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Radial versus Femoral Approach for STEMI Patients Undergoing Primary or Rescue PCI: Alexandria University Experience

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Abstract

Background: Radial access for primary or rescue percutaneous coronary intervention (PCI) became the standard of care approach in most of the PCI capable centers and it is currently recommended by most recent guidelines as the vascular access of choice for performing such interventions being more convenient for the patient and associated with less bleeding complications and shorter hospital stay.

Aim of Study: To compare both transradial and transfemoral approaches in primary percutaneous coronary intervention (PCI) and rescue PCI for STEMI in two Primary PCI capable centers in Alexandria, Egypt.

Patients and Methods: This prospective observational study was done at Alexandria University Hospital and International Cardiac Center in the period between January 2020 and August 2020 by recruiting every patient who had met the study inclusion criteria (STEMI according to the third universal definition of MI) and admitted to the coronary care unit after undergoing primary or rescue PCI. 200 patients were included.

The patients were divided into two equal groups randomly assigned to either radial access approach or femoral access approach for primary or rescue PCI. Chest pain to time of first medical contact (FMC), and the procedural time were calculated. Coronary angiography and PCI procedure were described including materials used and the procedure complications. MACE (Major Adverse Cardiac Events) or other hemodynamic complications were documented. All the patients were followed-up for 6 months after the procedure by interviewing with the patients via telephone or through the responsible physician to determine the outcomes procedure.

Results: The 2 groups were well matched concerning the demographic variables and risk factors. There had been significant differences between the groups concerning the primary end point (MACE) after 6 months in favor of radial group patients with p-value (0.004). Furthermore, there was significant difference between the two studied groups concerning the total bleeding complication with higher risk in femoral group (11%) compared to radial group (3%), p-value (0.02).

The total procedural time was significantly longer in radial group compared to femoral group with (p-value 0.037). However, the rate of non-culprit vessel revascularization was significantly higher in radial group 17% compared to 6% in femoral group with p-value of (0.015). In-hospital stay was significantly shorter in the radial group patients.

Conclusion: Transradial approach is safe, and effective with a high procedural success rate as the transfemoral approach but with lower risk for bleeding. Transradial approach has additional advantages in decreasing the incidence of MACE and shortening the hospital stay compared to transfemoral approach.

Key Words: *STEMI – Primary percutaneous coronary interventions – Rescue PCI – MACE – Bleeding – Radial – Femoral.*

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Introduction

CORONARY artery disease (CAD) is the single most common cause of death and its prevalence is increasing all over the world **[1]**. In patients with ischemic heart disease (IHD) who develop acute coronary syndromes (ACS), ST segment elevation myocardial infarction (STEMI) is the most serious presentation **[2,3]**. Primary percutaneous coronary intervention (PCI) in STEMI have the ability of achieving reperfusion of the infarct-related vessel with less bleeding risk **[4]**.

In patients with acute STEMI, PCI has a mortality benefit **[5]**. Moreover, antithrombotic medications are also shown to improve mortality **[6]**. However, they increase the bleeding risk which increases the mortality, and may reduce the benefits of those therapies **[7]**. Therefore, every effort to reduce the bleeding risk in acute STEMI is needed, as it could reduce morbidity, mortality, and financial costs **[8,9]**.

Femoral access for PCI seems to be associated with a higher bleeding risk **[7]**. In comparison with the femoral artery, the radial one is smaller and

more superficial, easy compressible, safe and better for hemostasis, do not necessitate long rest in the bed which allowed early ambulation, more patient comfort, and earlier hospital discharge. These could be translated into less hospitalization costs and better quality of life **[6,10]**.

However, the radial access could be challenging due to difficult puncture in some patients, lack of support during coronary artery engagement, longer procedural duration, or occasionally procedural failure, all these factors raise the concerns to whether radial access is beneficial where timely reperfusion is critical **[6,11]**.

