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EDITORIAL COMMENT

Hand, Foot, and Word of Mouth

Combined Transradial and Transpedal Access for Femoral Artery Interventions*

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The benefits of transradial vascular access (TRA) have been consistently described in coronary intervention (1). Those include significant reductions in vascular and bleeding complications as well as enhanced patient comfort. These benefits are magnified in patients with severe peripheral vascular disease, especially among those with common femoral disease.

As a result, there has been significant interest in extending the benefits of TRA to peripheral vascular intervention (PVI). Similar to the slow transition to TRA as the primary approach for coronary intervention (2–4), concerns remain regarding the efficacy and safety of TRA for PVI, and significant barriers to adoption remain. Not only are there challenges in navigating the tortuosity and arterial spasm associated with TRA, but restrictions in sheath size and longer distances from the access site to the target lesion limit options for definitive therapy and "bailout" interventions. This is especially true for infrainguinal target lesions. Sheath size limitations for stent platforms, specifically covered stents, and available shaft lengths for drug-coated balloons, nitinol stents, and atherectomy and re-entry devices, leave operators with a restricted set of tools for complex interventions when operating from a transradial approach. Hence, many operators have been willing to accept the risks of femoral access during PVI in exchange for maintaining a full array of treatment options to ensure procedural success and maximize patient safety.

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Emerging data on technical success, feasibility, and safety of TRA in PVI are encouraging (5–7), albeit in lesions with limited complexity. In this issue of *JACC: Cardiovascular Interventions*, Ruzsa et al. (8) further these data, describing a single-center case series of a primary transradial approach with optional secondary transpedal or popliteal access for endovascular treatment of symptomatic superficial femoral artery lesions. The investigators analyzed 145 consecutive patients with lesions of varying complexity (Trans-Atlantic Inter-Society Consensus classification ranging from A to D), including chronic total occlusions. Patients with critical limb ischemia accounted for more than 50% of the study patient population. The investigators demonstrated technical success in 95% of patients (90% in cases of chronic total occlusions), requiring crossover to femoral access in only 2%. Major access-site complications were limited to asymptomatic radial artery occlusions and 1 forearm hematoma that was successfully treated conservatively. Major amputation occurred in 11 patients, all of whom initially presented with critical limb ischemia, with 8 of those 11 undergoing the initial PVI to minimize the level of amputation. These are promising data, suggesting that transradial interventions for femoral lesions are feasible across lesion subtypes.

Despite the overall success and safety demonstrated in this analysis, there remain some concerns to address. First, this study was a single-center case series, in which all procedures were performed by 2 highly skilled operators. It is unclear if these results can be extrapolated to other centers or operators

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of varying levels of skill and expertise. Second, procedural complications were limited to 1 episode of distal embolization and 7 edge dissections. Manual aspiration and stenting (from both radial and pedal access points) were used to successfully resolve the issues. More complex or severe complications (e.g., perforation) could tax a transradial/transpedal system and require a higher level of crossover (with potential costly delays) than described in this analysis. Finally, the "toolbox" available to the operators was well documented and described but remains quite limited. Sheath and shaft lengths adequate for a transradial femoral intervention, even among those available outside of the United States, are limited to a single sheath made to 120 cm and 3 balloons with shaft lengths >150 cm. In the United States, there is only 1 balloon with a shaft length of 180 cm (Pacific Plus, Medtronic, Minneapolis, Minnesota) available for use. None of these are drug coated, and there are no options for covered stents. When considering that the average distance from the radial to the common femoral artery is 150 cm or more (9), these remain major limitations to the approach and require substantial response from industry to develop the tools necessary to carry out such procedures.

Thankfully, this road has been at least partially traveled with the advent of primary transpedal intervention. Although multicenter cases registries do not approach the rigor of the randomized trials performed for transradial coronary intervention, the existence of such data for transpedal access is a promising first step and serves as a proof of concept to propel the evidence for such alternative accesses forward (10). No such analysis exists for transradial approaches, with the present analysis representing the most rigorous study of the technique. Additionally, industry has responded to operators' interest in transpedal techniques with the development of dedicated devices for access (e.g., pedal access kit, Cook Medical, Bloomington, Indiana), atherectomy (e.g., Diamondback 360 60-cm shaft, CSI Medical, Gallatin, Tennessee), and closure (e.g., BOA tibial hemostasis device, Lakeshore Medical Innovations, Grand Rapids, Michigan).

In conclusion, these novel approaches for alternative access for PVI remain promising but unproven. Single-center analyses demonstrate feasibility but do not offer strong enough evidence for safety or overall procedural success. A multicenter trial comparing combined radial and pedal approaches to femoral access is needed to truly begin to assess efficacy and safety. Response from industry is on the horizon, but greater diversity in device and therapeutic options is needed. Until these needs are met, such "hand and foot" approaches will remain "word of mouth."

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