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Progression of radial approach to PCI in the USA: from niche procedure to default approach

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"…US catheterization laboratories are experiencing a paradigm shift favoring the transradial approach."

The transradial technique for coronary angioplasty and intervention has become popular because of its associated lower bleeding risk and access site complications compared with the femoral access approach. The radial artery has long been known to be the preferred site of access of many countries, except for the USA. Recent observational studies show that US catheterization laboratories are experiencing a paradigm shift favoring the transradial approach.

Clinical evidence: safety & efficacy

Evidence suggests that post-percutaneous coronary intervention (PCI)-related bleeding is associated with increased risk of morbidity and mortality [1]. This association promoted the following: identification of high-risk bleeding patients; intensified development of anticoagulation/antiplatelet therapies with improved bleeding profiles; and advancement of access techniques at the time of PCI. It was within this framework that the transradial approach became an attractive procedure-related target to minimize bleeding complications in the setting of coronary angiography and intervention.

In 2004, Agostoni *et al.* performed a meta-analysis of 12 randomized trials (n = 3224) concluding that the transradial approach was a safe alternative to femoral access for diagnostic and therapeutic procedures. The decreased bleeding with radial access was primarily at the vascular access site, due to the superficial location of the radial artery and ease of compression. Reported drawbacks to the transradial approach were the learning curve with higher procedural failure rates among inexperienced operators, increased radiation exposure and radial artery occlusion [2].

One of first and largest observational studies assessed nearly 600,000 PCI procedures in the USA. Compared with the femoral approach, the transradial approach was associated with a significantly lower risk of bleeding complications (odds ratio: 0.42; 95% CI: 0.31-0.56) [3]. Shortly after, Jolly *et al.* retrospectively evaluated 18 randomized trials and found that radial access was associated with 73% reduction in bleeding compared with femoral access, but again at the expense of a slightly higher rate of procedure failure. There was also a trend toward reduced ischemic outcomes such as major adverse cardiac events [4]. These findings provided the rationale for a large prospective randomized trial comparing the transradial and femoral techniques among acute coronary syndrome (ACS) patients undergoing catheterization or PCI. The Radial VsfemorAL access for coronary intervention (RIVAL) trial was the largest multicenter randomized study to compare radial versus femoral access among 7000 ACS patients. The RIVAL study continued to validate the safety of transradial intervention (TRI), but also demonstrated following key findings: when a different definition of bleeding that included access site hematomas was applied *post hoc*, the radial approach was associated with a significant reduction in major vascular complications, with an event rate of 1.4% among patients assigned to radial access

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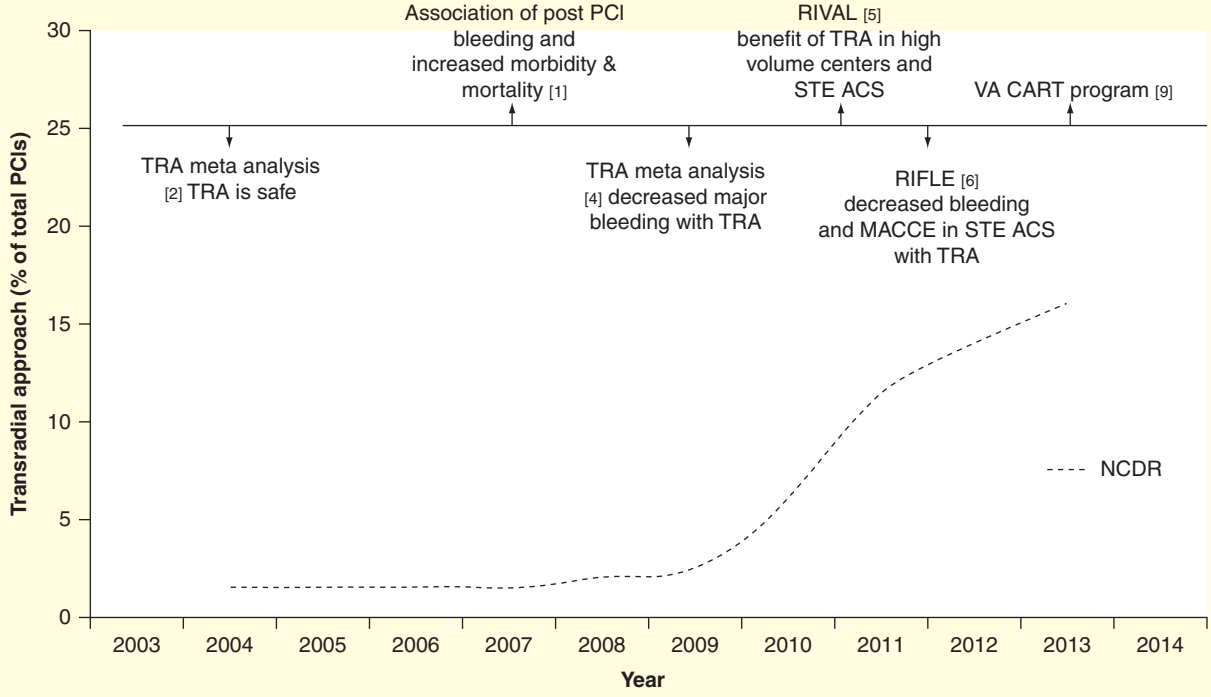

