

Transradial access approach for patients undergoing percutaneous coronary procedures – A new dawn

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Abstract

Historically, transfemoral approach (TFA) was the main access site for percutaneous coronary procedure. Over the past decade, transradial approach (TRA) has been gaining popularity over (TFA). With frequent use of TRA, we have recognized the advantage of TRA over TFA. Multiple trials have been conducted to investigate TRAs' benefits and risk. We have performed a literature search on TRA vs TFA, on the advantages and disadvantages of both approaches. A total of 140 citations were identified but only 38 filled our eligibility criteria.

In this review, we found that TRA is associated with reduction of access site complication, time to ambulation and cardiac related death. However, lack of training and hesitancy of older interventionalist to switch approach is an impediment to the increased use of TRA. While the transfemoral approach has a higher access site complication rate, it is still integral as an access option.

Introduction

Percutaneous coronary intervention has revolutionized the field of cardiology and has become the cornerstone of management of ischaemic heart disease [1,2]. Historically, coronary angiography or intervention has been predominantly performed via the common femoral artery [3]. However, this procedure is associated with bleeding complications, exacerbated by advances in aggressive periprocedural pharmacotherapy [4]. New technological advancements such as reduction in size of interventional devices and the introduction of vascular closure devices have reduced the incidence of major bleeding, but major complications still occur [5-8].

Campeau was the first to introduce coronary angiography via the transradial approach (through the forearm) in 1989 [9]. Several early studies reported a significant reduction in vascular complication with transradial approach compared with the transfemoral approach [10-12]. These studies raised interest in the transradial access site as a viable and attractive alternative to femoral access [13,14].

Methods

Relevant studies were identified by searching the following data sources – Medline via Ovid, Embase, Cochrane Library – and using the 'related citation' search tool in PubMed. Reference lists from identified studies were also scanned to identify any other relevant studies.

The following inclusion criteria were used: (i) studies comparing patients undergoing transfemoral or transradial approach (ii) comparison of outcome, benefit and risk between the two approaches. Meta analyses and systemic review were also included in this review. Duplicate publications were excluded.

The search strategy identified 140 citations. 20 studies were duplicated and after screening of titles and abstracts, a further 65

studies were excluded. Of the 65 studies selected, 38 fulfilled our eligibility criteria and are included in this systematic review (Table 1).

Summary of studies

The Radial Versus Femoral Access for Coronary Angioplasty and Intervention in Patients Acute Coronary Syndromes (RIVAL) study set out to determine whether radial access was superior to femoral access. This study demonstrated that transradial procedure were associated with a 60% reduction in vascular complications (especially in women) when compared with femoral approach, but showed no significance difference in rates of death, MI, stroke, or major bleed [15,16].

Minimizing Adverse Haemorrhagic Events by Transradial Access Site and Systemic Implementation of AngioX (MATRIX) trial compared transradial versus transfemoral approach in patients with ACS. The study showed no reduction in rates of MI, stroke, or major bleeding at 30 days; however a 63% reduction of vascular-access complications was seen in the transradial group [17].

Several early studies reported a reduction in mortality rates in patients undergoing transradial access for STEMI [18-20]. An example is the Radial Versus Femoral Randomized Investigation in ST Elevation Acute Coronary Syndrome (RIFLE-STEACS) trial. The study not only found a 47% reduction in the rate of access-site related bleeding

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Table 1. Summary of clinical studies assessing transradial and transfemoral approaches for cardiac catheterization

