Pedal Artery Revascularization: Where Are We in 2021?

An overview of current data and suggested indications for pedal artery revascularization.

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Critical limb ischemia (CLI) is a major cause of morbidity and mortality worldwide, and it is on the rise due to the increasing prevalence of diabetes mellitus (DM). Patients with DM often present with combined tibial and pedal artery disease and have an increased rate of amputation.[1-4] Clinical trials have demonstrated that treating tibial vessels only when there is significant coexisting pedal artery disease results in suboptimal wound healing.[5,6] Suboptimal wound healing increases morbidity, lowers quality of life, and increases medical costs even if limb loss is prevented.[6-9] Over the last 2 decades, the feasibility and safety of pedal artery revascularization (PAR) and the importance of an intact pedal arch on wound healing have become clearer. The last decade has resulted in improved endovascular equipment, including 0.014-inch support catheters, 0.014-inch guidewires, and low-profile angioplasty balloons. In addition, advanced endovascular techniques such as retrograde pedal artery access and subintimal arterial flossing with antegrade-retrograde intervention (SAFARI) have been perfected. Both of these factors have resulted in improved outcomes of previously unreconstructable pedal artery disease.[10] As a result, there is a renewed interest in PAR.[10-16]

EXPLORING THE DATA

More than a decade ago, Manzi and colleagues showed that PAR was feasible, safe, and provided clinical results at short- and midterm follow-up. In the study, 1,331 CLI

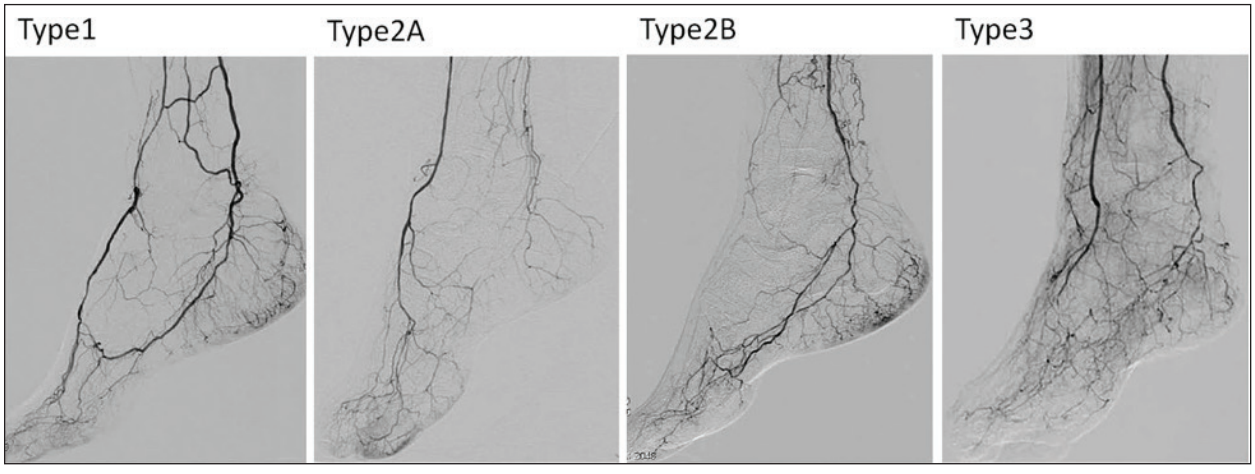

Figure 1. Kawarada pedal arch classification. Type 1: Both the dorsalis pedis and plantar arteries are patent. Type 2A: Only the dorsalis pedis artery is patent. Type 2B: Only the plantar artery is patent. Type 3: Both the dorsalis pedis and plantar arteries are occluded. Adapted with permission from Kawarada O, Fujihara M, Higashimori A, et al. Predictors of adverse clinical outcomes after successful infrapopliteal intervention. Catheter Cardiovasc Interv. 2012;80:861-871. doi: 10.1002/ccd.24370

