Hybrid approach to deep vein arterialization as an adjunct for patients with severe medial calcinosis

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ABSTRACT

Patients with no-option chronic limb-threatening ischemia are not candidates for conventional revascularization options and will inevitably require major amputation. Deep venous arterialization (DVA) is a potential option for these patients. A complete endovascular system to perform DVA has recently received great acclaim and US Foor and Drug Administration approval. However, patients with severe tibial medial calcinosis such as those with diabetes or renal failure may not be candidates for this because most endovascular needles cannot penetrate severe calcium. Here we describe a novel hybrid approach to DVA that provided technical success in three patients with end-stage renal disease and severe medial calcinosis. (J Vasc Surg Cases Innov Tech 2024;10:101545.)

Keywords: Chronic limb-threatening ischemia; Peripheral arterial disease; Peripheral vascular disease; Vascular calcinosis; Limb salvage; Endovascular procedure

Chronic limb-threatening ischemia (CLTI) is a severe and debilitating condition characterized by inadequate blood flow resulting in ischemic rest pain and tissue loss, often resulting in amputation. Limb salvage strategies have relied traditionally on arterial revascularization techniques to restore inline flow to the foot. Despite advances in open surgical and endovascular techniques, there remains a large population who are not candidates for conventional revascularization strategies owing to severe distal atherosclerotic disease with either no viable target or inadequate outflow to the foot. Deep venous arterialization (DVA) is a potential option for these patients with no-option CLTI (noCLTI). DVA involves making a connection between a proximal arterial inflow and a distal deep venous target, creating an unconventional outflow to provide oxygenated blood to the foot. Endovascular DVA has been previously described and has gained great acclaim with the LimFlow System (LimFlow SA, Paris, France).[1-3] However, most endovascular needles cannot penetrate severe calcium, making patients with severe tibial medial calcinosis, often diabetics and those with renal failure (end-stage renal disease), ineligible.

Here we describe a hybrid approach to DVA that involves a small posterior tibial exposure to create the arteriovenous connection (arteriovenous fistula [AVF]) along with endovascular DVA. This approach has provided technical success in three patients with end-stage renal disease and severe medial calcinosis. The patients provided written informed consent for the report of their case details and imaging studies.

CASE REPORT

Each of the three patients had tissue loss to the forefoot with no suitable bypass targets and no identifiable arterial runoff into the foot (Fig 1). Given these findings, each patient was consented for DVA. We had a high suspicion for severe medial calcinosis from preoperative imaging and consented each patient for a possible hybrid approach in the event that we could not cross the tibial arteries endovascularly.

The affected leg was circumferentially prepped and draped. Antegrade access was obtained in the common femoral artery. The posterior tibial vein at the level of the medial malleolus was also accessed with a microsheath. Diagnostic arteriogram confirmed calcified, but patent superficial femoral artery, popliteal artery and tibioperoneal trunk. A 0.014″ wire was advanced into the tibioperoneal trunk, and an intravenous ultrasound examination was performed. We used an intravenous ultrasound-guided reentry catheter to locate and to pass a needle through the tibioperoneal trunk into the posterior tibial vein. However, we were unable to cross, presumably owing to dense calcifications. We performed a venogram that showed the target area of crossover between the artery and vein.

Next, a posterior tibial cutdown was performed in the upper calf, just distal to the tibioperoneal trunk. Through the open incision the posterior tibial artery was felt to be calcified, but with good countertraction was able to be directly accessed with a microneedle, and an 0.018″ wire was snared from the common femoral artery. The back of the wire was then advanced into the posterior tibial vein through a venotomy and snared through the posterior tibial vein creating a through wire. This was exchanged over a crossing catheter for a stiff 0.018″ wire, creating a stable platform. Then from the tibial vein access, a balloon catheter was advanced to create the fistula between the posterior tibial artery and vein, followed by a 5-mm covered self-expanding stent from the groin

