International Journal of Research and Review
Vol. 9; Issue: 11; November 2022
Website: www.ijrrjournal.com
Original Research Article *E-ISSN: 2349-9788; P-ISSN: 2454-2237*

Safety and Efficacy of Transulnar Route in Percutaneous Coronary Intervention: 30 days follow-up

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DOI: https://doi.org/10.52403/ijrr.20221130

ABSTRACT

Background Percutaneous coronary intervention (PCI) is the mainstay treatment in patients with coronary artery disease (CAD). The utility of transulnar approach (TUA) has been a topic of debate. Therefore, we aimed to evaluate the safety and efficacy of TUA in this study.

Methods This was a prospective, single-center, interventional study conducted between September 2005 and November 2021 at a tertiary-care center in India. Consecutive patients (≥18 years) with CAD requiring PCI using TUA were enrolled in this study. Patients with a negative Allen's or reverse Allen's test (>10 seconds), nonpalpable ulnar artery, cardiogenic shock, and the need for a large guiding catheter were excluded. Patients were clinically followed-up at one week to monitor occlusion and 30 days to observe and manage major adverse cardiovascular events (MACE; composite of myocardial re-infarction, target vessel revascularization, disabling stroke, and death).

Results A total of 200 patients were enrolled in this study with a mean age of 58.2±10.7 years. Majority of patients (38%) belonged to the age group of 56-65 years and this study observed a male predominance (80.5%). Follow-up of one week revealed no anatomical variations of the ulnar artery and there was no trauma to the ulnar nerve. Ulnar occlusion, however, was seen in three (1.5%) patients. Forearm hematoma was observed in one patient which was then managed conservatively. At 30-days follow-up, (MACE) did not occur in any of the patients.

Conclusion In the case that TRA cannot be performed, TUA can be used as a safe and effective alternative access route for PCI, avoiding the transfemoral approach.

Keywords: Coronary artery disease, catheterization, transulnar approach, transradial approach

INTRODUCTION

Coronary artery disease (CAD) is the leading cause of mortality and morbidity worldwide.(1) One of the commonly used techniques to enhance myocardial perfusion in CAD is percutaneous coronary intervention (PCI).(2) Well-established arteries for performing PCI are the femoral (transfemoral) and radial (transradial) arteries. Just about two decades ago, Terashima and colleagues performed PCI using the ulnar artery (transulnar) for the first time.(3) The need for this new approach stemmed from the drawbacks of the earlier approaches. Bleeding complications are higher with femoral access and there may be other hindrances to this route such as the presence of active groin infection, prior surgery, radiation therapy to the groin, and presence of iliac or aortoiliac aneurysms, etc.(4) In such events, the transradial approach (TRA) is preferred. However, vascular occlusion is seen in approximately 6% of patients undergoing PCI via the TRA, necessitating repeat procedures through a different artery – femoral or another radial artery.(5) Moreover, TRA may not be feasible for patients with an abnormal Allen's test, anatomical variations in the radial artery, synovial cysts, local hematomas, and aberrant origin.(6) There has been debate regarding whether TRA and transulnar approach (TUA) are equally safe and effective routes, and whether TUA can be employed when TRA is not feasible. Previous studies have found that TUA and TRA are equally safe and efficacious and that TUA should be considered when the risk of failure via TRA is high.(7, 8) In this study, we aimed to check the rates of switching to another route and the long-term outcomes of performing PCI via TUA in consecutive patients with a broad inclusion.

METHODS

Study Design and Participants

This prospective, single-center, interventional study was conducted between September 2005 and November 2021 at a tertiary-care center in India. During this time, 200 consecutive CAD patients (≥18 years) requiring PCI using the translunar route were enrolled in this study. The study was approved by Institutional Ethics Committee and was conducted in accordance with the Declaration of Helsinki. At the time of the index procedure, written informed consent was obtained from all patients or their designees.

Patients with a negative Allen's or reverse Allen's test (>10 seconds), nonpalpable ulnar artery, cardiogenic shock, and patients with the need for a large guiding catheter were excluded.