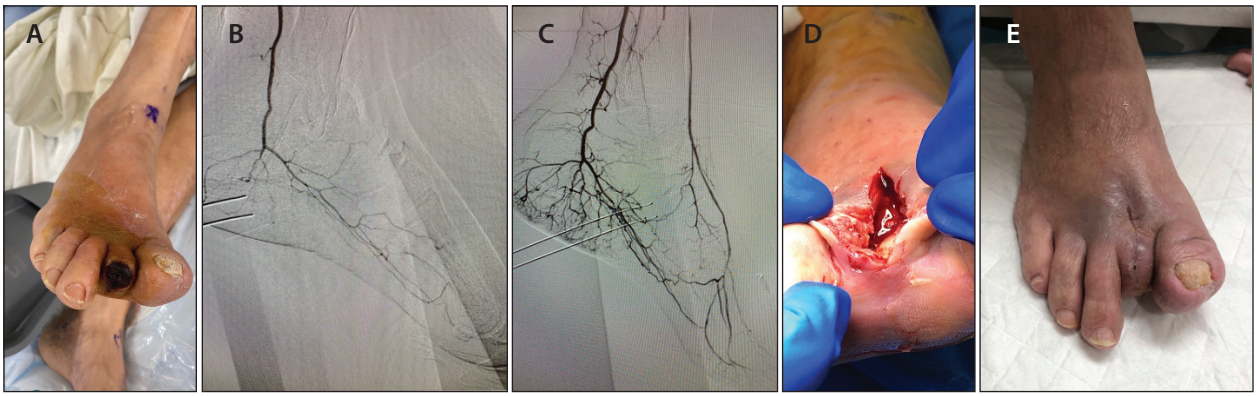

Figure 2. Patient after second toe resection for a nonhealing ulcer and associated osteomyelitis with development of gangrene at the operative site (A). The preintervention angiogram showed incomplete pedal loop and suboptimal digital flow (B). After successful PAR (C), robust intraoperative bleeding was seen during surgery (D) with subsequent complete healing (E).

patients were treated, with 135 (10.1%) undergoing PAR using the pedal-plantar loop technique. Technical success for this technique was 85%, with clinical improvement and functional status obtained and maintained after an average of 12 months.[10]

A few years later, Kawarada et al classified the pedal arch into types 1 to 3 and showed that arch status was an independent predictor of wound healing (Figure 1). At that time, the authors suggested that clinically driven distal revascularization to establish a pedal arch was vital to facilitate complete wound healing.[5]

In 2017, results from the multicenter RENDEZVOUS registry demonstrated that the speed and extent of wound healing were improved after endovascular PAR.[17] A total of 257 CLI patients with de novo infrapopliteal and pedal artery disease from five experienced Japanese cardiovascular centers were divided into two groups: pedal artery angioplasty (PAA) (n = 140) or no PAA (n = 117). In the PAA group, the rate of wound healing was higher (57.5% vs 37.3%; *P* = .003) and the time to wound healing shorter (211 vs 365 days; *P* = .008). In addition, a subset analysis of this study demonstrated that PAR improved the wound healing rate of CLI patients at 12 months regardless of pedal artery disease severity compared to the no PAR group.[18]

Two studies further reinforced the importance of the pedal arch on wound healing, limb salvage, minor amputation–free survival, and overall survival in diabetic CLI patients.

Troisi et al retrospectively studied 137 patients with nonhealing foot ulcers who underwent infrainguinal endovascular treatment. Patients were divided into three groups based on pedal arch status at the time of angiography: 42 (30.7%) with complete pedal arch (CPA), 60 (43.8%) with incomplete pedal arch (IPA), and 35 (25.5%) with an absent pedal