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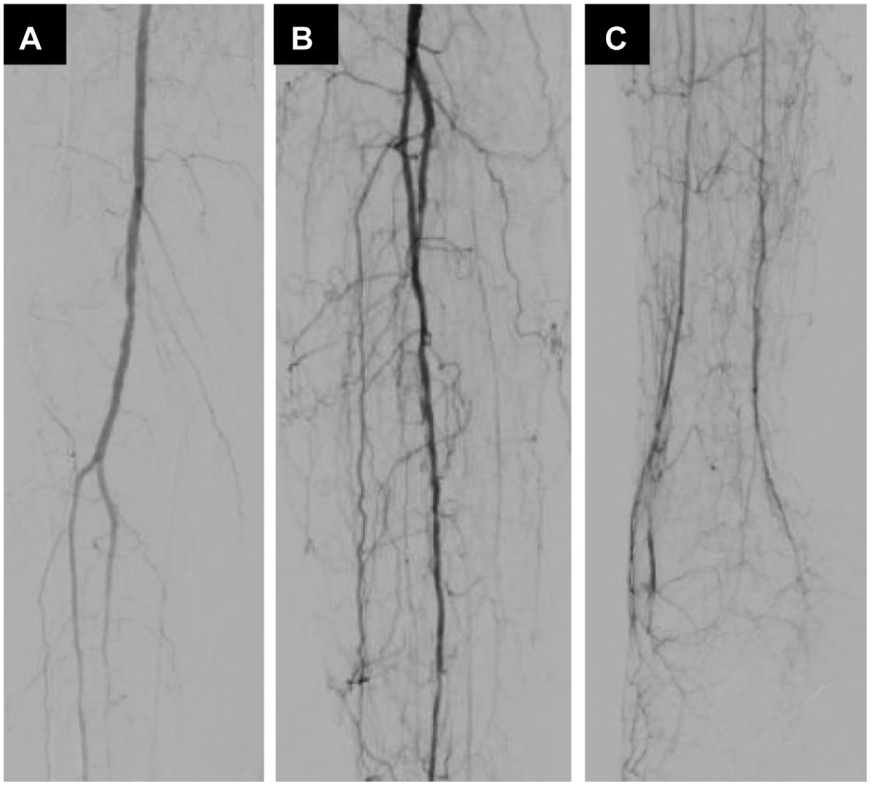

Fig 1. Preoperative angiogram demonstrating severe tibial disease without suitable bypass target or adequate outflow in three patients **(A-C)**.

access. The stent was visible within the field and hemostatic (Fig 2, *A*). The posterior tibial vein was then serially dilated with a 4-mm balloon, followed by another 5-mm covered self-expanding stent down to the level of the posterior tibial vein access. A second wire was then advanced past the posterior tibial vein access point into and around the pedal venous arch. The through wire was then removed at this point and a third, 5-mm, covered self-expanding stent was placed to cover the tibial vein puncture. A 2.5-mm cutting balloon was then advanced through the pedal venous arch, rendering valves incompetent, but no additional stents were placed. In one patient, the pedal venous arch could not be traversed via the posterior tibial vein, so the arch was crossed retrograde via with anterior tibial vein for venous valvuloplasty (Fig 2, *B*). Completion angiogram showed good flow through the DVA with arterialization of the deep pedal venous arch (Fig 3). The groin access was then closed with a closure device. The posterior tibial artery cutdown site was closed in layers and dressed in a sterile fashion. The patients had a palpable pulse in the foot and were planned to be maintained on 75 mg daily clopidogrel (Plavix) and systemic anticoagulation for ≥3 months. Postoperatively, all patients underwent arterial duplex and had a patent AVF with good volume outflow past the distal covered stent ranging from 45 to 184 mL/min that increased in subsequent duplex. Patients experienced leg swelling that was not limiting and managed with leg elevation alone. At one month, all DVAs remained patent with plans for minor amputations for attempts at limb salvage.

DISCUSSION

Approximately one-quarter of patients with CLTI will undergo a major amputation within 1 year,[4] and nearly 40% of patients with noCLTI will undergo amputation within 6 months.[5] As venous arterialization grows as an option to treat noCLTI patients, understanding and refining its technique to manage this difficult population is necessary. Open surgical venous arterialization has been a concept for >100 years,[6] but the procedure continues to evolve. There are multiple open surgical series with varying methodologic qualities and unreliable outcomes.[7,8] This inconsistency in technical success and limb salvage rates attests to the complexity and difficulty of this operation in a challenging patient population with very limited options. Moreover, the open surgical technique necessitates creating large and deep incisions to create the AVF and an arduous task of venolysis to prevent steal phenomenon.

