Comparative study of complications associated with femoral and radial approach for coronary angiography

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Abstract Background: The knowledge about different diameter of the head and neck of the femur is essential in orthopedic surgery and for radiological practice in identifying pathology of bone. The femoral normative values are also essential to plastic and reconstructive surgeons and medical rehabilitation. **Aim:** To evaluate the morphological features of head and neck of diameter of the human left and right femur. **Material and Methods:** In this prospective study 353 dried, intact human femora were classified into Right side and Left side. Variables studied were vertical diameter of head and neck of the femur and Neck-shaft angle of the femur. Digital slide caliper and goniometer were used for the measurements. **Results:** The circumference of the neck and Neck-shaft angle were found to be significantly different on both the sides. Whereas, the vertical diameter of the head and neck did not show significant difference on comparison of both the sides. **Conclusion:** This study was an attempt to construct morphological data on head and neck diameter of femur. The data allow safe instrumentation and fixation and also help in formulating parameters for manufacturing implants using data derived from a studied population.

Key Words: Femur, Neck circumference, Head diameter, Neck-Shaft angle.

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INTRODUCTION

Andreas Gruentzig is considered as the father of interventional cardiology¹. The interventional cardiology deals with the catheter-based treatment of structural heart diseases. It uses diagnosing and treating the cardiovascular diseases, including congenital and structural heart diseases through catheter-based angioplasty procedures such as and stenting. Transfemoral is considered as a classical approach over transradial due to the unlimited repetition of puncturing,

easy access, less radiation time, and less contrast. In the last two decades, transradial approach emerged as mostly being used for the interventional and diagnostic approach in cardiology. In 1989 the transradial approach coronary angiography was reported for the first time in Campeau². The reason behind the popularity of transradial approach is reduced bleeding risk, reduced hematoma formation, early discharge, it is patient preferred, low cost, and lower risk of morbidity and mortality³⁻⁶. Many trials have proved that transradial approach has the lower risk of bleeding in ST-Segment elevation myocardial infarction (STEMI) patients using anticoagulation as compared to transfemoral approach⁷⁻⁹. The transition from femoral access to a radial access is safe and efficient in many procedures in interventional cardiology. It has fewer side effects of low bleeding, pseudoaneurysm, low cost, morbidity and mortality^{10,11}. The outcome of the transradial is much better as compared to the transfemoral approach in catheterization^{1,2,5}. Therefore, the rationale for the transradial approach is the intention to reduce access site bleeding complications, earlier ambulation,

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and improved patient comfort.¹²⁻¹⁴One of the major criticisms of the radial approachis that it takes longer overall procedure and fluoroscopy time, which means not only more staff (interventionists, radiographers, nurses, and anesthetists if needed clinically) will be exposed during the procedures, but they will also stand close to the patient where rates of radiation scattered by the patient are higher.¹⁵ The American Heart Association/American College of Cardiology clearly state that "the responsibility of all physicians is to reduce the radiation injury hazard to their patients, to their professional staff and to themselves".¹⁶ thus the present study was conducted with the aim to study the complications associated with Femoral and Radial approach for coronary angiography.

MATERIAL AND METHODS

The present prospective, randomized study was conducted with the objective to study and compare the complications associated with Femoral and Radial approach for coronary angiography. The study was conducted in the department of cardiology of B J Government Medial College and Sassoon General Hospital, Pune. The study protocol was approved by the institutional ethics committee and informed consent from each patient was obtained. All patients admitted in Sassoon General Hospital who were undergoing coronary angiography were included in the study after taking written informed consent. The selected patients were randomized by using web based software for simple randomization into two groups:

- 1. Those undergoing CAG through femoral route
- 2. Those undergoing CAG through radial route

The demographic data, relevant history and examination findings were recorded on a pre-structured proforma.

Radial artery was punctured by 21G needle and 0.021" guide wires (Cordis, USA) were inserted. 5-F sheath and6-F sheath were used for diagnostic purpose and ad hocintervention depending on need. After sheath replacement, cocktail containing 200 μ g nitroglycerin, 2.5mg diltiazem, and 2500 IU unfractionated heparin was injected. Angiogram was performed by 5-F TIG catheter (Terumo, Japan). For those having abnormal take-off where cannulation was not possible with TIG catheter, Judkin's left or right (JL/JR) catheter was used. Radial sheath was removed just after procedure and manual performed compression was using the "patenthaemostasis" protocol proximal to puncture site¹⁷. Light pressure bandage was applied which was removed next day. Transfemoral procedures were performed by 6Fr diagnostic catheters (JL/JR). At the end of the procedure, sheath was removed and manual compression was performed until satisfactory haemostasis had been achieved followed by placement of compressive bandage with dynaplast for 6h.Patients were stratified into two groups, transradial and transfemoral, according to arterial access used to performprocedure. Crossover to transradial access was defined as failed access, extreme tortuosity and peripheral arterial disease. The CAG findings and complications observed during the procedure were recorded. Procedure duration, total fluoroscopytime and contrast volume was also recorded. All the patients were followed till they were discharged from hospital. The complications observed during the hospital stay and the total hospital stay was also recorded. All the collected data was entered in microsoft excel and was presented with appropriate graphs and tables. Statistical analyses were performed using the SPSS 17.0.