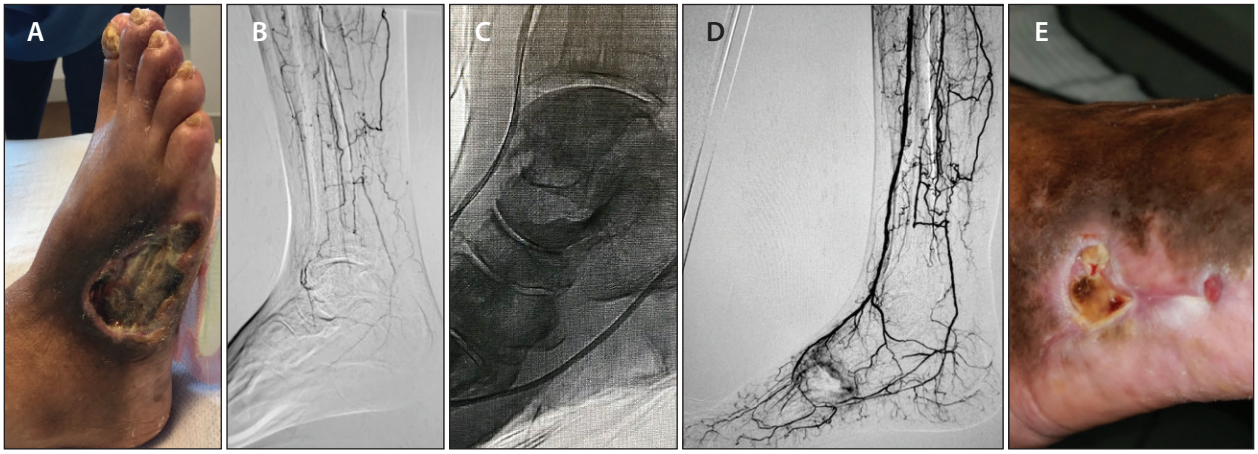

Figure 3. Large area of nonhealing ulceration in the foot (A). The preintervention angiogram showed severe tibial and pedal artery disease (B). After tibial intervention and PAR (C), final angiography showed inline flow in the anterior tibial and dorsalis pedis arteries, a patent pedal plantar loop, robust filling of the posterior tibial artery via collaterals, and an angiographic wound blush (D) that resulted in significant healing (E).

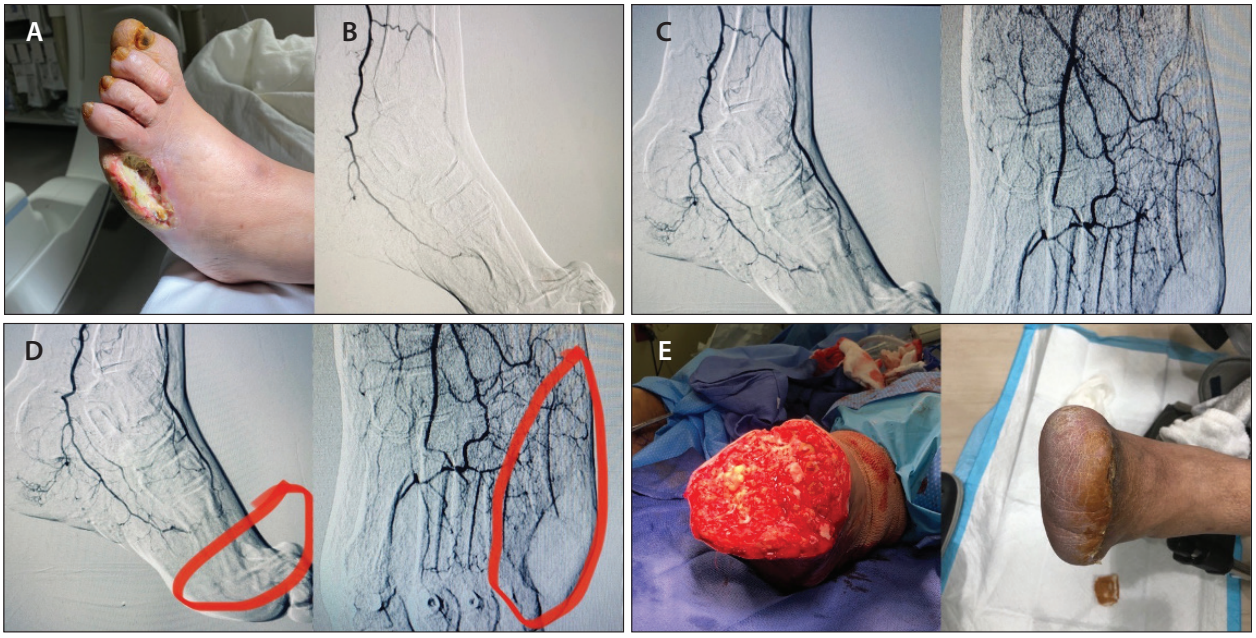

Figure 4. A diabetic patient with wound dehiscence at left fifth toe amputation site (A). The preintervention angiogram showed no dorsalis pedis artery and poor filling of the pedal plantar loop (B). Despite successful PAR with an intact pedal plantar loop (C), there was no healing at the amputation site due to diabetic microcirculation disruption (red circles) (D). However, the successful PAR did allow healing of a transmetatarsal amputation (E).