Figure 1. Progression of transradial approach to percutaneous coronary intervention in the USA.
MACCE: Major adverse cardiac and cerebrovascular events; NCDR: National Cardiovascular Data Registry; PCI: Percutaneous coronary intervention; RIFLE: Radial Versus Femoral Randomized Investigation in ST-Elevation Acute Coronary Syndrome (RIFLE) trial; RIVAL: Radial VsfemorAL access for coronary intervention trial; STE ACS: ST-elevation acute coronary syndrome; TRA: Transradial approach; VA CART: Veterans Affairs Clinical Assessment Reporting and Tracking.

and 3.7% among patients treated with the femoral approach. A significant interaction between access site and center volume was also seen for the primary outcome with the transradial approach being associated with a 51% reduction in primary outcome of death, MI, stroke or non-CABG major bleeding among centers with the highest radial volume. Finally, patients undergoing TRI who presented with a ST elevation acute coronary syndrome (STEACS) experienced a significant 40% relative reduction in the primary end point of death, MI, stroke or non-CABG major bleeding and a 61% relative reduction in mortality, although not major bleeding [5]. This latter subgroup was studied specifically in the Radial Versus Femoral Randomized Investigation in ST-Elevation Acute Coronary Syndrome (RIFLE-STEACS) study, which randomized 1001 acute STEACS patients undergoing primary PCI to either the transradial or femoral approach at four very experienced radial centers in Italy. Requirements for participating as an investigator in this trial included >150 PCIs a year with ≥50% interventional cases via the transradial approach. Compared with the femoral approach, the radial access was associated with significantly lower rates of cardiac mortality (5.2 vs 9.2%; p = 0.020), and Bleeding Academic Research Consortium defined bleeding (7.8 vs 12.2%; p = 0.026) [6].

Taken together, the clinical data presented over the last 10 years support TRI as being as safe as the femoral approach, and when performed by expert transradial operators, is likely superior to femoral access with respect to access-related bleeding complications, and potentially reduced mortality in high-risk patients such as those with STEACS.

Increasing trend of transradial approach in the USA

Currently, the transradial approach is the dominant PCI technique in many European and Asian countries, as well as in Canada, being implemented in as high as 80% of PCI procedures in some regions [7]. The transradial approach's strong following outside the USA is evidenced by the fact that the two largest randomized trials evaluating the procedure heavily relied on patient enrollment from Europe: the RIVAL trial enrolled 44% (n = 3133) patients from 16 European countries and the RIFLE-STEACS trial enrolled 100% (n = 1001) of patients from Italy.

By contrast, in the USA, TRI was initially implemented in a minority of PCI cases only. An analysis of the procedures performed at 606 US sites between 2004 and 2007 demonstrated that the transradial approach was used in as little as 1.3% of cases. It is unclear why there was little uptake of TRI in the USA, but it may have been due to lack of systematic training in the technique and a lack of concerted industry effort to promote it [3]. Recent epidemiologic studies show that the transradial approach to PCI is experiencing substantial growth, up to 13-fold, in the USA over the last 10 years [8,9]. Figure 1 depicts the use of the transradial approach as outlined by the

two largest ongoing US PCI registries, the National Cardiovascular Data Registry (NCDR) and Veterans Affairs Clinical Assessment Reporting and Tracking (CART) program in relation to the accumulation of registry and trial data supporting the safety and favorable outcomes. These data demonstrate an exponential growth of TRI among the US medical centers occurring in parallel with the publication of peer-review data [8,9].

Beyond the data

In addition to the increase in evidence defining the role of TRI, there are likely other influences that have led to its increased adoption in the USA. For example, the transradial approach has recently garnered a place in practice guidelines. In 2011, the Society for Cardiovascular Angiography and Interventions (SCAI), the primary professional association for invasive and interventional cardiologists, published an executive summary endorsing the use of the transradial approach for coronary and peripheral procedures [7]. More recently, the European Society of Cardiology (ESC) published a consensus statement recommending the transradial approach as the preferential access choice for PCI [10]. In addition, there has been proliferation of training courses both in and outside of the USA, both by academic institutions and industry. Such programs range from didactic to hands-on training courses and have allowed for rapid effective diffusion of the transradial access technique under the tutelage of experts. The aforementioned are merely a fraction of the many complex intangibles prompting the surge of TRI in the USA. Regardless of the true etiology for the recent uptake of TRI, with one of six PCIs among US catheterization laboratories occurring via the radial artery, it is safe to say that the transradial approach is no longer a niche procedure [8].

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