RESULTS

 Table 1: Distribution according to demographic characteristics and

	FISK FACTORS		
Charactoristic	Transradial	Transfemoral	р
Character Istic	CAG	CAG	value
Age (years)	54.14±13.09	58.94±12.33	0.062
Male: Female	1: 1	1: 1.38	0.422
BMI (kg/m2)	24.54±5.86	25.12±4.74	0.587
Smoking	13	7	0.083
Dyslipidemia	16	18	0.544
HTN	11	17	0.087
DM	21	24	0.157
CSA	11	14	0.396
UA	17	11	0.087
AMI	16	21	0.106
PRE VALVE	4	1	0.157
POST CABG	2	0	0.148
	Characteristic Age (years) Male: Female BMI (kg/m2) Smoking Dyslipidemia HTN DM CSA UA AMI PRE VALVE REPLACEMENT POST CABG	CharacteristicTransradial CAGAge (years)54.14±13.09Male: Female1: 1BMI (kg/m2)24.54±5.86Smoking13Dyslipidemia16HTN11DM21CSA11UA17AMI16PRE VALVE4REPLACEMENT4POST CABG2	Transradial CAG Transfemoral CAG Age (years) 54.14±13.09 58.94±12.33 Male: Female 1:1 1:1.38 BMI (kg/m2) 24.54±5.86 25.12±4.74 Smoking 13 7 Dyslipidemia 16 18 HTN 11 17 DM 21 24 CSA 11 14 UA 17 11 PRE VALVE 4 1 POST CABG 2 0

It was seen that the mean age of patients undergone Transradial CAG and Transfemoral CAG was 54.14 ± 13.09 years and 58.94 ± 12.33 years respectively and the difference observed was not statistically significant. The sex wise distribution was also not significant. Difference in the distribution of various risk factors such as BMI, addiction of smoking, dyslipidemia, hypertension and diabetes among the Transradial CAG and Transfemoral CAG group was non-significant. It was seen that CSA, UA, history of AMI, history of pre valve replacement and CABG was comparable in both the groups and the difference observed was statistically non significant.

The procedure was successful among both the study groups and no crossover of procedure was required. Among the Transradial CAG group; radial spasm was noted in 6 patients. Nonobstructive CAD was diagnosed among 5 patients of each group. The Angiographic severity of CAD (obstructive) among the both groups was comparable and the difference was statistically non significant.

Procedure data	Transradial CAG	Transfemoral CAG	p value
Access Site Success	50	50	NA
Non-obstructive CAD	5	5	NA
CAG –SVD	5	3	0.4609
CAG-DVD	6	6	NA
CAG TVD	7	4	0.3376
Normal CAG	40	45	0.1614
Procedure Duration	25.44±6.97	16±4.60	0.0000
Fluoro Time	3.01±1.58	1.75±0.67	0.0000
Contrast Volume	45.6±21.03	31.8±6.20	0.0000
Hospital Stay	2.16±1.35	3.54±1.46	0.00000

Table 2: Distribution	according to	procedure data
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The mean procedure duration was more Transradial CAG (25.44±6.97min) group as compared to Transfemoral CAG (16±4.60min). The fluoroscopy time for coronary angiography was longer in transradial CAG group than transfemoral CAG group (3.01±1.58min and 1.75±0.67min respectively). The mean contrast volume among the Transradial CAG was 45.6±21.03 while among the transfemoral CAG group was 31.8±6.20 and the difference was statistically significant. The mean duration of hospital stay among the transradial CAG group was significantly lower $(2.16\pm1.35 days)$ as compared to transfermoral CAG group $(3.54 \pm 1.46 days)$.

	Table 3:	Distribution	according	to C	Complication
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Complication	Transradial CAG	Transfemoral CAG	p value
Major Hematoma	0	2	0.475
Minor Hematoma	0	8	0.009
Loss Of Pulse	7	1	0.065
Pseudoaneurysm	0	2	0.475
AV Fistula	0	2	0.475
Limb Ischemia	0	2	0.475
Major Bleed	0	1	1.000
CVA/TIA	3	1	0.609
Radial Spasm	6	NA	NA

The complications after CAG were observed in both Transradial and Transfemoral group. Major and minor hematoma were observed in 2 and 8 patients of Transfemoral group while none in Transradial group. Loss of pulse was seen in 7 patients of transradial and one patient of transfemoral CAG group and the difference observed was statistically significant. Pseudoaneurysm, AV fistula and limb ischemia was noted in 2 patients each of transfemoral while none in transradial group. Major bleed was observe din patients of transfemoral CAG group. CVA/TIA was reported in 3 patients of Transradial group while one in transfemoral group.