arch (APA). The CPA group had higher rates of wound healing at 3 months compared with IPA and APA groups (50% vs 28.3% vs 20%, respectively; $P = .01$). At 1 year, limb salvage rates (100% vs 93.8% vs 70.1%) and overall survival (90% vs 80.8% vs 62.7%) were both significantly higher in patients with CPA compared with IPA and APA status, respectively ($P < .001$). The 1-year minor amputation–free rates were also higher in the CPA cohort (84.1% vs 82.4% vs 48.9%; $P = .001$).[19]

Ismail et al assessed 60 consecutive diabetic CLI patients who were divided into three groups based on pedal arch status. Fifteen (25%) patients had CPA, 26 (43.3%) had IPA, and 19 (31.7%) had APA. Limb salvage rates were significantly improved in patients with CPA (100%) compared to IPA or APA patients (88.5% and 68.4% respectively; $P = .01$). Healing time was also quicker in the CPA group (3.4 vs 4 vs 6.1 months; $P = .02$).[20]

In 2019, Huizing et al published a systematic review and meta-analysis of PAA in CLI patients that evaluated the safety and effectiveness of PAR and assessed whether additional PAR after tibial artery intervention would improve clinical outcomes.[21] This review included 10 articles, 478 patients, and 524 legs treated with PAR. The pooled 12-month limb salvage and amputation-free survival rates were 92% and 78%, respectively. No statistically significant difference was seen when tibial plus pedal artery intervention was compared with tibial artery revascularization alone. However, wound healing rates were better in patients who had both tibial and pedal artery disease treated successfully.

More recently, Jung et al performed a retrospective analysis of PAR in 141 CLI patients and demonstrated higher wound healing rates (76% vs 67%; $P = .031$) and greater freedom from major amputation (96.3% vs 84.2%; $P = .009$) at 1 year in patients who underwent successful PAR compared to those who did not.[22] Major adverse limb event, freedom from reintervention, and overall survival did not differ significantly between the two groups.

PAR IN PRACTICE

Although newer data are showing the positive impact of PAR, there has been a lack of widespread adoption due to the lack of randomized controlled trials (RCTs), the lack of societal guidelines of when to intervene, and discrepancies in operator skills.

More data, including RCT data, can help confirm if pedal artery interventions are appropriate and lead to better outcomes. This, in turn, would help determine society guidelines of when to perform PAR. At present, non-RCT data and expert opinion have helped to support common scenarios in which PAR may be beneficial. These include CLI patients with tissue loss (ie, Rutherford class 5 and 6) (Figures 2 and 3), as well as postsurgical ischemic wounds (including forefoot amputations) because surgery can separate the anterior and posterior circulations of the foot

(Figure 4). In these cases, direct inline flow based on the concept of angiosome and angiographosome revascularization can optimize blood flow to the ischemic wound or surgical flap.[23-29] PAR should also be considered for patients in whom optimal healing does not occur after successful tibial intervention when there is coexisting pedal artery disease and insufficient flow to the ischemic territory. Patients who are nonambulatory, wheelchair bound, or have no hope for functional recovery of their limb despite revascularization should not undergo pedal artery interventions.

Although PAR has been part of clinical practice at experienced vascular centers for years, discrepancies in operator skills have also limited its widespread use, even in cases where it may be appropriate and beneficial. Those physicians who are highly experienced in endovascular tibial artery interventions and devices are the best equipped to learn and master PAR given the use of a similar tool kit for both territories. In addition, as endovascular techniques and skills continue to develop and are heavily incorporated into vascular training programs, more physicians will be comfortable and skilled in PAR in the coming years.

CONCLUSION

Recent studies continue to show the promise of PAR, but several challenges still exist, including clear indications, the extent of pedal arch reconstruction needed for success, and the feasibility and efficacy of newer dedicated balloons and devices. Despite this, PAR can be beneficial for CLI patients and must be considered in certain clinical scenarios. ■

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