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COMPARATIVE STUDY BETWEEN RADIAL AND FEMORAL ARTERY APPROACHES IN ACUTE ST SEGMENT ELEVATION MYOCARDIAL INFARCTION; IMMEDIATE AND SHORT-TERM FOLLOW UP

By

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ABSTRACT

Background: Trans-radial approach (TRA) gained sound acceptance as an alternative to trans-femoral approach (TFA), however, still having numerous pitfalls as hematoma, spasm and radial artery occlusion.

Objectives: To evaluate the feasibility and safety of TRA for coronary angiography (CAG) and percutaneous coronary intervention (PCI) compared with the TFA in ST segment elevation myocardial infarction (STEMI) patients.

Methods: Our study was a prospective analysis enrolled 100 consecutive patients presented with acute STEMI. The patients were randomly assigned to get vascular access either from TFA (Group I, 50 patients) or from TRA (Group II, 50 patients). The clinical, technical, procedural and post-procedural data collected.

Results: Group I was younger than Group II (53.0±8.4) versus (55.8±10.9 years), however didn't reach a statistical significance (p= 0.156). History of prior STEMI was significantly more in group II (6% versus 16%, p=0.032). There was no difference between the two groups regarding the procedural success (98% versus 96%) and number of attempts to fix the femoral or radial sheath. However, the total procedure time, amount of contrast usage and fluoroscopic time were significantly higher in radial group (42.2 ± 16.8 versus 77.4 ± 27.1 minutes), (157.4 ± 10.8 versus 181.2 ± 16.7 milliliter) and 8.74 ± 3.8 versus 18.64 ± 7.1 minute) with p=0.001 respectively. The frequency of acute complications was similar in both groups despite hematoma was less in group II, however, it didn't reach statistical significance.

Conclusions: Our study demonstrated the radial access is a safe and practical approach for coronary angiography or angioplasty in ST segment elevation myocardial infarction patients compared to femoral access, without major complications, however, the procedure time was significantly longer with higher usage of contrast media and fluoroscopic time.

Key words: radial, femoral, coronary angiography, local vascular complications.

INTRODUCTION

Acute coronary syndrome/ST segment elevation myocardial infarction is a one of the major health problems worldwide[1,2]. The role of early primary percutaneous coronary intervention (pPCI) within 90 minutes of hospital contact is well recognized in ST-segment elevation myocardial infarction (STEMI)[3]. Since the introduction of trans-radial coronary intervention (TRI), it has been getting more popularity throughout the world[4].

The trans-femoral and trans-radial approaches are the most popular vascular access routes for PCI worldwide[5].

Compared with femoral access, radial approach decreases mortality and major adverse cardiovascular events and improves safety, with reduction in major bleeding and vascular complications across the whole spectrum of patients with ischemic heart disease[6-8].

Accordingly, we conducted the current study among patients presenting with STEMI who eligible for to undergone PCI, in order to compare feasibility and safety between radial & femoral accesses.

PATIENTS AND METHODS:

Patient population:

This is a prospective comparative study enrolled total of 100 patients admitted at our institutes from the period of July 2019 to Oct. 2020. STEMI patients included in the study were subjected to coronary angiography (CAG) plus or minus percutaneous coronary intervention (PCI) and divided according to their vascular access into two groups; Group I subjected to transfemoral access (TFA, n = 50 patients) and Group II transradial access (TRA, n = 50 patients). The clinical, technical, procedural and post-procedural data collected. The patients registered in the study after obtaining a written informed consent and approval from our local ethics committee of the hospital.

Inclusion criteria:

All patients presenting to our institutes with acute coronary syndrome /STEMI with no contraindication to perform diagnostic and primary percutaneous coronary intervention (pPCI) either from femoral or radial access.

Exclusion Criteria:

We excluded patients who refused to sign an informed consent, as well patient's history of prior angiography via radial access, cardiogenic shock, and history of CABG using radial grafts, chronic renal failure, and patients with arteriovenous fistula or any bone deformity in the arm/forearm.

Radial artery puncture:

After full explanation to the patients about the procedure and examining the suitability of the target artery, the arm was positioned comfortably for both the patient and operator to ensure puncture success, local infiltration anesthesia was given. The radial artery was punctured with a 21-gauge open needle to obtain a pulsatile blood flow 2–3 centimeters proximal to the styloid process. The wires that are supplied are usually 30-50 cm and often have floppy tip and a more rigid shaft. A dedicated hydrophilic radial sheathes were used in all patients. The

anterior-puncture technique was used in all patients.

