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Original Research

Percutaneous Deep Venous Arterialization: Treatment of Patients with End-Stage Plantar Disease

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ABSTRACT

Background: Percutaneous deep venous arterialization (pDVA) is a minimally invasive technique connecting the tibial arteries below the knee to the tibial venous system into plantar venous circulation to deliver oxygenated blood to otherwise nonperfused foot. This study demonstrated outcomes of pDVA with commercially available equipment and described single-center experience on pDVA for critical limb-threatening ischemia patients with small artery diseases and end-stage plantar disease (ESPD) who were deemed no-option cases.

Methods: A single-center retrospective review was performed on patients who underwent pDVA. Primary end points were successful establishment of tibial vein flow with venous pedal loop, rate of major amputation, and major adverse events over 6 months. Secondary end points were primary and secondary patency rates, minor amputation rates, and wound healing over 6 months.

Results: Forty-two patients with ESPD underwent pDVA. Risk factors identified were hypertension (92.8%), hyperlipidemia (85.7%), diabetes (78.6%), tobacco abuse (42.9%), and chronic kidney disease $\geq$ stage 3 (42.8%). Three patients were categorized as Rutherford Class 4, 14 patients Class 5, and 25 patients (59.5%) Class 6. Of 42 procedures, 33 (78.6%) were deemed successful. Amputation-free survival at 6 months was reported in 25 patients (60.9%); 16 patients (38.1%) reported minor amputations. Wound healing rate reported at 6 months was 23.8%.

Conclusions: This is one of the largest case series to date with real-world no-option patients undergoing pDVA. pDVA seems a reasonable option for limb salvage in patients with ESPD where traditional arterial revascularization is not feasible. Identifying criteria for patient selection and advanced wound care is important to ensure clinical success. Additional research is required to establish diagnostic guidelines for patients being evaluated for pDVA.

Introduction

Critical limb-threatening ischemia (CLTI) is the most advanced form of peripheral arterial disease where the lack of arterial blood flow to the lower extremities may result in major amputation. It is estimated that 11% of adults in the United States experience CLTI, which is highly prevalent in older patients with diabetes and chronic kidney disease.[1-3] Patients with CLTI present with multilevel and multivessel disease, including disease within the foot itself, referred to as small artery disease (SAD). SAD is defined as the occlusion of the inframalleolar vessels, including the medial/lateral plantar, arcuate, and dorsalis pedis (DP) arteries.[4] The rates of SAD are not well defined. Criteria to define SAD vary in the literature, and treatment options for this patient population are limited. Furthermore, to our knowledge, the criteria for establishing guidelines for end-stage SAD have not been discussed.

Surgical deep venous arterialization (DVA) for patients with CLTI has been described in the literature, with limb salvage rates reported to be as high as 70%.[5-7] However, given that patients with CLTI often experience multiple comorbidities, there is a significant interest in percutaneous deep venous arterialization (pDVA). This less-invasive technique connects the tibial arteries below the knee to the tibial venous system into the plantar venous circulation to deliver oxygenated blood to the otherwise nonperfused foot in the

Abbreviations: AT, anterior tibial; AV, arteriovenous; CLTI, chronic limb-threatening ischemia; DP, dorsalis pedis; DVA, deep venous arterialization; ESPD, end-stage plantar disease; EVUS, extravascular ultrasound; pDVA, percutaneous deep venous arterialization; PT, posterior tibial; SAD, small artery disease.

Keywords: amputation-free survival; critical limb ischemia; deep venous arterialization; end-stage plantar disease; no-option CLTI; small artery disease.

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endovascular suite. The concept of pDVA is not new. Recent trials used a proprietary system (LimFlow system; LimFlow) to connect the tibial artery and tibial veins. The system uses its in-built ultrasound-mediated catheters for creating of an arteriovenous (AV) fistula, valvulotome, and tapered self-expanding stent–graft system. Early trials showed promising limb salvage and wound healing rates.[8-11] However, this system is not yet commercially available in the United States. We are awaiting the results of the second clinical trial phase, PROMISE II.

This study aimed to demonstrate the outcomes of patients who underwent pDVA with commercially available equipment and describe a single-center experience in performing pDVA on patients with CLTI presenting with SAD and end-stage plantar disease (ESPD).

Methods

The WCG institutional review board reviewed and approved this research. The requirement for informed consent was waived. A single-center retrospective chart review was performed on patients who underwent pDVA by 2 operators (J.A.M. and F.A.S.). The primary end points were successful establishment of tibial vein flow with a venous pedal loop, rate of major amputation over 6 months, and major adverse events over 6 months. The secondary end points were primary patency rates, secondary patency rates, minor amputation rates, and wound healing over 6 months.