Author and the year of publication	Study Design	Sample size	Study objectives	Study findings
Brueck et al. [30]	Randomized controlled trial	1024 patient undergoing PCI assigned to TRA or TFA (1:1)	Evaluate the safety and feasibility of TRA	TRA is safe and effective. However, procedural duration and radiation exposure are higher
Cantor et al. [21]	Randomized controlled trial	50 patients with MI randomized to TRA or TFA (1:1)	To assess success rate of PCI and procedure time with TRA vs TFA	PCI has high success rates with both radial and femoral access
Chase et al. [20]	Retrospective cohort study	From a review of registry, 38 872 procedures were analysed	To assess if TRA is associated with reduction in bleeding and transfusion.	Transfusion patients had increased 30-day mortality (OR – 4.01). TRA halved transfusion rates
De Carlo et al. [25]	Prospective cohort study	531 patients undergoing PCI with GPI treatment were enrolled and randomized to TRA and TFA arm	To assess rate of bleeding, graded according to TIMI classification	TRA have significantly lower rates of all types of bleedings.
Dobies et al. [33]	Retrospective cohort study	55 729 patients undergoing PCI identified. 94.7% TFA and 5.3% TRA	Comparison of TFA and TRA in terms of safety and efficacy	TRA associated with longer fluoroscopy times with less major bleeding.
Gandhi et al. [35]	Systematic review and meta-analysis	6 observational studies, with 7753 patients included	Safety of TRA compared to TFA approach in patients with AMI and CS	Lower adverse events in TRA PCI group
Huang et al. [37]	Systematic review and meta-analysis	15 studies, involving 3 921 848 participants were included	To investigate gender disparity in the safety and efficacy of TRA and TFA	TRA reduced risk of bleeding in both sexes. MACE reduced cross-over rate increased in females.
Johnman et al. [22]	Retrospective cohort study	4534 patients undergoing PCI from April 2000 to March 2009	Assessment of procedural success, periprocedural complications and MACE.	TRA for PCI is associated with improved clinical outcomes
Jolly SS [16]	Randomized clinical trial	7021 patients with ACS randomised to either TRA or TFA (1:1)	To determine whether TRA was superior to TFA in patients with ACS undergoing coronary angiography and angioplasty.	TRA is associated with reduction in vascular complications and reduction in 30-day all-cause mortality in STEMI patients.
Kasasbeh et al. [31]	Prospective cohort study	1112 diagnostic TRA were divided into 2 groups, performed by high-volume or low-volume operators.	Assess reduction in fluoroscopy and procedural time over a 27-month period	Higher-volume operators have reduced procedure and fluoroscopy times.
Kolkailah et al. [34]	Meta-analysis	RCTs comparing TRA and TFA undergoing PCI. 31 studies were identified which includes 27,071 participants	Assess the benefits and harm of TRA compared to TFA	TRA for PCI reduces short-term MACE, cardiac death, all cause mortality, bleeding and access site complications.
Koltowski et al. [39]	Randomized controlled trial	103 patients with STEMI were randomized to either TRA or TFA (1:1)	To compare the cost between TRA and TFA in STEMI patients	Indirect cost was lower in the TRA group
Looi et al. [29]	Prospective cohort study	1001 patient identified (661 – TRA and 340 – TFA). Further analysis performed according to operators' TRA experience (RExs vs nRExs) with 12 months follow up	Comparison of TRA to TFA coronary angiography procedural times and learning curve of TRA	In the TRA group, nRExs had longer fluoroscopic and procedural times compared to RExs. However, both were equivalent in the final 3 months of analysis.
Mann et al. [24]	Prospective cohort study	218 patients underwent PCI (1:1, TRA: TFA)	Measurement of multiple outcomes including cost and time to ambulation	TRA resulted in better outcomes, earlier ambulation and lower cost.
Mehta et al. [17]	Subgroup analysis of RIVAL (16)	Randomized to TRA vs TFA	To compare outcomes in both groups, such as MACE and vascular access site complication.	Reduction of major vascular complications with TRA especially in women (3.1 vs 6.1%, p<0.0001). PCI success rate was similar in both genders.
Michel Le [34]	Multicentre randomized controlled trial	Patients with STEMI with symptoms onset less than 12 hours for PCI. 1136 patients in TRA and 1156 patients in TFA group	Primary outcome is 30-day mortality rate and secondary outcome is MACE event and bleeding rate	No significant difference in 30-day mortality rate (1.5% vs 1.3%). Secondary outcomes were similar in both groups.
Mitchell et al. [28]	Systematic review and meta-analysis	14 studies were identified	A cost-benefit analysis of radial catheterization	TRA favoured over TFA
Pancholy et al. [32]	Randomized controlled trial	1493 patients undergoing CA randomized in 1:1 ratio to TRA or TFA	Comparison of radiation exposure time between TRA and TFA	Radiation exposure was similar during diagnostic CA with TRA and TFA
Pancholy et al. [36]	Systematic review	8 studies, involving 8131 patients with CS undergoing PCI	Determine the benefit of TRA in patient with CS undergoing PCI	TRA associated with reduced mortality and MACE at 30 days
Romagnoli et al. [23]	Randomized control trial	1001 STEMI patients undergoing PCI. 500 patients randomized to TRA and 501 to TFA	To assess if TRA for STEACS is associated with better outcome compared to TFA	30-day MACE is lower in the TRA arm (13.6%) compared to TFA arm (21.0%)
Saito et al. [19]	Randomized control trial	149 patients with AMI randomized to TRA and TFA (1:1)	Comparing MACE between the two approaches	Success rate of reperfusion and MACE similar in both groups (TRA - 96.1 and 5.2% vs TFA - 97.1% and 8.3%)
Sirker et al. [38]	Systematic review and meta-analysis	Pooled data from >24 000 patients in RCT and >475 000 patients from observational studies used	To evaluate stroke complicating PCI through TRA versus TFA	TRA is not associated with increased risk of stroke events
Valgimigli M [18]	Randomized clinical trial	8404 participants with ACS undergoing PCI. Participants allocated to either TRA or TFA (1:1)	To compare TRA versus TFA approach in terms of MACE and episodes of major bleeding	TRA associated with reduced vascular-access complications, MACE, all-cause mortality and major bleeding rates.