The aim of the current study was to compare transradial and transfemoral approaches in primary and rescue PCI for STEMI.

Patients and Methods

This prospective observational study was approved by the Ethical Committee of Alexandria University Hospital. An informed written consent was obtained from all patients. To be included in the study, every patient had to fulfill the inclusion criteria and was admitted in the coronary care unit after doing primary or rescue PCI at Alexandria main University Hospital and International Cardiac Center (ICC) in the period between January 2020 to August 2020. Two hundred patients were included.

Primary PCI was done for patients who had rise and/or fall of cardiac biomarker values (preferably troponin) with at least one value above the 99th percentile of the upper reference limit (URL) and with at least one of the following: **[12]**

- Ischemic symptoms which persisted more than 30 minutes but less than 24 hours.
- New or presumably new significant ST-T changes or new left bundle branch block (LBBB).
- Pathological Q waves development of in the electro- cardiogram (ECG).
- Imaging evidence of new loss of viable myocardium, or new regional wall motion abnormality.

Rescue PCI was done for all patients if failed fibrinolysis:

- Less than 50% ST-segment resolution within 60-90 min of fibrinolytic therapy.
- Instability whether hemodynamic or electrical or persistent chest pain **[13]**.

Exclusion criteria:

- Thrombophilia and thrombocytopenia.
- Known hematological disease.
- Patients who had significant peripheral arterial disease.

Randomization was made by a computer-generated program into two equal groups and assigned to either radial or femoral approach for primary or rescue PCI. Chest pain to time of first medical contact (FMC), time of FMC to STEMI diagnosis and time from STEMI diagnosis to reperfusion (puncturing time, from end of puncturing to vessel engagement, and the procedural time were reported).

Coronary angiography and PCI procedure were described including materials used and the intra-procedure complications were also documented. Patients were kept under observation after the procedure to detect the occurrence of any in-hospital major adverse cardiac events (MACE) or bleeding complications. All the patients were followed-up for 6 months after the procedure by telephone call or or through the responsible physician to report the outcomes.

Thrombolysis in myocardial infarction (TIMI) definition of bleeding in CABG settings was used as the following **[14]**:

Major: Any intracranial bleeding (excluding microhemorrhages <10mm evident only on gradient-echo MRI), clinically overt signs of hemorrhage associated with a drop in hemoglobin of ›_5g/dL or a ›_15% absolute decrease in haematocrit or fatal bleeding (bleeding that directly results in death within 7d).

Minor: Clinically overt (including imaging), resulting in hemoglobin drop of 3 to <5g/dL or ≥10% decrease in haematocrit, no observed blood loss: ›_4g/dL decrease in the haemoglobin concentration or ≥12% decrease in haematocrit, any overt sign of hemorrhage that meets one of the following criteria and does not meet criteria for a major or minor bleeding event, as defined above.

- Requiring intervention (medical practitioner-guided medical or surgical treatment to stop or treat bleeding, including temporarily or permanently discontinuing or changing the dose of a medication or study drug).
- Leading to or prolonging hospitalization.
- Prompting evaluation (leading to an unscheduled visit to a healthcare professional and diagnostic testing, either laboratory or imaging).

Minimal: Any overt bleeding event that does not meet the criteria above, any clinically overt sign of haemorrhage (including imaging) associated

with a <3g/dL decrease in haemoglobin concentration or <9% decrease in haematocrit **[14]**.

Statistical analysis of the data:

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, and standard deviation, median and interquartile range (IQR). Significance of the obtained results was judged at the 5% level.

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.

Results

Considering the gender, males represented 82% of the radial group and 83% of the femoral group. Hypertension was the most frequent clinical risk factor in STEMI patients, representing 63% in radial group compared to 66% in femoral group. Another important clinical risk factor was diabetes mellitus that was found in 43% and 45% in radial and femoral groups, respectively. Dyslipidemia was found in 46% of radial group patients compared to 43% of femoral group patients. No statistically significant difference between both groups concerning the gender, presence of diabetes mellitus, hypertension or dyslipidemia.

