The Role of the Transradial Approach for Complex Coronary Interventions in Patients with Acute Coronary Syndrome

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Abstract

Despite advances in antithrombotic and antiplatelet therapy, bleeding complications remain an important cause of morbidity and mortality in patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention (PCI). A significant proportion of such bleedings are related to the access site, and adoption of transradial access (TRA) may reduce these complications. In patients with ST-segment elevation myocardial infarction (STEMI), TRA reduced cardiac mortality in comparison with the femoral approach (TFA). High-risk patients such as women, obese patients and elderly subjects who are at increased risk for vascular complications and bleeding, might particularly benefit from the TRA. However, specific radial expertise providing procedural time and a success rate comparable to those with the TFA are strongly recommended before using this technique in the emergency setting.

Keywords

Transradial approach, acute coronary syndrome, percutaneous coronary intervention, non-ST-segment elevation acute coronary syndromes, ST-segment elevation myocardial infarction, cardiogenic shock, left main culprit

An invasive strategy including percutaneous coronary intervention (PCI) improves clinical outcomes in patients with ST-segment elevation myocardial infarction (STEMI) and in high-risk patients with non-ST-segment elevation acute coronary syndrome (NSTEACS). The femoral approach (TFA) is the preferred and most widely used percutaneous access site in most cardiac catheterisation laboratories worldwide. However, being a relatively deep and terminal vessel, the femoral artery may expose the patient to frequent bleeding and vascular complications, especially in the setting of acute coronary syndrome (ACS) where potent antithrombotic drugs are frequently used.

Since its initial description as a safe and feasible access route for cardiac catheterisation, the transradial access (TRA) has increasingly been used for PCI. The main advantage over the TFA is a reduced risk of access site bleeding and major vascular complications, particularly in the presence of multiple and more powerful antiplatelet and antithrombotic agents. This is mainly ascribed to the more favourable anatomy of the radial artery that runs superficially, separated from major neurovascular structures, thus allowing shorter times to haemostasis and ambulation as compared with the TFA.

More recently, the radial approach has been shown to confer mortality benefits for STEMI patients and a reduction in mortality, myocardial infarction (MI) and stroke for patients undergoing the procedure at high-volume radial centres.

Reported access failure for radial procedures in primary PCI (PPCI) is low with an access crossover rate between 3.8 % and 9.6 % with negligible time delay by expert operators. There are several reasons leading to failure – inability to cannulate, severe radial artery spasm (RAS) and anatomical variations. In some of these difficult transradial cases, ulnar artery cannulation has been proposed as a reasonable and useful alternative to the TRA if performed by an experienced radial operator, before crossover to the TFA.

Bleeding Complications in Acute Coronary Syndrome

Peri-PCI procedural bleeding complications have been consistently associated with worse outcomes and increased short- and long-term mortality. Access site-related bleeding, accounting for as many as 30–50 % of all causes of bleeding in patients with ACS, has repeatedly been found to be the major contributor for bleeding events. Due to the firm link between bleeding, ischaemic events and mortality, more attention has recently been focused on bleeding avoidance strategies. Despite the development of new more potent, selective and safe antithrombectics, the use of TRA remains likely the best way to significantly influence access site-related bleeding risk.

Recently, the Registro regionale AngiopLastiche dell’Emilia-Romagna (REAL) Registry of 11,068 STEMI patients undergoing PPCI, showed that TRA was associated with a decreased two-year mortality rate compared with the traditional TFA (8.8 versus 11.4 %, hazard ratio [HR] 1.303; p=0.025). The observed difference in death was not explained by the incidence of MI or stroke, which did not differ between groups. By
contrast, TRA was associated with a significant and marked reduction of in-hospital major bleeding or vascular events.

The available clinical evidence summarised in recent meta-analyses demonstrated a significant reduction in mortality, major adverse cardiac events (MACE), major bleeding events and major access site complications associated with the TRA. Therefore, the use of the TRA for high-risk patients with ACS certainly has a key role in the prevention of access site bleeding complications.