TRA = transradial approach; TFA = transfemoral approach; PCI = percutaneous coronary intervention; GPI = glycoprotein inhibitor; TIMI = Thrombolysis in Myocardial Infarction Score; AMI = acute myocardial infarction; CS = cardiogenic shock; MACE = major adverse cardiac event; RExs = radial expert; NRExs = non-radial expert

complications, but also a reduction in the rate of cardiac death and hospital stay with transradial procedure [21].

Further advantages of transradial approach include immediate ambulation, reduced post-procedure nursing care, reduced hospital stay and related costs, and an overwhelming patient preference for transradial angiography [22-26]. Opponents of radial access have cited an associated learning curve [27] with adopting the transradial approach resulting in longer procedural time and increased radiation exposure [28]. Higher-volume radial operators however exhibit shorter procedural and fluoroscopy times as their procedural experience increases [29]. Multivariate analysis found the highest radial volume centres and operators had the lowest radiation exposure [30].

An analysis of safety outcomes for Radial Versus Femoral Access for Percutaneous Coronary Intervention from a large clinical registry was performed. This study involves the use of a multi-site registry of 58,862 percutaneous coronary intervention (PCI) procedures in a national healthcare system, the largest clinical registry of treatment practices comparing radial and femoral access outcome. The primary end points were major bleeding and radiation exposure [31].

The results showed that femoral access accounted for 94.7% and radial access 5.3% of the procedures. There were fewer bleeding events in the radial group (0.9%) than those in the femoral group (2.2%). Among patients receiving anticoagulants, the femoral bleeding rate was 4.3% compared with radial bleeding rate of 0.7%. For patients receiving bivalirudin, bleeding occurred in 337 patients (1.6%). Radiation exposure in radial cases was significant in cases involving prior coronary artery bypass graft history and non-ST-elevation myocardial infarction. The fluoroscopy time overall was longer among radial cases (19.9min) compared to femoral access (15.7 min) [31].

The limitation of this study is the difference in patients' characteristics between the two groups, where sicker patients are more likely to receive femoral access and more stable patients receive transradial approach. Additionally, the registry did not include how many failed radial routes were converted to femoral procedures and did not account for bias related to operator experience and learning curves [31].

The Safety and Efficacy of Femoral Access versus Radial Access in STEMI (The SAFARI-STEMI Trial) is a recent multicentre randomized controlled trial performed in the United States. STEMI patients referred for primary PCI with symptom onset < 12 hours were recruited and randomized to either transradial or transfemoral approach. Major exclusion criteria were fibrinolytic therapy, oral anticoagulants and prior Coronary Artery Bypass Grafts (CABGs). The primary outcome investigated was all-cause mortality measured at 30 days. The trial also evaluated bleeding events and the composite of major adverse cardiac event (MACE) [32].

