Research Highlights

Highlights from the latest articles in the radial approach in ST-elevation myocardial infarction

Radial approach in ST-elevation acute coronary syndrome: the latest evidence

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ST-elevation myocardial infarction (STEMI) is a clinical syndrome where the rapid achievement of coronary flow restoration is mandatory. To achieve that target, whenever it is possible, percutaneous mechanical revascularization is preferred to systemic thrombolysis [1].

Transradial interventions (TRIs) have always been seen as more time consuming than transfemoral interventions, owing to a longer learning curve for operators, a smaller size of the equipment that can be used and the risk of spasm of the radial artery.

In view of that, the impact of the radial approach on the outcomes of STEMI patients is still debated.

In this article, we will review four recently published studies that evaluated the radial approach versus the femoral approach in patients undergoing percutaneous coronary intervention (PCI) for ST-elevation acute coronary syndrome (STEACS).

First, we will analyze two large randomized studies, both published in the same issue of the *Journal of the American College of Cardiology* in December 2012. Second, we will focus our attention to data coming from a US registry, which give us a good snapshot of the real world. Finally, we will make a step forward, reviewing a study that specifically included patients with STEMI-related cardiogenic shock, which has always been considered to be an absolute contraindication for radial access.

Reference

1 Task Force Members, Steg PG, James SK *et al.* ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation: the Task Force on the management of ST-segment elevation acute myocardial infarction of the European Society of Cardiology (ESC). *Eur. Heart J.* 33(20), 2569–2619 (2012).

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An analysis of RIVAL trial data: radial approach improves outcomes in patients with STEMI

Evaluation of: Mehta SR, Jolly SS, Cairns J *et al.* Effects of radial versus femoral artery access in patients with acute coronary syndromes with or without ST-segment elevation. *J. Am. Coll. Cardiol.* 60(24), 2490–2499 (2012).

The RIVAL trial was a large randomized multicenter study that randomized 7021 patients with acute coronary syndrome to undergo diagnostic angiogram and PCI (if needed) with a radial or femoral approach. The authors failed to demonstrate a benefit of the radial approach to reduce the primary outcome of death, myocardial infarction, stroke or non-coronary artery bypass graft

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(CABG)-related major bleeding at 30 days, despite a significant reduction of incidence of vascular access complications [1].

Mehta *et al.* published the results of a prespecified analysis of the RIVAL population according to the prerandomization diagnosis of STEMI or non-STEACS [2].

A significant interaction was found between the prerandomization diagnosis of STEMI or NSTEACS and the access site used (radial or femoral), for the primary composite end point of death, myocardial infarction, stroke and non-CABG-related major bleeding (p = 0.025).

The rate of crossover was higher in the radial approach than the femoral approach, both in the STEMI and NSTEACS cohort; however, the procedural success rate was similar in both groups (more than 95%).

Among STEMI patients, a significant 40% reduction of the primary end point incidence in the radial group versus the femoral group at 30 days (3.1 and 5.2%, respectively, hazard ratio [HR]: 0.60, 95% CI: 0.38–0.94; p = 0.026) was observed. The same benefit was not seen in the NSTEACS patients (3.8 vs 3.5%, HR: 1.11, 95% CI: 0.83–1.48; p = 0.49).

Surprisingly, there was no significant difference in terms of non-CABG-related major bleedings, which occurred very infrequently in both arms, among both STEMI and NSTEACS patients. The better outcome of the radial approach observed among STEMI patients was driven mainly by the single end point of death (1.3 vs 3.2%, HR: 0.39, 95% CI: 0.20–0.76; p = 0.006).

When the occurrence of access-site bleeding complications (large hematomas or pseudoaneurysms requiring surgical closure) was included into the major bleeding definition, the radial approach was more beneficial than the femoral approach in both STEMI and NSTEACS cohorts. In addition, STEMI patients who died at follow-up had a higher incidence of major bleeding events compared with those who survived (11.0 vs 1.0%, respectively; p < 0.0001).