Randomised Controlled Trials and Registries of Transradial Access Versus the Femoral Approach in Acute Coronary Syndrome

The radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL) is the largest randomised comparison of radial and femoral artery access of 7,021 patients with ACS; 1,958 with a pre-randomisation diagnosis of STEMI; and 5,063 patients with NSTEACS. In patients with STEMI, TRA significantly reduced the primary outcome: death, MI, stroke or non-coronary artery bypass graft surgery (CABG)-related major bleeding within 30 days (3.1 versus 5.2; HR 0.60; p=0.026) and mortality alone (1.3 versus 3.2; HR 0.39; p=0.006). In patients presenting with NSTEACS, there were no significant differences in any of these outcomes. In both STEMI and NSTEACS patients, TRA reduced major vascular access site complications (1.4 versus 3.7; HR 0.37; p=0.0001), and major bleeding as defined by the Acute Catheterization and Urgent Intervention Triage strategy (ACUITY) definition (1.9 versus 4.5; HR 0.43; p<0.0001). In STEMI patients, the reduction in the primary and secondary composite outcomes was driven mainly by a reduction in mortality with a directionally consistent reduction in MI. No such benefit was observed in patients with NSTEACS. Access site crossover was higher in the radial group compared with the femoral group (7.6 versus 2.0; HR 3.82; p<0.0001), and this was consistent in both STEMI and NSTEACS cohorts.

The Radial Versus Femoral Randomized Investigation in ST Elevation Acute Coronary Syndrome (RIFLE-STEACS) is the first large randomised clinical trial of 1,001 patients with STEMI specifically designed to compare the radial (500 patients) and femoral approaches (501 patients) for primary/rescue PCI. In this nearly all-comers study, the TRA was associated with significantly lower rates of clinically relevant access site bleeding (2.6 versus 6.8%; p=0.002) and subsequent 30-day mortality (5.2 versus 9.2%; p=0.020) in comparison with TFA. The reduction in cardiac mortality and clinically relevant access site bleeding by 60% with a significant decrease in the need for transfusion in the radial arm of the RIFLE-STEACS, support the link between mortality and ‘clinically relevant’ access site bleeding. Furthermore, there were no differences in the symptom-to-balloon and door-to-balloon times between the two study groups. Vascular approach crossover was 9.6% in the radial arm and 2.8% in the femoral arm with negligible time delay by expert operators.

Recently, A Prospective Randomized Trial of Radial vs. Femoral Access in Patients with ST-Segment Elevation Myocardial Infarction (STEMI-RADIAL) showed that TRA was associated with a significantly lower incidence of major bleeding and access site complications, and a significantly better net clinical benefit – composite of death, MI and stroke, and major bleeding (4.6 versus 11.0%; p=0.0028). Moreover, TRA significantly reduced intensive coronary care unit (ICU) stay (p=0.0016) and contrast volume (p<0.01) compared with TFA.

The post hoc analysis of the Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction Trial (HORIZON-AMI), showed improved event-free survival in patients undergoing primary PCI by the TRA and confirmed the advantage of the TRA with regard to haemorrhagic complications also in patients treated with bivalirudin.

Based on data derived from the RIFLE-STEACS and STEMI subgroup of RIVAL, in the latest 2012 European Society of Cardiology (ESC) STEMI Guidelines recommendations, TRA is preferred over TFA if performed by an experienced operator (Class IIa, Level B).

In a cohort of 21,339 patients suffering from STEMI in the Swedish Coronary Angiography and Angioplasty Registry (SCAAR), the adjusted one-year cumulative risk of death was lower in patients treated via TRA (odds ratio [OR] 0.78, 0.64–0.96; p=0.018).
A recent meta-analysis of nine randomised controlled studies involving 2,977 patients suggested that the TRA is associated with a 47% reduction in mortality and a 38% reduction in major adverse cardiac events in STEMI patients undergoing PCI.24 Similarly, analysis of the North American National Cardiovascular Data Registry – CathPCI® Registry – that included 90,879 patients who underwent either primary or rescue PCI for STEMI showed that TRA was independently associated with the reduction of in-hospital mortality (OR 0.76, 95% confidence interval [CI] 0.57–0.99) and of bleeding (OR 0.62, 95% CI 0.53–0.72).30

Finally, the analysis of 46,128 PPCI cases recorded in the British Cardiovascular Intervention Society database over a five-year period, suggested that TRA was independently associated with a lower 30-day mortality (HR 0.71, p<0.05), in-hospital major adverse cardiac and cerebrovascular events (MACCE) (HR 0.73, p<0.05), major bleeding (HR 0.37, p<0.01) and access site complications (HR 0.38, p<0.01).31

However, the 0.7% absolute reduction in major bleeding and 0.3% absolute reduction in access site-related complications associated with TRA use cannot fully explain the scale of the mortality benefit associated with TRA in PPCI.31

Additional unmeasured factors may contribute to the benefit of TRA PCI. Although some access site complications will not result in significant blood loss, they may lead to systemic inflammation, activation of prothrombotic pathways and activation of the clotting cascade. This could further increase the risk of cardiovascular events even though the initial insult is not haemodynamically significant.32,33 Bleeding or access site complications can also lead to withdrawal of antiplatelet agents, increasing the risk of ischaemic complications.

