New Frontiers in Transradial Intervention

A present-day assessment of three important clinical issues.

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Transradial angiography and intervention is widely practiced throughout the world[1] but accounts for a minority of cardiac procedures in the United States.[2] Although the transradial approach offers many clinical and economical advantages, the most tangible benefit is a reduction in vascular access site bleeding complications after percutaneous coronary intervention (PCI).[3] Recently, the science of transradial PCI has been advanced with the publication of several studies pertaining to radial artery access,[4-6] right versus left radial artery approaches,[7] and understanding the mechanisms of transradial PCI failure.[8] Despite this, there remain several unanswered questions. What is the best anticoagulation strategy for transradial PCI? Is there a role for transradial access in the treatment of acute myocardial infarction? How can radial artery patency be maintained for future procedures? This article summarizes the state of evidence that is available to answer each of these questions and proposes recommendations based on consensus where evidence is lacking.

WHAT IS THE OPTIMAL ANTITHROMBOTIC STRATEGY FOR TRANSRADIAL PCI?

The past decade has seen vast changes to the anticoagulation landscape for PCI. Commonly used regimens include unfractionated heparin (UFH) with or without a glycoprotein inhibitor (GPI), low-molecular-weight heparin with or without GPI, and bivalirudin. Although the specific data supporting each regimen are beyond the scope of this article, each medication(s) received approval based on demonstrating a favorable clinical benefit-to-risk relationship and, in particular, minimizing periprocedural or 30-day ischemic endpoints in patients with acute coronary syndromes (ACS).[9-13] In each of these landmark trials, vascular and bleeding complications were considered in determining the net clinical utility of each treatment strategy. It is important to note that all of these landmark studies predominantly used a femoral approach to access.

Because transradial PCI is associated with a < 1% vascular access complication rate,[14] it is reasonable to reconsider the traditional antithrombotic paradigm. Although access site bleeding and vascular complications are nearly eliminated with transradial access, non–access site bleeding continues to be an appreciable risk. It is clear that the risk of non–access site bleeding varies with the population studied and the antithrombotic regimens used.[15] For example, in patients undergoing PCI, access site bleeding accounts for the majority of bleeding events; in contrast, non–access site bleeding predominates in patients with non–ST-segment elevation ACS because a significant proportion of them do not undergo PCI. In a recent retrospective analysis of > 17,000 PCI patients, non–access site bleeding accounted for more than half of all bleeding events.[16] Genitourinary, gastrointestinal, and head/neck bleeding were the most common sources of non–access site bleeding.

The relative impact of the radial approach on bleeding associated with a particular antithrombotic therapy is difficult to assess due to the rarity with which transradial PCI is represented in published trials. The prevalence of transradial PCI in the ACUITY trial of bivalirudin was 6.2%.[17] Although the radial approach was associated with a significant reduction in ACUITY-defined major bleeding compared with the femoral approach, the impact of bivalirudin over heparin/enoxaparin plus GPI was attenuated by the use of radial access such that the type of anticoagulant was no longer significant for access site bleeding. Similarly, the radial approach accounted for only 4.4% of cases in the SYNERGY trial of enoxaparin for ACS treatment[18] but accounted for 67% of the patients in the ATOLL trial of intravenous enoxaparin in primary PCI for ST-segment elevation myocardial infarction (STEMI).[19] Intravenous enoxaparin was associated with a significant reduction in major bleeding over UFH when used with femoral access in the STEEPLE trial;[13] however, the high use of transradial PCI negated the bleeding advantage of intravenous enoxaparin in the ATOLL trial. The use of transradial PCI was rare in the pivotal trials of GPI.[9,11,20,21] However, the advantage of a radial approach on bleeding complications in the con-