Consequently, endovascular approaches to DVA have developed by creating the AVF with reentry catheters like the Pioneer Plus (Philips, San Diego, CA), performing endovascular valvuloplasty, and deploying long covered stents along the target vein to minimize steal and maximize oxygenated blood flow distally to the foot.[2] The LimFlow System (LimFlow SA) has recently been approved by the US Food and Drug Administration for complete transcatheter arterialization of deep veins after

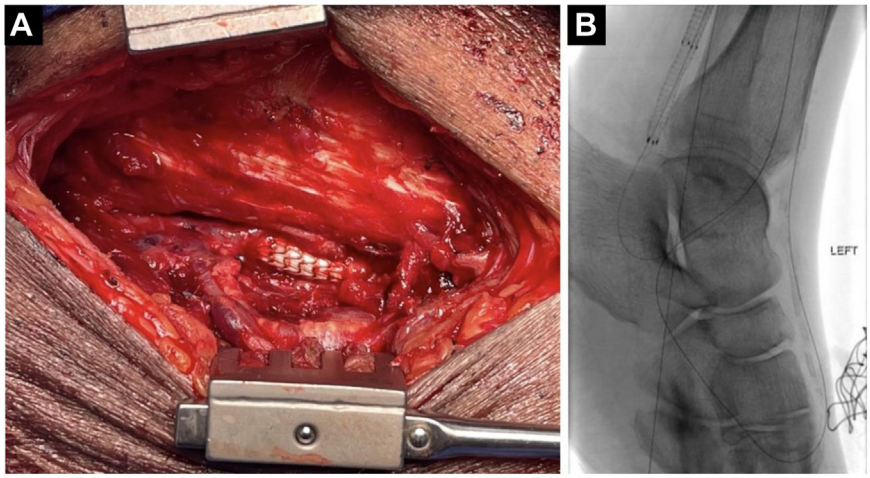

Fig 2. **(A)** Posterior tibial artery to vein covered stent placement. **(B)** Wire access into the saphenous system via the posterior and anterior tibial veins allowing venoplasty of the pedal arch.

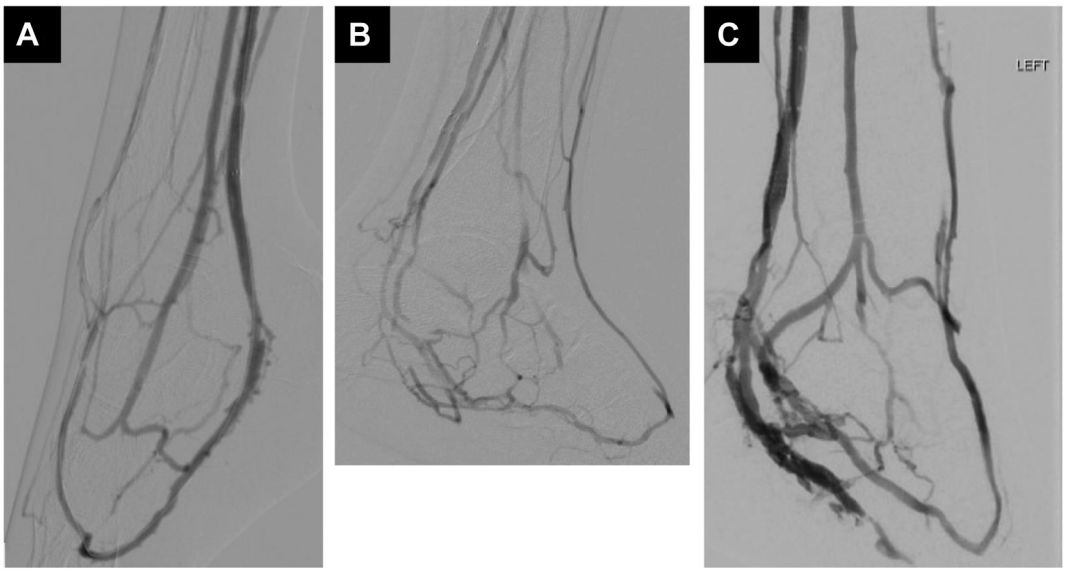

Fig 3. Completion angiogram of the three patients **(A-C)** with filling of the deep venous system and pedal arch.

successful outcomes reported in the PROMISE I and II studies.[1,9] This development has provided standardization and procedural ease to performing percutaneous DVA. The PROMISE II study demonstrated that patients with noCLTI who underwent transcatheter arterialization with the LimFlow System had an amputation-free survival at 6 months in 66%, avoided an above-ankle amputation in 76%, and had completely healed wounds in 25%.[9]

