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RESEARCH ARTICLE

RADIAL VERSUS FEMORAL ARTERY APPROACH FOR DIAGNOSTIC CORONARY ANGIOGRAPHY – A COMPARATIVE OBSERVATIONAL STUDY

*¹Sajad Ul Islam Mir, ²Abdul Khaliq, ³Hilal Ahmad Dar, ⁴Aadil Ashraf, ⁵Dr. Khalid Mohiuddin, ⁶Sajad Ahmad Tak and ⁶Javed Ahmed Khan

¹Medicine GMC Srinagar, Senior Resident HIMSR New Delhi, India

²Department of medicine GMC Srinagar, India

³Medicine SKIMS Srinagar, D.N.B. Gastroenterology BHMRC New Delhi, India

⁴Medicine GMC Srinagar, Senior Resident GMC Srinagar, India

⁵Department of Cardiology GMC Srinagar, India

⁶Medicine GMC Srinagar, Senior Resident GMC Srinagar, India

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ABSTRACT

Background & Objective: The femoral artery has been the usual route of access for Coronary Angiography. In recent past some trials have suggested that radial artery as a route of access for Coronary Angiography reduces local vascular complications & bleeding as compared to femoral route. We present our study aimed to assess the two routes viz. a viz. complications & feasibility.

Methods: Our study is of prospective comparative design, conducted in SMHS Hospital Srinagar, a tertiary care institute, associated hospital of Government Medical College Srinagar. A total of 400 patients were enrolled; 240 patients for radial and 160 patients for femoral approaches for Coronary Angiography. Patients fulfilling the inclusion and exclusion criteria were included in the study.

Results: In our study we found that the access time was more with the radial compared to femoral approach (5.763+_{3.101} min vs 3.11+_{1.16} min, p <0.001). The total procedure time was also more in radial than femoral approach group (30.03+_{6.728} vs 28.26+_{10.637} min, p _{0.06}). Similarly the total fluoroscopic time was more in radial compared to femoral group (6.39+_{2.89} vs 6.02+_{1.53} min, p _{0.09}). The radial access had a strong trend towards more contrast volume use as compared to femoral access (54.58+_{25.919} ml & 52.06+_{18.053} ml, p _{0.252}). The post procedure complications were more common in the femoral compared to radial group. The common complications were puncture site ecchymosis (p<0.05), thrombophlebitis (p<0.05), local site hematoma (p <0.001) & access site bleeding (p<0.05). Patient comfort was higher in the radial (4.2±0.6) than in the femoral group (4.1± 0.7) (p_{0.03}). The patients who would undergo CAG via radial group would spend 3.85±2.6 hours in the hospital whereas the femoral group would need 7.15±2.2 hours hospitalization (p_{0.001}).

Interpretation & Conclusion: The radial approach for Diagnostic Coronary Angiography is more favourable than femoral approach. However, the same needs longer learning curve, has increased access failure and crossover.

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INTRODUCTION

Coronary angiography is an invasive investigation employed to demonstrate the presence or absence of arterial narrowing related to atherosclerotic CAD. Coronary angiography provides the most reliable anatomic information for determining the

appropriateness of medical therapy, PCI or Coronary artery bypass graft (CABG) surgery in patients with ischemic CAD. First "selective" coronary arteriogram was performed by Dr. F Mason Sones in 1959, at the Cleveland Clinic⁸. This method has since then revolutionized our understanding of CAD and has become the basis for selecting and evaluating therapeutic intervention. Femoral Artery has traditionally been the site of access for CAG. The femoral artery approach for coronary interventions could be complicated by serious vascular access

*Corresponding author: Sajad Ul Islam Mir,
Medicine GMC Srinagar, Senior Resident HIMSR New Delhi, India.

site complications, as suggested by some trials, including hematomas, significant blood loss, arterial pseudo aneurysm and arteriovenous fistulas (Moinuddin Khan *et al.*, 2010). In addition the femoral route has several limitations. It is relatively contraindicated in the presence of severe peripheral vascular disease and in patients receiving anticoagulation treatment. A longer period of post-procedure bed rest is needed to avoid disruption of the puncture site.

These factors together affect patient's satisfaction, morbidity, length of hospital stay, and costs and thus, have driven the development of alternative vascular access for coronary procedures. Radial Approach for diagnostic CAG has gained progressive acceptance since its first introduction by Campeau in 1989. In comparison to femoral route, major vascular access site complications are minimized from radial artery approach. The radial artery is easily compressible, thus bleeding is controllable and hemorrhagic complications are significantly reduced (Rognoni *et al.*, 2012).

