Venous Arterialization for CLI: When, Why, and How?

Identifying appropriate patients and techniques for treating no-option CLI with percutaneous deep vein arterialization.

BY DANIEL A.F. VAN DEN HEUVEL, MD; MICHIEL A. SCHREVE, MD; AND STEVEN KUM, MD

An aging population and the rising incidence of diabetes have contributed to the increasing number of patients with critical limb ischemia (CLI).[1,2] Although some CLI patients will achieve wound healing with conservative therapy, it is impossible to predict who these patients will be, and it is therefore recommended that revascularization remains an important first-line treatment.[3] Unfortunately, failure to achieve sufficient blood flow to the wound remains a problem in both surgical and endovascular revascularization attempts, especially for patients with diabetes and end-stage renal disease who commonly present with severe, heavily calcified stenotic and occlusive disease that frequently extends below the ankle. In this advanced disease stage, with occlusions of the pedal arteries and lack of reasonable distal targets for angioplasty or bypass surgery, there are no further options to improve perfusion of the wounds (Figure 1). In these "no-option" patients, venous arterialization could be the only way to help wounds heal, prevent major amputation, and/or relieve rest pain. This article describes the use of venous arterialization as a last-resort treatment for patients with CLI who have no other treatment options.

PATIENT SELECTION

Typically, candidates for deep vein arterialization (DVA) have Rutherford class 5 and 6 disease and no available surgical or endovascular treatment options. Patients with ischemic rest pain who fail to respond to conservative treatment and are also not candidates for surgical or endovascular treatment could also be considered DVA candidates.

When selecting patients for DVA, close attention should be paid to the clinical status of the foot. Patients with extensive tissue loss are not appropriate candidates for DVA or other forms of conventional revascularization. Critical structures, such as the deep venous arch, must be intact to achieve good flow and a well-perfused foot. In addition, it is important that infection is adequately treated by surgical drainage and antibiotics prior to performing DVA. Superficial infection at the distal venous puncture site, which is most commonly at the medial malleolar level, should be treated before the procedure to prevent graft infection.

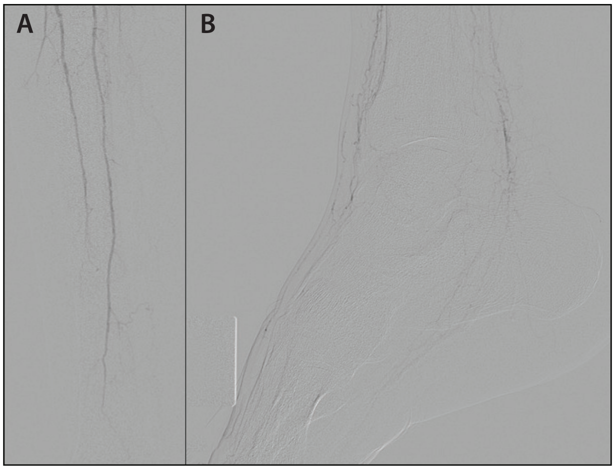

Figure 1. A no-option patient with CLI and desert foot. There is only a very small peroneal artery reaching down to the ankle (A). At the foot, there are no target vessels to perform bypass or endovascular intervention (B).

Apart from the clinical status of the foot, eligibility also depends on the arterial and venous vascular status of the index leg. Inflow has to be optimal, with uninterrupted flow up to the occlusion and crossing point. In addition, the venous outflow has to be sufficient enough to provide good flow through the DVA. Although imaging of the arterial inflow is available from previous revascularization attempts in most cases, the venous outflow should still be imaged because patent deep veins (ie, posterior tibial vein [PTV], lateral plantar vein, and deep venous arch) are mandatory to have a successful procedure. Venous imaging can be done with classic phlebography,[4] MRI, or duplex ultrasound.

VENOUS ARTERIALIZATION TECHNIQUES

Superficial Surgical Venous Arterialization

The superficial venous arch of the foot is used for arterialization. Different techniques can be used for superficial venous arterialization, but we prefer in situ bypass because of its simplicity. The first step of the in situ technique is to expose the great saphenous vein at the suitable site for the proximal anastomosis and the median marginal vein at the dorsum of the foot for the treatment of the valves. An anastomosis is created between the great saphenous vein and the appropriate inflow artery, which is usually the popliteal artery.

A transverse venotomy is made at the origin of the median marginal vein, after which a valvulotomy is performed. The proximal valves are made incompetent by retrograde introduction of an expandable valvulotome. In an antegrade fashion and with the aid of a small plastic probe, the distal valves of the hallux and the superficial venous arch are destroyed. After the venotomy has been closed and all tributaries of the great saphenous vein have been ligated, completion angiography is performed to visualize the perfusion of the foot through the superficial venous arch. The Achilles heel of this technique is achieving distal valve destruction without perforating the wall.[5]

Deep Surgical Venous Arterialization

In deep surgical venous arterialization, the deep venous arch is used for arterial outflow. The preferred vein is one of the concomitant veins of the posterior tibial artery (PTA) at the malleolar level or even one of the concomitant veins of the plantar artery. One of the advantages of DVA is that it does not rely on communication between the saphenous vein and the deep system below the ankle to create good perfusion to the foot. A second advantage is that fewer valves have to be destroyed, compared with superficial venous arterialization, as the last valve is located at the midfoot.[5]

Percutaneous Venous Arterialization

It is generally accepted that an endovascular-first approach is preferred over a surgical approach in the treatment of CLI. This may be even more so in venous arterialization, where extensive wounds are created for proximal and distal anastomoses. Because these wounds are made in ischemic tissue, they carry a relatively high rate of complications such as infection and the inability to heal. In addition, with a surgical approach, it is more difficult to direct blood to the foot because of the numerous connecting and branching veins requiring ligation at multiple levels, adding to the complexity, duration, and the number of complications of the procedure. In contrast, with DVA, the wounds are limited to a small cut in the skin at the groin and at the malleolar level to facilitate the sheath introduction. Furthermore, it is relatively easy to perform venous arterialization in the deep system, making it a first-line approach at our institutions.