Patient selection

All patients who underwent pDVA had failed traditional surgical and endovascular revascularization methods. They were diagnosed with the institutional diagnosis of ESPD defined by ultrasonic and angiographic criteria, as shown in Figure 1. This diagnosis requires evidence of ultrasonic luminal obliteration of the plantar arteries using extravascular ultrasound (EVUS). Angiographic evidence of the desert foot was established with the performance of selective angiography. A catheter was placed in the popliteal artery with contrast angiography used as the gold standard for angiographic imaging. No clear plantar arteries were defined, and there was no reconstitution of the tibial arteries at the level of the ankle (Figure 2).[12]

Technical procedure

For the procedures performed in this study, commercially available devices were used to connect the arteries to the veins by creating an AV fistula. All arterial and venous access was obtained under ultrasound guidance. At the start of the procedure, antegrade access was obtained with a 5F catheter system (Pinnacle Precision; Terumo Medical Corp). The second access was obtained in the distal tibial venous system. For posterior tibial (PT) vein conduits, access was obtained at either the distal PT vein at the ankle level or the plantar vein in the plantar aspect of the foot. For anterior tibial (AT) vein conduits, access was obtained in the DP or distal AT vein at the ankle. Accessing the pedal portion of the foot allowed for less challenging crossing into the venous loop of the foot. Crossing the ankle segment after connecting the artery to the vein is challenging from a retrograde venous approach and limits the technical success of the procedure. Pedal venous access was obtained using a Glidesheath Slender 5F sheath (Terumo) (Figure 3). The procedure is as follows: Typically, a 0.018-inch wire (V-18 Control Wire; Boston Scientific Corp) is advanced to the proximal tibial vein, followed by a long 4.0-mm balloon that was advanced to the wire to the desired site of the AV fistula.

At this point, an antegrade wire is advanced to the target tibial artery. Patients with ESPD tend to have a preserved proximal tibial artery flow, and in the operators' experience, vessel obliteration is most often observed in the distal tibial and plantar arteries. The proximal tibial artery is treated to maintain as much of the native vessel as possible. The treatment of the proximal arterial conduit involves vessel modification with atherectomy, followed by balloon angioplasty. Connecting the artery to the vein is a critical step in the success of the procedure. Currently, there are several commercially available reentry devices that can be used to create an AV fistula by puncturing from the tibial artery into a balloon in the tibial vein. Available reentry devices include the Outback Elite (Cordis Corp), Pioneer Plus (Philips), and GoBack catheter (Upstream Peripheral Technologies) (Figure 4).

The reentry catheter is advanced over the antegrade wire to the AV site. A balloon is then advanced over the retrograde venous wire and inflated at the desired AV site. The reentry device needle is deployed to puncture through the artery and into the venous balloon. Once the balloon is punctured, the wire is advanced from the artery to the venous balloon. Then, the balloon is slowly retracted from the venous pedal

End Stage Plantar Disease Patient Work Up
Initial Presentation: *Patient presents with CLI (RF Class 4-6)* - Detailed arterial duplex evaluation to include plantar arteries assessing for white stop sign and distal tibial artery obliteration - Selective diagnostic angiogram with catheter placed above the tibial trifurcation with DSA imaging performed - Traditional revascularization attempted in CLI center with dedicated CLI team
After Failed Traditional Revascularization: - DSA imaging demonstrated obliterated tibial arteries in the distal calf (desert foot) and ultrasound demonstrated obliterated/white stop sign vessels confirming diagnosis of ESPD - Ultrasound evaluation of plantar veins to assess for patency adequate conduit size
Decision to Proceed with pDVA: - Arterial preparation with atherectomy and balloon angioplasty; goal of achieving minimum vessel diameter of 3.5-4.0mm to optimize flow dynamics for AV conduit - Venous preparation with sequential balloon venoplasty; goal of achieving minimum vessel diameter of 4.5-5.0mm to accommodate stent graft - Stent graft deployed 3cm above AV anastomosis and extends to the distal tibial vein
Post pDVA: - Establish flow velocities at proximal and distal edge of stent graft - Patient education regarding symptoms expected post pDVA (edema, refractory pain, etc). - Wound care established (if applicable) with provider discussion regarding expectations post pDVA - Maturation may take 6-8 weeks, requiring major wound intervention be delayed if possible

Figure 1. Institutional workup for patients presenting with critical limb ischemia in determining end-stage plantar disease and the need for a percutaneous deep venous arterialization procedure.

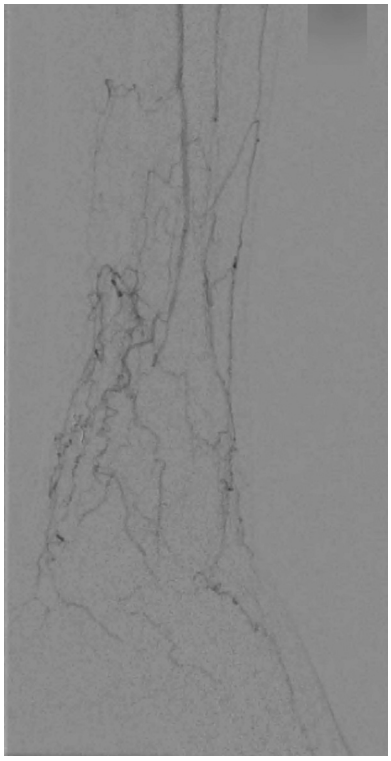


Figure 2. A selective angiogram performed of the foot demonstrated no tibial arteries crossing the ankle with no intact pedal flow.

