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Transulnar Versus Transradial Access for Coronary Angiography or Percutaneous Coronary Intervention: A Meta-Analysis of Randomized Controlled Trials

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Background: Although transfemoral access (TFA) remains the standard of care for patients undergoing coronary angiography (CA) or percutaneous coronary intervention (PCI) in the USA, TRA is being increasingly used over TFA due to lower bleeding and mortality rates on the basis of meta-analyses and recently published MATRIX trial. In patients with unsuccessful ipsilateral radial access, TUA has been used as an alternative approach. The randomized controlled trials (RCTs) comparing TUA and TRA have reached mixed conclusions regarding the use of transulnar approach for coronary procedures. **Objectives**: To systematically review and perform a meta-analysis of published RCTs comparing the safety and efficacy of transulnar access (TUA) vs. transradial access (TRA) in patients undergoing CA or PCI. **Methods**: PubMed, EMBASE, and CENTRAL databases were searched for RCTs since inception through December, 2014. Meta-analysis was performed using random-effects model. **Results**: Five RCTs involving 2,744 total patients were included in the meta-analysis. TUA compared with TRA had similar risks of MACE [risk ratio (RR): 0.87; 95% confidence interval (CI): 0.56–1.36; $P = 0.54$] and access-related complications [RR: 0.92 (0.67–1.27); $P = 0.62$]. Higher rates of access cross-over [RR: 2.31 (1.07–4.98); $P = 0.003$] and number of punctures [1.57 vs. 1.4; mean difference (MD): 0.17; 95% CI: 0.08–0.26; $P = 0.0002$] were noted with TUA. There was no difference in arterial access time [12.8 vs. 10.9 min; MD: 1.86 (−1.35–5.7); $P = 0.26$], fluoroscopy time [7.6 vs. 7.2 min; MD: 0.37 (−0.39 – 1.13); $P = 0.34$] and contrast volume [151 vs. 153.7 ml; MD: −2.74 (−17.21 – 11.73); $P = 0.71$]. **Conclusion**: For patients requiring CA or PCI, TUA compared with TRA has similar efficacy and safety except for higher puncture rates and access cross-over.

Key words: transulnar access; transradial access; PCI; coronary angiography; coronary artery disease; access-related complications; access cross-over

INTRODUCTION

In patients undergoing coronary angiography (CA) or percutaneous coronary intervention (PCI), transfemoral access (TFA) remains the standard and most popular route of vascular access in the United States [1]. Transradial access (TRA) is preferred over TFA due to lower rates of bleeding, access-related complications and reduced mortality [2–4]. In patients with unsuccessful ipsilateral radial access, transulnar access (TUA) has been used successfully for the performance of CA and PCI [5,6]. In addition, Gokhroo et al. showed that TUA could be successfully used as a default access site for patients undergoing coronary procedures [7,8]. TUA may also be used for vascular access for repeat catheterization procedures [9], or if the

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Conflict of Interest: Nothing to report.

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radial artery is considered as a potential conduit for coronary artery bypass grafting (CABG) [10].

Several single arm studies and randomized controlled trials (RCTs) have evaluated TUA in patients undergoing coronary procedures [5,6,11–15]. The RCTs that compared TUA versus TRA reached different conclusions [10,16]. The largest RCT by Hahalis et al. did not recommend the use of TUA as either a default or an alternative access site to TRA owing to higher access cross-over rates with TUA while other published RCTs concluded that TUA could be safely used in patients undergoing coronary procedures including primary PCI [12,17]. Therefore, to evaluate the safety and efficacy of TUA versus TRA in patients undergoing CA or PCI, we performed a meta-analysis of the available RCTs.

METHODS

Search Criteria and Study Selection

This meta-analysis was designed according to PRISMA guidelines [18]. Two investigators (K.D. & J.R.) independently performed electronic database searches on PubMed, EMBASE and Cochrane Central Register of Clinical Trials (inception through December 2014) for English-language publications with prespecified terms “transulnar” OR “TUA” AND “transradial” OR “TRA”. The relevant references were manually searched as well.