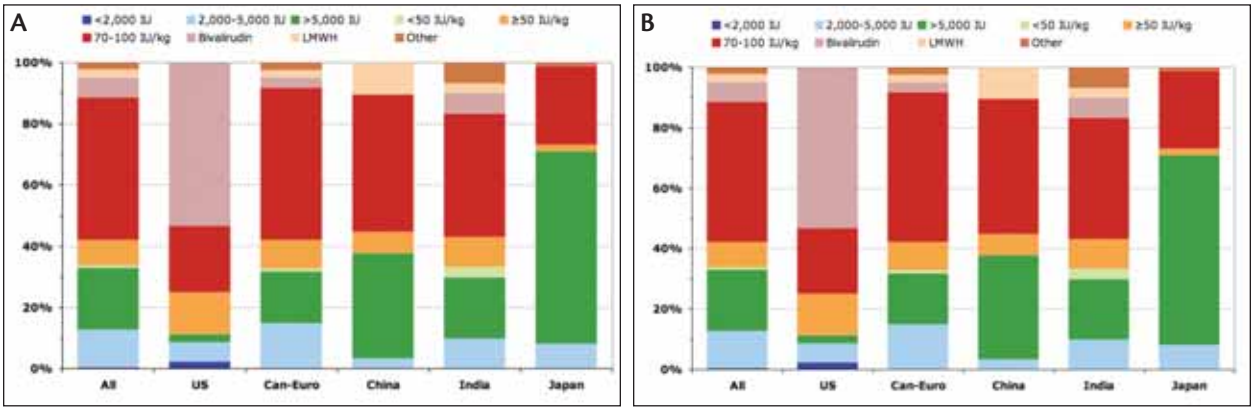

Figure 1. Global anticoagulation utilization patterns for elective (A) and urgent (B) transradial PCI. Reprinted with permission from Bertrand OF et al. *JACC Cardiovasc Interv*. 2010;3:1022–1031.[1]

text of GPI has been reported in studies that have compared radial with femoral PCI.[3,4]

Interestingly, from the recently published survey of global practice patterns among transradial operators, there does not seem to be a consensus on the antithrombotic strategy used for PCI.[1] For elective and low-risk PCI cases, a majority of operators in the United States use bivalirudin (53.2%), whereas in other countries, UFH alone is most commonly used. For ACS patients, UFH with or without GPI is frequently used outside of the United States. In the United States, UFH with or without GPI and bivalirudin with or without GPI regimens are similarly used (Figure 1).

Given the available data, it is difficult to make a strong evidence-based recommendation for any particular regimen. What does appear important is an adoption of approaches that reduce both access site and non–access site bleeding. As previously mentioned, radial access nearly eliminates access site bleeding but would not be expected to reduce non–access site bleeding. Concomitant pharmacological approaches are necessary to accomplish "global" reduction in bleeding risk. Therefore, combining transradial PCI with appropriate dosing of antithrombin and antiplatelet agents,[22] or with bivalirudin or intravenous enoxaparin, appears to be a reasonable approach until further data are available.