There were no statistical differences between groups regarding demographics or risk factors (Table 1). The mean days for hospital stay was 3.13± 1.8 in the radial group compared to 3.82± 2.24 in the femoral group, with significant difference between them in favor of radial group ($p<$ 0.001).

Patients presented with cardiac arrest were not excluded from our study they represent 8% in the radial group and 7% in the femoral one. Cardiogenic shock represented 7.0% in radial group and 9% in femoral group without significant differences.

In the present study rescue PCI was performed in 11 % of the radial group and 10% of femoral group patients. There were non-significant differences between both groups concerning the angiographic data (number of diseased vessels, infarct-related artery, and initial TIMI flow in the culprit). Procedural success (Table 3) of transradial coronary intervention was 93% compared to 92% in transfemoral approach with no significant difference.

Despite the nearly equal mean time from pain to FMC (9.01 hours in radial group and 9.2 hours in femoral group), the total procedural time was significantly longer in radial group compared to femoral group with p-value of 0.037. This prolonged time in the radial group in our study could be explained by the higher rate of non-culprit vessel revascularsation as it was 17% in radial group compared to 6% in femoral group (p-value 0.015).

There was no significant difference between both groups regarding the mean time from puncture to engagement and the mean contrast volume.

Three patients from the radial group (3%) crossed over to the femoral group one patient had inadequate guide catheter support, one patient developed recurrent spasm on the catheter and the third patient had radial artery puncture failure.Two patients from the femoral group were shifted to radial group due to aorto-iliac disease. We observed no significant difference between both groups concerning the rate of cross over.

No significant difference between both groups regarding the incidence of target vessel MI, stroke and death.

Concerning MACE (Table 2 and Fig. 1) which was the primary outcome, there was significant difference between both groups in favor of the radial approach with p-value (0.030). Four patients died in this study from the radial group (4%) compared to 5 patients (5%) in femoral group. One patient developed target vessel reinfarction in radial group compared to five patients in the femoral group. One patient underwent target vessel revascularization in radial group compared to four patients in femoral group.

Regarding the local vascular complications (Fig. 2), only one patient (1%) in the radial group suffered from minor puncture site complication in the form of small hematoma. However, six patients (6%) in the femoral group suffered from access site complications (4 patients had groin hematoma, while one had AV fistula and one had retroperitoneal hematoma).

In the present study there was significant deference between the two studied groups concerning the total bleeding complication with higher risk in femoral group 11% compared to radial group 3% with p-value (0.02).

Table (1): Radial versus femoral medical history demographic and clinical data and hospital stay.

	Radial group (100)	Femoral group (100)
Demographic data:		
Age, mean (SD), y	58.74 (9.80)	58.40 (11.26)
Male sex, No. (%)	82 (82.0)	83 (83.0)
Medical history, No. (%):		
Hypertension	63 (63.0)	66 (66.0)
Hyperlipidemia	46 (46.0)	43 (43.0)
Diabetes mellitus	43 (43.0)	45 (45.0)
Previous MI	5 (5.0)	3 (3.0)
Previous CABG	1 (1.0)	1 (1.0)
Smoking	59 (59.0)	53 (53.0)
Hospital stays in days Mean ± SD	3.1±1.88	3.82±2.24 (p<0.001)
Clinical data:		
Systolic blood pressure Mean (SD), mm Hg	114.30 (19.86)	114.70 (17.26)
Diastolic blood pressure Mean (SD), mm Hg	71.50 (13.66)	71.60 (12.61)
Heart rate Mean (SD), bpm	72.65 (12.11)	73.80 (14.89)
Shock No. (%)	7 (7.0)	9 (9.0)

SD : Standard deviation.
MI : Myocardial infarction.
CABG : Coronary artery bypass grafting.
bpm : Beat per minutes.