Although the success of the transcatheter arterialization is remarkable, the system requires that the donor artery, most frequently the posterior tibial artery, can be traversed into the venous system percutaneously. Unfortunately, in this subset of noCLTI patients and particularly in dialysis-dependent patients, this critical step may be difficult, if not impossible, owing to long segments of medial calcinosis. Gandini et al[10] evaded this challenge by creating the AVF much more distally at the plantar artery and vein, but this approach relies on a much longer segment of inline flow via the posterior tibial artery. Others have elected to create an open AVF, either with great saphenous vein or PTFE conduit, but this technique disrupts the valves with an endovascular approach.[11,12]

Here, we describe a novel hybrid technique for DVA using the tibial arteries without creating a new anastomosis, which is also often difficult with severe calcinosis. Postoperative and follow-up duplex ultrasound examinations have shown technical success and feasibility of this method in three patients. Although our approach requires an open incision (~5 cm) to assist

in the cannulization of the tibial artery to the deep vein, the remaining steps are nearly identical to the endovascular approaches previously described that have very encouraging results. We, therefore, believe that this new hybrid approach will expand the number of patients that could benefit from this limb salvage procedure.

CONCLUSIONS

We demonstrate good technical and clinical success using a hybrid approach to facilitate DVA for limb salvage as an adjunct for patients with severe medial calcinosis.

DISCLOSURES

None.

REFERENCES

1. Clair DG, Mustapha JA, Shishehbor MH, et al. Promise I: early feasibility study of the LimFlow System for percutaneous deep vein arterialization in no-option chronic limb-threatening ischemia: 12-month results. *J Vasc Surg*. 2021;74:1626–1635.
2. N'Dandu Z, Bonilla J, Yousef GM, White CJ. Percutaneous deep vein arterialization: an emerging technique for no-option chronic limb-threatening ischemia patients. *Cathet Cardiovasc Interv*. 2021;97:685–690.
3. Kum S, Huizing E, Schreve MA, et al. Percutaneous deep venous arterialization in patients with critical limb ischemia. *J Cardiovasc Surg*. 2018;59:665–669.
4. Abu Dabrh AM, Steffen MW, Undavalli C, et al. The natural history of untreated severe or critical limb ischemia. *J Vasc Surg*. 2015;62:1642–1651.e3.
5. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FGR. Inter-society consensus for the management of peripheral arterial disease (TASC II). *J Vasc Surg*. 2007;45:S5–S67.
[6]. Halstead AE, Vaughan RT. Arteriovenous anastomosis in the treatment of gangrene of the extremities. *Trans Am Surg Ass*. 1911;29:265–315.
7. Schreve MA, Minnee RC, Bosma J, Leijdekkers VJ, Idu MM, Vahl AC. Comparative study of venous arterialization and pedal bypass in a patient cohort with critical limb ischemia. *Ann Vasc Surg*. 2014;28:1123–1127.
8. Ho VT, Gologorsky R, Kibrik P, et al. Open, percutaneous, and hybrid deep venous arterialization technique for no-option foot salvage. *J Vasc Surg*. 2020;71:2152–2160.
9. Shishehbor MH, Powell RJ, Montero-Baker MF, et al. Transcatheter arterialization of deep veins in chronic limb-threatening ischemia. *N Engl J Med*. 2023;388:1171–1180.
10. Gandini R, Merolla S, Scaggiante J, et al. Endovascular distal plantar vein arterialization in dialysis patients with No-option critical limb ischemia and posterior tibial artery Occlusion: a technique for limb salvage in a challenging patient subset. *J Endovasc Ther*. 2018;25:127–132.
11. Ferraresi R, Casini A, Losurdo F, et al. Hybrid foot vein arterialization in No-option patients with critical limb ischemia: a preliminary report. *J Endovasc Ther*. 2019;26:7–17.
12. Alexandrescu V, Ngongang C, Vincent G, Ledent G, Hubermont G. Deep calf veins arterialization for inferior limb preservation in diabetic patients with extended ischaemic wounds, unfit for direct arterial reconstruction: preliminary results according to an angiosome model of perfusion. *Cardiovasc Revasc Med*. 2011;12:10–19.

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