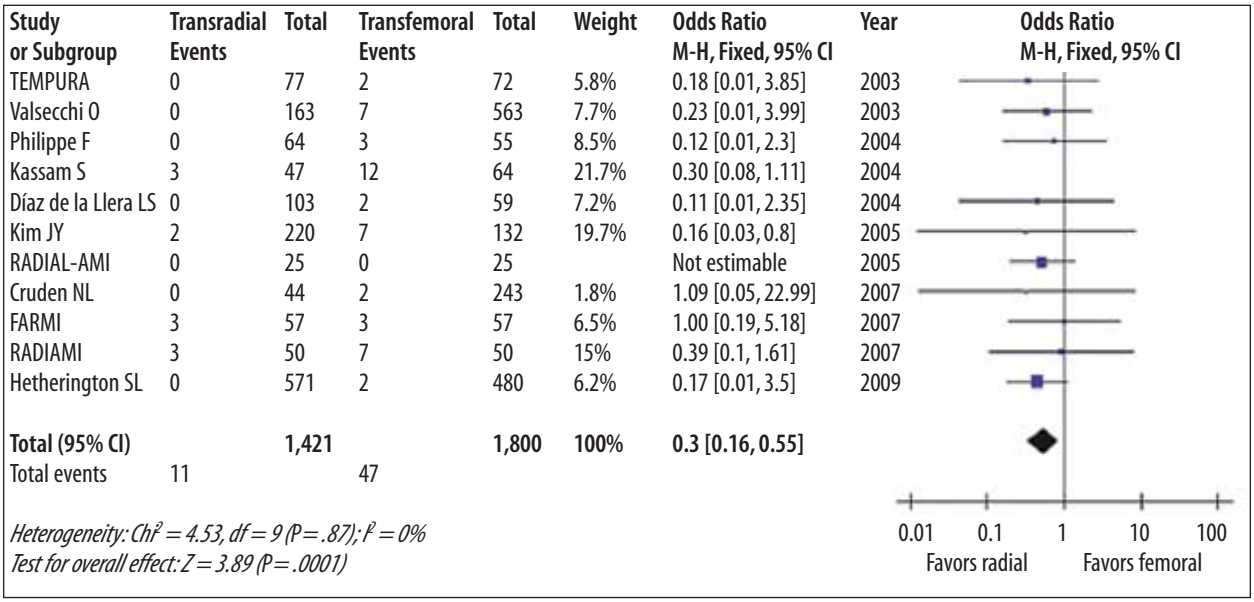

Figure 2. Comparing the risk of death. A meta-analysis of clinical trials of transradial versus transfemoral access for treatment of acute myocardial infraction. Reprinted with permission from Vorobcsuk A et al. *Am Heart J*. 2009;158:814–821.[24]

TABLE 1. RANDOMIZED CLINICAL TRIALS COMPARING TRANSRADIAL TO TRANSFEMORAL ACCESS FOR ACUTE MYOCARDIAL INFARCTION

Trial	Design	Exclusion Criteria	Key Findings
RADIAMI[31]	Prospective, randomized (TR vs TF), single-center, 50 patients in each group	> 12 hours from symptom onset, > 75 y or height < 150 cm, Killip class 3 or 4, need for IABP/pacemaker before angiography, previous CABG	Procedural success in all patients, no difference in bleeding between groups, increased door-to-balloon time in TR group (76.9 ± 25.9 min vs 64.6 ± 26.9 min; *P* = .02), time to ambulation less in TR group
FARMI[32]	Prospective, randomized (TR vs TF), single-center, 57 patients in each group	Killip class > 2 or shock, need for an IABP or pacemaker, previous CABG, intolerance to abciximab	Improved time to ambulation in TR group, less vascular complications in TR group (3.5% vs 19.3%; *P* = .05), similar rates of angiographic success of PCI, higher rate of crossover in the TR group (12.3% vs 1.8%; *P* = .03), duration of symptoms to re-establishment of normal flow was similar between the groups
TEMPURA[33]	Prospective, randomized (TR vs TF), single-center, 77 patients in TR and 72 patients in TF groups	> 12 hours from symptom onset, abnormal Allen's test results, shock with a nonpalpable radial pulse, previous CABG	Total procedure time shorter in TR group (44 ± 18 min vs 51 ± 21 min; *P* = .03), successful reperfusion over 95% in both groups, shorter length of stay for TR group among survivors, 6-month restenosis rates were similar
RADIAL-AMI[34]	Prospective, randomized (TR vs TF), multicenter, 25 patients in each group	> 12 hours from symptoms or receiving thrombolytics, cardiogenic shock, abnormal Allen's test results, contraindication to GP IIb/IIIa inhibitors	Increased door-to-balloon time in the TR group (32 vs 26 min; *P* = .04), no major bleeding in either group

Abbreviations: CABG, coronary artery bypass grafting; IABP, intra-aortic balloon pump; TF, transfemoral; TR, transradial.

TRANSRADIAL ACCESS FOR STEMI

The treatment of STEMI has evolved over time[23] such that outcomes have significantly improved.[25] Despite this improvement, patients with STEMI undergoing PCI have higher acute mortality rates, lower procedural success rates, higher resource utilization, and more bleeding complications compared with patients undergoing elective PCI or PCI for non–ST-segment elevation ACS.[26-29] Bleeding in particular appears to be a major risk factor that is linked to subsequent mortality in the STEMI population, and strategies associated with a reduction in bleeding risk are also related to decreased mortality.[30] Transradial access offers another approach to lowering bleeding risk in this high-risk cohort of patients. A meta-analysis of radial primary PCI studies showed an association between transradial primary PCI and reduced mortality,[24] which was ostensibly driven by limiting postprocedural vascular and bleeding complications (Figure 2).