Among patients undergoing primary PCI (74% of the entire STEMI group), the radial approach confirmed its benefit in reducing the incidence of the primary composite end point, but caused a minimal, albeit significant, increase in the time from randomization to the end of PCI. The incidence of major bleeding, including access-site complications, was significantly lower in the radial approach compared with the femoral approach as well.

References

1 Jolly SS, Yusuf S, Cairns J *et al.* Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomised, parallel group, multicentre trial. *Lancet* 377(9775), 1409–1420 (2011).

2 Mehta SR, Jolly SS, Cairns J *et al.* Effects of radial versus femoral artery access in patients with acute coronary syndromes with or without ST-segment elevation. *J. Am. Coll. Cardiol.* 60(24), 2490–2499 (2012).

Radial approach reduces mortality in patients with STEMI: results from a multicenter randomized trial

Evaluation of: Romagnoli E, Biondi-Zoccai G, Sciahbasi A *et al.* Radial versus femoral randomized investigation in ST-segment elevation acute coronary syndrome. *J. Am. Coll. Cardiol.* 60(24), 2481–2489 (2012).

The RIFLE-STEACS study is a multicenter randomized study, which evaluated the benefits of the radial approach in 1001 patients with STEACS undergoing primary/rescue PCI in four Italian high-volume centers [1].

The authors included patients with suspected STEACS undergoing PCI (within 24 h of symptoms onset) in this study, and randomized them to have radial or femoral access. Interestingly, while the study protocol excluded patients with contraindication to radial or femoral access (positive Allen's test or known peripheral vasculopathy) or higher risk of bleeding, other high-risk characteristics, such as cardiogenic shock and/or hemodynamic instability, were not considered to be exclusion criteria, leading to a study population with a profile of risk similar to the real world.

Radial access significantly reduced the incidence of primary end point of the study (30-days incidence of composite end point of death, myocardial infarction, stroke, target-lesion revascularization and non-CABG-related major bleeding, 13.6 vs 21.0%, 95% CI: 2.7–12.0%; p = 0.003), as well as the single end point of mortality at 30 days (5.2 vs 9.2%, 95% CI: 0.8–7.3%; p = 0.020).

Notably, patients of the radial group had lower incidences of total bleeding events (7.8 vs 12.2%; 95% CI: 2.7–12.0%; p = 0.026) owing to a low rate of access-site-related bleeding complications (2.6 vs 6.8%; 95% CI: 1.6–7.0%; p = 0.002), as well as reduced need for blood transfusions (1 vs 3.2%; 95% CI: 0.4–4.2%; p = 0.025).

The radial approach was demonstrated to be feasible in the setting of STEACS, leading to a significantly shorter stay in hospital than the femoral approach. The rate of crossover was higher in the radial approach group and it occurred more frequently in case of cardiogenic shock presentation. The time from puncture to the first balloon inflation was slightly, but significantly, higher in the radial group than the femoral approach, as well as the fluoroscopy time.

Reference

1 Romagnoli E, Biondi-Zoccai G, Sciahbasi A *et al.* Radial versus femoral randomized investigation in ST-segment elevation acute coronary syndrome. *J. Am. Coll. Cardiol.* 60(24), 2481–2489 (2012).

Radial approach and outcomes in patients with STEMI: a look at the real world

Evaluation of: Baklanov DV, Kaltenbach LA, Marso SP *et al.* The prevalence and outcomes of transradial percutaneous coronary intervention for ST-segment elevation myocardial infarction. *J. Am. Coll. Cardiol.* 61(4), 420–426 (2013).

The National Cardiovascular Data Registry is a large US database where data from 1315 catheterization laboratories around the country are collected.

Baklanov *et al.* analyzed data from this registry to evaluate the prevalence and outcomes of the radial approach in patients undergoing primary or rescue PCI between January 2007 and September 2011 [1].

