Overarching Radial Data

The available retrospective and prospective data highlight the safety and efficacy of radial access for peripheral intervention.

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Vascular access complications have been a leading cause of mortality in both coronary and peripheral interventions. Many trials evaluating the safety and effectiveness of the radial access approach in coronary intervention have been published over the years, as early as 2015 when the MATRIX trial showed a statically significant reduction of major bleeding and all-cause mortality. Other trials such as RIVAL, RIFLE-STEACS, and MORTAL have shown similar results. In 2022, Gargiulo et al published a meta-analysis in *Circulation* where 21,600 interventions were reviewed, showing that radial access is associated with lower all-cause mortality and major bleeding at 30 days compared with femoral access.[1] The decrease in major bleeding only partially explains the mortality benefit.

The radial approach for peripheral interventions faced many challenges in the past due to lack of a long shaft sheath and other devices designed specifically for the radial approach. In 2015, Coscas et al published their data assessing the success of radial access for peripheral intervention in 526 patients, with the majority of interventions using right radial access.[2] Although the study demonstrated the feasibility of radial access for peripheral percutaneous transluminal angioplasty, there was a higher than usual rate of radial artery occlusion (13%), and the authors emphasized the need for better, smaller-diameter equipment. Kumar et al published data from their first 80 patients and concluded that radial artery access for peripheral endovascular procedures appears to be safe and effective; they encouraged the adoption of this technique, as the complication rates are lower than those reported for femoral artery access.[3]

In March 2022, our team at Baylor Scott & White The Heart Hospital–Plano published data for our first 92 radial-to-peripheral interventions, demonstrating that peripheral vascular intervention performed via radial artery access is safe and feasible and allows for simultaneous bilateral and multilevel intervention.[4] One year later at the 2023 TCT meeting, we presented data for 165 procedures that reconfirmed the safety and efficacy of this approach.[5] This same year, Ansari et al published a retrospective analysis of 184 procedures comparing radial access to femoral access. The study concluded that the radial approach decreased not only perioperative times and contrast use but also radiation exposure.[6] The radial approach is undoubtedly a safe, feasible, efficient, and cost-saving route for peripheral interventions.

REVIEWING THE PROSPECTIVE DATA

The common issues with the previous papers are that the data were all retrospectively collected and analyzed. In October 2023, Castro-Dominguez et al published the first prospective registry to assess the safety and efficacy of radial access for peripheral artery interventions.[7] This was a multicenter observational study that enrolled 120 patients in eight United States sites who were scheduled for peripheral intervention via radial access. The primary efficacy endpoint was procedural success, defined as successful completion of the intended procedure without needing to convert to femoral access and without periprocedural radial access complications. The primary safety endpoint included evaluation of radial access–related complications at 30 days. There were 224 lesions treated, with most lesions being femoropopliteal (55.3%), followed by below-the-knee and iliac lesions (19.5% and 12.9%, respectively). Thirty (25%) patients required an additional access site to facilitate crossing and/or complete the planned treatment (5 femoral, 10 tibial, 17 pedal access). All procedures used ultrasound-guided access, followed by long, 6-F radial sheaths. Of the 168 patients screened, 48 patients were excluded due to various reasons, including radial artery diameter < 2.5 mm.

The dedicated radial-to-peripheral devices used in the study included, but were not limited to, the R2P Metacross balloon (Terumo Interventional Systems), Crosstella balloon (Terumo Interventional Systems), and Misago self-expanding stent (Terumo Interventional Systems). Other devices were used at the discretion of the operator. Hemostasis of the radial access sites was achieved using the TR Band (Terumo Interventional Systems). All patients

were followed to 30 days, with evaluation of complications including stroke and access site complication. A radial artery ultrasound was obtained for every patient at 30 days to assess patency.

Among all treated patients, 95% received plain balloon angioplasty, 7.5% received drug-coated balloon (DCB), and 38.3% received self-expanding stent; 53.3% of lesions were treated with orbital atherectomy.

The primary efficacy endpoint was achieved in 93.3% of patients. Radial access site complications were seen in seven patients and included one pseudoaneurysm, four spasms, and two minor site bleedings. Stroke was not documented in any of the patients. At 30 days, arterial ultrasound showed a radial artery occlusion rate of 2.8%.

Similar to previous reports in the radial-to-coronary intervention literature, same-day discharge was encouraged and achieved in this registry in 86.7% of all patients and 93.3% of patients who underwent radial access only. This prospective study is the first of its kind; the results of previously reported retrospective studies were confirmed, with the safety and efficacy of the radial access approach being proven again in patients with complex peripheral artery disease (PAD).

Limitations of this study included that some patients were excluded due a smaller radial artery, thus emphasizing the importance of sheaths with small French sizes. Also, only 7.5% of patients in this registry received DCB. At the time of conducting this study, the 0.018-inch In.Pact balloon (Medtronic) with a 200-cm shaft for radial access was not available. This DCB is now commonly used as first-line therapy. With a growing experience in the radial-to-peripheral technique, increased operator skills, and advancement of device options (longer microcatheters, DCBs, other available atherectomy devices), operators are using fewer secondary access sites, thus lowering the risk of complications and increasing the rate of same-day discharge.

DISCUSSION

While these data validate the radial approach, larger prospective studies with longer follow-up duration and more inclusive criteria to mimic the real-world population are still needed. As more patients continue to develop, these future data have the potential to drive standards of care for PAD/chronic limb-threatening ischemia in years to come. ■

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