Given the learning curve that is associated with adopting transradial PCI[35] and the clinical priority given to door-to-balloon times, starting a transradial primary PCI program should be reserved for those operators and

catheterization laboratory staff who are experienced with complex transradial PCI. No clear guidelines are available, and each operator's learning will likely differ. In addition, the catheterization laboratory staff, who are an integral part of the STEMI team,[36] must be proficient with the patient setup, equipment, and postprocedure care that are unique to radial procedures.

There are certain principles that can facilitate the performance of transradial primary PCI in the context of current door-to-balloon time pressures. First, tests for determining dual circulation to the hand (eg, Allen's test, Barbeau test[37]) can be performed quickly either in the emergency department or immediately upon arrival in the procedure area. Second, radial access can be achieved simultaneously with patient setup because fluoroscopy is usually not necessary. Third, it is important to have a bailout strategy in case radial access, traversing the arm

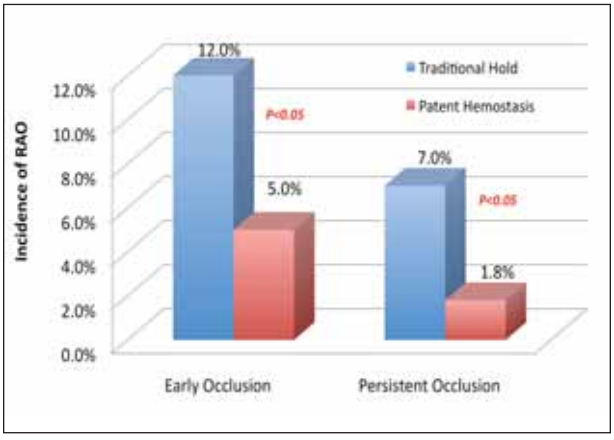

Figure 3. Impact of patent hemostasis on radial artery occlusion. Adapted with permission from Pancholy S et al. *Catheter Cardiovasc Interv*. 2008;72:335–340.[4]

TABLE 2. COMMON STRATEGIES TO DECREASE RADIAL ARTERY OCCLUSION

Anticoagulation			**Bottom Line**
UFH[35]	Heparin dose	Rate of radial artery occlusion	Increasing doses of heparin led to decreased rates of radial artery occlusion
	No heparin	71%	
	2,000–3,000 units	24%	
	5,000 units	4.30%	
Low-molecular-weight heparin[44]	Enoxaparin (60 mg intra-arterial) was administered to patients undergoing transradial diagnostic and/or PCI procedure		Rate of radial artery occlusion was 4% in this trial
Bivalirudin[45]	UFH (5,000 units) given at end of diagnostic angiography compared to bivalirudin (bolus + infusion) for ad hoc PCI		There was no difference in the rate of radial artery occlusion between UFH and bivalirudin groups (7% vs 3.5%; *P* = .18)
Patent hemostasis			
PROPHET[4]	Hemostasis with attempt to maintain radial artery patency compared to conventional hemostasis		Patent hemostasis was superior to conventional methods
RACOMAP[41]	Hemostasis with conventional method was compared with compression guided by the mean arterial pressure		Significant decrease in radial artery occlusion in patients who had compression guided by mean arterial pressure compared to standard protocol (1.1% vs 12%; *P* = .0001)
Sheath size[46]			
	Compared inner diameter of radial artery to outer diameter of sheath to determine impact on radial artery occlusion		Larger sheaths were associated with more severe flow reduction in the radial artery after transradial catheterization

TABLE 3. PATENT HEMOSTASIS TECHNIQUE

1. Prior to pulling sheath, apply hemostasis band.
2. Pulse oximeter with visible plethysmographic waveform is placed on ipsilateral hand.
3. Remove sheath and tighten hemostasis band.
4. Apply manual pressure over ulnar artery until waveform is no longer present.
5. Decrease pressure over radial artery access site until waveform returns or bleeding is observed. If bleeding occurs prior to observing a waveform, then switch to manual compression. If no bleeding occurs with a patent radial artery (as documented by the presence of a plethysmographic waveform), maintain radial artery compression at current level for 2 hours.
6. Assess for hemostasis on a regular basis.

