

## Radial versus Femoral Access in Patients with Acute Coronary Syndrome

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### ABSTRACT

**Background:** Acute coronary syndrome (ACS) necessitates immediate and efficient management, often using percutaneous coronary intervention (PCI) as a popular treatment method. The selection of the access site, whether it is transradial access (TRA) or transfemoral access (TFA), may have a substantial effect on clinical results.

**Objective:** This study aimed to compare TRA and TFA in terms of PCI-related bleeding complications, access site complications, procedural duration, and hospital mortality in ACS patients undergoing PCI.

**Patients and Methods:** A prospective, randomized, controlled trial was conducted on a total of 150 patients presenting with ACS indicated for PCI. They were randomized into two groups: 75 patients in the TRA group and 75 patients in the TFA group. Primary outcomes were bleeding complications and major adverse cardiac events (MACE). Secondary outcomes included cardiovascular death, stent thrombosis, and urgent revascularization.

**Results:** Hematoma occurred significantly more in the TFA group (13.3%) compared to the TRA group (0%) ( $P = 0.001$ ). The incidence of MACE was higher in the TFA group (13.3%) than in the TRA group (6.7%) but without statistical significance ( $P = 0.174$ ). Multivariate logistic regression analysis revealed that femoral access was associated with a non-significant two-fold increased risk of MACE (OR = 2.181, 95% CI: 0.697–6.824,  $P = 0.18$ ).

**Conclusion:** TRA is associated with fewer hematoma complications and a trend toward lower MACE compared to TFA in ACS patients undergoing PCI. TRA may be preferred for reducing access site complications.

**Keywords:** Acute coronary syndrome; Transradial access; Percutaneous coronary intervention; Transfemoral access; Major adverse cardiac events.

### INTRODUCTION

Cardiovascular illnesses are a global health concern that has a considerable influence on rates of illness and death. Over time, there have been significant advancements in the care of acute coronary syndrome (ACS), and percutaneous coronary intervention (PCI) is now widely acknowledged as a crucial therapeutic approach [1]. Originally, percutaneous coronary intervention (PCI) was often conducted using the transfemoral approach (TFA). However, this method has been mostly substituted by the transradial approach (TRA) because of its enhanced safety, efficacy, and practicality [2,3].

Coronary angiography and PCI are widely regarded as the most effective methods for addressing blockages in ST-segment elevation myocardial infarction (STEMI). TRA has gained popularity as the preferred approach for vascular access over TFA. Multiple international cardiology guidelines strongly suggest TRA for STEMI therapies [4].

The advantages of TRA in STEMI include a decrease in significant bleeding, a reduction in access site problems, and a possible decrease in overall mortality after primary PCI [5].

The growing preference for the transradial approach is attributed to its lower vascular complication rates, increased patient comfort, earlier discharge, shorter hospital stays, and quicker ambulation [6]. Despite its high success rate, which can be as high as 90% in some populations, TRA is not without its challenges. Issues can arise due to the smaller size of the radial artery and the possibility of arterial occlusion following the procedure [7]. Although the right radial route is most commonly used due to procedural

familiarity, the left radial route is also viable [6,8]. However, one criticism of TRA is the longer procedure and fluoroscopy times, which increase radiation exposure for catheterization laboratory staff [9].

The most recent recommendations from the European Society of Cardiology state that TRA should be the preferred method for all PCI operations, regardless of the patient's clinical condition, unless there are particular reasons to choose another route [10]. When considering coronary artery disease and ACS, TRA has shown to decrease short-term negative clinical events, cardiac death, overall mortality, hemorrhage, and problems related to accessing the site, in comparison to TFA. In addition, TRA has many advantages, such as reduced problems at the access site, improved patient comfort, earlier ability to walk, and shorter hospital stays [11].

This study aimed to compare the TRA and the TFA in terms of PCI-related bleeding complications, access site complications, procedural duration, and hospital mortality in acute coronary syndrome patients who underwent PCI.

### PATIENTS AND METHODS

#### Study Design and Population:

This study was a prospective, randomized, controlled experiment done at a tertiary care hospital between January 2023 and December 2023. A cohort of 150 patients diagnosed with ACS, including STEMI, NSTEMI, and unstable angina, who required PCI were included.

