Transulnar versus Transradial Access as a Default Strategy for Percutaneous Coronary Intervention

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ABSTRACT

Background: Percutaneous coronary interventions (PCI) are undergoing a paradigm shift from femoral to forearm approach due to obvious advantages in terms of patient safety, comfort, and faster ambulation. Transradial access (TRA) has been established as a primary forearm access site. Use of transulnar access (TUA) as an alternative to radial route can serve as novel forearm access to the interventionalists.

Aim: The aim of this study is to evaluate TUA versus TRA access as a default strategy for PCI.

Materials and Methods: This was a prospective, single-center randomized controlled trial involving 2700 patients, of whom 220 underwent PCI in 1:1 randomization to TUA (n = 110) or TRA (n = 110). The primary endpoint was composite of major adverse cardiac events during hospital stay, cross-over to another arterial site, major vascular events of the arm during hospital stay (large hematoma with hemoglobin drop of ≥5 g%) and occlusion rate. Secondary endpoints were individual components of primary endpoint and spasm of the vessel.

Results: Two groups did not differ in baseline characteristics. On intention to treat (ITT) analysis, primary end point occurred in 10.91% of TUA and 12.73% of TRA arm (odds ratio [OR]: 0.84; 95% confidence interval [CI], 0.37–1.91; P = 0.68 at α = 0.05). Further on per protocol (PP) analysis, primary end point occurred in 9.21% of TUA and 11.11% of TRA arm (OR: 0.81; 95% CI, 0.29-2.30; P = 0.68 at α = 0.05). Secondary endpoints also did not differ significantly between the two groups in ITT and PP analysis.

Conclusions: TUA is an excellent alternative to TRA, while performing PCI when performed by an experienced operator. When utilized as an option, TUA increases the chance of success with forearm access and reduces the need for cross over to femoral route.

Key words: Percutaneous coronary intervention, transradial access, transulnar access

INTRODUCTION

Percutaneous coronary interventions (PCI) are undergoing a paradigm shift from femoral to forearm approach due to obvious advantages in terms of patient safety, comfort, and faster ambulation.[1,2]

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Vascular complications are more common with PCI owing to the intensified antithrombotic regimen. Use of TUA as an alternative to radial route can serve as novel optional forearm access for the interventionalists to decrease vascular complications. This study aimed to evaluate TUA versus TRA access as a default strategy for PCI.

MATERIALS AND METHODS

Methods
This was a prospective, randomized, single-center, parallel design study. Written informed consent was obtained from all patients. Procedures in the current study were performed by operators who were default radialists (cannulation experience of >150 RA/year) with experience of having cannulated at least 50 UAs.\(^7\)

Patients’ selection
Of 2700 patients requiring coronary angiography between January 2014 and March 2015, eligible patients who consented for ad hoc PCI were enrolled.

The preprocedural exclusion criteria were the inability to palpate one or both forearm vessels (radial or UA of either side), cardiogenic shock, patients on chronic hemodialysis, vasospastic disease (Raynaud’s disease), severe skeletal forearm deformities, history of prior CABG.

The allowed arterial puncture time was kept at ≤15 min for most catheterization studies and ≤5 min for primary PCI. Pulse quality was graded clinically as low volume, normal volume, and high-volume pulse. Operator attempted arterial access even if the pulse was of low volume clinical grade on palpation. Crossover from the ulnar to the radial or an alternative site was done at the discretion of the operator, and the cause for the same was documented. Allen’s test was not performed routinely and it was assumed that palpable radial and ulnar pulses were normal before considering forearm approach.\(^8\)

Randomization
Patients were randomized using table of randomized numbers. Table containing double digits randomization codes (from 11 to 40) was generated using computer program. Randomization codes were allotted to the enrolled patients by starting at random point in the table. Patients receiving code from 11 to 20 were assigned for TUA and those with code from 21 to 40 were assigned for TRA.

Procedure and vascular access
6F RA sheaths (Terumo Corporation, Japan) were used. After the insertion of the sheath, a cocktail (composed of 50 μg nitroglycerine +1 ml 2.5 mg DILTIAZEM + 2 ml of 2% LIGNOCAINE without preservative) was given intra-arterial as a rapid bolus. An intravenous bolus of unfractionated heparin (100 IU/kg) was given preprocedure and was repeated (60 IU/kg) if procedure time exceed 1 h. Post- PCI use of glycoprotein Ib/IIia inhibitors, if indicated, was given as per guideline.

Arterial spasm during the procedure was managed by additional dose of the cocktail. Arterial sheaths were removed immediately after the procedure regardless of anticoagulation and local hemostasis was achieved using a pressure bandage with sticky straps attached to the bandage to occlude the site of the puncture. These bandages were removed on the same day after 4–5 h postprocedure. The activated clotting time was maintained <300 s.