After excluding patients with cardiogenic shock, with procedural access other than the radial or femoral artery, who had undergone other PCIs during the same admission or those without enough data to properly evaluate bleeding complications, a total of 90,879 patients from 541 sites were included in the study population.

The primary end point of this study was the in-hospital mortality. Other end points evaluated were the procedural success rate and bleeding complications within the first 72 h after the procedure.

In the USA, the preferred access site for PCI in case of STEMI is still the femoral artery. Only 6.4% of the procedures were performed via a radial approach in 2011, although this percentage had increased compared with the previous 5 years.

The authors showed that the radial approach lead to a 4 min longer door-to-device median time ($p < 0.0001$) and to a 2 min longer fluoroscopy median time ($p < 0.0001$). On the other hand, the rate of procedure success was similar in the two groups.

More importantly, taking into account the limitations of data coming from a registry and after the appropriate statistical adjustments, the radial approach reduced the adjusted rate of both in-hospital mortality (odds ratio: 0.76, 95% CI: 0.57–0.99; $p = 0.0455$) and bleeding complications (odds ratio: 0.62, 95% CI: 0.53–0.72; $p < 0.0001$). The number needed-to-treat with the radial approach to prevent one bleeding was 25, while the number needed-to-treat to prevent one death was 207.

Reference

1 Baklanov DV, Kaltenbach LA, Marso SP *et al.* The prevalence and outcomes of transradial percutaneous coronary intervention for ST-segment elevation myocardial infarction. *J. Am. Coll. Cardiol.* 61(4), 420–426 (2013).

Radial approach is not a taboo in STEMI presenting with cardiogenic shock

Evaluation of: Bernat I, Abdelaal E, Plourde G *et al.* Early and late outcomes after primary percutaneous coronary intervention by radial or femoral approach in patients presenting in acute ST-elevation myocardial infarction and cardiogenic shock. *Am. Heart J.* 165(3), 338–343 (2013).

Cardiogenic shock has always been considered to be a contraindication for TRIs. The low peripheral perfusion makes the arterial puncture more challenging than usual: the concern of wasting precious time for the myocardial revascularization make many operators routinely opt for the femoral approach in this setting.

In this study, Bernat *et al.* retrospectively evaluated the outcomes and characteristics of 197 patients that presented to the catheterization laboratory of two high-volume centers in Canada and Poland with STEMI and cardiogenic shock from 2006 to 2010, in order to receive coronary angiogram and primary PCI (7.4% of all the STEMI patients of the same period of time) [1].

The access (radial or femoral) was chosen by operators, but if at least one radial artery was palpable, patients received TRI. In the case of impalpable radial artery, intravenous adrenaline bolus to temporarily raise blood pressure was allowed, as well as the usage of an intraortic balloon pump.

TRIs were successfully performed in the 55% of patients with STEMI presenting with cardiogenic shock.

Surprisingly, the radial approach did not significantly increase the symptoms-to-balloon time, the overall procedure duration or the fluoroscopy time. Thrombolysis in myocardial infarction-3 (TIMI-3) flow was achieved in the same percentage of patients in both femoral and radial group (67 and 69%, respectively).

The non-CABG-related major bleedings were less frequent in the radial group than the femoral group (13 vs 25%; $p = 0.042$), as well as the access-site bleeding complications (0.9 vs 9%; $p = 0.012$).

The prognosis of cardiogenic shock as presentation of STEMI was poor, but mortality at 1 year of follow-up seemed to be significantly lower in the radial group (44 vs 64%; p = 0.0044). Moreover, the radial approach was shown to be an independent factor that reduced late mortality (HR: 0.65, 95% CI: 0.42–0.98; p = 0.041).

Reference

1 Bernat I, Abdelaal E, Plourde G *et al.* Early and late outcomes after primary percutaneous coronary intervention by radial or femoral approach in patients presenting in acute ST-elevation myocardial infarction and cardiogenic shock. *Am. Heart J.* 165(3), 338–343 (2013).