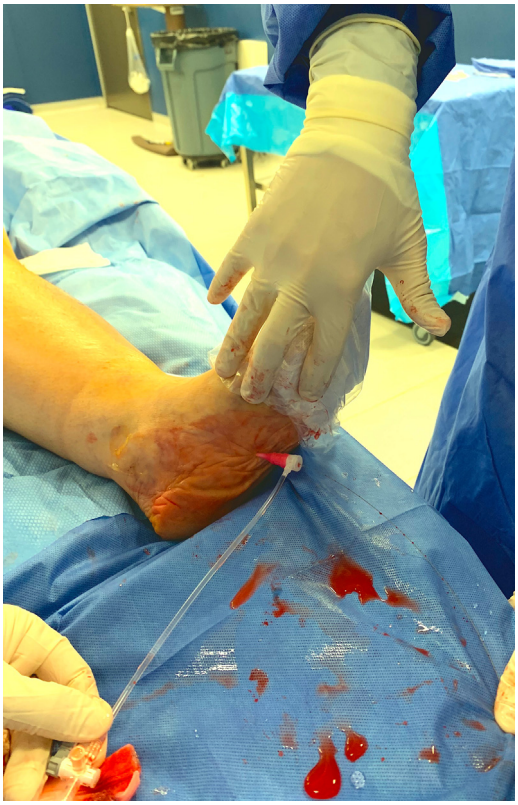


Figure 3. Intraoperative photograph of plantar venous access obtained on the plantar surface of the foot.

sheath, acting as a snare, and the wire is externalized, creating a through-and-through system.

Several alternative methods have been described in the literature. In this case series, the most frequently used method for AV fistula creation comprised a manual double-balloon puncture with EVUS guidance, similar to the "AV Spear Technique" described by Ichihashi et al.[13] For this method, 2 balloons are inflated, 1 in the artery over the antegrade wire and 1 in the vein over the retrograde wire. A 7-cm 21-gauge needle is used to access the AV site in the mid to distal calf. Once the first balloon is punctured, the needle is carefully advanced to puncture the deeper balloon. In the operators' experience, the artery tends to be more superficial than the vein. Once confirmed that both balloons have been punctured with a loss of pressure in the endoflator, another wire is advanced into the lumen of the venous balloon through the needle (Figure 5). The deeper balloon is immediately deflated, which acts as a snare to the wire while the balloon is slowly pulled out through the venous sheath.

The technique described by Ysa et al,[14] referred to as the venous arterialization simplified technique, uses overlapping a snare in the tibial vein with a balloon in the tibial artery. The snare loop is targeted under a fluoroscopy guidance and punctured percutaneously with a 21-gauge needle through the venous walls and into the arterial balloon. After advancing a 0.014-inch guide wire, the needle is removed, and the wire is externalized into both the venous and arterial sheaths. Nakama et al[7] described the modified VAST technique using a balloon puncture of the vein while directing the wire into an angled catheter in the artery. The wire is then drawn back into the catheter and redirected into the vein with a balloon guidance. Another modified version of this technique, referred to as the "gunsight technique" uses 2 snares, 1 in the artery and 1 in the vein. The snares are targeted for a percutaneous puncture and externalized through the venous and arterial sheaths similarly. However, the VAST technique was not used in this case series (Figure 6).

Once this wire has been externalized, a 0.018-inch catheter (CXI Support Catheter; Cook Medical), is inserted over the wire and advanced in a retrograde fashion to then connect and rendezvous with the arterial wire at the AV site of the initial balloon puncture in the artery. The wire is advanced through a 0.035-inch catheter (NaviCross Support catheter; Terumo) to the antegrade groin access to create a through-and-through system.

At this point, sequential balloon angioplasty is performed at the anastomosis site between the artery and the vein. An AV fistula is immediately seen. However, extravasation outside the artery on angiogram was rarely seen. Balloon angioplasty of the tibial vein with a particular focus on the ankle area is then performed using a high pressure or specialty balloon (eg, Peripheral Cutting Balloon; Boston Scientific Corp). This area around the ankle tends to be difficult to dilate, likely related to the space with the compartment, extensive ligamentous complex around the ankle (ankle strap), and venous valves. As described earlier, the proximal to the mid arterial tibial vessel can be treated with atherectomy with stenting reserved for bail-out options. Once the arterial inflow disease is treated, focus is turned to the venous side.

Typically, the operator will proceed with the placement of a 5.0 or 6.0-mm self-expanding stent–graft (Viabahn; Gore). The length varies from 100.0 to 250.0 mm, depending on the location of the AV fistula. The deployment of the covered stent requires a 7F catheter system; therefore, rather than delivering the stent from the arterial side, the stent is delivered from the venous access via a Glidesheath Slender 7F catheter (Terumo). This secures the arterial end within 1.0 to 2.0 cm within the tibial artery proximal to the anastomosis. Because the stent is delivered via a venous approach, the distal end of the graft lands in the tibial artery and the proximal end lands in the distal tibial vein. Sequential balloon angioplasty of the arterial side 3.5 to 4.0 cm beyond the anastomosis ensures that arterial inflow is adequately treated to maintain patency.

The final stage of the pDVA procedure determines the success of the procedure. Establishing flow beyond the venous access is important to establish the venous pedal loop. In the operators' experience, establishing a venous loop from the plantar veins to the DP vein versus a branch of the superficial great saphenous vein will increase the possibility of