Femoral artery puncture:

When obtaining transfemoral access, a single anterior wall puncture is highly desirable. An 18-gauge needle is inserted with the bevel up at a 30–45-degree angle and advanced along the direction of the femoral artery until a good, pulsate blood flow returns. A 0.035 J-tip guide wire is then advanced through the needle into the femoral artery, iliac artery, and descending aorta. If resistance was felt, fluoroscopy was immediately used to visualize the position of the wire.

Adjunctive pharmacological therapy:

As the radial artery is prone to spasm, we used nitroglycerine 100 microgram as an antispasmodic agent whenever hemodynamics permitted. A routine intra-radial infusion of 5,000 units unfractionated heparin (UFH) we given.

Vascular hemostasis:

After the procedure, routine infusion of 50 microgram nitroglycerine were given then the sheath was removed and pressure was held over the arteriotomy site to achieve hemostasis with dedicated trans-radial bands (TRB) used to seal the vascular puncture site for approximately 150 minutes.

For femoral arterial access, manual compression is the most commonly used. Before removing the sheath, the activated clotting time (ACT) should be <180 s for unfractionated heparin.

Primary endpoint:

The chief primary endpoint of our study was procedural success defined as ability to accomplish the procedure (either diagnostic and or intervention) from the assigned puncture site.

Secondary endpoints:

We had many secondary objectives:

Procedural safety: including incidence of hematoma, bleeding and vascular occlusion.

Procedural outcome: as procedural time, number of attempts to access the artery, radiation exposure and amount of contrast.

Major adverse cardiac events: death, myocardial infarction or stroke.

Follow-Up:

- Patients were followed up immediately and one month after the procedure.
- The vessel patency was confirmed by manual palpation and finger pulse oximeter.

Statistical analysis:

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range (IQR).

The used tests were:

1. **Chi-square test:**

For categorical variables, to compare between different groups.

2. **Fisher's Exact or Monte Carlo correction:**

Correction for chi-square when more than 20% of the cells have expected count less than 5.

3. Student t-test:

For normally distributed quantitative variables, to compare between two studied groups.

4. Mann Whitney test:

For abnormally distributed quantitative variables, to compare between two studied groups.

Level of significance:

For all above mentioned statistical tests done, the threshold of significance is fixed at 5% level (p-value), the results were considered:

- Non-significant when $p > 0.05$.
- Significant when $p \leq 0.05$.

The smaller the p-value obtained, the more significant are the results.

Pearson correlation (parametric) and Spearman correlation (non-parametric) was used to correlate continuous data.

Significant variables entered into Logistic regression model using enter statistical technique to predict the most significant determinants and to control for possible interactions and confounding effects. Sensitivity and specificity at different cut off points were tested by roc curve.

RESULTS

Table 1 demonstrates the baseline clinical data of both groups: The mean age was 53.0±8.4 versus 55.8±10.9 years in group I and II respectively, however didn't reach a statistical significance (p= 0.156), whereas there was a non-significant difference among the studied groups regarding gender, risk factors of CAD and laboratory results.

Table 2 displays the procedural characteristics of our patient population: all patients undergone PCI to the infarcted related artery and occasionally to a non-infarcted related artery if it was significantly diseased as directed per guidelines. Success rate was high in both groups (98% versus 96% in TFA opposed to TRA (72% from right radial and 28% left radial) that didn't reach a statistical difference. Owing to early experience of the two operators in the TRA group, the attempt trials to puncture the radial artery and fix the radial sheath was bit higher as opposed to TFA, however, it didn't reach the statistical significance (p= 0.083).

The total procedure time was significantly shorter in TFA group as compared to TRA (42.2 ± 16.8 versus 77.4 ± 27.1 minutes, p= 0.001), the amount of contrast usage was greater in TRA (157.4 ± 10.8 versus 181.2 ± 16.7 milliliter, p=0.001) as well as longer fluoroscopic time (8.74 ± 3.8 versus 18.64 ± 7.1-minute, p=0.001).

Table 3 documents the low incidence of major and minor complications reported in both groups as hematoma, or limb ischemia, death and/or stroke, with no significant difference between both groups.