#### Inclusion and Exclusion Criteria:

Inclusion Criteria: Patients were eligible if they presented with any of the following conditions: STEMI,

NSTEMI, unstable angina, or STEMI equivalent, and were indicated for PCI. Both male and female patients of any age, with or without a history of previous myocardial infarction (MI), were included.

**Exclusion Criteria:** Exclusion criteria included patients with previous coronary artery bypass graft (CABG), history of complications from previous catheterization access sites, diagnosed peripheral vascular disease, chronic kidney disease (CKD) stage 3 or higher, and ongoing acute or uncontrolled chronic infections.

#### **Study Groups:**

Patients were randomized into two groups: TRA Group: 75 patients underwent PCI through radial access and TFA Group: 75 patients underwent PCI through femoral access.

#### **Data Collection**

Data collection included detailed demographic information, medical history, and baseline clinical characteristics such as age, sex, comorbidities (DM, HTN), smoking status, and family CAD history. HTN and DM were defined according to established criteria, and smoking status was recorded based on recent tobacco use.

#### **Clinical Examination and Investigations**

Patients underwent a complete clinical examination including heart rate, blood pressure, chest and heart examination, and assessment for signs of HF. Investigations included electrocardiographic examination (assessing ST elevation or depression, T-wave changes, resting heart rate, and atrial fibrillation) and laboratory tests (including complete blood count, serum creatinine, troponin, and CK-MB levels).

#### **Baseline Electrocardiography and Echocardiography:**

Baseline ECG was performed to detect patterns indicative of STEMI, NSTEMI, or unstable angina. Echocardiography was conducted with simultaneous ECG recording, capturing two-dimensional cine loops from standard views, and measurements were obtained according to guidelines from the American Society of Echocardiography/European Association of Cardiovascular Imaging.

#### **PCI Intervention:**

##### **Transradial Access (TRA) Procedure:**

TRA involved verifying the presence of an appropriate pulse, using IV midazolam and sublingual trinitroglycerin to minimize stress and arterial spasm, and performing the puncture and sheath insertion with a spasmolytic cocktail and anticoagulant. Hemostasis was achieved through compression and bandage packs.

##### **Transfemoral Access (TFA) Procedure:**

TFA involved local anesthesia, femoral artery puncture, sheath insertion, and catheter advancement under fluoroscopic guidance. Post-procedure hemostasis was achieved through compression or closure devices, and patients were monitored for

complications with delayed mobilization compared to TRA.

#### **Follow-Up and Outcomes:**

Patients were followed up during their hospital stay. Primary outcomes included any bleeding requiring medical intervention (PLATO major or minor bleeding) and MACE, which included MI, stroke, and PLATO major or minor bleeding. While, secondary outcomes included the individual components of the net clinical benefit outcome, definite stent thrombosis, cardiovascular death, urgent revascularization, unstable angina, and transient ischemic attack.

#### **Sample size calculation:**

G\*Power software version 3.1.9.7 was used to estimate the required sample size according to **Romagnoli *et al.***, with a significance level of 0.05 and a type II error of 0.2<sup>[12]</sup>. The minimal required sample size was 130 participants.

#### **Ethical considerations:**

**The study was done after being accepted by the Research Ethics Committee, Benha University. All patients provided written informed consents prior to their enrolment. The consent form explicitly outlined their agreement to participate in the study and for the publication of data, ensuring protection of their confidentiality and privacy. The research has been conducted in compliance with the World Medical Association's Code of Ethics (Declaration of Helsinki) for studies involving human subjects.**

#### **Data Management:**

The data management and statistical analysis for this investigation were performed using SPSS version 28 (IBM, Armonk, New York, USA). The normality of quantitative data was assessed using the Kolmogorov-Smirnov test, as well as direct data visualization approaches. Quantitative data were reported either as means with standard deviations or as medians with ranges, based on the normality findings. The categorical data were shown as frequencies and percentages. In order to compare quantitative data across groups, the independent t-test was used for variables that followed a normal distribution, whilst the Mann-Whitney U test was applied for variables that did not follow a normal distribution. Comparisons of categorical data were conducted using the Chi-square test. For the purpose of predicting MACE, a multivariate logistic regression analysis was conducted, resulting in the calculation of odds ratios and 95% confidence intervals. The statistical tests conducted were two-tailed, and a P-value below 0.05 was considered to indicate statistical significance.