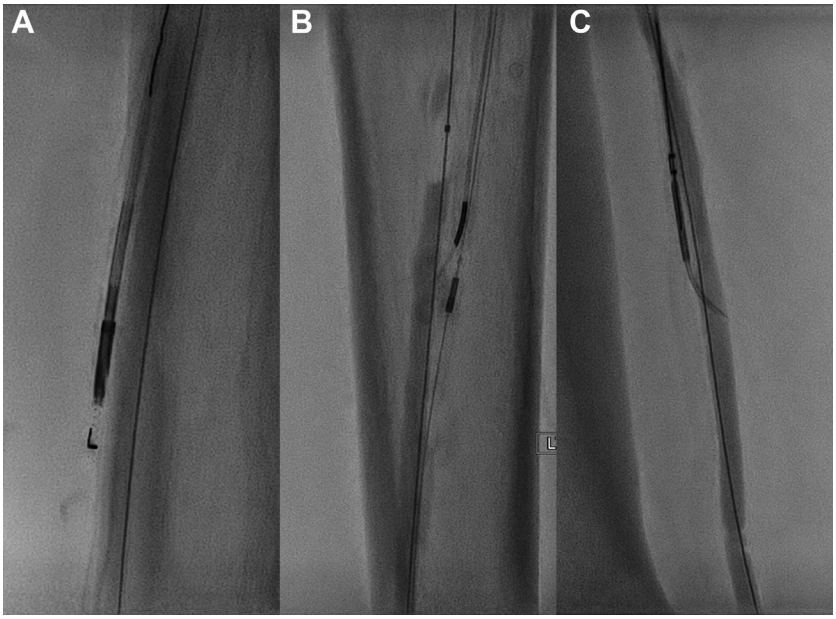


Figure 4. Fluoroscopic imaging of commercially available reentry devices. (**A**) Cordis Outback Elite, (**B**) Philips Volcano Pioneer Plus, and (**C**) Upstream GoBack.

continuous blood flow to the venules within the plantar circulation. Once the venous loop is crossed with a 0.014 or 0.018-inch wire, prolonged balloon angioplasty with a 4.0-mm balloon for 4 minutes will tamponade the access site and secure venous flow through the loop (Central Illustration).

Wound care management

After successful pDVA leading to increased blood flow with increased perfusion and healing potential, physicians encounter clinical challenges after forefoot amputation. These include decreased venous outflow leading to edema and possible hematoma formation. This is further complicated by the need for continued anticoagulation secondary to recent endovascular intervention. Another concern is the fact that the authors have observed that a newly placed AV graft/fistula takes 6 to 8 weeks to mature and become fully functional to best optimize the reversed flow.

In most cases, surgical intervention for gangrenous lesions in the forefoot cannot be delayed. pDVA surgical procedures on the foot must be managed differently from conventional arterial interventions. A major vein has been used/not excised to act as a conduit to attain perfusion in the foot. An active drain is placed to aid in the prevention of hematoma and venous engorgement (Figure 7). An incisional negative pressure system is used to encourage the removal of any excessive fluids. Light compression and a 30° limb elevation is used with hourly ankle range of motion exercises for compression therapy and to help "pump" excessive fluids, preventing hematoma, wound breakdown, and delayed healing.

Antibiotics are prescribed for an extended postoperative period to avoid infection from preexisting gangrene and cellulitis with the additional placement of a long AV stent graft. Wound healing is aggressively

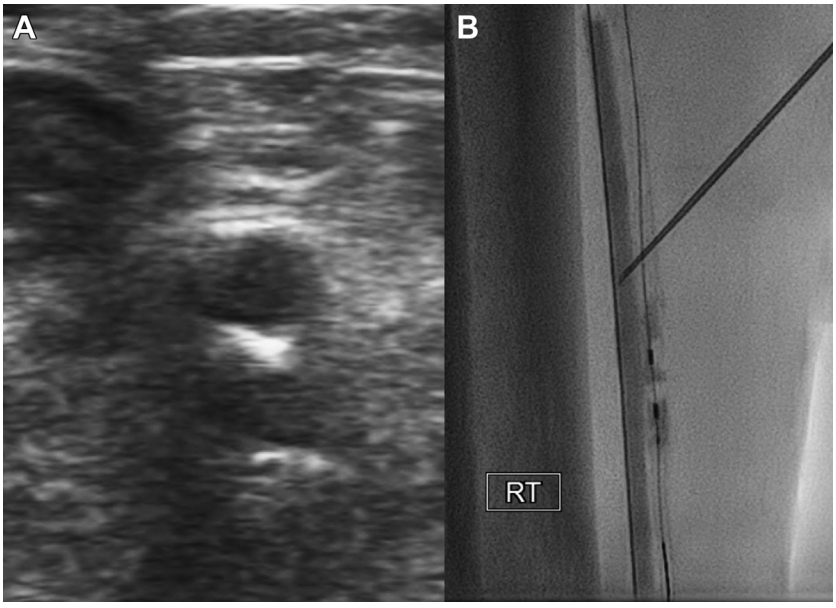


Figure 5. Side by side imaging. (**A**) Ultrasound visualization of venous and arterial balloons prior to puncture and (**B**) a fluoroscopic view of needle successfully puncturing the arterial balloon before puncturing the venous balloon.