Procedure and follow-up

The Allen and reverse Allen tests at the initially attempted forearm were performed in all patients with a cut-off time of ≤10 seconds for normal post-ischemic palmar perfusion to estimate the adequacy of the ulnar-dependent and transradial-dependent collateral circulation, respectively. Indication for TUR was given when Allen's test was positive for radial artery. 6F sheaths (Terumo Corporation, Japan) and 6F guiding catheters were used. Intravenous loading dose of aspirin (300 mg) and clopidogrel (150–300 mg) were given pre-procedure. Post-PCI, aspirin (150 mg/day) and clopidogrel (75 mg/day) were prescribed for at least 12 months followed by aspirin indefinitely.

Procedural success was defined by thrombolysis in myocardial infarction (TIMI) grade 3 flow. Ulnar artery was examined clinically on the day of the procedure and at one-week follow-up. Detailed examination for ulnar nerve was also done at scheduled one-week follow-up and ulnar nerve injury, if any, was noted. Procedural complications such as vascular occlusion, hematoma at the access site and forearm, arteriovenous fistula, pseudoaneurysm, were also recorded. Clinically impalpable pulse at one week was labeled as artery occlusion. Patients were also followed-up at 30 days for clinical events.

Endpoints and definitions

The primary outcome was major adverse cardiac events (MACE), a composite of myocardial re-infarction, target vessel revascularization, disabling stroke, and death. Myocardial reinfarction was defined by recurrent clinical signs and symptoms of ischemia distinct from the index event, along with concomitant electrocardiographic changes and serum biomarker evidence of myocardial necrosis.(9) Disabling stroke was defined as stroke requiring inpatient rehabilitation or skilled nursing care.(10) Target vessel revascularization was defined as unplanned repeat PCI or bypass graft implantation for stenosis in a different area of the vessel treated at the index PCI.(11)

STATISTICAL ANALYSIS

All variables were analyzed and expressed as numbers (n) and percentages (%). Continuous variables displaying normal distribution were expressed as mean ± SD. Statistical analyses were performed using Statistical Package for Social Sciences version 21.0 (IBM, Chicago, IL, USA).

RESULTS

The mean age of patients was 58.2±10.7 years and majority of patients (38%) belonged to the age group of 56-65 years. This study observed a male predominance (80.5%). Out of all patients, 74 (37%) had hypertension and 84 (42%) had diabetes mellitus. The complete baseline and clinical characteristics of all the patients are outlined in **Table 1**.

Table 1: Patient characteristics

Characteristic (N=200)	**n (%)**
Age, n (%)	
≤45 years	27 (13.5)
46-55 years	49 (24.5)
56-65 years	76 (38)
66-75 years	31 (15.5)
>75 years	17 (8.5)
Gender, n (%)	
Male	161 (80.5)
Female	39 (19.5)
Hypertension, n (%)	74 (37)
Diabetes mellitus, n (%)	84 (42)
Smoking, n (%)	97 (48.5)
Clinical presentation, n (%)	
Unstable angina	93 (46.5)
NSTEMI	89 (44.5)
STEMI	18 (9)
Culprit vessel , n (%)	
Left anterior descending artery	102 (51)
Right coronary artery	67 (33.5)
Left circumflex artery	29 (14.5)
Left main	2 (1)
Multivessel disease, n (%)	32 (16)
Pre-PCI TIMI flow grade, n (%)	
≤1	169 (84.5)
≥2	31 (15.5)
Post-PCI TIMI flow grade, n (%)	
3	200 (100)
≤2	0 (0)

NSTEMI: Non-ST elevated myocardial infarction; STEMI: ST-elevated myocardial infarction; PCI: Percutaneous coronary intervention; TIMI: Thrombolysis in myocardial infarction

Majority of patients were diagnosed with unstable angina (46.5%), followed by non-ST elevation myocardial infarction (44.5%). The most common culprit vessel was left anterior descending artery, affecting 102 patients (51%), and 32 patients (16%) had multivessel disease. Prior to PCI, 169 patients (84.5%) had a TIMI flow ≤1, and post-procedure, all patients had TIMI 3 flow. In 196 patients, the intervention was

performed via the right ulnar artery, while 4 patients were accessed via the left ulnar artery.