## **RESULTS**

### **Demographics**

The studied groups were comparable regarding age, sex, DM, hypertension, family history of CAD, smoking, and chest pain (**Table 1**).

**Table 1: Demographic characteristics in the studied groups**

		Radial access (n = 75)	Femoral access (n = 75)	P-value
Age (years)	Mean ±SD	55 ±10	53 ±7	0.243158
<b>Sex</b>				
Males	n (%)	39 (52)	37 (49.3)	0.744
Females	n (%)	36 (48)	38 (50.7)	
<b>DM</b>	n (%)	60 (80)	54 (72)	0.251
<b>HTN</b>	n (%)	51 (68)	45 (60)	0.307
<b>FH of CAD</b>	n (%)	26 (34.7)	20 (26.7)	0.288
<b>Smoking</b>	n (%)	29 (38.7)	32 (42.7)	0.618
<b>Chest pain</b>	n (%)	73 (97.3)	75 (100)	0.155

SD: Standard deviation; DM: Diabetes Mellitus; HTN: Hypertension; FH: Family History; CAD: Coronary Artery Disease.

### ECG and ECHO findings

ECG findings, including ischemia and arrhythmia were comparable between the studied groups. Arrhythmias included either accelerated idioventricular rhythm, sinus tachycardia, ventricular tachycardia, or complete heart block. ECHO findings demonstrated no significant differences between the studied groups, including EF, valve lesion, and RWMA (Table 2).

**Table 2: ECG and ECHO findings in the studied groups**

ECG		Radial access (n = 75)	Femoral access (n = 75)	P-value
<b>Ischemia</b>	n (%)	69 (92)	73 (97.3)	0.146
<b>Arrhythmia</b>	n (%)	24 (32)	17 (22.7)	0.2
<b>ECHO</b>				
<b>EF (%)</b>	Mean ±SD	51 ±8	51 ±7	1
<b>Valve lesion</b>	n (%)	40 (53.3)	31 (41.3)	0.141
<b>RWMA</b>	n (%)	46 (61.3)	41 (54.7)	0.408

ECG: Electrocardiography, ECHO: Echocardiography, EF: Ejection Fraction, SD: Standard Deviation, RWMA: Regional Wall Motion Abnormalities.

### Laboratory findings

Laboratory findings, including troponin, CK-MB, and after procedure creatinine showed no significant differences between the studied groups (Table 3).

**Table 3: Laboratory findings in the studied groups**

		Radial access (n = 75)	Femoral access (n = 75)	P-value
<b>Troponin (mg/L)</b>	Median (range)	1.3 (0.03 - 5)	1.08 (0.02 - 3.08)	0.11
<b>CK-MB (IU/L)</b>	Median (range)	225 (13 - 852)	178 (23 - 854)	0.421
<b>Create after procedure</b>	Median (range)	1.1 (0.4 - 3.6)	1.2 (0.5 - 3.01)	0.908

CK-MB: Creatine Kinase-MB, Create: Creatinine.

### Complications

Patients with femoral access exhibited significantly higher hematoma (13.3%) than those with radial access (0%) (P = 0.001). Additionally, allergic reactions, dissection, bleeding and mortality rates were clinically higher in those with femoral access than in those with radial access but with no statistical significance (Figure 1).