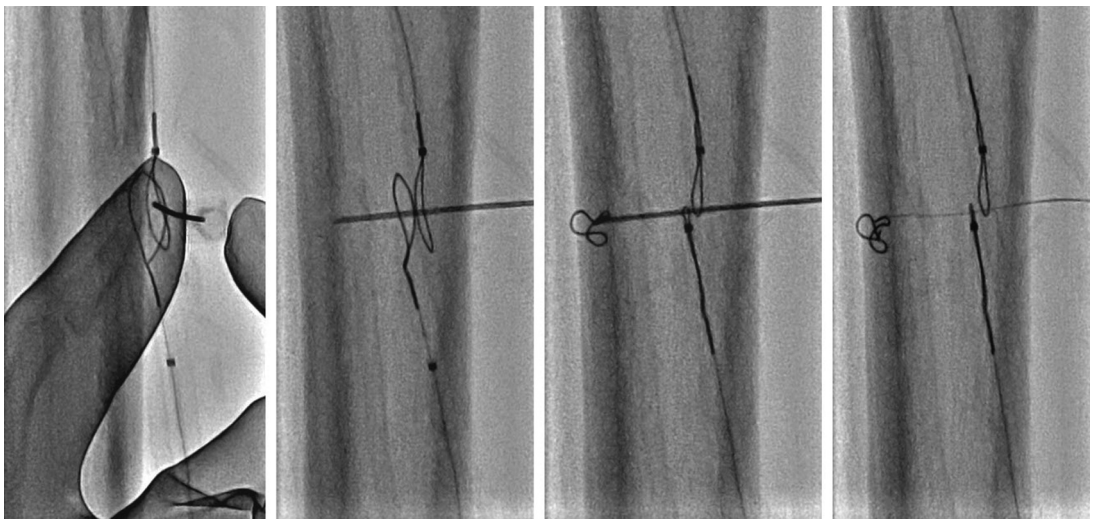


Figure 6. Step-by-step imaging of the "gunsight technique" for creating an AV fistula.

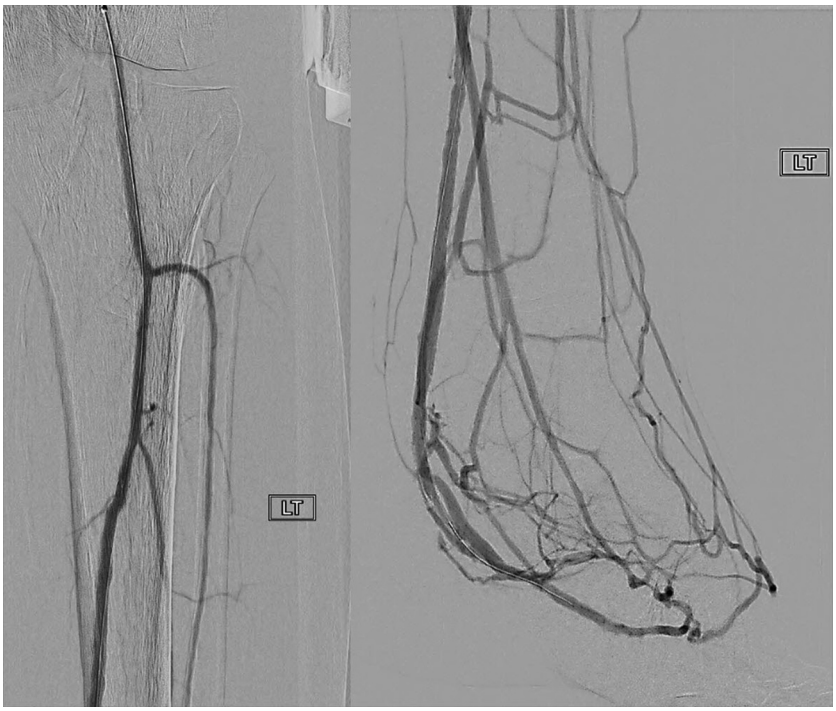
monitored for progress, and changes in protocolster pDVA, persistent wound care is pursued to attain successful healing in such challenging cases with end-stage CLTI.

Results

Forty-two patients with ESPD who underwent pDVA between February 1, 2018, and June 24, 2021, were identified. Of the 42 patients, 8 (19%) were women and 34 (81%) were men, with an average age of 70.6 years. Comorbidity and risk factors identified were the presence of hypertension (92.8%), hyperlipidemia (85.7%), diabetes (78.6%), tobacco abuse (42.9%), and chronic kidney disease $\geq$ stage 3 (42.8%). Based on the Rutherford classification, 3 patients (7.1%) were categorized as class 4, 14 patients (33.3%) as class 5, and 25 patients (59.5%) as class 6 (Tables 1-3 and Figures 8 and 9).

Procedural success was defined as the deployment of a covered stent with the establishment of a venous pedal loop/venous outflow. Of the 42 procedures, 33 (78.6%) were deemed successful. The most common reason for a procedural failure was inability to cross into the venous pedal loop to establish a venous conduit outflow. One patient experienced balloon dislodgment from the catheter during the final stages of the procedure and could not be retrieved owing to venous spasm. However, this patient ultimately met the 6-month end point of amputation-free survival.

Sixteen of the 42 patients (38.1%) were identified to have undergone major amputation, defined as below-the-knee amputation (BKA) or above-the-knee amputation (AKA), within 6 months of the procedure



Central Illustration. Post procedure. Postprocedural selective angiogram of a completed pDVApercutaneous deep venous arterialization with an intact flow in the plantar venous circulation.

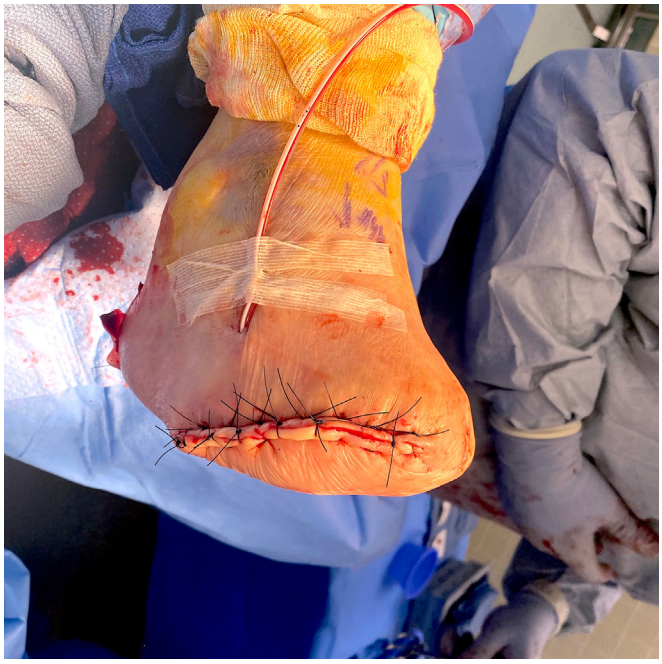


Figure 7. An active drain in the foot after transmetatarsal amputation.