All RCTs comparing TUA with TRA in adult patients ($\geq$18 years) undergoing CA or PCI were included in the meta-analysis. Nonrandomized studies, meeting abstracts, single-arm studies and studies describing use of TUA for procedures other than CA or PCI (i.e., for vascular or valvular procedures) were excluded.

Data Extraction

Two investigators (K.D. and J.R.) independently extracted data from the selected RCTs in standardized data-extraction table. We obtained data on study and patient characteristics (age, sex, risk factors including diabetes, hypertension and hyperlipidemia, indication etc.) inclusion/exclusion criteria, duration of follow-up, angiographic procedural data (anatomy, use of antithrombotic agents etc.), major adverse cardiac events, access-related complications, number of punctures and access crossover.

Main Outcomes

The primary outcome was major adverse cardiac events (MACE), a composite of myocardial infarction (MI), target vessel revascularization, stroke and death. The secondary outcomes were the composite of access-related complications (including bleeding/hematoma, artery stenosis, pseudoaneurysm or arteriovenous fistula (AVF) formation, artery occlusion and ulnar nerve injury), access cross-over rates, number of punctures, arterial access time, fluoroscopy time and amount of contrast volume.

Statistical Analysis

Mean difference (MD) with 95% confidence interval (CI) was used to pool continuous variables and risk ratio (RR) with 95% CI for the categorical variables. Meta-analysis was performed with Review Manager (RevMan 5.3, Cochrane Collaboration, Nordic Cochrane Center, Copenhagen, Denmark) software using DerSimonian-Laird random-effects model. The $P < 0.05$ (two-tailed) was considered statistically significant for computed effects. Begg’s funnel plot was used to visually examine the publication bias at outcome level. We used Jadad scale [19] to assess the quality of studies on the basis of randomization, blinding, and attrition of participants. Study heterogeneity was evaluated with Cochran’s Q and I^2 statistics and I^2 >60% was considered significant heterogeneity, in which case sensitivity analyses were performed by excluding one study at a time.

RESULTS

Description of Included Studies

The flow diagram for study selection is shown in Fig. 1. We had a total of 688 citations from prespecified electronic database search of PUBMED, EMBASE, and CENTRAL and manual search of relevant bibliography. We screened 580 publications for eligibility after removal of 108 duplicates. Finally, we extracted 23 studies for full-text review, of which 5 RCTs [10–12,16,17] with 2,744 total patients (TUA arm: $n = 1{,}384$ and TRA: $n = 1{,}360$) were included in the meta-analysis.

The follow-up period was between 1 and 12 months with the Liu et al. study having the longest follow up of 12 months. The participation of female patients was between 21 and 35% across studies and 37–100% underwent PCI. Tables I and II, respectively, show the individual study and patient characteristics, and procedural angiographic data. In two studies [10,12] abnormal Allen’s or reverse Allen’s test was an exclusion criteria, in another two [11,16] the patients were randomized regardless of Allen’s test or reverse Allen’s test results and in one study [17] there was no mention of Allen’s test but they had utilized Doppler ultrasound to assess forearm vessels before the procedure. The PCI success by establishment of thrombolysis in myocardial infarction grade 3 flow was similar between two strategies in all studies. All studies used vascular ultrasound as part of the study.

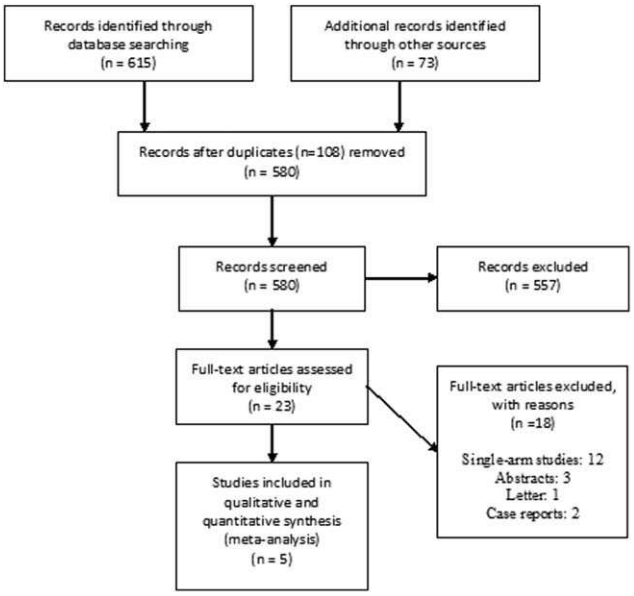

Fig. 1. Flow diagram of study selection.