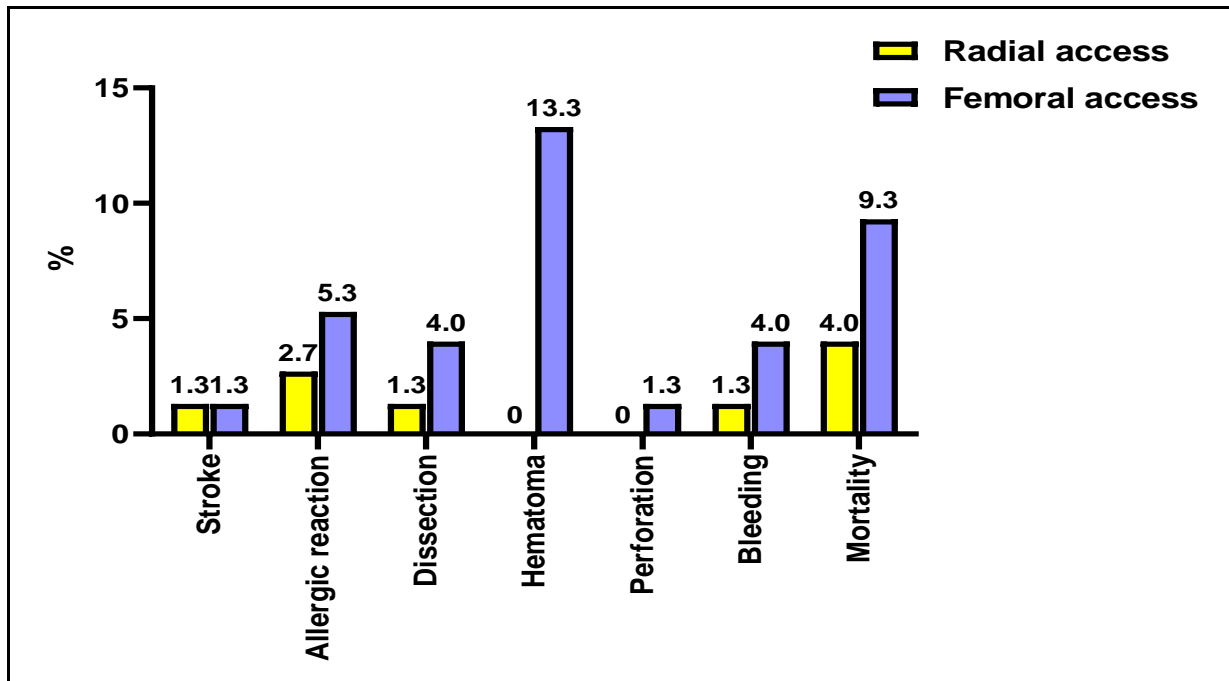


Figure 1: Complications in the studied groups.

**Major adverse cardiac events (MACE)**

Major adverse cardiac events, including stroke, bleeding or mortality were clinically higher in those with femoral access than in those with radial access but without statistical significance (P = 0.174) (Figure 2).

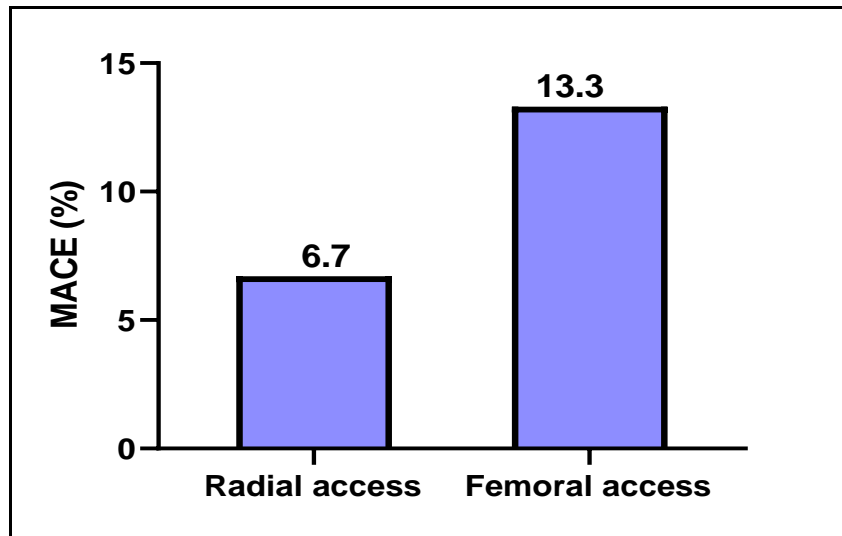


Figure 2: MACE in the studied groups

**Prediction of MACE**

Multivariate logistic regression analysis was done to predict MACE. The model revealed that femoral access was associated with two times increased risk of MACE, controlling for age, gender, diabetes, and hypertension, but with no statistical significance (Table 4 and figure 3).