date. In this study, 1 patient underwent 2 pDVA procedures on the same limb and was counted as a single amputation. Six patients died before the 6-month end point, 4 of whom had no reports of major amputation prior to death. Overall amputation-free survival at 6 months was reported in 25 patients (60.9%); 16 patients (38.1%) reported minor amputations, defined as toe or transmetatarsal, within 6 months, 1 of which was referred to attempt to avoid a planned major amputation.

Patency was identified using duplex ultrasound or presence of pulses on physical examination. A 30-day patency was reported in 19 patients (45.2%) and a 6-month patency in 11 patients (26.2%). A primary 6-month patency was reported in 8 patients (19%), and secondary patency was reported in 3 patients (7.1%). Clinically driven reintervention was performed in 8 patients (23.8%).

Wound healing was assessed by physical examination on follow-up visits. Partial wound healing at 30-days was reported in 8 patients (19%). At 6 months, 8 patients reported partial wound healing (19%) and 2 patients reported complete wound healing (4.8%) with an overall wound healing rate at 6 months of 23.8%.

Other factors identified included venous access location (PT vein, 54.8%; plantar vein, 31%; and AT vein, 11.9%), AV fistula creation method (Pioneer IVUS-guided reentry catheter, 14.3%; Outback reentry catheter, 11.9%; GoBack reentry catheter, 14.3%; and external needle

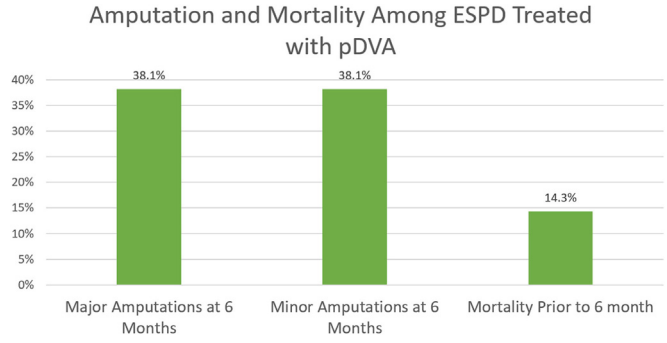


Figure 8. Bar chart demonstrating amputation and mortality rates among patients who underwent pDVA. ESPD, end-stage plantar disease; pDVA, percutaneous deep venous arterialization. ESPD, end-stage plantar disease; pDVA, percutaneous deep venous arterialization.

Table 1. Baseline characteristics data of patients included in the analysis who underwent percutaneous deep venous arterialization.

Baseline characteristics	N = 42
Men	34 (81%)
Women	8 (19%)
Age, y	70.6
Hypertension	39 (92.8%)
Hyperlipidemia	36 (85.7%)
Diabetes	33 (78.6%)
Tobacco use (current or former)	18 (42.9%)
Chronic kidney disease (≥stage 3)	18 (42.8%)
Rutherford classes	
4	3 (7.1%)
5	14 (33.3%)
6	25 (59.5%)

Values are n (%) or mean.

balloon puncture, 57.1%). Procedural complications were identified in 1 patient who experienced balloon rupture and dislocation of the balloon from the catheter, resulting in a retained balloon segment in the venous pedal loop. Postprocedural complications were identified in 3 patients who experienced acute kidney injury, as defined by the facility as 25% increase and/or absolute 0.5 mg/dL increase in the serum creatinine level; 3 patients who experienced BARC type 3a drop in hemoglobin; and 1 patient who required transfusion 3 days after the procedure. The relationship with the procedure is unclear because the patient had underlying chronic anemia and no active source of bleeding was identified.

Discussion

Patients with CLTI require revascularization to avoid major amputation, referred to as BKA or AKA. Major amputation may be necessary only in extremely limited situations. Unfortunately, major amputation continues to be a first line of therapy in up to 20% of cases.[15,16] Patients who undergo major amputation experience high rates of perioperative morbidity and mortality and range from 14% to 35% with BKA and AKA, respectively.[17] Less than one third of patients with AKA are able to ambulate because of patient frailty and comorbidities.[18]

Patients with no-option CLTI is a further subset of patients presenting with advanced forms of CLTI.[19] In this study, our facility classified these patients as patients presenting with end-stage pedal/plantar disease (ESPD). The patients included in this series had exhausted traditional surgical and endovascular options. At this institution, if a traditional arterial endovascular revascularization is attempted and not successful, the patient is evaluated for ESPD. The diagnostic criteria to determine ESPD have not been established; however, the patients in this series underwent institutional ultrasonic and angiographic testing prior to pDVA. ESPD findings include complete ultrasonic arterial lumen obliteration; calcific obliteration and complete vessel atresia of the chronically occluded distal tibial arteries have been observed. Most often, EVUS

Table 2. Data of procedures included in the analysis

Procedure	N = 42
Laterality	
Right	23 (54.8%)
Left	19 (45.2%)
Vein access location	
Posterior tibial	23 (54.8%)
Plantar	13 (31%)
Anterior tibial	5 (11.9%)
AV crossover method	
Outback Elite reentry	5 (11.9%)
Pioneer IVUS-guided reentry	6 (14.3%)
GoBack reentry	6 (14.3%)
Double-balloon puncture	24 (57.1%)

Values are n (%).
AV, arteriovenous; IVUS, intravascular ultrasound.