Table 4 illustrates the significant increase in ejection fraction in both femoral and radial groups after one month follow up. Bedside echo for femoral group showed mean EF of 54.30 ± 4.34. After one month showed significant increase to become 55.76 ± 4.25. Bedside echo for radial group showed mean EF of 52.50 ± 4.31. After one month showed significant increase to become 64.26 ± 75.25.

Table (1): Baseline criteria among the studied groups

Variable	Group I (n=50)	Group II (n=50)	P value
Age (years)	53.02±8.44	55.82±10.99	0.156
Male Gender (%)	84	80	0.603
Smoking (%)	68	62	0.529
DM (%)	34	38	0.677
HTN (%)	36	46	0.309
Dyslipidemia (%)	58	40	0.072
Prior MI (%)	6.0	16	0.032
Prior PCI (%)	8.0	20	0.110
INR	1.05±0.07	1.06±0.09	0.414
Hb	12.36±1.65	11.88±1.39	0.119
Platelets	254.2±68.19	252.6±63.30	0.912

DM: diabetes mellitus. HTN: hypertension. MI: myocardial infarction. PCI: percutaneous coronary intervention.

Table (2): Procedural characteristics of both groups

Variable	Group I (n=50)	Group II (n=50)	P value
Successful procedure	49 (98%)	48 (96%)	1.00
Number of attempts	1 (41) 2 (8) 3 (1)	1 (31) 2 (16) 3 (3)	0.083
Procedure time (minutes)	42.22 ± 16.81	77.46 ± 27.16	<0.001
Amount of dye (milliliter)	157.4 ± 10.84	181.2 ± 16.74	<0.001
Radiation time (minutes)	8.74 ± 3.84	18.64 ± 7.16	<0.001

Table (3): Procedural complications and patient satisfaction for both groups

Variable	Group I (n=50)	Group II (n=50)	P value
Minor Hematoma	7 (14%)	4 (8%)	0.160
Major Hematoma	1 (2%)	0 (0%)	1.000
Perforation or dissection	0 (0%)	0 (0%)	--------
Artery Spasm	0 (0%)	2 (4%)	0.495
Vasovagal	1 (2%)	1 (2%)	0.99
Nerve Injury	0 (0%)	0 (0%)	------
CVA	1(2%)	1(2%)	^{FE}p=1.000
Death	0(0%)	0(0%)	-

Table (4): Comparison between the two studied groups according to EF

EF	Group I (n=50)	Group II (n=50)	U	p
Bedside Echo				
Min. – Max.	45.0 – 62.0	40.0 – 65.0	972.50	0.053
Mean ± SD.	54.30 ± 4.34	52.50 ± 4.31		
Median (IQR)	54.50 (50.0–58.0)	52.50 (50.0–55.0)		
One month later				
Min. – Max.	48.0 – 65.0	45.0 – 585.0	917.0*	0.020*
Mean ± SD.	55.76 ± 4.25	64.26 ± 75.25		
Median (IQR)	55.0(53.0 – 60.0)	54.0(50.0 – 55.0)		
p1	<0.001*	<0.001*		

DISCUSSION

The current study demonstrated that the transradial access (TRA) has a similar efficacy as opposed to transfemoral access (TFA). A similar high success rate has been observed in many randomized and non-randomized controlled studies conveying the TRA would be an appealing alternate to the femoral access for coronary angiography and interventions either in acute and elective situations[4,9,10]. Despite a similar efficacy compared to TFA, the TRA requires a learning curve that is different from operator to another based on many parameters as prior experience with the TFA. Our learning curve was namely in longer cannulation time, which is a period from giving local anesthesia until fixing the radial sheath that disclosed frequent attempts to insert the radial sheath compared to the TFA, however, this duration didn't reach the statistical significance.

The total procedure as well as fluoroscopic time was significantly prolonged in TRA group in our study consistent with other studies[11,12], however, many other studies that enrolled large number of patients have definitely revealed no significant difference in the procedure time, fluoroscopic duration and amount of contrast, most likely attributed to building up a learning curve[7,8].

One of the most salient advantage of the TRA compared to TFA is scarcity of local vascular complications, our study documented numerically less local vascular events as minor and major hematomas, however didn't reach statistical significance most likely due to small sample size, fundamentally many analyses have shown similar reduction of the complication rate consistent with our findings but with a significant statistical difference[13,14]. Being more superficial, the radial artery is easy to be compressed ensuing expected reduction in local vascular complications namely hematoma, moreover, radial artery is considerably smaller compared to femoral artery that added profit in reducing hematomas. The major cardiovascular adverse events including death, pulmonary edema and cerebrovascular stoke were not identifiable in both groups demonstrating high safety profile of both accesses and goes with the many studies[7,15].