Finally, post procedural bed rest is not required, permitting immediate ambulation, more comfort, and early discharge and thus allowing more efficient outpatient CAG. This last advantage has shown to improve quality of life for patients and to reduce the costs of hospitalization (Mann *et al.*, 1996; Goldberg *et al.*, 1998). Despite this large amount of benefits, the radial approach is more demanding than femoral access and requires a longer learning curve for the operator (Goldberg *et al.*, 1998; Mansour Sallam *et al.*, 2009). Moreover, it is not always feasible, because some patients may have an anomalous palmar arch that does not provide sufficient blood supply to the hand in case of thrombotic or traumatic occlusion of the radial artery.

Finally, access site failure is a possibility, often because of anatomic variation and tortuosity of the radial artery (Louvard *et al.*, 2001). The major problems for the radial approach are small radial artery that cannot be accessed successfully. Compared to western population the size of radial artery in Asians is small (Monsegu *et al.*, 2002).

Conversely, the femoral approach is still considered by many as the standard technique because of its optimal catheter control, uncommon thrombotic complications, and immediate access to large-diameter devices. Moreover, one of the major criticisms of the radial approach is 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 (Tayeh *et al.*, 2014).

The American Heart Association/American College of Cardiology clearly states that "the responsibility of all physicians is to reduce the radiation injury hazard to their patients, to their professional staff and to themselves" (International Commission on Radiological Protection, 1997). Despite of these few limitations, radial approach has the potential to become the default technique for invasive cardiology in the next few years.

Procedure

Aim & Objective

The purpose of this study was to assess and compare the feasibility and success of radial and femoral artery approaches for diagnostic coronary angiography (CAG).

Study Endpoints

- **Procedural Characteristics:** Access time, Procedure time, Fluoroscopy time, Amount of contrast used, Crossover and Patient comfort for either route.
- **Complications:** Including Local Vascular complications like thrombophlebitis, hematoma, ecchymosis, bleeding etc. and MACE (Major Adverse Cardiovascular Events) defined as stroke, MI, death and/ or emergency revascularization (PCI or CABG) following either route.

MATERIALS AND METHODS

Our study was of prospective comparative design, conducted in SMHS Hospital Srinagar, a tertiary care institute, an associated hospital of GMC Srinagar. The hospital is equipped with a state of art, cardiac cath lab with well trained cardiologists, medical & paramedical staff. The study was conducted from March 2013 to November 2014. A total of 400 patients were enrolled in the study; 240 patients for radial and 160 patients for femoral approaches for diagnostic coronary angiography. Patients admitted in ICCU of SMHS hospital or otherwise following the outpatient department of medicine and fulfilling the inclusion and exclusion criteria were included in the study:

Inclusion Criteria

- Stable angina.
- Unstable angina/NSTEMI.
- STEMI.

Exclusion criteria

- Liver/kidney disease
- Bleeding diathesis.
- Coagulopathy (INR >2).
- Severe anemia (Hb < 8g/dl).
- Severe electrolyte imbalance.
- Uncontrolled systemic hypertension.
- Known difficulties with femoral/radial approach.
- Sepsis or local site infection
- Previous contrast allergy
- Pathological Allen's test for the radial route
- Peripheral vascular disease for the femoral route.

A proper written informed consent was taken before enrolling patients for the study. A detailed history was taken from the patients regarding the presenting illness, past illness and drug history. A thorough general physical examination was done. All relevant investigations were done. Routine laboratory investigations including urea and electrolytes, full blood counts, liver and renal function tests, coagulation profile, HIV and hepatitis serology were performed.

The patients were defined according to the American College of Cardiology/ American Heart Association (ACC/AHA) Task Force established indications for coronary angiography (Rik Hermanides *et al.*, 2012). Patients were labeled as stable angina, unstable angina/NSTEMI (Christopher and Braunwald, 2015) and STEMI (Alpert and Thygesen, 2000) as per following definitions:

Stable Angina

It is characterized by chest or arm discomfort that may not be described as pain but is reproducibly associated with physical exertion or stress and is relieved with 5-10 minutes by rest and/or sublingual nitroglycerine.

Unstable Angina

It is defined as angina pectoris or equivalent ischemic discomfort with at least one of the three features:

- It occurs at rest (or with minimal exertion) usually lasting more than 10 minutes.
- It is severe and of new onset (i.e. within the prior 4-6 weeks) ; and/or
- It occurs with a crescendo pattern (i.e. distinctly more severe, prolonged or frequent than previously).