Study quality as assessed by Jadad scale was 1 for Liu et al's study and 3 for all others. The funnel plots were symmetrical for all outcomes except for the risks of access cross-over and arterial occlusion, which were asymmetrical.

Primary Outcome: MACE

All five trials contributed to this outcome (Fig. 2). TUA compared with TRA had similar risks of MACE [3.1% vs. 3.5%, risk ratio (RR): 0.87, 95% CI: 0.56–1.36, $P = 0.54$, I^2: 0%]. In the Li et al. study there were no MACE events at follow-up in either arm. Due to limited data, it was not feasible to perform meta-analysis on individual components of MACE.

Secondary Outcomes

Access-related complications. The composite of all access-related complications included bleeding/hematoma, artery occlusion, artery stenosis, ulnar nerve injury and pseudoaneurysm, or AVF formation. TUA compared to TRA had similar access-related complications [14.9% vs. 15.4%; RR: 0.92 (0.67–1.27); $P = 0.62$; I^2: 57%] as shown in Fig. 2. The majority of access-related complications were minor bleeding/hematoma, artery occlusion, and stenosis, all of which were managed conservatively without major consequences. We performed meta-analysis of individual components of access-related complications as shown in Fig. 3. Compared with TRA, TUA resulted in similar risks of arterial spasm [9.4 vs. 8.9%; RR: 0.82 (0.38–1.79); $P = 0.62$; I^2: 68%], arterial stenosis [10.1 vs. 12.4%; RR: 0.77 (0.52–1.16); $P = 0.21$; I^2: 0%], arterial occlusion [6.8% vs. 4.7%; RR: 1.04 (0.50–2.16); $P = 0.91$;

TABLE I. Study and Patient Characteristics of Included Studies

First author, year (ref #)	Total patients (TUA/TRA), N	Age in years ($m \pm SD$) (TUA/TRA)	Female % (TUA/TRA)	DM % (TUA/TRA)	HTN % (TUA/TRA)	HLD % (TUA/TRA)	Smoking % (TUA/TRA)	STEMI % (TUA/TRA)	NSTEMI % (TUA/TRA)	Aspirin Use % (TUA/TRA)	Clopidogrel Use % (TUA/TRA)	IIb/IIIa inhibitor Use % (TUA/TRA)
Aptecar, 2006 (10)	216/215	63 ± 12/63 ± 12	26/27	20.7/22.6	na	na	46.8/47.8	17.5/16.7	22.5/27.6	na	na	na
Geng, 2014 (11)	271/264	64.2 ± 10.1/65.4 ± 9.4	31/35.3	26.6/28.4	63.5/67	52.8/50	30.3/34.1	14.4/13.6	72.7/70.4	99.3/99.2	88.2/86	20.6/23.5
Hahalis, 2013 (16)	462/440	64.3 ± 10.8/64.6 ± 11.9	21.6/22	28.4/27.4	59.5/60.2	56.1/52.5	43.9/44.1	14.1/13.2	37.4/38.4	68.4/67.5	66.9/66.8	3.7/2.5
Li, 2010 (17)	118/122	60 ± 10/61 ± 10	32.2/34.5	32.2/38.5	62.7/66.4	40.7/50	47.5/40.2	4.2/4.9	77.1/73	100/100	100/100	23.7/29.5
Liu, 2014 (12)	317/319	58.6 ± 11.5/59.2 ± 11.4	30.7/32.7	20.5/19.4	46.8/44.8	17.7/18.4	49/46	19.6/20.4	75.9/77.4	na	na	14.8/16.9

DM: diabetes mellitus; HTN: hypertension; HLD: hyperlipidemia; $m \pm SD$: mean ± standard deviation; N: number; na: not available; NSTEMI: non-ST elevation myocardial infarction; STEMI: ST elevation myocardial infarction; TUA/TRA: transulnar access/transradial access.