Table (2): Radial versus femoral outcome and complications.

Diabetes mellitus	43 (43.0)	45 (45.0)
Previous MI	5 (5.0)	3 (3.0)
Previous CABG	1 (1.0)	1 (1.0)
Smoking	59 (59.0)	53 (53.0)
Hospital stays in days Mean ± SD	4.7 (3.2)	7.7 (4.06)
Clinical data:		
Systolic blood pressure Mean (SD), mm Hg	114.30 (19.86)	114.70 (17.26)
Diastolic blood pressure Mean (SD), mm Hg	71.50 (13.66)	71.60 (12.61)
Heart rate Mean (SD), BPm	72.65 (12.11)	73.80 (14.89)
Shock No. (%)	7 (7.0)	9 (9.0)

Table (3): Comparison between the two studied groups according to PCI procedures.

	Radial group (100)	Femoral group (100)	(Xi) chi square
	No. (%)	No. (%)	(p) p-value
Primary Endpoint:			
MACE at the 6th month	7 (7.0)	17 (17.0)	4.735 (0.030)
Major Bleeding	0 (0.0)	2 (0.2)	2.020 (0.497)
Death	4 (4.0)	5 (5.0)	0.116 (1.000)
TV reinfarction	1 (1.0)	5 (5.0)	2.749 (0.212)
TVR	1 (1.0)	4 (4.0)	1.846 (0.369)
Stroke	1 (1.0)	1 (1.0)	0.00 (1.000)
Secondary Endpoint:			
Total bleeding	3 (3.0)	11 (11.0)	4.916 (0.027)
Fatal bleeding	1 (1.0)	1 (1.0)	0.000 (1.000)
Major bleeding	0 (0.0)	2 (2.0)	2.020 (0.497)
Minor bleeding	0 (0.0)	3 (3.0)	3.046 (0.246)
Minimal bleeding	2 (2.0)	5 (5.0)	1.332 (0.445)
Cross over	3 (3.0)	2 (2.0)	0.205 (FEp=1.000)
Other complications:			
CIN	6 (6.0)	7 (7.0)	0.082 (0.774)
Dialysis	0 (0.0)	1 (1.0)	1.005 (1.000)
TPM insertion	0 (0.0)	2 (2.0)	2.020 (0.497)
Access site complication	1 (1.0)	6 (6.0)	3.701 (0.118)
Drug balloon	1 (1.0)	1 (1.0)	χ^2=0.0 (FEp=1.000)
Thrombus aspiration	16 (16.0)	14 (14.0)	0.157 (0.692)
Direct stenting	21 (21.0)	17 (17.0)	0.520 (0.471)
Post dilatation	69 (69.0)	79 (79.0)	χ^2=2.599 (0.107)
Dissection	1 (1.0)	2 (2.0)	χ^2=0.338 (FEp=1.000)
No reflow	11 (11.0)	12 (12.0)	χ^2=0.049 (0.825)
Final TIMI flow in culprit:			
0	0 (0.0)	2 (2.0)	χ^2=2.022 (MCp=0.722)
1	2 (2.0)	2 (2.0)	χ^2=2.022 (MCp=0.722)
2	3 (3.0)	2 (2.0)	χ^2=2.022 (MCp=0.722)
3	95 (95.0)	94 (94.0)	χ^2=2.022 (MCp=0.722)
Angiographic success	98 (98.0)	96 (96.0)	χ^2=0.687 (FEp=0.683)
Procedural success	93 (93.0)	92 (92.0)	χ^2=0.072 (0.788)

TMI: Thrombolysis in myocardial infarction.