Follow-up and ulnar pulse evaluation
Ulnar and radial arteries were examined clinically on the day of the procedure and at scheduled 1-week follow-up. Clinically impalpable pulse at 1 week was labeled as artery occlusion. Detailed examination for ulnar nerve was also done at scheduled 1-week follow-up and ulnar nerve injury if any was noted down.

Primary and secondary endpoints
The primary endpoint of the study was a composite of major adverse cardiac events (MACEs) (death, myocardial infarction, stroke and urgent target vessel revascularization, [MACEs]) during hospital stay, major vascular events during the hospital stay and crossover rate to another arterial site. Major vascular events were composed of large hematoma with hemoglobin drop >3 g% or need of blood transfusion and occlusion rate. The secondary endpoints were individual components of the primary end point, failed attempts (need of more than three attempts for successful cannulation), total procedural and fluoroscopy time, the volume of contrast used, and spasm.

Data collection
Baseline demographic and clinical characteristics
In all the patients, the history related to age, diabetes, hypertension, dyslipidemia, and chronic kidney disease was acquired, and preprocedural echo parameters and electrocardiogram findings were noted.

Baseline vessel characteristics
Forearm vessels (radial and UA of either side) were examined clinically and data were collected for the following features: (1) volume of pulse (low volume, normal volume, high volume); (2) palpability of pulse (easy versus difficult): palpability of UA was labeled as easy if it was found to course in between forearm tendons versus difficult if it was running beneath forearm tendons, RA palpability was labeled as difficult if it followed course deviated from its natural course; (3)
presence or absence of tortuosity; (4) calcification of vessel wall, if present, was confirmed by forearm X-ray.

**Peri-procedural parameters**

Following parameters were recorded for analysis purpose: (1) Number of attempts (number of times skin was entered by the puncture needle until successful arterial access) made till successful puncture, (2) Arterial access time or puncture time, (3) Cross over and final access site, (4) Failed attempts (need of >3 attempts to cannulate artery), (5) Total procedure time defined as the time elapsed during coronary angiography after sheath insertion, (7) Spasm (as per ease for maneuverability of catheter and need of cocktail during procedure), (8) Total fluoroscopy time, (9) Early and late post-procedural complications: major and minor bleeds, Volkmann’s ischemia/contracture, forearm hematomas, pseudoaneurysms, arteriovenous fistula, acute closure of the UA, and gangrene of the upper limb.

The definitions of major and minor bleeding were used according to those of the RIVAAL study. The definition of nonCABG-related major bleed was according to the definitions used in the ACUITY trial. Intractable vasospasm was defined as a condition where the operator had to change the access site. The maneuvers for improving the passage of the catheter include asking the patient to do deep breathing or the Valsalva maneuver, repeating the cocktail intra arterially, in an anxious patient talking to him/her to divert his/her attention, waiting for the spasm to improve, and these were all performed before the patient access site was changed.

**Statistical analysis**

The statistical analysis was performed using IBM SPSS statistics version 20 (Armonk, NY, USA) and Review manager 5.3. Continuous variables were expressed as mean ± standard deviation, and categorical variables were presented as absolute number and proportion (%). Data were analyzed using the two-tailed test to identify differences between groups and analysis of variance for repeated measures with Bonferroni correction for intragroup data. Nominal data were analyzed using the Chi-square test. We considered 95% confidence intervals (CIs) that excluded unity, or, equivalently, \( P < 0.05 \), as statistically significant.

**RESULTS**

Of 2700 patients requiring coronary angiography between January 2014 and March 2015, 218 (8.07%) eligible patients who consented for ad hoc PCI were enrolled in the study. These patients were randomized in a 1:1 manner into two arms: TRA (n = 110 patients) and TUA (n = 108 patients). 2 (1.81%) patients in TRA arm were crossover to TUA and 2 (1.85%) patients in TUA arm were crossover to TRA. 27 (24.55%) patients in TRA arm excluded (10 had recanalized vessel, 17 had unfavorable vessel anatomy). 30 (27.78%) patients in TUA arm excluded (9 had recanalized vessel, 21 had unfavorable vessel anatomy). Per protocol (PP) analysis of 156 patients (TRA-81 and TUA-76) was done (Figure 1).

**Preprocedural parameters**

The present study was conducted at a dedicated center for radial intervention. The demographic and baseline characteristics did not differ in 2 groups (Table 1).