TABLE II. Procedural Angiographic Characteristics

First author, year (ref #)	1-VD (TUA/TRA)	2-VD (TUA/TRA)	3-VD (TUA/TRA)	Successful Vascular Access (TUA/TRA)	PCI (TUA/TRA)	Follow-up in month (s)
Aptecar, 2006 (10)	36/33.3	15.6/18.6	12.5/9	93.1/95.5	43.5/44.2	1
Geng, 2014 (11)	28.8/25.4	22.5/19.3	18.1/19.7	91.5/95.1	62.4/52.3	1
Hahalis, 2013 (16)	30.9/30.9	19.3/18.4	16.2/16.8	67.7/99.1	36.4/32.7	2
Li, 2010 (17)	12.5/10.3	5/7.7	10/5/1	98.3/100	65/69.2	1
Liu, 2014 (12)	na	na	55/57.7	92.7/95.9	100/100	12

VD: vessel disease, TUA/TRA: transulnar access/transradial access, na: not available.

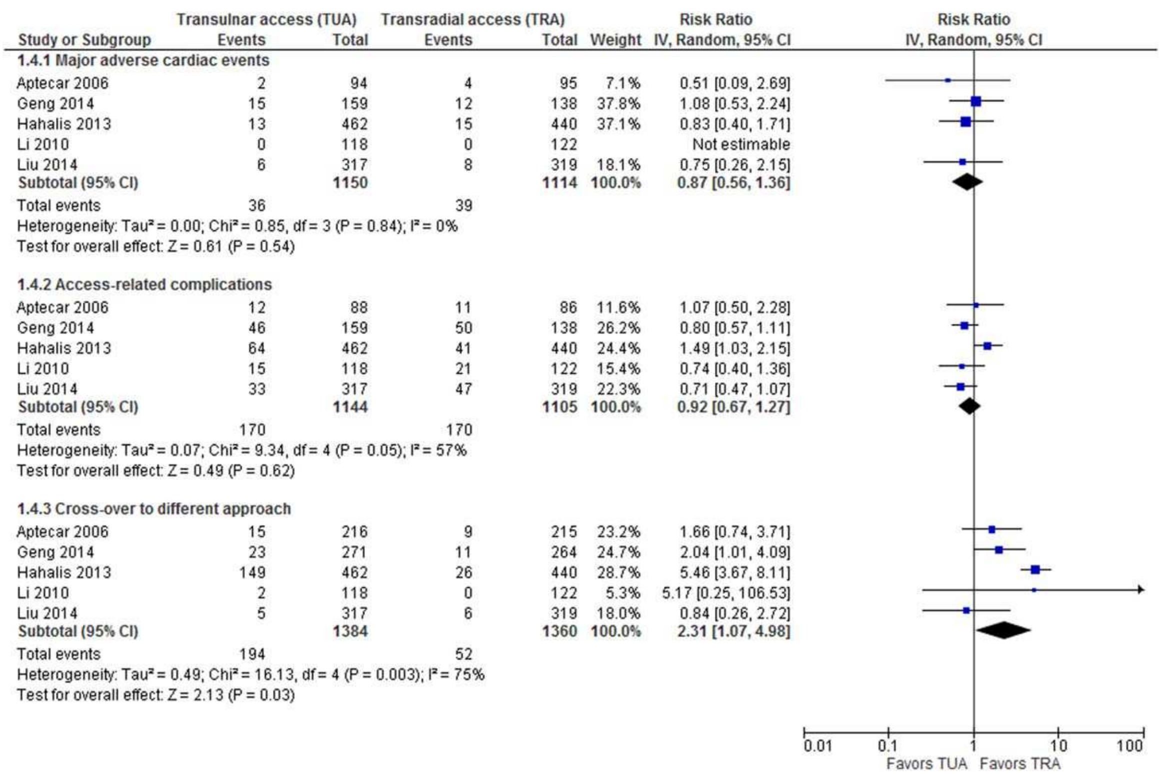

Fig. 2. MACE, composite of access-related complications, and cross-over rates. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

I^2: 67%] and bleeding/hematoma [6.9 vs. 8.3%; RR: 0.87 (0.45–1.71); $P = 0.69$; I^2: 62%]. Due to significant heterogeneity observed in all outcomes except arterial stenosis, sensitivity analyses were performed (figures not shown) that showed the studies by Liu et al. and Hahalis et al. introduced significant heterogeneity to the meta-analysis results. Analysis removing those studies did not change the direction of the effect but reduced heterogeneity.