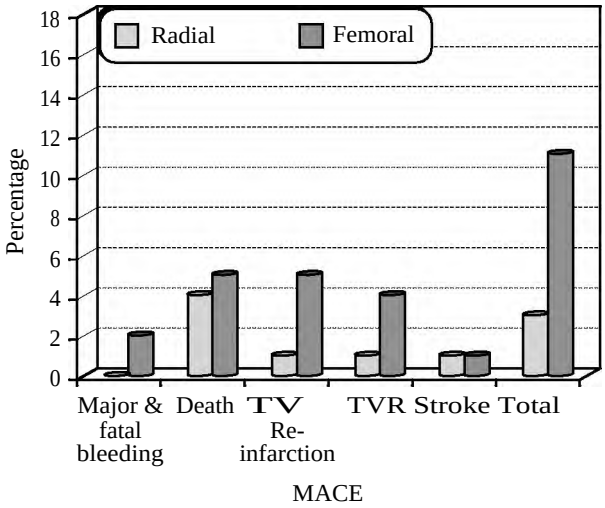

Fig. (1): Comparison between the two studied groups according to Major adverse cardiovascular events (MACE).

TV: Target vessel, TVR: Target vessel revascularization.

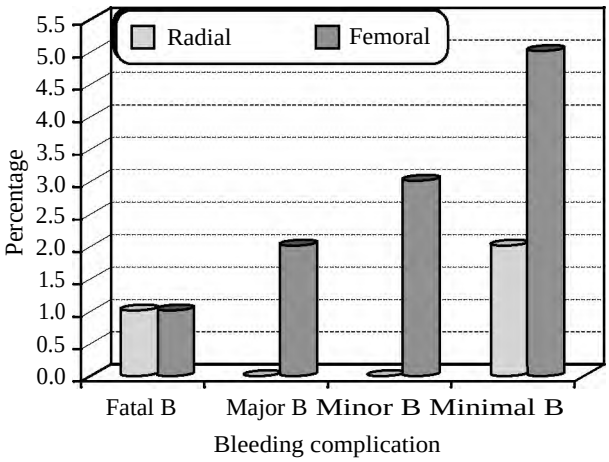

Fig. (2): Comparison between the two studied groups according to bleeding complication, TIMI definition of bleeding was used [14].

Discussion

Primary PCI has a mortality benefit among patients presenting with STEMI, especially when added to the optimal antithrombotic therapy. However, the bleeding complications remain an important issue that have been associated with increased mortality [15]. Fibrinolysis still has its role for patients presenting with STEMI where the expected primary PCI delay is likely to exceed 120min. [16].

In case of thrombolytic failure, rescue PCI is highly recommended [17]. However, risk of bleeding complications is likely to be greater in those who received fibrinolytic therapy [18,19]. The majority of bleeding problems related to the procedure came from the arterial puncture site. Therefore, the radial approach gained much interest as it reduced access site-related complications [20,21].

In the present study, rescue PCI were performed in 11 % of radial group and 10% of femoral group patients. In the study of Bernat I, et al., [22], and Valgimigli M, et al., [9], rescue PCI patients were not included. The inclusion of those patients in the present study could be explained by limited 1ry PCI capable centers. Moreover, it enabled us to study the differences between femoral and radial approaches concerning the bleeding risks associated with thrombolytic therapy.

In the present study, procedural success of transradial approach was 93% compared to 92% in transfemoral approach with no significant difference between both approaches. This was close to what was reported by Bernat I, et al., in the STEMI-RADIAL Trial where angioplasty was successful in 97% in radial group and 96% in femoral group patients. Moreover, Valgimigli M, et al in MATRIX trial reported procedural success of 93.7% in radial group and 93.9% in femoral group [9].

In the present study, despite the nearly equal mean time from pain to FMC (9.01 hours in radial group and 9.2 hours in femoral group), the total procedural time was significantly longer in radial group compared to femoral group (p-value 0.037). Bernat I, et al., [22] reported no significant difference between the 2 groups concerning the procedural time, this prolonged time for the radial group in our study could be explained by the higher rate of non-culprit vessel revascularsation as it was 17% in radial group compared to 6% in femoral group (p-value 0.015).