**Table 4: Multivariate logistic regression analysis to predict MACE**

	OR (95% CI)	P-value
Femoral access	2.181 (0.697 - 6.824)	0.18
Age (years)	0.936 (0.861 - 1.018)	0.123
Sex	0.837 (0.281 - 2.492)	0.749
DM	1.642 (0.375 - 7.197)	0.511
HTN	1.397 (0.428 - 4.557)	0.58

OR: Odds Ratio; CI: Confidence Interval; DM: Diabetes Mellitus; HTN: Hypertension.

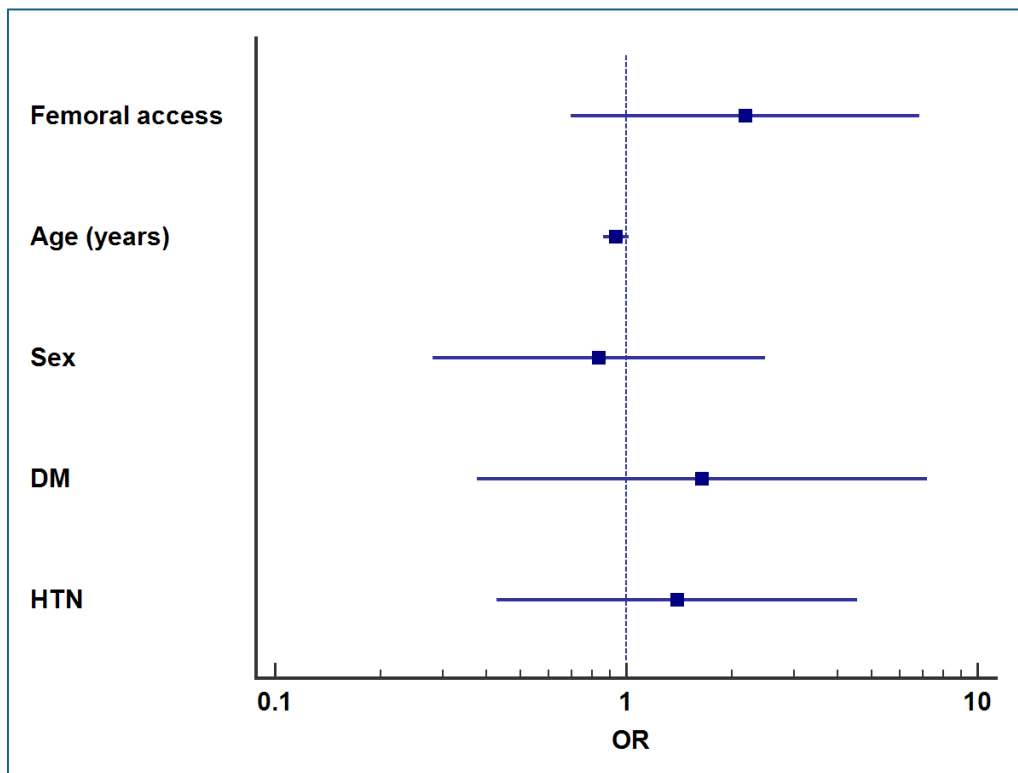


Figure 3: Forest plot for predictors of MACE.

## DISCUSSION

Cardiovascular diseases are a leading cause of morbidity and mortality worldwide, with PCI established as a treatment for ACS [13].

Initially favored, the TFA has largely been replaced by the TRA due to its safety, efficacy, and feasibility. TRA offers numerous advantages, including decreased vascular complications, greater patient convenience, earlier discharge, shorter hospital stays, and early ambulation [14].

Despite some criticisms, such as longer procedure and fluoroscopy times, recent guidelines from the European Society of Cardiology recommended TRA as the standard approach for PCI, citing its benefits in reducing short-term adverse clinical events, cardiac death, all-cause mortality, and bleeding compared to TFA [5]. Therefore, this study aimed to compare TRA and TFA on PCI-related bleeding complications, access site complications, procedural duration, and hospital mortality in ACS patients undergoing PCI.