**Peri-procedural and postprocedural parameters**

Total procedural time, fluoroscopy time, number of attempts, and amount of contrast used did not differ in two arms (Table 2 and Figure 2). Comparison of peri-procedural and post-procedural complications is shown in Table 3.

Intractable vasospasm was defined as a condition where the operator had to change the access site. The maneuvers for improving the passage of the catheter include asking the patient to do deep breathing or the Valsalva maneuver, repeating the cocktail intra arterially, in an anxious patient talking to him/her to divert his/her attention, waiting for the spasm to improve, and these were all performed before the patient access site was changed.

![Figure 1: Study protocol of the trial. Between January 2014 and March 2015, a total of 218 patients were enrolled in the study. Eligible patients were randomized to TUA and TRA arms. TUA: Transulnar access, TRA: Transradial access, CABG: Coronary artery bypass grafting, PCI: Percutaneous coronary intervention](image-url)
Table 1: Baseline characteristics

| Parameters          | Radial (n=110) | Ulnar (n=108) | P     |
|---------------------|----------------|---------------|-------|
| Age, years (SD)     | 55.32 (9.87)   | 53.8 (9.58)   | 0.25  |
| Women (%)           | 23 (20.90)     | 18 (16.67)    | 0.489 |
| Diagnosis (%)       |                |               |       |
| STEMI               | 64 (58.18)     | 57 (52.78)    | 0.416 |
| NSTEACS             | 37 (33.64)     | 45 (41.67)    | 0.264 |
| CSA                 | 9 (8.18)       | 6 (5.56)      | 0.594 |
| Comorbidities (%)   |                |               |       |
| Diabetes            | 41 (37.27)     | 29 (26.85)    | 0.112 |
| Hypertension        | 38 (34.55)     | 35 (32.41)    | 0.775 |
| Dyslipidemia        | 31 (28.18)     | 24 (21.82)    | 0.351 |
| Smoking             | 23 (20.91)     | 30 (27.78)    | 0.271 |
| Obesity             | 24 (21.82)     | 17 (15.74)    | 0.299 |
| CKD                 | 7 (6.36)       | 6 (5.56)      | 1     |
| Treatment in hospital (%) |          |               |       |
| Fibrinolysis        | 51 (46.36)     | 43 (39.81)    | 0.342 |
| LMWH                | 94 (85.45)     | 98 (90.74)    | 0.297 |
| Aspirin             | 110 (100)      | 108 (100)     | 1     |
| Prasugrel loading, 60mg | 91 (82.73) | 96 (88.89)    | 0.245 |
| GpIIb/IIIa          | 29 (26.36)     | 27 (25.0)     | 0.877 |
| Beta blocker        | 74 (64.27)     | 70 (64.81)    | 0.775 |
| ACEI/ARB            | 59 (53.64)     | 60 (55.56)    | 0.787 |

Data are presented as mean±SD or n (%). STEMI: ST elevation myocardial infarction, NSTEACS: Non-ST elevation acute coronary syndrome, CSA: Chronic stable angina, CKD: Chronic kidney disease, LMWH: Low-molecular-weight heparin, ACE: Angiotensin-converting enzyme, ACEI/ARB: ACE inhibitor/angiotensin receptor blocker, SD: Standard deviation

Table 2: Procedural characteristics

| Parameters          | Radial (n=81) | Ulnar (n=76) | P     |
|---------------------|---------------|--------------|-------|
| SV PCI (%)          | 71 (64.55)    | 81 (75.0)    | 0.180 |
| MV PCI (%)          | 39 (35.45)    | 26 (24.07)   | 0.076 |
| Fluoroscopy time (SD) | 10.96 (4.44) | 10.09 (3.56) | 0.112 |
| Procedure time (SD) | 15.99 (4.43)  | 15.18 (3.53) | 0.137 |
| Puncture time (SD)  | 4.04 (1.1)    | 4.08 (1.19)  | 0.797 |
| Contrast volume (SD) | 100.93 (29.5) | 96.91 (28.96) | 0.311 |
| Number of attempts (SD) | 1.46 (0.67)   | 1.45 (0.68)  | 0.913 |
| Clinical arterial pulse grade (%) |         |              |       |
| Low volume          | 16 (14.55)    | 11 (10.19)   | 0.412 |
| Normal volume       | 67 (60.91)    | 80 (74.07)   | 0.436 |
| High volume         | 27 (24.55)    | 17 (15.74)   | 0.129 |

Data are presented as mean±SD or n (%). PCI: Percutaneous coronary interventions, SV PCI: Single vessel PCI, MV PCI: Multivessel PCI, SD: Standard deviation

OR: 0.86; 95% CIs: 0.38–1.95; P = 0.835 [Figure 3]. In PP analysis, the composite primary endpoint did not differ in two arms (92.1% versus 11.1% in TUA versus TRA, respectively, OR = 0.81, 95% CIs: 0.29–2.30; P = 0.694) [Figure 4]. Bleeding complications were 6.36% (major bleeding - 0.93%, minor bleeding - 5.56%) in TUA and 7.27% (major bleeding - 0.91%, minor bleeding - 6.36%) in TRA arm (p = NS).

