In the first report of complications after balloon angioplasty in the seminal National Heart, Lung, and Blood Institute registry, myocardial infarction and coronary artery dissection are each reported in 5% of patients. The phrase “blood loss” is mentioned twice, the word “bleeding” is mentioned once, and “transfusion” is not mentioned at all. As the former set of events becomes increasingly uncommon, considerable attention has been redirected from preventing ischemia to bleeding avoidance strategies. A search of PubMed (accessed May 11, 2015) using the terms <PCI> and <bleeding> yielded 1851 hits. An academic consortium to address the issues posed by bleeding is already 4 years old, and a considerable body of literature now documents the association between bleeding and subsequent mortality. The effort to manage bleeding has largely consisted of a 2 pronged approach: the adoption of transradial access (TRA) for angiography and percutaneous coronary intervention (PCI) and the modification of pharmacological regimens. The transradial approach was first described by Campeau4 >25 years ago. Since that time, procedural success rates have equaled those for transfemoral access (TFA), with crossover to the transfemoral route occurring ≈6% of the time. Meta-analyses have suggested its superiority to TFA for reduction of bleeding, vascular access complications, and probably mortality. Two large randomized trials, RIVAL (A Randomized Comparison of Radial vs Femoral Access for Coronary Intervention in ACS) and MATRIX (Minimizing Adverse Hemorrhagic Events by Transradial Access Sites and Systemic Implementation of AngioX) Access, including >15,000 patients have provided more concrete evidence of its superiority to TFA in patients with acute coronary syndromes. Two modestly sized trials1,12 and a prespecified substudy of RIVAL13 suggest that this benefit may be greatest in patients undergoing PCI for ST-segment-elevation myocardial infarction, presumably because of the more intense antithrombotic treatment that these patients receive. The European Association of Percutaneous Cardiovascular Interventions consensus document has described TRA as the default approach to intervention, particularly in high-risk patients.5

See Article by Hamon et al

In the current issue of Circulation: Cardiovascular Interventions, Hamon et al14 provide an intriguing and refreshing, if different, perspective. Their observations are taken from the EUROMAX (European Ambulance Acute Coronary Syndrome Angiography) trial of bivalirudin versus heparin begun before primary PCI in patients with ST-segment-elevation myocardial infarction, performed between 2010 and 2013. Patients were randomized to receive either bivalirudin or heparin (89% received unfractionated heparin) approximately an hour beginning before PCI. Operators selected TRA in 47% of patients and TFA in 53%. Interestingly, patients undergoing TRA had lower baseline risk (younger age, more likely to be men, and less likely to have prior coronary bypass or chronic kidney disease), were more likely to receive a P2Y12 antagonist before PCI, and were less likely judged to be in need of a glycoprotein IIb–IIIa antagonist before PCI was begun. The primary outcome in the current observation, a composite of death and major non-CABG (coronary artery bypass graft surgery) bleeding, was less common in patients with radial access (5.2% versus 7.4%; odds ratio, 0.69 [0.49–0.99]). However, after adjustment for baseline risk, there were no differences in either the primary composite outcome (6.6% versus 3.9%; odds ratio, 0.58 [0.33–1.03]) or in the key secondary end point, which included major or minor bleeding (7.0% versus 5.1%; odds ratio, 0.72 [0.42–1.21]), although they were directionally similar to prior trial results. Bivalirudin reduced bleeding risk who underwent PCI using either access strategy. A multivariable risk model indicated that bivalirudin was a predictor of bleeding risk, whereas access site was not.14

These results stand in contradistinction with those of the large randomized trials that have shown TRA to be more effective than TFA. Although it is easy to dismiss them as observations now that powerful randomized data are available, that view would be mistaken. It is important to take these data seriously as they tell us how strategies are implemented in the day-to-day world. Patient selection for lower risk and less than impressive findings for TRA might not have been unexpected had they come from the US, where TRA is still relatively uncommon. However, they are surprising in the context of a trial that was performed largely in France, where even 7 years ago, 55% of PCIs were reported to be performed using TRA.16