Transradial approach was performed in 1136 patients versus 1156 patients receiving transfemoral approach, with similar baseline characteristics and antithrombotic treatment in both groups. The study revealed no significant difference between the 30-day mortality rate in the transradial and transfemoral group (1.5% vs 1.3%). The rate of secondary outcomes was similar for both groups and no major difference in bleeding rates [32].

The trial was stopped early by the Data Safety and Monitoring Board because it was highly unlikely that the trial would show a clinically important difference in 30-day all-cause mortality. The findings suggest that adequately trained operators should be able to

achieve similar results using either radial or femoral access for primary PCI. The limitation of this study is that it is an underpowered trial and it is not clear whether similar good outcomes with femoral access seen in the trial can be achieved in clinical practice [32].

A systematic review of Transradial versus Transfemoral Approach for Diagnostic Angiography and Percutaneous Coronary Intervention in people with Coronary Artery Disease was performed examining the benefit versus harms of the transradial compared to the transfemoral approach in people with CAD undergoing PCI. This review searched multiple databases including the Cochrane Central Register of Controlled Trials (CENTRAL) [33].

After the application of exhaustive inclusion and exclusion criteria, 31 studies were identified which includes 27 071 participants. Transradial access was associated with a reduction in net adverse clinical events, including death from cardiac causes, myocardial infarction, stroke, the need to reintervene on the same site of coronary artery stenosis, and bleeding during the first 30 days following intervention. While transradial access reduced death from cardiac causes, death from all causes during the first 30 days following intervention, bleeding, and local complications at the access site. Further radial cases shortened the length of stay in hospital but was associated with a higher radiation exposure and more technical failures requiring an alternate vascular access route. Procedural success was less with the transradial approach, due to a higher rate of cross-over to a different arterial access [33].

A review article of 'Transradial versus Transfemoral Approach in Cardiac Catheterization: A Literature Review' have found similar findings to our review [34]. The search strategy used established databases, with inclusion of articles focusing on transradial versus transfemoral approach [34].

Findings of this review is consistent with our results. Transradial approach had the advantage of lower morbidity and mortality, reduction in bleeding complication and hematoma and early discharge. However, transfemoral approach has greater availability of trained and experienced doctors in this approach, larger artery diameter and known procedural complications with known prevention [34].

Two studies compared the transradial and transfemoral approaches in people with cardiogenic shock. Both reported a reduction in mortality and MACE with the transradial approach. One study showed a reduction in access site-related and major bleeding (7753 participant) [35], while the other study (8131 participants) reported a reduction in short-term MACE [36].

Gender disparity between the two approaches was examined in another study, showing transradial approach was safer and more efficacious in both genders with females having a higher cross-over rate to the femoral approach [37]. Sirker et al. [38] addressed stroke as an outcome of interest in their meta-analysis and showed no differences between the two approaches.

Cost-effectiveness of radial vs femoral approach in primary percutaneous intervention in STEMI was assessed. A sub-analysis of the OCEAN RACE trial recruited 103 patients with myocardial infarction, and they were randomized to either radial or the femoral group. The procedures and length of hospital stay were meticulously logged, and costs were evaluated using the micro-cost method. The indirect costs, such as the patients' absence from work, were measured using the human capital approach [39].

This study revealed that clinical success was numerically higher in the radial group (90.4 vs 80.4%) and there were no differences in

MACE. The cost of therapeutic success was lower in the radial group at 3060 EUR versus 3374 EUR ($p < 0.01$). The indirect costs were lower in the radial group compared to the femoral group. Although total in-hospital cost was similar between the study groups, the indirect cost is much lower in the radial group [39].

Conclusion

The transradial approach for PCI reduces access site complications, time to ambulation and reduces cardiac related death and morbidity in acute coronary syndrome populations. Whether this approach is applicable across all interventions including elective cases remains uncertain. The major impediment of such approach is the lack of training and hesitancy of older interventionalists to switch approaches. While the transfemoral approach has a higher access site complication rate, it is still integral as an access option. The possibility that radial approach (compared to femoral) may have a higher long-term rate of periprocedural stroke requires vigilant surveillance.

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