**High-risk Subgroups for Bleeding and Vascular Complications**

Patients undergoing PCI in the context of ACS are expected to receive a combination of potent multiple antithrombotic drugs that may lead to an increased risk of bleeding and subsequent morbidity and mortality.

Women are at higher risk of bleeding and other adverse outcomes after PCI than men.24,25 In a recent observational study, routine TRA was associated with reduced bleeding risk in women.26 Unfortunately, muscular arterial hyper-reactivity, procedural discomfort and small artery diameter increases the risk of first radial access failure (9.6% in women versus 1.6% in men). However, successful radial access does not allow the operator to use more aggressive combinations of anticoagulants and antiplatelet agents in this group, given that women remain at higher non-access site bleeding risk.27,28

Elderly patients are also at high risk for bleeding and vascular complications post-PCI. Lower limb peripheral artery disease (PAD), tortuosity of the iliac arteries and aneurysms of the abdominal aorta may represent relative or absolute contraindications to TFA. As a result of PAD in the elderly, radial access appears to be as feasible as femoral access. In two randomised trials, the TRA was associated with fewer vascular complications in elderly patients.29,30

**Cardiogenic Shock and Left Main Culprit in Acute Coronary Syndrome**

Cardiogenic shock has a poor outcome compared with less severe presentations of ACS. The Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock (SHOCK) trial40 showed the importance of revascularisation to improve outcomes, but the recent Intraaortic Balloon Pump in Cardiogenic Shock II (IABP-SHOCK II) trial41 failed to show any marginal benefit of adding haemodynamic support with intra-aortic balloon counterpulsation in the setting of shock.

Cardiogenic shock is associated with a doubling of the risk of bleeding compared with the absence of shock.42 There may be a safety advantage of using the radial artery for the coronary intervention and reserving the femoral artery for larger devices in patients with cardiogenic shock (see Figures 1–4).

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**Figure 3 and 4: Final Result of Transradial Access Percutaneous Coronary Intervention with Drug-eluting Stent of Unprotected Left Main Culprit in Patient Presenting with ST-segment Elevation Myocardial Infarction and Cardiogenic Shock**

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Rodriguez-Leor analysed their single-centre registry experience with radial access in cardiogenic shock patients. From a 1,400-patient experience, 122 (8.7 %) developed cardiogenic shock with 80 undergoing transfemoral and the remaining 42 undergoing transradial catheterisation. Mortality (64.3 versus 32.5 %, p<0.001), serious access site complications (11.9 versus 2.5 %, p<0.03), access site complications requiring blood transfusion (7.1 versus 0.0 %, p<0.04) and MACCE (death, infarction, stroke, serious bleeding and postanoxic encephalopathy) (73.8 versus 43.8 %, p<0.001) were greater in patients treated by the femoral route. After multivariate analysis, initial TRA was associated with lower mortality (OR 0.39; 95 % CI 0.15–0.97) compared with an initial TFA.41

Bernat et al. evaluated outcomes of 197 STEMI patients with signs of cardiogenic shock who were treated with primary PCI at two high-volume centres. The TRA was used successfully in 55 % of cases where at least one radial artery was weakly palpable. TRA emerged as an independent predictor of survival with more than half of the patients treated successfully. Mortality at one-year was 44 % in the radial group and 64 % in the femoral group (p=0.0044).42

Romagnoli et al. analysed 241 consecutive patients (91 % with ACS and left main culprit in 26 % of cases) receiving IABP support during PCI in four high-volume centres. Patients were further divided in two groups – 116 patients receiving double femoral access (FF) and 125 receiving both radial and femoral (RF) approaches. NACEDs were more frequent in the FF group when compared with the RF group (67 versus 41 %, p<0.01). In particular, this difference originated from an increase of access site-related bleeding (21 versus 7 %, p<0.01) and cardiac death (41 versus 25 %, p<0.01).43 These data show that a radial-femoral access strategy is safer than a femoral-femoral access strategy, and this safety advantage is associated with reduced mortality.44