Figure 1: Distribution according to Complication

DISCUSSION

Transradial approach for cardiac catheterization (TRC) is an appealing alternative to transfemoral access for both diagnostic and therapeutic purposes though it requires a steep learning curve initially. Because of its anatomy and inherent nature, technical challenges will always be there. Transradial access has been associated with a greater access crossover rate, which was reported to be 4%-7%in various studies¹⁸⁻²⁰. It was seen that the mean age of patients undergone Transradial CAG and Transfemoral CAG was 54.14±13.09years and 58.94±12.33years respectively and the difference observed was not statistically significant. The sex-wise distribution was also not significant. Difference in the distribution of various risk factors such as BMI, addiction of smoking, dyslipidemia, hypertension and diabetes among the Transradial CAG and Transfemoral CAG group was nonsignificant. It was seen that CSA, UA, history of AMI, history of pre valve replacement and CABG was comparable in both the groups and the difference observed was statistically non significant. Santosh Kumar Sinha *et al*²¹ and Satyendra Tewari *et al*²²also observed similar findings in their study. The procedure was successful among both the study groups and no crossover of procedure was required. Among the Transradial CAG group; radial spasm was noted in 6 patients. Nonobstructive CAD was diagnosed among 5 patients of each group. The Angiographic severity of CAD (obstructive) among the both groups was comparable and the difference was statistically non significant. The mean procedure duration was more Transradial CAG (25.44±6.97min) group as compared to Transfemoral CAG (16 \pm 4.60min). Santosh Kumar Sinha *et al*²¹ and Satyendra Tewari *et al*²² also observed similar findings in

their study. The fluoroscopy time for coronary angiography was longer in transradial CAG group than transfemoral CAG group (3.01±1.58min and 1.75 ± 0.67 min respectively). Louvard *et al.*²³ in their study reported that fluoroscopy time in transradial group was longer than transfemoral group (4.5±3.7min and 6.0±4.4min respectively) for coronary angiography. Plourde et al.²⁴ in theirmeta-analysis reported that transradial access was associated with a small but significant increase in fluoroscopy time for diagnostic coronary angiography which narrows down over time; the clinical significance of this small increase is uncertainand is unlikely tooutweigh the clinical benefits of transradial access. Agostoni et al.²⁵ and Brasselet et al.²⁶ also observed similar finding sin their study. The mean contrast volume among the Transradial CAG was 45.6±21.03 while among the transfermoral CAG group was 31.8 ± 6.20 and the difference was statistically significant. The mean duration of hospital stay among the transradial CAG group was significantly lower (2.16±1.35days) as compared to transfemoral CAG group $(3.54\pm1.46$ days). Similarly Satyendra Tewari*et al*²² also reported that the hospital stay was significantly shorter with the transradial procedures as compared to transfemoral procedures in their study. Patient who underwent CAG through transfemoral approach had mean hospital stay of 1.9±0.8 days as compared to those who had transradial CAG and had hospital stay of 1.1±0.6 days. The complications after CAG were observed in both Transradial and Transfemoral group. Major and minor hematoma was observed in 2 and 8 patients of Transfemoral group while none in Transradial group. Loss of pulse was seen in 7 patients of transradial and one patient of transfemoral CAG group and the difference observed was statistically significant. The findings were comparable with the findings observed by Santosh Kumar Sinha *et al*²¹, Satyendra Tewari *et al*²² and Osama Tayeh et al.²⁸ Pseudoaneurysm, AV fistula and limb ischemia was noted in 2 patients each of transfemoral while none in tranradial group. Major bleed was observe din patients of transfemoral CAG group. CVA/TIA was reported in 3 patients of Transradial group while one in transfemoral group. The findings were comparable with the findings observed by Santosh Kumar Sinhaet al^{21} , Satyendra Tewari et al^{22} and Osama Tayeh et $al^{.28}$ Compared with the femoral artery, the radial artery is more superficial, smaller in caliber, lacks any important adjacent structure or potential spaces (such as the retroperitonealspace), and is easily compressible. Observational and small errandomized trials have found a significant reduction in the rate of major bleeding and major vascular access site complications with radial compared with femoral access in patients undergoingPCI^{27,29}, even when femoral vascular closure devices are used³⁰. Vorobcsuk, *et al*³¹. performed a pool of data collection on the population of 3324 patients in 12 different studies, who underwent percutaneous coronary intervention [PCI] either via transradial or transfemoral approach. They found a 70% risk reduction in access-site bleeding with the transradial approach. This attainment further converted into the lower incidence of hospital major adverse cardiac events and mortality.

CONCLUSION

Thus we conclude that the Transradial coronary catheterization is safe, feasible, effective and nearly abolishes entry site complications, in comparison with significantly higher rates in patients undergoing transfemoralcatheterization. However Procedure Duration, Fluoro Time and Contrast Volume required in Transradial approach is significantly higher as compared to trans femoral approach.

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