Nerve injury and pseudoaneurysm or AVF formation were rare events. Only one incidence of nerve injury resulting in motor deficit was noted in the TUA arm of Geng et al. study that resolved with conservative therapy. There were two incidents of pseudoaneurysm formation in Liu et al. study (TRA arm) and one incident of AVF formation in Aptecar et al. study (TUA arm), all of which resolved with conservative therapy.

Number of punctures and access cross-over rates. TUA compared with TRA resulted in higher access cross-over [14% vs. 3.8; RR: 2.31 (1.07–4.98); $P = 0.003$; I^2: 75%] and number of punctures [1.57 vs. 1.4; MD: 0.17; 95% CI: 0.08–0.26; $P = 0.0002$; I^2: 0%] shown in Figs. 2 and 5, respectively. For patients randomized to TUA, 88.7% ($n = 173$), 7.2% ($n = 14$), and 4.1% ($n = 8$) patients were crossed-over to radial, femoral and contralateral ulnar routes, respectively, while for those randomized to TRA, 47.2% ($n = 25$), 43.4% ($n = 23$), and 9.4% ($n = 5$) were crossed-over to ulnar, femoral and contralateral radial, respectively.

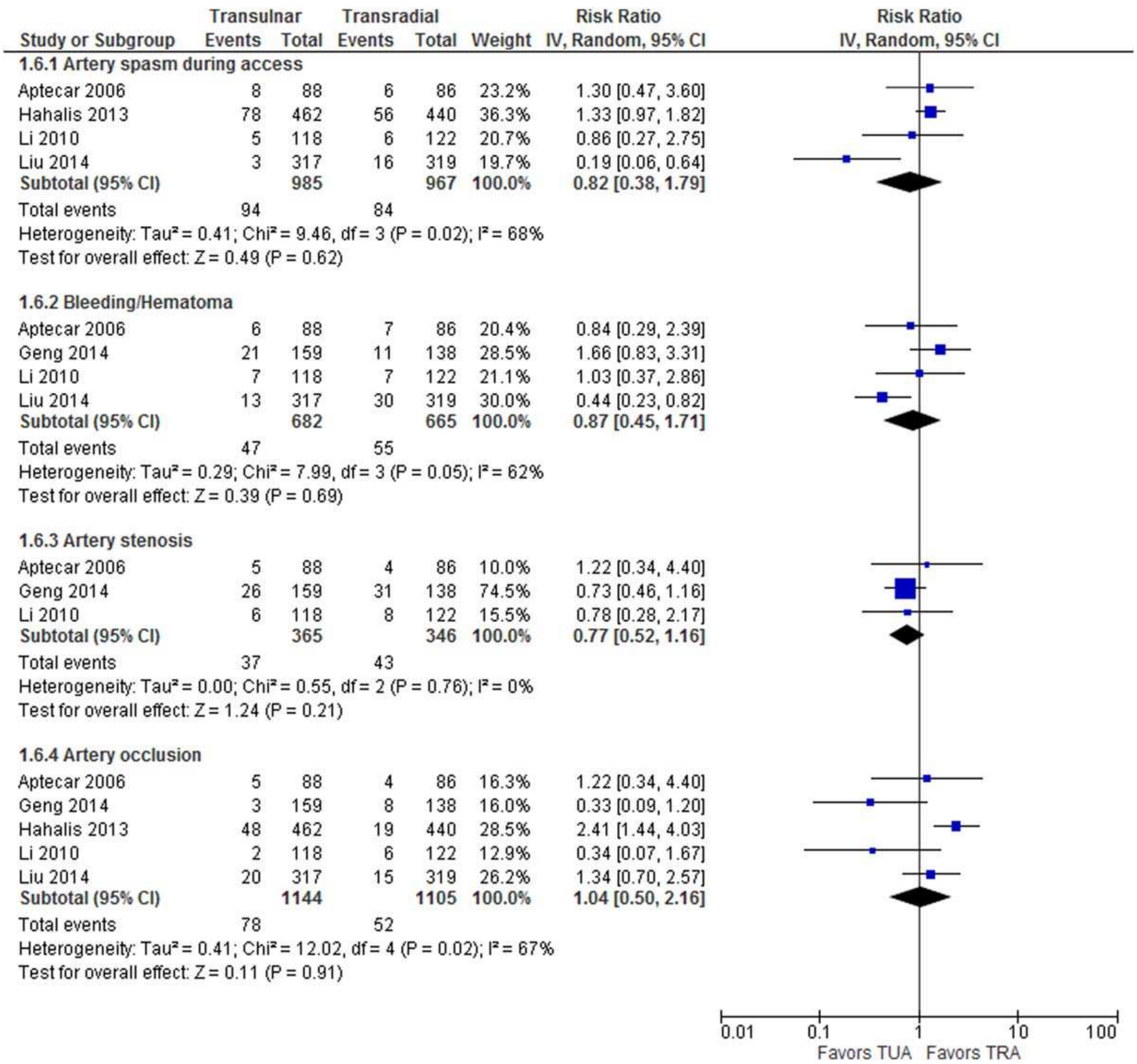

Fig. 3. Individual access-related complications. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

Due to significant heterogeneity in the access cross-over rates, we performed sensitivity analysis by excluding one study at a time and found that the study by Hahalis et al. contributed to the heterogeneity. Sensitivity analysis after removal of Hahalis et al. study resulted in new RR of 1.68 (1.04–2.70) with $P = 0.03$ and I^2: 0%.