NSTEMI: it is defined in a patient with clinical features of UA with evidence of myocardial necrosis as well, as reflected in elevated cardiac biomarkers.

STEMI: The diagnosis of ST elevation myocardial infarction (MI) will be based on: a) a clinical history of prolonged ischemic chest pain ≥ 30 minutes in duration; b) evolution of typical changes in at least two adjacent leads of the electrocardiogram (ECG); c) appearance of ST segment elevation > 2 mm 0.08 seconds after J point persisting for at least 24 hours with or without Q waves, and a time-dependent rise in troponins and subsequent fall.

Diagnosis of all the patients and the indication to undergo diagnostic coronary angiography was reviewed by consultant cardiologist. Selection of the access site was individualized according to the preferences of the operator and appropriateness of radial or femoral artery pulsations. Allen's test was performed by simultaneously occluding the radial and ulnar arteries while the patient is making a fist. Afterwards, the patient would open the hand, and the ulnar artery was released. A delay of 15 s before the return of color to the blanched hand was considered an abnormal Allen's test (Allen, 1929).

The preference was to use the right radial and right femoral routes for the procedure as they are nearer to the operator while facing the cardiac monitors and the fluoroscopic images in our hospital. After the written informed consent and positive Allen's test, for transradial route, the wrist was sterilized and draped in usual fashion. Hyperextension over an arm board and skin over the puncture site was anesthetized with 2 to 3 ml of 2% lignocaine. A small scaled incision was performed 1cm proximal to styloid process of radius where arterial pulse was best felt.

The radial artery was punctured with a 21 G needle and 5-6 F sheath (cardis, terumo) were introduced into the artery, using Seldinger technique (Olivier, F. Bertrand, 2012). All patients received cocktail consisting of Diltiazem (5mg), NTG (100 μ g) to reduce radial artery spasm and heparin (5000 IU) to prevent artery occlusion. Appearances of pulsatile flow from the end of the needle confirmed that the needle is inside the lumen of the artery. The 5F diagnostic catheter (TIG) was introduced into aortic route over 150cm long 0.025 terumo guide wire under fluoroscopic guidance. The catheters used for transradial approach were specially designed for transradial route such as tiger catheter (terumo) sized 5-6 F.

Similarly in case of transfemoral approach our preference was to use right femoral artery. The groin was prepared and draped in usual fashion and the site was punctured for femoral access after anesthetizing the skin with 2-4 ml of 2% lignocaine. Once the femoral puncture was done 6F or 7F sheath of cardis variety was introduced and 6F or 7F Judkin's catheter was introduced and it was guided under fluoro through the aortic route. All patients for femoral route received 1000 IU of heparin. The "Access time" was defined as the mean time interval from administration of local anesthesia at the arterial puncture site to successful placement of an arterial sheath (Yazdankhah *et al.*, 2013). The "procedure time" was defined as the time of entry of the patient to the catheterization laboratory to the end of the procedure. The time required for the hemostasis was not included (Mansour Sallam *et al.*, 2009). The need to puncture a second access site due to any procedural failure (inability to puncture the entry site artery, failure to cannulate the coronary artery, impossibility to perform the procedure due to major access site complication) was defined as a "crossover" (Bertrand *et al.*, 2008). Crossover from one arterial site to another was permitted at any time at the physician's discretion, for the same reason groin was kept prepared and vice versa. The access time, procedure time, fluoroscopy (X ray) time and the amount of contrast used was calculated for either route separately.

Arterial sheaths were removed immediately after diagnostic radial procedures. Hemostasis was obtained using a pressure bandage with 4 elastic sticky straps immediately applied to the puncture site with a period of manual compression. The patients were transferred back to the ward, where the route of access, radial or femoral was clearly observed for bleeding and other local vascular complications (during and just after the procedure). The patient was monitored for any major adverse cardiovascular event (MACE) as stroke, MI, death or emergency revascularization during and just after the procedure. The patient comfort in terms of subjective feeling estimated on a scale ranging from 0 to 5 prior to hospital discharge was noted accordingly for the either route.

Statistical Analysis

The statistical analysis was carried out using the Statistical Package for the Social Sciences (SPSS), Version 20. Continuous data are expressed as mean value \pm SD and categorical data as percentages. Continuous variables were compared using the Student's paired t-Test.

Categorical data were compared using chi-square (X²) analysis. A *p* value of 0.05 or less was considered to be statistically significant.