In the current study, the studied groups were comparable regarding age, sex, DM, hypertension, family history of CAD, smoking, and chest pain. ECG and ECHO findings demonstrated no significant differences between the studied groups. Furthermore, laboratory findings, including troponin, CK-MB, and after procedure creatinine showed no significant differences between the studied groups. In addition, patients with femoral access exhibited significantly higher hematoma (13.3%) than those with radial access (0%) ( $P = 0.001$ ). Additionally, allergic reactions, dissection, bleeding, and mortality rates were clinically

higher in those with femoral access than in those with radial access but with no statistical significance. Furthermore, MACE, including stroke, bleeding, or mortality, were clinically higher in those with femoral access (13.3%) than in those with radial access (6.7%), but without statistical significance ( $P = 0.174$ ).

In a meta-analysis by **Ferrante et al.** [15], included 24 trials including 22,843 individuals. The research found that radial access was linked to considerably reduced risks in comparison to femoral access. The odds ratios (OR) for all-cause mortality, MACE, major bleeding, and major vascular complications were 0.71, 0.84, 0.53, and 0.23, respectively. All of these results had p-values less than 0.05. The incidence of myocardial infarction or stroke was comparable in both groups. Moreover, **Kolkailah et al.** [16] performed a meta-analysis to evaluate the effectiveness of the TRA compared to the TFA in patients with CAD who were receiving diagnostic coronary angiography or PCI. The use of the TRA demonstrated a reduced risk of death from any cause (relative risk [RR] 0.77), bleeding (RR 0.54), and problems at the access site (RR 0.36), with all outcomes displaying statistically significant p-values.

The RIFLE-STEACS study randomized 1,001 acute ST-segment elevation ACS patients to radial or femoral access. The 30-day net adverse clinical events (NACEs) were significantly lower in the radial group (13.6% vs. 21.0%). Radial access was associated with lower cardiac mortality (5.2% vs. 9.2%), bleeding (7.8% vs. 12.2%), and shorter hospital stays [12]. **Januszek et al.** analyzed 32,225 cases with prior CABG, comparing femoral and radial access. Post-

propensity score matching, femoral access was significantly associated with higher periprocedural deaths (OR 1.79) and cardiac arrests (OR 1.98) [17].

In a randomized trial by **Valgimigli *et al.*** [18], involving 8,404 ACS patients, radial access was associated with fewer major adverse cardiovascular events (369 vs. 429; RR 0.85). High-volume radial centers reported significantly better outcomes for radial access compared to femoral access. **Dowling *et al.*** [19] noted that in centers with a high proportion of radial access cases, radial access had significantly better outcomes for MACE and net adverse clinical events compared to femoral access. This was not observed in low-to-intermediate radial access centers.

The MATRIX study highlighted higher MACE rates with femoral access, particularly in high radial volume centers, suggesting a pronounced benefit for radial access in these settings [20]. Also, **Jolly *et al.*** conducted a meta-analysis showing a robust reduction in all-cause mortality with radial access compared to femoral access in ACS patients [21].

Our multivariate logistic regression analysis showed an increased, though not statistically significant, risk of MACE (OR 2.181) for femoral access compared to radial access, with a 95% CI of 0.697 to 6.824 and a p-value of 0.18. The odds ratio (OR) of 2.181 suggests that, on average, patients with femoral access were about twice as likely to experience MACE compared to patients with radial access, after adjusting for the other variables in the model. However, since the confidence interval included 1 (which represents no effect), we cannot conclude that there was a true association between femoral access and increased risk of MACE in the population from which the sample was drawn.

Finally, this study had some limitations. Firstly, being a single-center study with a relatively small sample size, the findings may not be generalizable to other settings with different patient populations and procedural practices. Secondly, the study focused on patients with acute coronary syndrome undergoing PCI via transradial or transfemoral access, excluding elective PCI cases. Lastly, the follow-up duration was limited to hospital discharge, potentially missing longer-term outcomes such as late bleeding events or cardiovascular incidents beyond the initial hospitalization.

## CONCLUSIONS

In ACS patients undergoing PCI, TFA was associated with higher rates of hematoma and possibly higher rates of other complications and MACE compared to TRA, although the differences were not statistically significant. These findings suggest that TRA may be a preferred access route in ACS patients undergoing PCI, potentially reducing bleeding complications and improving clinical outcomes.

**Financial support and sponsorship: Nil.**

**Conflict of interest: Nil.**

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