Follow-up of one week revealed no anatomical variations of the ulnar artery and there was no trauma to the ulnar nerve. Ulnar occlusion, however, was seen in three (1.5%) patients. Other vascular complications following PCI are given in **Table 2**. Forearm hematoma was observed in one patient which was then managed conservatively. At 30-days follow-up, no MACE was reported in any of the patients.

Table 2: Vascular complications following percutaneous coronary intervention

Complication, n (%)	n (%)
Pseudoaneurysm	0 (0)
Access site hematoma	0 (0)
Forearm hematoma	1 (0.5)
Severe artery spasm	0 (0)
Ulnar occlusion	3 (1.5)

DISCUSSION

TRA is a frequently employed and well-established strategy for elective PCI. Over the last two decades, TUA has gained attention as an alternative route to TRA. This route has several advantages and disadvantages which need to be taken into consideration.

The mean age of patients in our study was 58.2±10.7 years which was comparable with the age of patients in a study conducted by Liu et al. (58.6±11.5 years).(6) In this study, we had a high success rate of ulnar cannulation. Notably, we did not observe a single case of ulnar artery spasms as opposed to the spasms noted by Shafiq et al.(12) and Varenne et al.(13) in TRA. This may be attributed to the fact that there are fewer alpha-adrenergic receptors in the transulnar route as compared to the transradial route. Secondly, the ulnar artery has a diameter greater than that of the radial artery, and hence, it can accommodate catheter sizes up to 7F, although we restricted the size to 6F only. Liu et al. (6) have also noted the lower prevalence of vasospasm in the transulnar route. The higher prevalence of spasms in the TRA may be due to its smaller size and greater tortuosity.(14)

The second most prominent finding of our study was that there was no need for crossover to femoral route. On the contrary, a study conducted by Hahalis et al. in the AURA of ARTEMIS study (15) concluded that the TUR was inferior to TRA because of greater crossover rates in the former (9.4% vs. 4.1%, OR 1.92, 95% CI [0.91, 4.06], $P = 0.09$, $I^2 = 87\%$). A meta-analysis by Sedhom et al.(7) also found that TUA had higher crossover rates than the TRA ($P = 0.09$). However, Bhanwar et al.(5) allied with our finding that the ulnar approach reduces crossover rates.

In the current study, we observed one forearm hematoma (0.5%) (not life and limb threatening) which required conservative management. The observed percentage was much lower than what Roghani-Dehkordi et al. (14) and Shafiq et al.(12) found (10.4% and 2.5%, respectively). Presence of large hematomas may compress the ulnar nerve, owing to its proximity to the ulnar artery, leading to paresthesia and possible motor dysfunction. Although the hematoma was not serious in our study, Sedhom et al. (7) found a significantly higher occurrence of major hematomas in patients accessed via the TUR compared to the TRA ($P = 0.24$). At 30-days follow-up, we found no occurrence of MACE (myocardial re-infarction, target vessel revascularization, disabling stroke, and death). At 60 days, Hahalis et al. found that the transulnar route was non-inferior to transradial route according to per-protocol and intention-to-treat analyses.(15)

This study should be considered in the light of its limitations. First, this was a single-center study with a limited number of patients. Secondly, there was no control arm to compare TUA with TRA. Therefore, further studies should include larger number of patients and a control group of TRA to validate our findings.

CONCLUSION

Taken together, our results add to the existing knowledge that TUA has good success rates, lower MACE occurrence, and lesser chances of hematological complications. TUA can be used as a safe and effective alternative in patients undergoing PCI in the event that TRA cannot be used, avoiding the need for a transfemoral approach.

Acknowledgement: None

Conflict of Interest: None

Source of Funding: None

Ethical Approval: Approved

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How to cite this article: Raghava Sarma Polavarapu, Yudhistar Siripuram, Keerthika Chowdary Ravella et.al. Safety and efficacy of Transulnar route in percutaneous coronary intervention: 30 days follow-up. *International Journal of Research and Review*. 2022; 9(11): 226-231.
DOI: *https://doi.org/10.52403/ijrr.20221130*

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