RESULTS

Our study comprised of total 400 patients for diagnostic CAG, 240 patients were accessed via (right) radial approach & 160 patients were accessed via (right) femoral approach. Out of total number of 400 patients; 240(40.0%) were accessed via radial approach & 160 (60.0 %) were approached via femoral approach for diagnostic CAG. In the both the arms of transradial & transfemoral approach the most of the studied subjects were in the age group of 51 to 70; with the mean age in the transradial group was 59.80 ± 7.98 years & in transfemoral group it was 60.42 ± 9.52years. The final results obtained at the end of the study period, regarding the end points are summarised below. The mean access time via In our study we found that the access time was more with the radial approach compared to femoral approach (5.763+_3.101 minutes vs 3.11+_1.16 minutes, *p* value of <0.001).

The total procedure time was also more in radial approach group compared to femoral approach group (30.03+_6.728 vs 28.26+_10.637 minutes, *p* value of 0.06); though statistically not significant. Transradial & transfemoral approach was 5.763 ± 3.101 min & 3.116 ± 1.164 min respectively & it was statistically significant with *p* < 0.001. The mean fluoroscopy time was more in radial than femoral group respectively of 6.39 ± 2.892 min & 6.01 ± 1.534 min with a *p* value of 0.09. Thus the two groups did not show a statistically significant difference viz. a viz. fluoroscopy time. The mean procedure time was more in transradial group than in transfemoral group (30.03 ± 6.728min vs 28.26 ± 10.637 min) , though statistically not significant (*p* _ 0.06). The average contrast volume of 54.58 ± 25.919 ml & 52.06 ± 18.053 ml for transradial & transfemoral approach group & it was more for radial group; though statistically not significant (*p*_0.252). The patient comfort, computed on an arbitrary scale grading from 1 to 5, was more with radial group than the femoral group (4.27±0.642 vs 4.12±0.729) and it would made a statistically significant difference (*p*_0.039). Regarding the hospital stay; the patients who would undergo diagnostic CAG via radial group would

Table 1. Age Distribution of Radial And Femoral Group

Age (in years)	Site of access				Total N
	Femoral		Radial		
	N	%	N	%	
<40	6	3.75	10	4.17	16
41-50	16	10.00	18	7.50	34
51-60	43	26.87	94	39.17	137
61-70	81	50.62	102	42.57	183
>70	14	8.75	16	6.67	30

Table 2. Mean BMI of the Radial and Femoral Group

	Site of access	N	Mean	Std. Deviation	P value
BMI	radial	240	25.83	2.736	0.643
	femoral	160	25.70	2.826	(ns)

Table 3. Access Time (min)

Site of access	N	Mean	Std. Deviation	P value
radial	240	5.763	3.1011	0.001(sig.)
femoral	160	3.116	1.1645	

Table 4. Flouroscopy Time (min)

Site of Access	N	Mean	Std. Deviation	p value
Radial	240	6.393	2.892	0.09(NS)
Femoral	160	6.016	1.534	

Table 5. Procedure Time (min)

Site of Access	N	Mean	Std. Deviation	p value
Radial	240	30.03	6.728	0.06(NS)
Femoral	160	28.26	10.637	

Table 6. Contrast Volume (ml)

Site of access	N	Mean	Std. Deviation	p value
Radial	240	54.58	25.919	0.252(NS)
femoral	160	52.06	18.053	

Table 7. Patient Comfort (on a scale grading 1 to 5)

Site of access	N	Mean	Std. Deviation	p VALUE
Radial	240	4.27	.642	0.039(SIG)
Femoral	160	4.12	.729	

spend 3.85 ± 2.6 hours in the hospital whereas the femoral group would need 7.15 ± 2.2 hours hospitalization; and the difference was statistically significant ($p < 0.001$). The commonest post procedure complication was puncture site ecchymosis in 20.6% in femoral group compared to only 12.1% in radial group which is statistically significant (p value of 0.021). Similarly 17.5% developed thrombophlebitis in transfemoral group compared to only 7.9% in the transradial group, which is statistically significant (p value of 0.004). Hematoma developed in 15.0% in transfemoral group compared to none in transradial group with a statistical significance of p value of < 0.001 . The post procedure access site bleeding was seen in 2.1% patients in radial group compared to 6.9% in femoral group, which was statistically significant (p value 0.017). There was more access site failure in transradial group (2.1%) than in transfemoral group (0.00%). Similarly the procedure failure rate was 1.3% in transradial group compared to none in transfemoral group which was 100% successful. The total of 8 patients (3.3%) were crossed over to femoral route from the radial group (5 because of access failure & 3 because of procedure failure) while was none was crossed over from femoral to radial group & the result was statistically significant (p value 0.020).

