Is It Time for Radial Access to Become a Quality Metric for Percutaneous Coronary Intervention?

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The preferred arterial access site for cardiac catheterization has evolved over time as improved catheter and device design has allowed for smaller and easier-to-use equipment. Selective coronary angiography was first performed via the brachial artery and the Sones technique. It then evolved to transfemoral access (TFA) with the Judkins technique and now transradial access (TRA) is frequently utilized for cardiac catheterization and percutaneous coronary intervention (PCI).1

When each of these techniques were first introduced, it took time before they were adopted into standard clinical practice. Just as TFA gradually replaced the brachial artery cutdown, TRA is becoming the standard of practice worldwide.

See Article by Hulme et al

These advancements have reduced vascular complications while increasing patient satisfaction. TRA has a clear qualitative benefit to patients and a higher proportion of patients prefer TRA to TFA.2,3 Well-designed clinical studies and randomized clinical trials soon followed, which began to quantify the clinical benefits of radial access.4 A Trial of Trans-Radial Versus Trans-Femoral PCI Access Site Approach in Patients With Unstable Angina or Myocardial Infarction Managed With an Invasive Strategy (RIVAL) was one of the first large, adequately powered clinical trials to examine the effects of TRA on cardiovascular events in patients undergoing PCI for acute coronary syndrome.5 In this trial, the primary end point of death, myocardial infarction, stroke, or Bleeding Academic Research Consortium (BARC) major bleeding.6 In particular, patients treated with TRA had lower risk of death (RR, 0.67; P=0.01) and bleeding (risk ratio [RR], 0.72; P=0.045). The relationship between TRA volume and outcomes seen in the RIVAL trial was also seen in the MATRIX trial. In the sites with the highest proportion of patients undergoing TRA, the effects of TRA on mortality and bleeding were the greatest.

In this issue of Circulation: Cardiovascular Interventions, Hulme et al7 add further observational evidence in support of both TRA and the relationship between TRA volume and outcomes. The authors analyzed 164,395 PCIs performed over a 2-year period (2012–2013) in England and Wales. TRA increased during this period of time and in the last quarter of 2013, it was used for >70% of all interventions. TRA was associated with significantly lower odds of mortality (odds ratio, 0.61; P<0.001). Interestingly, the magnitude of the association between TRA and death varied depending on both the total number of PCI performed, total number of PCIs performed via TRA, and the proportion of cases performed via TRA. For every 100 cases performed via TRA, there was a corresponding 11% decrease in the odds of death. This relationship was limited to operators and was not seen as the number or the proportion of PCI performed via TRA increased at the center level. Those operators who had the highest overall volume of PCI also performed the highest proportion of cases via TRA.

How does one explain the finding that the magnitude of benefit with TRA increases based on the proportion and number of cases an operator performs via TRA? Prior studies have found a relationship between increasing procedural volume and improved outcomes for high-risk, complex surgery, and cardiovascular care.8,9 The relationship between volume and outcomes is complex; yet, the associations seen in this observational study and in the RIVAL and MATRIX randomized clinical trials (which are less susceptible to confounding) reflect that patients have better outcomes when TRA PCI is performed. This may be especially true when performed by high-volume, predominately TRA operators. TRA PCI is more technically challenging than TFA; however, efficiency and procedural success increase with the number of TRA cases.10 Thus, it seems feasible that those operators who have mastered the technique and use it most are best able to perform TRA and have outcomes reflective of this.

As operators gain increased proficiency with TRA, the population in whom they feel comfortable using it grows. Operators just beginning to perform TRA or those who perform only a small proportion of cases through TRA are most likely to implement radial access in stable, nonacute patients who are the lowest risk population. As operators become more

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proficient in the procedure, previous study has shown that the bleeding reduction seen with TRA increases. In addition, the population for whom they are likely to offer TRA changes to incorporate higher risk patients. This is important because these higher risk patients, such as those with acute coronary syndrome who are being treated with potent antithrombotic agents, are more likely to benefit from TRA. Thus, the use of strategies to avoid bleeding in those patients who are at the highest risk of adverse events and death may be the key factor that is driving the benefit of TRA.

