred in (0.89% in Trans Radial VS 1.4% Transfemoral), 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 Transfemoral 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, Transfemoral, Safety, Feasibility, Efficacy.*

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INTRODUCTION

Cardiovascular diseases are among the most common causes of noncommunicable disease deaths. Its numbers 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 Artery Intervention (PCI) are standard diagnostic and therapeutic strategies for coronary artery disease respectively [5]. Transfemoral Approach (TFA) is considered an old and classical one over Trans radial approach (TRA), because it has a large caliber that makes accessibility easier, a couple of repetition of puncturing, much less radiation time and less contrast use. Bleeding being the most common complication of TFA and is associated with poor clinical results. In the previous two decades, TRA emerged as in most cases getting used for the interventional and diagnostic approach in cardiology [6-9]. Following the primary report of radial CAG by Campeau and radial PCI by Kiemeneij et al. in 1989 and 1992 respectively, there is a trend toward increasing use of TRA because of lower

at the rate access site, patient satisfaction and preference, earlier ambulation, less morbidity and procedural cost over TFA [10-12]. Although TRA has lots of benefits, it has a longer mastering curve for the operator, making it more challenging. The devices which are used like intra-aortic balloon pumps and larger devices for coronary interventions cannot be used through [13]. in our locality the preferred vascular route access is being radial artery over the last 5-10 years.

MATERIAL AND METHOD

Design. This cross-sectional study, done in Slemani Cardiac Center and shar hospital. The study was approved by the "Scientific and Ethical Committee" of KBMS in September 2021. Informed written consent to participate in the study was provided by all participants. Over a 6-month period (August 2021 to February 2022),

One hundred eighty patients were admitted to Slemani Cardiac Center and Shar hospital and underwent trans radial or Transfemoral CAG and/or PCI by different operators.

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 the diagnostic procedure and some patients underwent PCI.

Patients who refused to give informed consent, severe sepsis, infection at the access site, allergy contrast, coagulopathy (International normalized ratio > 2) were excluded from the study. Exclusion Criteria for TFA was the same as TRA and included peripheral lower limb arterial disease including (Iliofemoral 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 in patients with absent Radial pulses, instant or previous Radial cannulation failure, failure of previous Radial approach other than cannulation failure and with coronary artery bypass grafts (CABG). Radial approach, sterilization of the wrist done and draped. over an arm board Hyperextension was done, the puncture site sterilized and anesthetized with (2 ml Xylocaine 5%), Radial vascular access gained using the trans radial kit (Prelude, Merit Medical company) which is a 21-gauge needle, 0.018 guide-wire, and a short (7 cm long) sheath using Seldinger technique. after sheath insertion, 200µg nitroglycerin and 5000 IU unfractionated heparin (UFH) was injected into the artery.

For TFA sterilization of the groin done and draped, the site was anesthetized and punctured with 10 ml of 1% Xylocaine. For diagnostic purposes, we used the following catheters: 5F or 6F Tiger (TIG) catheter (Terumo, Japan company) or 6F Ultimate catheter (Merit Medical company) to cannulate both right and left coronary arteries or Judkin's left (JL 6/3.5 and 6/4) for canulation of left coronary sinus and Judkin's right (JR 6/4 and 6/3.5) catheters to cannulate the right coronary sinus. Patients undergoing PCI, guiding catheters (Judkin's JL6/ 3.5 and JR 6/4) and extra back-up (EBU) catheter (6/3.5) were used for coronary sinus 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 anticoagulation. A drug eluting stent (DES) ("Xience", Abbott Vascular or "Resolute", Medtronic companies) were used when the stenting was required. Radial sheath removal done immediately after the procedure;

compression of the radial artery done for 2 hours with (TR band; Terumo) using the "patient hemostasis" protocol. TR band inflation done with 15–20 mL of air. Radial artery patency was checked every 15 minutes by observing the color and temperature of the hand, it was removed 2 hours after the removal of the sheath. at the end of the procedure light pressure bandage was applied. femoral sheath removal was directly after the procedure if no anticoagulation is used and kept in place for 4 hours in contrary, compression done manually till satisfactory hemostasis being achieved, then placement of compressive bandage with dynaplast for eight hours.

According to the Arterial Access site, 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 engage through right radial access and classified into four subgroups: Puncture failure (inability to canulate radial Artery) Radial and Brachial failure (tortuosity, spasm, loops or other anomalies), Supra-aortic failure (aortic tortuosity), and Coronary cannulation failure The duration of the procedure was the time between the first needle-skin entry to removal of the last catheter. Total fluoroscopy time and the amount of contrast were recorded. If no complications occurred in the first 6 hours after the procedure, most of the elective PCI patients were discharged on the same day. Patients with ACS who underwent PCI were discharged after 24-48 hours when they were stable. The Radial and Femoral punctures sites were examined before the hospital discharge.