Adapted with permission from Pancholy S et al. Catheter Cardiovasc Interv. *2008;72:335–340.*[4]

or chest vasculature, or engaging the coronary arteries creates a delay to prompt reperfusion. Another strategy that has been described is the routine use of the left radial approach for primary transradial PCI due to a lower incidence of subclavian tortuosity compared with the right side.[38] Subclavian tortuosity has been described as the cause of transradial PCI procedural failure in up to 18% of cases.[8] This may be even more relevant among elderly patients and those of short stature; therefore, either a routine left radial approach or a selective left radial approach in older patients and those who are < 65 inches in height may reduce primary transradial PCI procedural failure.[7,8,38]

There are several reports in the literature that have demonstrated the feasibility of using the radial approach for the treatment of STEMI (Table 1). Given the relatively localized expertise with this technique, these studies are limited to a few centers. Each of these studies required the operators to have performed >100 transradial PCI procedures. In these studies, they were able to achieve similar procedural success rates with less bleeding complications when compared to the transfemoral approach. In some cases, the door-to-reperfusion time was increased by a few minutes, whereas in other cases, there was no difference between transradial and transfemoral access. The recently completed RIVAL trial will report on major adverse cardiac outcomes between STEMI patients who were randomized to radial or femoral approaches to primary PCI and will provide further data on the efficacy and safety of primary transradial PCI.

RADIAL ARTERY OCCLUSION

Radial artery occlusion after transradial PCI has been shown to occur in up to 8% of patients. Although the pathogenesis is not well understood, it is likely related to arterial injury during catheter manipulation that leads to spasm and thrombosis.[39] The current literature suggests that most radial artery occlusion is clinically silent,[4,40,41] but most studies have not routinely surveyed patients for this event and often exclude patients that lack dual circulation to the hand. Importantly, there is inconsistent evidence supporting the utility of the Allen's test for identifying patients who are at risk of developing symptomatic radial artery occlusion.[42,43] Further, many patients who develop radial artery occlusion will often recanalize their radial artery at 30 days.[4] Risk factors for radial artery occlusion include high ratio of the arterial sheath diameter to the radial artery diameter,[46] lack of systemic anticoagulation during transradial procedures,[35] multiple arterial accesses in the same artery,[47] and prolonged occlusive arterial compression.[48]

Given these risk factors, several strategies can be adopted to minimize the risk of radial artery occlusion (Table 2). These include the use of systemic anticoagulation (either UFH, low-molecular-weight heparin,[44] or bivalirudin[45]), minimizing arterial sheath size, and using patent hemostasis (Figure 3).[4,41] The concept of patent hemostasis revolves around maintaining antegrade flow in the radial artery while achieving hemostasis (Table 3). This technique is of paramount importance and has been shown to significantly decrease the rate of radial artery occlusion—almost tenfold in one study.[41]

CONCLUSION

As transradial PCI gains worldwide popularity, developing a strong evidence base for the individual aspects of the procedure has become a priority. Three areas of interest include antithrombotic strategies for transradial PCI, transradial primary PCI, and prevention of radial artery occlusion. Although definitive data on the optimal antithrombotic regimen for transradial PCI have not yet emerged, attention must be paid to both access site and non–access site bleeding. The radial approach addresses the former but not the latter. Combining radial and pharmacological approaches may achieve the lowest bleeding risk. With respect to primary PCI, transradial access is associated with reduced mortality but should only be adopted by experienced operators and catheterization laboratory staff. Finally, radial artery occlusion is a major complication of transradial PCI, and operators should adopt preventive strategies. ■

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