Arterial access and fluoroscopy times and contrast volume. There was no difference in arterial access time [12.8 vs. 10.9 min; MD: 1.86 (−1.35–5.7); $P = 0.26$; I^2: 88%], fluoroscopy time [7.6 vs. 7.2 min; MD: 0.37 (−0.39–1.13); $P = 0.34$; I^2: 81%] and contrast volume [151 vs. 153.7 ml; MD: −2.74 (−17.21–11.73); $P = 0.71$; I^2: 84%] as shown in Fig. 4. Due to significant heterogeneity, we performed sensitivity analyses by excluding one study at a time and noted that the study by Liu et al. contributed to heterogeneity. After removal of Liu et al. study, the MDs were fluoroscopy time, 0.01 (−0.53–0.55) with $P = 0.97$ and I^2: 56% and contrast volume, −8.61 (−17.22, 0), $P = 0.05$, and I^2: 22%. We did not perform sensitivity analysis for arterial access time as doing so would have resulted in only one study for meta-analysis.

DISCUSSION

The current meta-analysis of RCTs of transulnar compared with TRA in patients undergoing coronary procedures resulted in similar rates of major adverse cardiac events and access-related complications. Significantly, higher access cross-over rates, and a small but significantly higher number of punctures were noted with the transulnar approach. No differences were