One patient in TUA arm had transient ulnar nerve parasthesia with no residual manifestation at the time of discharge suggesting that damage to ulnar nerve is uncommon and a reversible adverse event of UA cannulation. On follow-up at 1 week, there was no significant difference in arterial occlusion rates between ulnar (6.1%) and radial routes (6.6%).

DISCUSSION

UA interventions reduce the need for crossover to femoral route. AURA of ARTEMIS study concluded that TU strategy is inferior to TR strategy as a result of high cross over rates in TUA arm.[11]

In this study, comparison was between experienced trans-radialists performing RA cannulation versus naive transulnarists (no/minimal transulnar experience of operators) performing UA cannulation. To emphasize, because of its deep location and weak (but definite) palpability UA has its own learning curve and cannulation of UA is difficult for an operator naïve for transulnar cannulation. AJULAR study showed that when transulnar interventions were performed by operators who were default radialists with experience of at least 50 UA cannulations, TUA was noninferior to TRA arm for patients undergoing coronary angiographies.[7]

About 6% of patients after transradial procedure develop vascular occlusion, thereby making repeat procedures, if required, difficult, thus switching either to other RA or to transfemoral access.[12] Prior puncture of RA is associated with more intimal hyperplasia and reduced early graft patency if RA is used as graft in CABG.[8] Hence, provides additional forearm access and decreases the chances to switch to femoral access. In addition, it spares RA to be used as graft if needed. UA is relatively large size as compared to RA and can easily accommodate catheter size up to 7 Fr, has straighter and least occlusive course, similar occlusion rates and lesser tendency to spasm (mainly due to less alpha-adrenergic receptors for epinephrine), making TUA a viable alternative to TRA both during default and crossover strategy.[13-16]

Figure 2: Histogram showing procedural characteristics in TRA and TUA group. Time is expressed in minutes and volume in milliliter (ml). TUA: Transulnar access, TRA: Transradial access.
Bleeding complications are higher with femoral access as compared to radial access in patients undergoing PCI due to intensified antiplatelet and anticoagulant regimen in patients undergoing PCI. Furthermore, the bleeding risk is quite high with femoral access in STEMI patients being planned for pharmaco-invasive strategy.

In this study, we enrolled patients undergoing ad hoc PCI. TUA access had similar outcomes as TRA in terms of primary and secondary endpoints, suggesting that TUA is a reasonable option for PCI and can also be used as default forearm access for PCI by experienced operators. In the current study crossover to femoral artery was nil as compared to 7.7% in contemporary
Large hematoma was seen in 0.9% in both TUA and TRA arm which is quite less to that noted with femoral route (3.02%).\textsuperscript{[9]} Having an additional forearm access reduces complications.

We did not include patients undergoing primary PCI as time is crucial for primary PCI.

The results of the current study showed that time for cannulation (4.08 ± 1.19 min vs. 4.04 ± 1.1 min, \(P = 0.797\)) and procedure time (15.18 ± 3.53 min vs. 15.99 ± 4.43 min, \(P = 0.137\)) were similar for TUA and TRA, suggesting that TUA can be a potential access site for experienced operators. However, this warrants a future study enrolling patients undergoing primary PCI to validate the noninferiority of TUA to TRA.

**Study limitations**

Following limitations in the current study needs to be addressed: (a) This is single center study enrolling only 218 patients. A multicenter larger study is required to validate the results. (b) There was no follow-up protocol for Doppler interrogation of cannulated vessel to assess occlusion rates, if the vessels were palpable, it was considered that there was no occlusion. Delayed vessel occlusion due to intimal injury was not addressed. (c) Operators in the current study were default radialists with experience in UA cannulation, and hence, these results may be difficult to reproduce by physicians without such experience. (d) Patients with primary angioplasty and cardiogenic shock were not included in the study population, since time to intervene was of paramount importance in both these situations.

**CONCLUSIONS**

TUA is an excellent alternative to TRA for PCI when performed by an experienced operator. When utilized as an option, TUA increases the chance of success with forearm access and reduces the need for cross over to femoral route. Experienced operators may even consider TUA as default route, thereby sparing RA for future need.

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**Conflicts of interest**

There are no conflicts of interest.

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