Left Main Culprit

A significant involvement of the left main coronary artery occurs in 4–7 % of patients presenting with an acute myocardial infarction (AMI).45,46 These critically ill patients frequently present with cardiogenic shock or cardiac arrest and are at high risk for in-hospital major cardiac adverse events.45,46

Primary PCI for an AMI due to an unprotected left main coronary artery (ULMCA) culprit lesion is a rare procedure, frequently associated with adverse clinical outcomes. The incidence of AMI due to an ULMCA culprit lesion is reported to be 0.8–5.4 %.20

Patients undergoing primary PCI for an AMI due to an ULMCA culprit lesion and presenting with cardiogenic shock have a high 30-day mortality compared with patients without cardiogenic shock, with the estimated 30-day all-cause mortality of 55 % for patients with cardiogenic shock and 15 % for patients without cardiogenic shock. A hybrid approach of initial revascularisation by primary PCI and elective surgery afterwards remains an alternative treatment option.

Treating patients with cardiogenic shock or after cardiac arrest is one of the most challenging PCI procedures due to the nature of the clinical presentation while targeting a coronary lesion associated with a very large area of the myocardium at risk. These haemodynamically unstable patients have an extensive amount of ischaemic myocardium. Immediate mechanical haemodynamic support may prevent from further multi-organ failure.

Whether newer and more powerful circulatory assist devices (Impella®, TandemHeart®, Extracorporeal Membrane Oxygenation [ECMO]) will result in better outcomes is the subject of ongoing clinical evaluation before widespread adoption.51

Most PCIs in high-risk ACS patients can be performed by TRA through conventional & French (Fr) guiding catheters, including complex cases, left main bifurcations and cardiogenic shock. However, a stepwise approach to learning is proposed and high-risk ACS-PCI is recommended as the last step.

Ultimately, the treatment of patients in shock requires an individualised approach. Although the radial pulse may return with vasopressor administration, there may be clinical situations in which radial access is not possible and femoral access must be used. From the available evidence supporting the safety of the TRA over the TFA, a ‘radial first’ strategy likely still applies in most patients, even those with large STEMI and shock if performed by a skilled and experienced radial operator. Haemodynamic support devices can be placed via the femoral route and temporary pacemakers can be placed through the forearm or femoral veins (see Figures 1–4).52

Ulnar Artery Access

The TRA may be difficult or associated with increased risk of complications in the presence of significant radial artery abnormalities, severe loops and curvatures, after failed radial artery cannulation and when the radial artery was repeatedly used previously.

Transulnar artery cannulation (TUA) has been proposed as an alternative access for interventions in patients with a small-calibre radial artery or a thin radial pulse and stronger pulsation of the ulnar artery. Larger studies have further confirmed the safety and effectiveness of TUA as an alternative wrist approach to TRA for coronary interventions.50,51

The procedural success, advantages and complication rates for transulnar interventions appear similar to those from the TRA.52,53 Adding the ulnar artery access expertise could further reduce the crossover rate to TFA and lower the intrinsic risk of bleeding and vascular complications associated with the TFA. When the TRA is not possible or fails, the TUA may be considered as a safe alternative before reverting to the TFA.54 The TUA is a viable option for the high-volume radial centres, when performed by the expert radial operators who are skilled in ulnar artery cannulation.53

Limitations of the Transradial Access for Complex Percutaneous Coronary Intervention in Acute Coronary Syndrome

Longer procedure duration and radiation exposure during the learning curve, and the potential influence on radial artery patency have slowed down acceptance of the TRA. Technique of TRA requires a specific set of skills, and is associated with a significant learning curve. With appropriate training, similar success rates with the TRA and TFA may be achieved even in complex ACS cases. The learning curve is highly individual and more experienced operators may become proficient sooner.

To achieve the best results in TRA interventions, individual operators and institutional teams should aim at maintaining the highest feasible rate of TRA. After the learning curve has been completed, for over
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50 % TRA in routine practice, a minimum of 80 procedures per year per operator is recommended.\(^{1,4}\)

A stepwise approach to learning is proposed according to clinical characteristics and PCI difficulty. ACS-PCI is proposed as the last step (NSTEACS and STEMI patients), due to multifaceted clinical settings and PCI complexity. The highest level of competency is obtained when patients requiring complex clinical management can be managed with timely and technically proficient control of PCI, irrespective of vascular access anatomy.\(^2\)

The TRA is associated with very low incidence (0.2 %) of major vascular complications.\(^{1,2}\) Haematomas are usually minor, affecting only subcutaneous tissue. Unlike groin bleeding, subcutaneous bleeding after TRA is rapidly noticed and can be controlled by local compression. Major vascular complications like compartment syndrome are completely avoidable.