Early one month follow up of our studied patients in both groups showed significant functional improvement that was coupled with escalation of the ejection fraction. The major and minor bleeding complications had almost subsided in both groups apart from minimal bruising and pain at the groin of few patients[15].

LIMITATIONS OF THE STUDY

The study represents our early experience in transradial access compared to trans-femoral approach in STEMI population and included a relatively small sample size. We followed our patients for one month post event and PCI, a longer duration would gather more information about the patients, however, was sufficient enough to illustrate the early outcome and postulate the patients requiring strict follow up. We excluded all patients presented with cardiogenic shock and patients with prior coronary bypass surgery, such patients represent a

challenge to be performed via TRA. Future studies are required to include such high risk and technically challenging cases.

CONCLUSION AND RECOMMENDATIONS

Our study demonstrated a similar efficacy profile of transradial approach as compared to transfemoral one in patients presenting with ST segment elevation myocardial infarction. Despite numerically less complications in the TRA group, however, it didn't reach the statistical significance. A learning curve was evident at the end of the study. Because of early ambulation and less bleeding risk, TRA considered as an appealing alternative to TFA in all acute coronary syndrome/STEMI patients.

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دراسة مقارنة بين نهج الشريان الكعبري ونهج الشريان الفخذي في التداخل الإكلينيكي عبر الجلد لمرضي جلطة القلب الحادة نتيجة ارتفاع قطعة ال إس تي

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هدف البحث: تقييم درجة أمان وفاعلية القسطرة القلبية التداخلية في حالات جلطات القلب الحادة عن طريق الشريان الزندي مقارنة بالشريان الفخذي.

الجزء العملي من البحث: اجريت هذه الدراسة على 100 مريض ممن خضعوا لأجراء القسطرة التشخيصية أو العلاجية بهدف تقييم جدوى وسلامة قسطرة الشرايين التاجية التشخيصية والعلاجية في مستشفى جامعة الأزهر ومركز قلب المحلة وقد تم تقسيم المرضي بصورة عشوائية الي مجموعتين: شملت المجموعة الاولي 50 مريض اجريت لهم القسطرة التشخيصية او العلاجية عن طريق الشريان الفخذي اما المجموعة الثانية فشملت 50 مريض عن طريق الشريان الزندي وذلك بعد تدوين التاريخ المرضي واجراء التقييم السريري لجميع المرضي.

نتائج البحث: أظهرت النتائج ان غابية الحالات التي خضعت لهذه الدراسة كانوا من الذكور بنسبة (84%), متوسط العمر كان 53 سنة تقريبا، كان التدخين العامل الخطر السائد يليه ارتفاع الكوليسترول في الدم ثم ارتفاع ضغط الدم واخيرا مرض السكري في كلا المجموعتين

ف هذه الدراسة كانت نسبة نجاح اجراء قسطرة الشرايين التشخيصية والعلاجية عن طريق الشريان الفخذي حوالي (100%) بينما وصلت نسبة النجاح الي (98%) من المرضي الذين خضعوا لمثل هذا الاجراء عن طريق الشريان الزندي.

اظهـرت دراسـتنا عـدم حـدوث مضـاعفات كبـري فـي الحـالات التـي خضـعت لإجـراء التـدخل عـن طريـق الشـريان الزنـدي بينمـا حـدثت حالـة ارتشـاح رئـوي فـي الحالات التي خضعت لإجراء التدخل عن طريق الشريان الفخذي.

فيمـا يتعلـق بـزمن التصـوير الفلـور وسـكوبي لـم تكـن هنـاك اختلافـات كبيـرة بين اجراء القسطرة التشخيصية والعلاجية عن طريق الشريان الزندي او الفخذي.

امـا المـدة الكليـة للقسـطرة التشخيصـية او العلاجيـة فقـد كانـت اطـول فـي الشريان الزندي عنها في الشريان الفخذي بصورة لا تمثل قيمة احصائية.

الخلاصـة: اسـتخدام الشـريان الزنـدي فـي اجـراء القسـطرة التشخيصـية والعلاجيـة بديل أمن وفعال ولم ينتج عنه حدوث مضاعفات كبرى.