In the current report, we are not given data on operator or site experience with TRA. Both are important determinants of the success of TRA relative to TFA. When Hess et al17...
examined indicators of procedural facility, specifically fluoroscopy times and contrast volumes after TRA among patients registered in the US National Cardiovascular Databank Registry (NCDR), they observed a steep learning curve that had an inflection point at ~50 operator cases, but that continued to improve through at least 200 cases. Both RIVAL and MATRIX Access had strict criteria for selection of operators. In the former trial, operators had to have ≥50 transradial catheterizations to participate, whereas in the latter study, a total of 75 TRA interventions with the preceding year were required. Similarly, site experience plays an important role. In RIVAL, there was a statistical interaction between assignment to TRA and site use of TRA. A benefit for TRA was observed only in the upper tertile (>146 TRA/operator/y) of site use, whereas in MATRIX Access, the benefit seemed to be restricted to sites in which ≥80% of procedures were radial. Closely related to the issue of operator and site experience is the issue of clustering. Feldman et al studied patients in the NCDR and reported that the use of TRA in the USA grew from 1.18% in the Q2 of 2007 to 16.6% in the Q2 of 2012. Its use was clustered in that only one-tenth of participating sites used radial PCI in more than one-fifth of their cases. In a recent report from ALKK (Arbeitsgemeinschaft Leitender Kardiologischer Krankenhausärzte) registry in Germany, TRA was also used in a small number (16.5%) of primary PCIIs and also seemed to be clustered in that 75% of centers used TRA in <10% of cases. In both reports, there was a clear case selection bias favoring low-risk patients for TRA. Conversely, in the current report, where operator and site experience are presumed to be high, there is still a bias favoring selection of lower risk patients for TRA. One wonders then, whether the operators and sites in the current report represented the low end of the TRA use spectrum or were in fact experienced TRA operators who were able to identify higher risk patients who might benefit from TFA for adjunctive reasons.

The other important observation was that unlike TRA, bivalirudin allocation was associated with a substantial reduction in the risk of bleeding, regardless of the selected access approach. This finding is in contradistinction to the observation reported from MATRIX Access in which bivalirudin did not reduce either major or fatal bleeding, and in which there was no statistical interaction between assigned access site and assigned antithrombin allocation. Why are the findings so different? The authors speculate that differential patient selection for trials of pharmacotherapy compared with trials of access site may have played a role. Another possible factor is the differential use of glycoprotein IIb–IIIa antagonists: 30% in the study by Hamon et al versus 12% in MATRIX Access. Alternatively, experienced TRA operators may have become good at discerning which patients were likely to benefit from TRA versus TFA.

These findings seem iconoclastic in the current era. They should give pause to the current impetus to adopt TRA uniformly. Here, we see a set of current data from well-characterized patients indicating that within a region where TRA is practiced frequently, and practiced well, operators still chose TFA in half of their patients with ST-segment–elevation myocardial infarction and obtained good results. In fact, when operators were able to select access site, this choice had less impact on patient outcomes than did using the appropriate pharmacological strategy. This is important as it becomes increasingly recognized that nonaccess site bleeding is associated with a greater risk of mortality than access site bleeding, probably because it signals patient frailty.

The practice of TRA has assumed nearly cult-like status. Many interventional cardiologists have adopted the appellation radialist and there are even radialist groups on such social media as Facebook and YouTube and scholarly articles whose titles have adopted a nearly evangelical tone with terms such as “transform” and “convert.” Alternatively, the European Association of Percutaneous Cardiovascular Interventions consensus document recommends a progressive rather than a radical transition to TRA for those who are so inclined. Although randomized trial data point out the procedural superiority of TRA, the current report should remind us that apparently the world of bleeding avoidance often extends beyond the wrist.

Disclosures

None.

References


Key Words: Editorials ■ acute coronary syndrome ■ bivalirudin ■ myocardial infarction ■ percutaneous coronary intervention
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