Table 3. Outcome data collected for patients included in the analysis.

Outcomes	N = 42
Procedure success	33 (78.6%)
Major amputation (6 mo)	16 (38.1%)
Death prior to 6 mo	6 (14.2%)
Overall amputation-free survival	25 (60.9%)
Minor amputation (6 mo)	16 (38.1%)
30-d patency	19 (45.2%)
Primary patency (6 mo)	8 (19%)
Secondary patency (6 mo)	3 (7.1%)
CD-TLR	8 (23.8%)
Wound healing	
Partial (30 d)	8 (19%)
Partial (6 mo)	8 (19%)
Complete (6 mo)	2 (4.8%)
Acute kidney injury	3 (7.1%)
Hemoglobin drop (BARC 3a)	3 (7.1%)
Transfusion required	1 (2.4%)

Values are n (%).

evaluation is completed after a traditional endovascular revascularization has been attempted, prior to the patient leaving the procedure table. Plantar venous assessment is performed in addition to arterial assessment to plan for potential future pDVA.

One of the important ultrasonographic features necessary for ESPD diagnosis is the "white stop sign." This ultrasonic feature suggests complete calcium obliteration of the artery, versus simply an occluded vessel (Figure 10). Differentiation of the type of occlusion in the artery is important to determine future treatment. An occluded vessel, or even hibernating lumen, would present a potential for a traditional endovascular revascularization and preclude patients from the need to undergo pDVA. Standard diagnostic arterial ultrasound examination does not involve a detailed evaluation of plantar arteries and venous structures, so, in this institution, this assessment is performed by an interventional sonographer while the patient is in the endovascular suite.

In addition, detailed angiographic evaluation with selective angiography is performed. Angiographic evidence of ESPD includes intact proximal tibial artery with distal occlusion and an extensive collateral network with no in-line tibial flow to the foot.

Wound healing and limb preservation require improved tissue perfusion and promotion of angiogenesis.[20-22] A meta-analysis by Schreve et al[23] evaluated surgical DVA and demonstrated limb salvage rates up to 75% at 12 months. A prior case series by Kum et al[8,9] evaluating pDVA showed promising results, reporting outcomes of 7 patients with wound healing rates up to 70% at 1 year. The PROMISE I trial evaluated pDVA using the new LimFlow system (30 day and 12 months outcomes) on 32 patients with CLTI. Amputation-free survival was 70%, and wound healing rates were 70% at 12 months. Notably, most patients were classified as Rutherford class 5 (87.5%) in the PROMISE I trial.[10] The current case series differs from those by Kum et al and PROMISE I in that it represents a real-world cohort of patients with advanced end-stage SAD and a high percentage of patients classified as Rutherford class 6 (59.5%).

Medical therapy of antiplatelet and anticoagulation varies depending on the risk profile of patients, and currently, there are no guidelines to support the best therapy for patients after pDVA. The authors prefer to have at least 1 antiplatelet agent, aspirin vs clopidogrel, in addition to the anticoagulation agent, rivaroxaban.

The authors believe that improving microvascular perfusion with increasing arterial flow through the venous conduit improves tissue oxygenation, and in their opinion, the optimal time for this process occurs in 6 to 8 weeks after pDVA. Further studies will be required to identify objective measures to assess tissue perfusion. The 30-day patency rates observed in this case series were low and may be due to the multiple mechanical and clinical limitations of the procedure, and the authors acknowledge that the hemodynamics of DVA was not fully understood. In this case series, patients who presented with a 30-day occlusion of the graft were revascularized prior to any planned amputation to attempt to salvage the limb. It is not fully understood why some patients remained amputation free despite the closure of the DVA graft.

One important aspect of performing pDVA is identifying failure mechanisms. Failure can be categorized into technical and clinical reasons. From a technical point of view, the success rates seem to be high in initial performance of the procedure. However, device failure and inadequate perfusion of the venous loop in the foot were observed in this case series. The rates of reintervention were in line with those of the PROMISE I trial.[10] The clinical reasons for failure seem to revolve around wound care. Treating patients with CLTI with advanced tissue loss represents an area that requires a significant improvement. Eight patients for whom the pDVA procedure was deemed unsuccessful underwent major amputation. The high rate of patients classified as Rutherford class 6 in this case series potentially explains the low rate of wound healing. Wound care was not centralized in this case series, creating a variation in wound care, and may have affected wound healing rates.

Limitations

This retrospective case series involved patients with pDVA procedures performed by 2 operators who have advanced skills in the treatment of CLTI. The high percentage of patients classified as Rutherford class 6 establishes the complexity in treating these patients. Early identification of patients with end-stage SAD may contribute to improving wound healing and preventing limb loss.

