

The State of Transradial Access for Lower Extremity Intervention

Reviewing the relevance, benefits, challenges, and needs for further innovation of radial access for lower extremity intervention.

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Lower extremity peripheral arterial disease results in significant limitations in quality of life and functional capacity for claudicants, and it is associated with an increase in morbidity and mortality for patients with chronic limb-threatening ischemia. Endovascular peripheral vascular interventions (PVI) have become a standard method to treat lower extremity arterial disease, particularly in carefully selected patients.¹ The choice of vascular access site for PVI has largely been dictated by convention and availability of dedicated equipment, and access site options have evolved greatly in the past decade, just as they have for coronary interventions.

The common femoral artery has historically been the preferred access for peripheral diagnostic angiography and PVI, as it provides easy access and adequate platform length for successful revascularization of varied lesions, both anatomically and in severity.² However, femoral access complications occur in 1.4% to 3.7% of patients, and include hematoma, retroperitoneal bleeding, transfusion requirement, pseudoaneurysm, arteriovenous fistula, and arterial thrombosis.³⁻⁵

The introduction and widespread adoption of transradial access (TRA) has revolutionized the management of coronary artery disease and percutaneous coronary intervention (PCI) practice such that the majority of PCI performed globally are now done from TRA. Access site complications for TRA have been shown to be significantly lower than transfemoral access (TFA) in randomized controlled trials in the PCI literature.⁵⁻⁷ Moreover, rapidity of patient throughput, the lack of need for prolonged bed rest, and patient preference have also factored into the widespread adoption of TRA in PCI.

TRANSFEMORAL VERSUS TRANSRADIAL ACCESS

In PVI, TFA is contraindicated or inappropriate in patients with an occluded common femoral artery, severe obesity, history of previous femoral surgery with prosthetic materials, when a contralateral femoral approach is needed in patients with prior bifurcated aortic bypass grafts or endografts, or when there is iliac artery occlusion.⁸ These situations have traditionally been managed using a brachial artery approach, usually using the left brachial artery to avoid crossing the aortic arch with wires, catheters and sheaths. However, the complications with brachial artery access can be devastating, with pseudoaneurysm, median nerve injury, and brachial artery thrombosis being most common, and resulting in subsequent upper limb ischemia in up to 11% of patients.^{9,10}

In addition to having lower complication rates than TFA, TRA also obviates the need for prolonged bed rest, and this shorter time to ambulation improves patient comfort in the recovery period. Furthermore, the decreased complication rate and shorter recovery times translate to the use of fewer resources and shorter hospital stays, leading to a reduction in cost.^{11,12}

Another potential benefit of TRA is the ability to intervene on lesions in bilateral lower extremities through one access point. With traditional retrograde TFA, interventions are limited to the ipsilateral iliac artery and/or the contralateral lower extremity, with a second access point required to intervene on the ipsilateral lower extremity. This is frequently performed as a separate procedure at an inconvenience to the patient and an increased risk of complications from a second access point.¹³

Despite the aforementioned benefits of TRA, some myths still exist around its use, particularly regarding stroke risk and radiation exposure. Although previous studies have suggested that procedural and fluoroscopy times may be increased with a transradial approach, studies comparing TRA and TFA in the peripheral vascular literature have failed to show a significant difference.^{11,14,15} Additionally, randomized controlled trials demonstrate an identical periprocedural stroke risk between the transradial and transfemoral approach to patients (0.2% within 48 hours) and a 30-day stroke risk of 0.6% to 0.8% for TRA versus 0.4% to 0.6% for TFA.^{5,6} Nonetheless, it is of the authors' opinion that precautions should be taken to minimize the risk of potential stroke regardless of approach, including meticulous catheter preparation, elimination of any air entrained in the system, target activated clotting time–guided heparinization with a goal of 300 seconds when performing interventions,¹⁶ prevention and early treatment of arterial spasm, and the use of hydrophilic catheters and sheaths to avoid excessive manipulation across the arch and its vessels.¹⁴