In the current study, concerning MACE over 6 months of follow-up, it was less with the transradial (p-value 0.030). Four patients died in this study from the radial group (4%) compared to 5 patients (5%) in femoral group. One patient developed target vessel reinfarction in radial group compared to five patients in the femoral group, only one patient underwent target vessel revascularization in radial group compared to four patients in femoral group.

TEMPURA Trial, showed no statistically significant differences between both groups over 6 months of follow-up concerning the composite MACE-free survival [23].

Regarding the local vascular complications in the present study, only one patient (1%) in the radial group suffered from minor puncture site complication in the form of small hematoma. However, six patients (6%) in the femoral group suffered from access site complications. These results were

consistent with the results of other trials showing the lower incidence of local vascular complications with the transradial approach in STEMI. Valgimigli M **[9]** et al., reported access site complication of 0.3% in radial group compared to 0.8% in femoral group, and this was close to the findings of Bernat I, et al., **[22]**.

In the present study there was significant deference between the two studied groups concerning the total bleeding complication with higher risk in femoral group (1 1%) compared to 3% in the radial group (*p*-value 0.02). This could be explained by the inclusion of patients who received thrombolytic therapy, which had increased the risk of bleeding specially in femoral group patients due to difficulties in femoral artery homeostasis compared to radial artery. Valgimigli M, et al., **[9]** reported that bleeding events fulfilling the TIMI criteria did not differ significantly between groups as patients received streptokinase were excluded.

Conclusion:

We concluded that in patients with STEMI undergoing primary or rescue PCI, the transradial approach is safe, effective with a high procedural success rate as the transfemoral approach but with lower risk for bleeding. Transradial approach has major additional advantages of decreasing the incidence of MACE compared to transfemoral approach. Transradial approach has another advantages of decreasing the in hospital stay.

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النهج الشعاعى مقابل النهج الفخذى لمرضى احتشاء عضلة القلب الذين يخضعون للقسطرة القلبية الأولية أو الانقاذية؛ تجربة جامعة الإسكندرية

الهدف من الدراسة : لمقارنة كل من النهج عبر الشعاع والفخذ فى التدخل التاجى الأولى عن طريق الجلد فى مرضى احتشاء عضلة القلب فى مركزين قادرين على التدخل التاجى عبر الجلد فى الإسكندرية، مصر.

مرضى وطرق : تم إجراء هذه الدراسة فى جامعة الإسكندرية فى الفترة ما بين يناير ٢٠٢٠ وأغسطس ٢٠٢٠ من خلال ضم كل مريض استوفى معايير تضمين الدراسة وتم دخوله وحدة العناية بعد الخضوع للقسطرة الأولية أو الإنقاذ تم تضمين ٢٠٠ مريض.

تم تقسيم المرضى إلى مجموعتين متساويتين تم تعيينهما إما لنهج الوصول الشعاعى أو نهج الوصول الفخذى من أجل القسطرة الأولية أو الإنقاذ. تمت متابعة جميع المرضى لمدة ٦ أشهر لتحديد النتائج.

نتائج : كانت هناك فروق ذات دلالة إحصائية بين المجموعات فيما يتعلق بالنتائج من حيث حدوث المضاعفات بعد ٦ أشهر لصالح مرضى المجموعة الشعاعية. علاوة على ذلك، كان هناك فرق معنوى بين المجموعتين المدروستين فيما يتعلق بمضاعفات النزف الكلى أيضاً لصالح المجموعة الشعاعية.

خاتمة : النهج عبر الشرايين الشعاعية آمن وفعال مع معدل نجاح إجرائى مرتفع مثل النهج عبر الفخذ ولكن مع مخاطر أقل للنزيف. النهج عبر الشعاع له مزايا إضافية فى تقليل الإقامة فى المستشفى مقارنة بالنهج عبر الفخذ.