Wound care was not uniform across all patients and is believed to contribute to varied rates of wound healing. At this institution, attempts for consistent wound care are made by referring to specialized podiatry and wound care providers familiar with the pDVA procedure and, however, is often limited by patient proximity and access to these few specialized centers. Failure to adequately address the wounds or transmetatarsal amputation sites may limit patient outcomes. After pDVA, the revascularized limb develops venous hyperperfusion because of the increased arterial flow and becomes edematous. The presence of significant edema may limit wound healing. In the opinion of the authors, after pDVA, a period of 6 to 8 weeks is recommended to allow for maturation and arterialization of the venous system. Advanced wound care techniques by wound care specialists and podiatrists in treating such

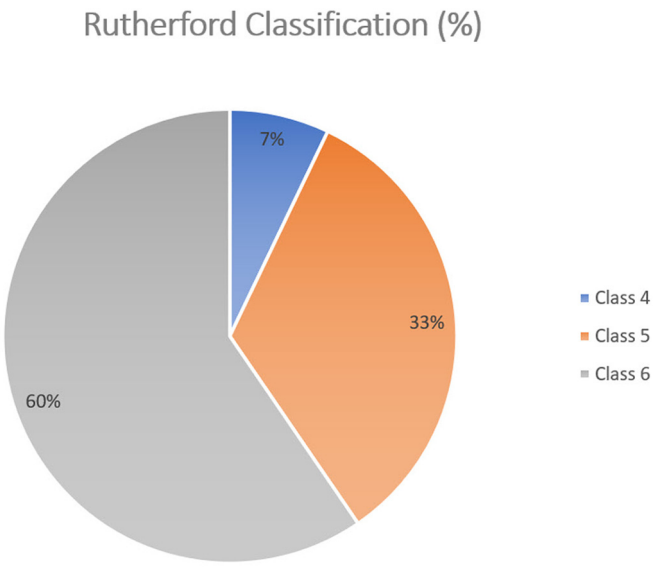


Figure 9. Pie chart demonstrating the breakdown of Rutherford classes in patients who underwent percutaneous deep venous arterialization.

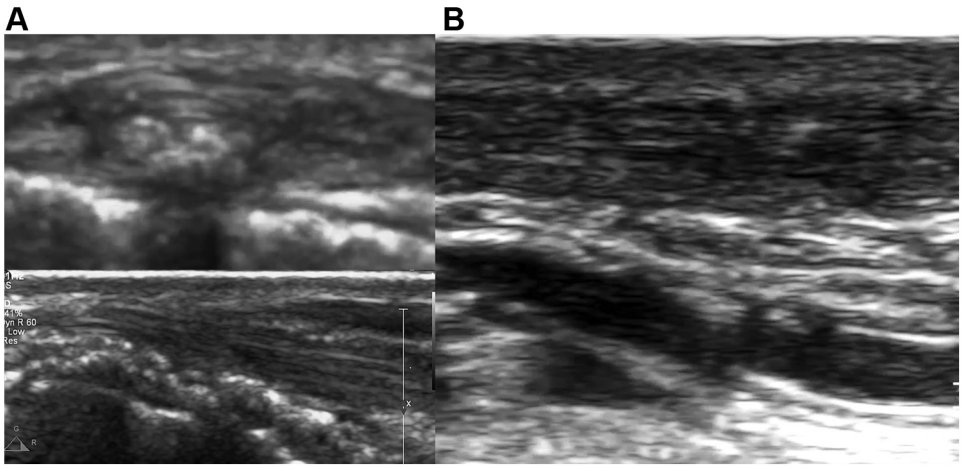


Figure 10. Side by side imaging. Ultrasonic evidence of (**A**) tibial "white stop sign" suggesting vessel obliteration versus (**B**) hibernating lumen.

challenging patients may affect the success rate of this approach for limb preservation.

Conclusion

To our knowledge, this is one of the largest case series to date with real-world patients with no-option CLTI who underwent pDVA at a CLTI center. Identifying criteria for patient selection and advanced wound care is an important aspect of this procedure to ensure clinical success. pDVA seems to be a reasonable option for limb salvage in patients with end-stage SAD where traditional arterial revascularization is not feasible. Additional research is required to establish diagnostic guidelines for patients being evaluated for pDVA to deliver appropriate therapy in a timely manner and to improve amputation-free survival for these patients with no-option CLTI.

Declaration of competing interest

Dr Saab receives consulting fees for physician education and training from Boston Scientific, Philips and Terumo. Research: Boston Scientific, Micro Medical Solutions, PQ Bypass. Dr Mustapha receives consulting fees for physician education and training from Angiodynamics, Avinger, BD Bard, Boston Scientific, Cardiovascular Systems Inc, Medtronic, Philips, PQ Bypass, and Terumo. Research: Avinger, Boston Scientific, PQ Bypass, Terumo. Dr Ansari receives consulting fees for physician education and training from Boston Scientific, Edwards, and Gore. Research: Abbott, Boston Scientific, BD Bard, PQ Bypass. Dr Pupp reported no financial interests. Dr Madassery receives consulting fees for physician education and training from Philips, Abbott, Penumbra, and Cook. Dr N'Dandu receives consulting fees for physician education and training from BD Bard, Gore, LimFlow, and Abbott. Research: LimFlow. Dr Wiechmann receives consulting fees for physician education and training from Angiodynamics, BD Bard, Boston Scientific, and Philips. Dr Bernstein receives consulting fees for physician education and training from Cardiovascular Systems, Inc. Dr Mize receives consulting fees for physician education and training from Cardiovascular Systems Inc, Terumo, and Philips. Dr Pliagas receives consulting fees for physician education and training from Asahi, Cardiovascular Systems Inc, Cook, Medtronic, and Philips.

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Ethics statement and patient consent

The research reported has adhered to the relevant ethical guidelines. The requirement for informed consent was waived.

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