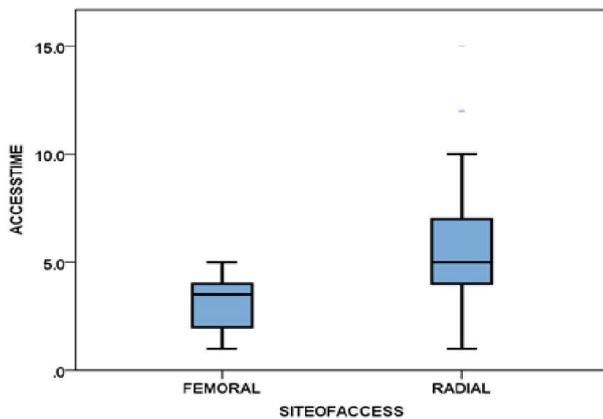


Fig. 1. Box & Whisker plot for access time

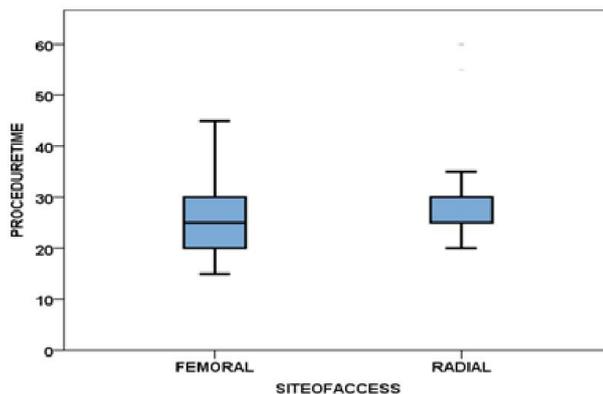


Fig. 2. Box & Whisker plot for procedure time, respectively

DISCUSSION

Radial approach via right radial artery was performed in 240 patients (172 males and 68 females), likewise femoral approach via right femoral artery was adapted in 160 patients (98 males and 62 females).

The mean age of the patients in the radial approach group was 59.80 ± 7.98 years and 60.42 ± 9.52 years was in femoral approach group and the difference was statistically not significant. The mean BMI (body mass index) of 25.8 ± 2.7 kg/m^2 and 25.7 ± 2.8 kg/m^2 were observed in the radial and femoral group of studied subjects respectively. The difference was statistically not significant ($p = 0.643$). Most of the patients in both the studied arms were in the age group of 51 to 70 years. Our results in terms of Access time in two approaches were similar to the results shown in the study of (Fatma Yigitz *et al.*, 2006), "An experience on radial versus femoral approach for diagnostic coronary angiography in Turkey" that statistically significant longer procedural access via radial approach ($p < 0.0001$). The same is supported by Veli Rafali *et al.*, (Velirafali and Ugur Arsalan, 2008) that access time was slightly higher in the TRA group ($P < 0.01$). Brueck *et al.* (Brueck *et al.*, 2009) in their study, "A Randomized Comparison of Transradial Versus Transfemoral Approach for Coronary Angiography and Angioplasty" also found that radial access was longer than the femoral approach ($p = 0.046$). Achieving access to the radial artery is technically more challenging and time consuming than gaining femoral access, but when the right skills are grasped, the technique is much easier and more reliable.

Regarding the procedure time the results of our study were comparable to the studies conducted by Agostoni P *et al.*²² (mean procedural time was 35 min in the radial group, whereas in the femoral group, it was 33.8 min, with no significant difference). Balwanz *et al.* (Christopher *et al.*, 2013) in their study, "transradial and transfemoral coronary angiography and interventions: 1-Year outcomes after initiating the transradial approach in a cardiology training program", found that there was no significant difference between the procedure time (31.8 ± 11.5 vs 33.2 ± 13.8 , $P = .55$) throughout the academic year; that was in conformity with our results.

Similarly the total fluoroscopic time was more in radial approach compared to femoral approach (6.39 ± 2.89 vs 6.02 ± 1.53 minutes, p value 0.09) with no statistically significant difference. The mean fluoroscopic time, which is a reliable marker of procedural complexity & surrogate of radiation exposure, was longer in the radial group, though statistically not significant, because yet we are in learning curve for the radial access. In our study we found that radial access had a strong trend towards more contrast volume use as compared to femoral access (54.58 ± 25.919 ml & 52.06 ± 18.053 ml, $p = 0.252$), comparable to the studies of (Brueck *et al.*, 2009) where the median amount of contrast agent was similar among both groups (132 ml, IQR 80 to 160 ml in the transradial group; 129 ml, IQR 90 to 160 ml in the transfemoral group; $p = 0.43$).