Radial artery occlusion (RAO) is the most common complication, affecting 1.5–33.0 % shortly after the procedure, depending on the antithrombotic regimen, sheath size and protocol for haemostasis.\(^{5,6}\) Although usually asymptomatic, RAO is an important consequence of TRA, as it prohibits future ipsilateral TRA. Preserving radial artery patency is of paramount importance. Proper anticoagulation, downsizing of material (sheathless catheters) and shorter and less forceful ‘patient haemostasis’ of the radial artery with the emphasis on maintaining adequate arterial flow, considerably reduces the risk of RAO. It is important to remember that almost all potential complications are preventable by accurate preprocedural evaluation, meticulous technique and optimal post-procedural management.

The incidence of RAS has varied considerably (4–30 %) depending on its definition, study population and the expertise of the operators.\(^{5,6}\) Spasm is the second most common cause of radial access failure after anatomical variations. The incidence of moderate/severe RAS is low in centres with a default TRA (2.7 %), its development and procedural failure (0.7 %) appears strongly related to the numbers of puncture attempts and the use of larger-bore sheaths.\(^{2,4}\)

**Technical Recommendations for Complex Percutaneous Coronary Intervention in Acute Coronary Syndrome**

Challenging anatomy must be avoided to minimise the risk of complications and shorten the duration of both the procedure and radiation exposure. For this reason, a systematic preliminary angiogram of the forearm arteries through the radial introducer is recommended.

The final choice of procedure will depend on the level of expertise of the operator, and the equipment required. In patients with cardiogenic shock, TRA procedures can be performed if the radial artery is palpable while leaving two potential femoral accesses for IABP counterpulsation or more complex cardiac-assist devices (see Figures 1–4).

The right side is usually more ergonomic to the operator; however, the left radial approach might be more convenient in the learning phase because of similar catheter handling when compared to the femoral approach. Even if dedicated catheter handling are available, traditional femoral shapes accommodate the radial approach easily. Coaxial alignment with the target coronary artery is mandatory and requires different handling for the right radial versus femoral approach.

The choice of guiding catheter (diameter, shape, size) is essential for adequate back-up. Most PCIs can be performed through 6 Fr guiding catheters, including complex cases, thrombus aspiration, post-CABG and left main bifurcations.

In selected patients of large stature, larger catheters (7 or even 8 Fr) or sheathless guiding catheters can be considered, allowing for large-lumen guiding catheters to be used in a small radial artery. However, these catheters, though useful in selected cases, are more difficult to handle in complex procedures due to lower back-up.

RAO should be prevented during and after the procedure with systematic assessment of the arterial patency.\(^{2}\) Spasm prevention with 3–5 milligrams (mg) verapamil administered intra-arterially through the sheath is routinely recommended. Specific early and delayed post-procedural attention to forearm haematomas is mandatory.

**Conclusion**

Considerable evidence supports conversion to TRA for most PCI procedures in ACS, with an emphasis on decreasing access site bleeding and vascular complications without compromising procedural outcome. Beside the development of new more selective and safe antithrombotic agents, the use of TRA remains likely the best way to significantly affect access site-related bleeding risk. A high-risk subset of patients for bleeding and vascular complications such as complex STEMI patients, women and the elderly, might particularly benefit from the TRA whenever appropriately available and performed by skilled operators.

Complications arising from the TRA are infrequent, negligible and mostly avoidable compared with TFA complications. Certain limitations to the TRA such as longer radiation exposure during the learning curve and the potential influence on radial artery patency have slowed down acceptance of this technique. Therefore, the modern interventional cardiologist should go through a high-volume radial training programme, and after developing the optimal radial expertise, adopt ‘the TRA first’ whenever possible. Adding the ulnar artery access expertise could further reduce the crossover rate to TFA, and lower the intrinsic risk of bleeding and vascular complications associated with TFA. Femoral approach will likely remain the viable alternative for patients not eligible for the wrist access and accessory access for larger devices in patients with cardiogenic shock. Complex PCIs in patients with ACS, cardiogenic shock and left main culprit, should be performed only by experienced high-volume radialists.

Finally, it is important to remember that the choice of access site is only one aspect of improving the patient’s outcome. All interventions should be performed according to the highest available standards, providing the best care for each individual patient without sacrificing procedural success and long-term prognosis.

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