There are other possible explanations for the finding of a relationship between TRA volume and outcomes. It is possible that operators who perform the majority of cases through TRA lose proficiency in TFA access thus increasing the number of vascular complications with that approach. It is also possible that the patients treated via TFA by providers who predominately use TRA are higher risk than patients treated via TFA by operators who default to this approach. For example, in this study, 2.5% of all TFA procedures performed by default femoral operators were in cardiogenic shock when compared with 9.2% of patients treated with TFA by operators who performed ≥75% of cases via TRA. Thus, the findings of this study could represent the fact that when default radial operators use the femoral approach, patients tend to be much sicker.

The authors accounted for these changes in patient population by controlling for a variety of potential confounders, including cardiogenic shock, and the results were consistent in those analyses. Although the authors adjusted for cardiogenic shock and similar findings were seen in the subgroup of patients who did not have cardiogenic shock, all observational studies are potentially subject to unmeasured confounding. Despite the use of appropriate statistical methods to account for differences in the populations, it remains possible that the differences in the patients treated with TFA when compared with TRA cannot be fully controlled for with adjusted analyses.

This study has several important implications. First, it represents further evidence, albeit observational, of the benefit of radial access. Although numerous studies, both observational and randomized, have shown that radial access reduces bleeding in patients undergoing PCI, a large, prospective registry provides further evidence that rates of bleeding are lower with TRA than with TFA. Furthermore, they also found that patients treated with TRA had lower rates of death when compared with patients undergoing PCI via TFA. This large, prospective, observational registry adds additional evidence in support of the mortality benefit with TRA that was seen in 2 randomized controlled clinical trials and a meta-analysis of clinical trials.

Second, these data illustrate that operators can perform the majority of cases via TRA and still be high-volume operators. One of the limitations with TRA is that the procedure is more technically challenging and can result in longer procedural times with higher contrast and radiation use early in the learning curve. Some operators have resisted transitioning from TFA to TRA because of these concerns. Yet, it is worth noting in this observational study, the operators with the highest overall volume were the operators with the highest proportion of cases performed via TRA, suggesting that there was no significant trade off with respect to procedural time and efficiency in the hands of experienced radial operators.

The overall clinical benefit seen in this study, as well as randomized clinical trials, suggests that TRA should be the preferred method of access in patients undergoing cardiac catheterization. After the publication of the MATRIX trial, the European Society of Cardiology guidelines for the treatment of patients with acute coronary syndrome gave their highest recommendation (level IA) for a radial first approach for coronary angiography and PCI. In a similar manner, a recent consensus paper on TRA in PCI by the European Association of Percutaneous Cardiovascular Interventions and Working Groups on Acute Cardiac Care and Thrombosis of the European Society of Cardiology supported a goal for operators to perform over half of all diagnostic and interventional procedures and at least 80 procedures/year per operator with radial access.

To date, TRA has followed a path seen before with other advances in cardiovascular care (Figure). The procedure was first shown to be feasible. Radial access was then incorporated into clinical practice and well-designed clinical studies found TRA to be a safe and effective strategy for patients undergoing PCI. TRA is now the preferred access site as a part of guideline-based clinical practice strategy. Based on recent clinical trials which are supported by the findings in this study, it is time for catheterization laboratories, hospital systems, and professional societies to make TRA a quality metric and set benchmarks for the proportion of cardiac catheterizations and PCI cases done via the radial artery.

There are many important considerations before implementing. What should the quality metric be—proportion of cases, absolute number of cases, etc? How many TRA PCI cases are required to define competency during subspecialty training? Future research efforts should help guide the conversation in this direction. However, given that we have multiple high-quality, multicenter randomized controlled trials involving >17000 patients which, when pooled together, demonstrate a reduction in mortality, cardiac events, and major bleeding, the benefits of transradial access over the femoral
approach should no longer be in question. Instead, we must focus on increasing utilization, especially in the United States. Although there has been a 13-fold increase in the adoption of transradial PCI between 2007 and 2013, the transradial approach continues to be significantly underutilized in the United States (<20% of all PCIs) compared with Canada, Europe, and Asia (>50%). Perhaps the implementation of TRA as a quality indicator will help improve the utilization and uptake of TRA for PCI.

Disclosures

None.

References


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