TECHNIQUES FOR TRA SUCCESS

Paramount to the success of TRA for lower extremity intervention is patient selection, specifically disease location within these patients. The distance that needs to be traversed to intervene on the lower extremities is significantly greater with TRA than TFA. Typical distances from the left radial artery to lower extremity arteries are as follows: iliac arteries, 105 to 125 cm; common femoral artery, 120 to 150 cm; superficial femoral artery, 130 to 170 cm; popliteal artery, 150 to 180 cm; and tibial arteries, 200 to 250 cm.^{13,17} Thus, with current commercially available devices, atherectomy, balloon angioplasty, and stenting can be reasonably performed to the level of the popliteal artery. However, limitations exist within the technology of these devices. Atherectomy is limited to orbital atherectomy, which is available in a 200-cm delivery system. There are limited options for drug-coated balloons, with only a single manufacturer offering catheters with shaft lengths of 150 cm; plain balloons with a 200-cm delivery system are limited to 2 to 8 mm in diameter and up to 200 mm in length. Likewise, no drug-eluting or covered stents are available for use with shaft lengths beyond 135 cm, with currently available self-expanding bare metal stents on a 200-cm delivery system limited to 6 to 8 mm in diameter and 40 to 150 mm in length.¹⁷

Additionally, the longer distance from the access site decreases the sheath purchase and catheter support, making crossing lesions and delivering devices more challenging. The longest sheath currently available for peripheral intervention via TRA is 149 cm. Furthermore, with a mean

radial artery diameter of 2.3 mm in males and 2.1 mm in females, this may preclude the use of larger-diameter sheaths greater than 6 F, which are required for covered and larger-diameter stents used in iliac interventions.¹⁸

In some angiography suites, when utilizing left TRA, the patient is typically positioned with their left arm abducted at a 90-degree angle on an arm board, with the operator standing caudal to the patient's left arm. The room is arranged such that the scrub table is parallel to and in continuity with the arm board to facilitate device entry and exchanges. We find it most useful to place the imaging monitor to the left of the patient's head so that the operator is directly facing the monitor when standing just caudal to the patient's outstretched left arm. Ultrasound measurements of the radial artery are obtained to ensure adequate diameter, and ultrasound-guided radial access is established two fingerbreadths from the wrist with a thin-walled 5-F introducer sheath. This is followed by intra-arterial administration of an antispasmodic cocktail consisting of a calcium channel blocker and nitroglycerin diluted with heparinized saline. If there is difficulty with traversal of the subclavian artery, an upper extremity and subclavian angiogram may be obtained, and a wire and catheter is advanced through the descending thoracic and abdominal aorta to the aortic bifurcation. Catheters for this advancement may include flush catheters such as a pigtail, or preshaped catheters such as a coronary JR4 to navigate through the upper extremity and into the descending thoracic aorta. A 6-F, long, thin-walled, reinforced sheath is then advanced over a supportive wire to its target, with the sheath length determined by location of lesion to be treated. The main challenge for TRA cases may be extracorporeal wire management, as the extended wire lengths may exceed the scrub table length and be difficult to control and maintain sterility. Using devices on a rapid exchange platform can help mitigate this issue.

CONCLUSION

With advances in endovascular device technology to include longer shaft lengths, lower extremity arterial interventions are now feasible from TRA to the level of the popliteal artery. However, significant limitations still exist in the availability of these devices. Continued development of long-shafted adjunctive tools such as laser and directional atherectomy, intravascular ultrasound, and thrombectomy devices, amongst others, are necessary in order to address a wider variety of lesions. Additionally, a need for covered and drug-eluting stents and drug-coated balloons with delivery systems lengths of at least 200 cm still exists. Furthermore, the evidence for use of TRA in lower extremity intervention remains scarce, with the majority stemming from case reports and observational series. Nevertheless, early studies

PERSPECTIVES ON RADIAL ACCESS FOR LOWER EXTREMITY PAD

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including the R2P Registry (NCT04371861) and the upcoming RADIANCE study sponsored by Cordis US Corp. will help contribute to defining the patient selection characteristics that will most favor successful radial to peripheral intervention. RADIANCE is an acute, multicenter, single-arm, nonrandomized, prospective, pivotal clinical study, with a primary objective to evaluate acute safety and efficacy of the S.M.A.R.T. RADIANCE™ Vascular Stent System (Cordis US Corp.), when used with the BRITE TIP RADIANCE™ Guiding Sheath and SABERX RADIANCE™ Percutaneous Transluminal Angioplasty Dilatation Catheter (Cordis US Corp.), to deploy the S.M.A.R.T.™ Nitinol Stent (Cordis US Corp.) via transradial artery access in patients with obstructive iliac or femoropopliteal arterial disease. The study is planned to include approximately 120 subjects enrolled across 10 to 15 investigational sites in Europe and followed up to 30 days postprocedure.

These may also be used to power larger randomized controlled trials necessary to properly compare TRA to TFA for peripheral interventions. However, as the number of available radial-specific devices continues to grow and the evidence accumulates, peripheral interventions may follow the coronary experience with TRA becoming a first-line approach for the treatment of lower extremity arterial disease as it has with PCI. ■

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