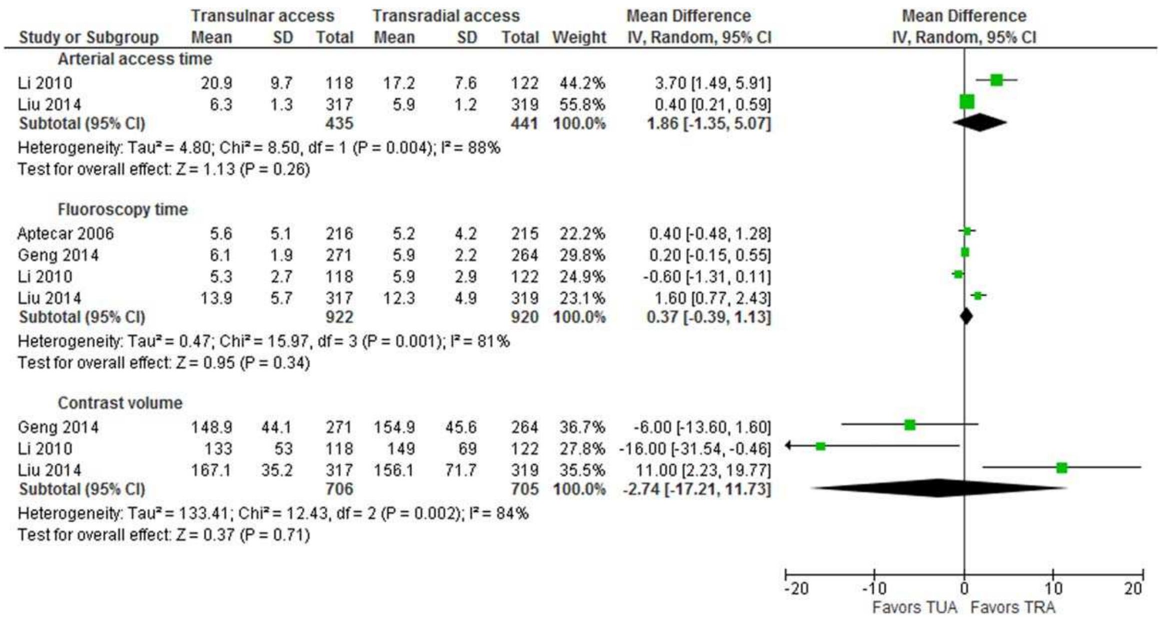

Fig. 4. Angiographic procedural outcomes. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

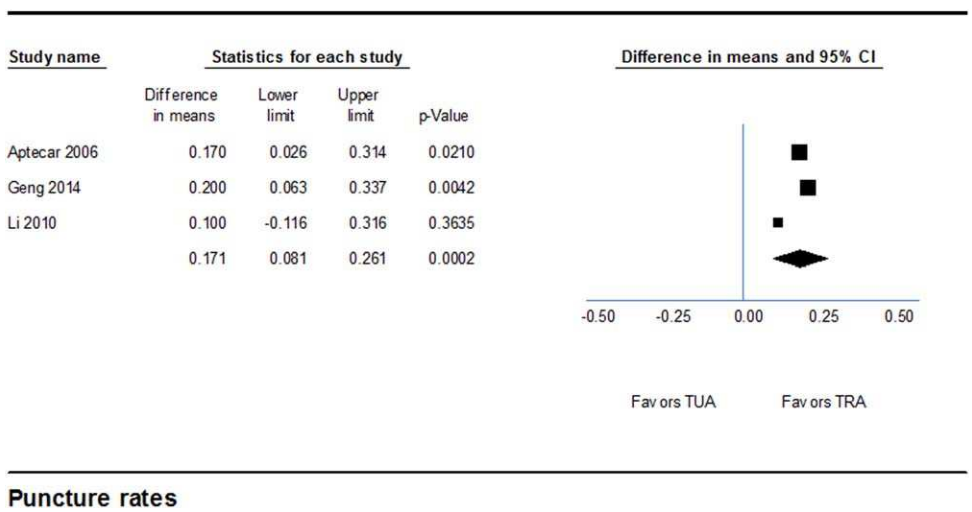

Fig. 5. Puncture rates. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

found in procedure time, fluoroscopy time, or contrast volume between two approaches.

TUA has been used as an alternative to TRA in the published single-arm studies [5,6]. The current ACCF/AHA/SCAI guidelines do not mention TUA as an alternative vascular access site for patients undergoing PCI [20]. In 4 of 5 RCTs included in the current meta-analysis, the TUA was found to be a safe and feasible alternative to TRA to reduce reliance on the femoral approach for such procedures. The study by Hahalis et al. did not recommend use of TUA as a first line vascular access or as an alternative to TRA owing to significantly higher access cross-over rates (6 vs. 32%, $P = 0.004$) [16]. In the same study, the major reasons for cross-over were higher puncture rates (3 vs. 1, $P < 0.001$), vascular spasm in patients randomized to TUA and the lack of operator experience with TUA. The authors noted that the operators in the study did not have adequate experience with the ulnar route as they were performing between 20 and 50 procedures via transulnar route. However, once cannulated, there was no difficulty finishing the angiographic procedure. At the recently held ACC meeting 2015, a large RCT ($n = 2{,}532$) comparing TUA versus TRA largely confirmed the findings of the current meta-analysis except for the cross-over rates [7]. In the intention-to-treat analysis, the rates of MACE (2.9 vs. 3.2%, $P = 0.79$), cross-over (4.4 vs. 3.8%, $P = 0.44$), artery occlusion (6.1 vs. 6.6%, $P = 0.65$), large hematoma (1 vs. 0.9%, $P = 0.69$), and artery spasm (6.9 vs. 8.7%) were similar. Unlike the study by Hahalis et al., the operator in this study had experience with both radial and ulnar artery access.