In our study we noticed that 2.1% (5 of 240) patients in radial group had access failure (because of vessel tortuosity & persistent radial artery spasm after the first trial) and 1.3% (3 of 240) patients had procedure failure (because of failure to cannulate the coronary ostia). These 8 patients were crossed over (3.3%) to femoral approach. None of the patients had failure in gaining vascular access in femoral group and it was 100% successful. In our study we found that post procedure

Table 8. Hospital Stay (hours)

	Site of access	N	Mean	Std. Deviation	P value
Hospital stay	Radial	240	3.85	2.684	0.001(sig)
	Femoral	160	7.15	2.215	

Table 9. Local vascular complications and crossover

Procedural complications	Site of access				P value
	Femoral		Radial		
	N	%	N	%	
Thrombophlebitis	28	17.5%	19	7.9%	0.004
Access site bleeding	11	6.9%	5	2.1%	0.017
Hematoma	24	15.0%	0	0.0%	0.000
Ecchymosis	33	20.6%	29	12.1%	0.021
Access failure	0	0.0%	5	2.1%	0.066
Procedure failure	0	0.0%	3	1.3%	0.156
Cross over	0	0.0%	8	3.3%	0.020

complications were more common in the femoral group compared to radial group. The common complications were puncture site ecchymosis in 20.6% in femoral group compared to only 12.1% in radial group ($p < 0.05$). Thrombophlebitis was more common in the femoral group (17.5%) compared to that in radial group (7.9%) with $p < 0.05$. Local site hematoma formed in 15.0% in femoral group compared to none in radial group which was statistically significant ($p < 0.001$). The access site bleeding was 2.1% in the radial group & it was 6.9% in the femoral group ($p < 0.05$) There was no death, MI or need for emergency revascularization by either PCI or coronary artery bypass graft (CABG) in our study. One patient in the femoral group experienced TIA like immediately post procedure manifested as left-sided weakness which improved of its own. One patient in the radial group developed documented arrhythmia (ventricular fibrillation) which was successfully resuscitated.

Patient comfort was higher in the radial groups (4.2 ± 0.6) than in the femoral group (4.1 ± 0.7) and the difference reached the threshold of statistical significance, ($p = 0.03$). The results were comparable to the study carried out by Louvard *et al.*, (2013) (Louvard *et al.*, 2001) "Coronary angiography through the radial or the femoral approach: the CARAFE Study" where he found that the patient comfort was higher in the transradial groups (4.3 ± 0.7) than in the femoral group (4.1 ± 0.7) and the difference reached the threshold of statistical significance ($p = 0.05$). The patients who would undergo diagnostic CAG via radial group would spend 3.85 ± 2.6 hours in the hospital whereas the femoral group would need 7.15 ± 2.2 hours hospitalization; and the difference was statistically significant ($p < 0.001$). Sallam *et al.* (Be Mansour Sallam *et al.*, 2009) found that the total length of hospital stay was significantly shorter in the radial group (4.1 hours) compared to the femoral group (23.8) hours with $p = 0.001$. Louvard Y *et al.* (Louvard *et al.*, 2001) the CARAFE study in their study derived that the bed confinement was: 9.9 (\pm 11.1) hours in the femoral group and 4.9 (\pm 3.9) hours in the radial groups (statistically significant).

Conclusion

The following important conclusions can be drawn from our study 1. Potential advantages of radial approach versus femoral approach.

- Safe and decreased access site complications
 - Decreased bleeding
 - Early ambulation, thus shorter duration of hospital stay
 - More patient comfort and convenience
 - Possibility of making coronary angiography and interventions on OPD basis (day care procedures)
2. Potential disadvantages of radial approach versus femoral approach.
 - Longer Learning curve needed.
 - Increased access failure and access site crossover.
 - Longer procedure & fluoroscopy time and greater radiation exposure at the beginning of learning curve
 - Possible lower procedure success rate at the beginning of learning curve
 3. Femoral approach is the easier and more operator-friendly technique; but with substantial access site complications.
 4. Radial approach is safer and more patient- friendly technique but it needs more experience and higher learning curve.

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