Statistical Evaluation

The SPSS 21.0 (SPSS Inc., Chicago, Illinois) was used for the Statistical analyses. 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, 180 patients with both chronic coronary syndrome (CCS) and ACS were enrolled in our study at Slemani Cardiac Center and Shar Hospital the 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 patient characteristics were relatively the same 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. Procedural characteristics are shown in (Table 2). in the Radial group, 64 patients (57%) underwent diagnostic CAG, 42 patients (37.5%) CAG & PCI and 6 patients (5.35%) underwent PCI, and the Femoral group 36 (53%) had diagnostic CAG, twenty (30%) CAG & PCI, and 12(17%) patients underwent PCI. The number of cases with crossover from Radial to Femoral 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 supra-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). 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, Table 4.

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(14%)	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%)	

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 to Femoral).	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. Crossover to Femoral or Left Radial.

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

Table 4. Predictors of radial access failure.

	B	S.E.	Sig.	Exp(B) (OR)	95% C.I. for EXP(B)	
					Lower	Upper
Male gender	1.364	.528	0.010	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	2.450
Dyslipidemia	1.728	1.080	0.110	5.627	0.678	46.702
Smoking	-25.324	40193.115	0.999	0.0001	0.000	0.000
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	0.290	0.447	0.101	1.987
CAG&PCI	-0.586	0.683	0.391	0.577	0.146	2.124
Age	0.009	0.024	0.719	1.009	0.962	1.058
2nd radial attempt	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

Trans Radial Approach (TRA) in cardiac catheterization is a good alternative to TFA for diagnostic and therapeutic purposes though it needs a gradual learning curve initially. Due to the Radial artery anatomy, there are technical challenges to overcome. In the current study the overall success rate for CAG and PCI through TRA was 80%, which is lower than other studies like in Agostoni et al [14] 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% [15]. This may be related to our low sample size in comparison to the other studies and our Operator higher experience with Femoral access.

Radial artery access is associated with a greater access crossover rate, and reported to be 4% to 7% in different studies [16-18]. Louvard et al [19] reported the crossover from TRA to TFA in 8.9%, while in this study the rate was 20% (85.7% to Right

Femoral and 14.3% to Left Radial). In the current study the most common cause for Femoral cross over was Radio brachial failure (50%) cases with spasm being the most common cause despite intraarterial vasodilators, followed by Radial loop, Radial artery perforation and dissection and this is near to the Brueck et al [18] results, Puncture failure being second most common cause (35.7%). being male and having previous radial artery puncture was risk factors, with 25% of patients had previous Radial artery canulation with p value of 0.01, 7% of the patients had tortuous subclavian artery and aorta and same number of patients had difficulty in coronary sinus engagement. This may be due to improper suitable radial case selections, inaccurate puncture techniques, coarse maneuvers of catheters, and improper ways in dealing with tortuous supra-aortic anatomy. Radial artery is a small vessel, easily gets spasm, an important factor contributing in radial spasm and puncture failure is pain at the puncture site.

In the current study the mean time of the procedure 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 non-significant (Pvalue of 0.36) and this matches with Louvard et al [19] and santosh et al [20] studies. 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 [21] and Ferdinand Kiemeneij et al [22] .

The total Fluoroscopy time in this study for both Radial and Femoral groups were not significantly different (5.51±4.70 vs 7.18 ±7.65 minutes respectively, P =0.07). this result is consistent with those of santosh et al [20] and Osama et al [23]. In Louvard et al [24] it was shown that the fluoroscopy time was longer for TRA than TFA (4.5 ±3.7 versus 6.0 ± 4.4 minutes < 0.05) for CAG, and this was obvious in elderly patients as they have more chance of having specific vascular abnormalities,

calcifications and arterial loops. Plourde et al [25] reported that TRA was associated with a significant increase in fluoroscopy time for CAG which narrows down as the time passes by.

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

In this study the overall local complications were lower in transfemoral access group than trans radial group (7.35% vs 9.0 % p value 0.048), Access site complications are considerably more frequent whenever an aggressive antiplatelet and/or antithrombotic treatment is needed. Consequently, transfemoral intervention carries a risk of bleeding complications ranging from 2.5% to 23% (27-29) that matches our study. 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 [30], Hibbert B et al [31] and Jolly SS et al [32] studies.

In conclusion, the current 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.

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