Two studies in this meta-analysis contributed to significant heterogeneity ($I^2 > 60\%$) for different outcomes. Hahalis et al. study contributed to significant heterogeneity to the outcomes of access-cross over and the number of punctures that could be due to the lack of operator experience as the authors mentioned in their article, and inclusion of patients with weak forearm pulses. Similarly, the Liu et al. study resulted in significant heterogeneity to the outcomes of arterial access and procedural times and contrast volume that could be potentially due to it being a quasi-randomized study in which patients were randomized on the basis of their birth year, and all patients in this study undergoing PCI.

There are several potential advantages of TUA. In 5–15% of patients, radial artery access may not be feasible due to anatomic variations including loops, tortuosity, or aberrations or arterial spasm [10,11,16]. In addition, since TRA suffers from cross-over up to 5% [3,21]. TUA would be a favorable alternative to TFA when TRA could not be achieved. In CABG, the radial artery can be used in place of saphenous vein or internal mammary artery with improved survival in patients who are elderly, diabetic or have COPD [22–24]. Radial artery catheterization may cause intimal hyperplasia and reduced patency rates [25], making the radial artery unsuitable for future use in CABG [9]. The ulnar artery may be an alternative route in these situations.

Catheterization of the ulnar artery may require a learning curve similar to catheterization of the radial artery [8,10]. The success of PCI through TRA depends on operator experience, and a case volume of ≥ 50 cases may be required to achieve outcomes comparable to experienced operators [26]. In addition, the ulnar artery is deeper in the wrist making it potentially more difficult to cannulate [10], although this can be overcome by using an ultrasound to guide access as reported in Li et al. study. Since there is no bony base underneath ulnar artery compared to radial artery, hemostasis might be challenging although no such observation was noted in the published RCTs. There is also concern for ulnar nerve injury due to the proximity of the ulnar artery to the ulnar nerve [16]. However, in the current meta-analysis, there was only one report of nerve damage with no consequence at follow-up.

In these studies, the indications for coronary procedures ranged from ST-elevation Myocardial Infarction (STEMI) to positive stress test. Although about one sixth of the patients had STEMI and procedural success through transulnar catheterization, there were no specific figures related to the outcomes in STEMI patients only. Higher cross-over rates and puncture rates as observed in the current meta-analysis may potentially limit the use of TUA in STEMI settings when door-to-balloon time is crucial. However, the likely advantage of this approach might be sparing radial artery for future CABG in such patients.

Ultrasound was used in all studies as part of the study in addition to clinical evaluation. Allen's test use was variable in the included studies pointing to the controversial utility of the test in assessing risk of hand ischemia [27,28]. However, regardless of the use of Allen's test as an inclusion criterion, there was no documented case of hand ischemia.

STUDY LIMITATIONS

The current meta-analysis has several limitations. There were only 5 RCTs and we did not have access to patient level data for analysis. Nonuniform reporting of the studies may have resulted in a smaller number of total studies and participants for analysis of some of the outcomes. However, this meta-analysis was strengthened by inclusion of all published RCTs of on this topic.

CONCLUSIONS

In conclusion, TUA is safe and effective compared to TRA in patients undergoing coronary procedures. Before it can be used as an alternative to TRA, more data on the arterial puncture and cross-over rates are needed.

AUTHOR CONTRIBUTIONS

Dr. Dahal had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Dahal, Rijal, Lee, and Azrin.

Acquisition, analysis, or interpretation of data: Dahal, Rijal, Lee, Korr, and Azrin.

Drafting of the manuscript: Dahal and Rijal.

Critical revision of the manuscript for important intellectual content: Lee, Korr, and Azrin.

Statistical analysis: Dahal.

Study supervision: Rijal, Lee, Korr, and Azrin.

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