Technical Aspects of Valvulotome-Assisted DVA

A DVA requires good inflow up to the level of the occluded below-the-knee vessels. In the majority of cases, the PTA will be the target vessel to cross from artery to vein. The tibioperoneal trunk (TPT) and the PTA have to be of sufficient caliber to facilitate the positioning and rotation of the arterial probe that is used to cross into the vein. This often requires predilatation in cases where there is a high calcium burden (Figure 2A).

To perform DVA, a long antegrade 7-F sheath is introduced in the common femoral artery and positioned at the distal popliteal segment or TPT to accommodate the arterial ultrasound-emitting probe. After uninterrupted inflow has been confirmed, the most suitable distal PTV is punctured at the malleolar level, which is usually done

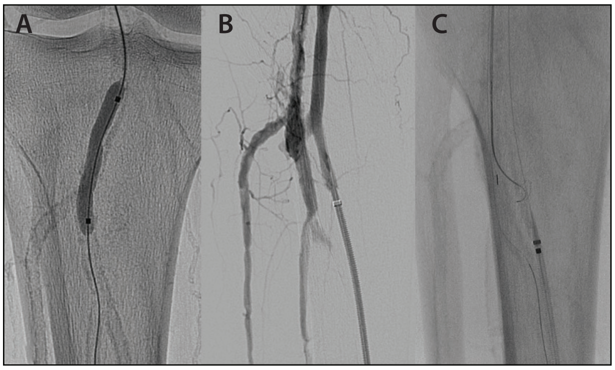

Figure 2. Predilatation to facilitate positioning of the arterial probe (A). Double injection to determine the optimal crossing point (B). In this case, the TPT was used to cross from because of an occluded and severely calcified PTA. Fluoroscopy image demonstrating the advanced needle and crossing into the PTV (C).

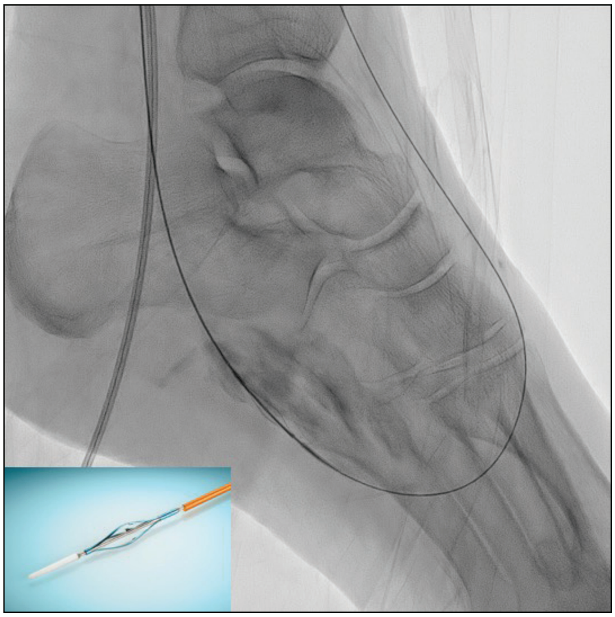

Figure 3. A 0.018-inch wire across the deep venous arch in the marginal vein. The wire facilitates lysis of the valves by supporting a forward cutting device (LimFlow). Special attention should be paid to destruction of the valves at the malleolar and plantar level.

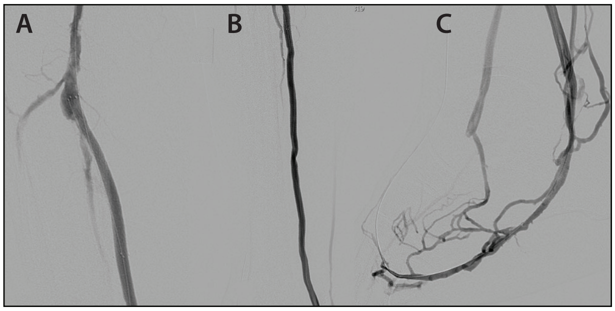

Figure 4. Completion angiogram at the crossing point showing successful DVA creation with flow through the covered stent (A). Flow through the covered extension stents and lateral plantar vein (B). Outflow is mainly via the great saphenous vein because of an obstructing wire in the deep venous arch (C).

with ultrasound guidance to enable excellent visualization of the paired veins, especially after applying a tourniquet. After successful needle puncture, a microintroducer set is placed and exchanged for a long 5-F sheath that is advanced into the proximal PTV. This sheath will accommodate the venous receiver probe. In the next stage of the procedure, the ideal crossing point from the target vessel is identified by performing simultaneous digital subtraction angiography through both sheaths, performing a so-called double injection (Figure 2B). The ideal crossing point should be 2 to 3 cm distal to the origin of the PTA. The venous probe and the arterial ultrasound-emitting probe containing the crossing needle are aligned at the crossing point. Once a maximal ultrasound signal is achieved, the needle is advanced into the vein. A 0.014-inch wire is introduced and used to wire the PTV past the level of the distal puncture site (Figure 2C), which requires the use of a support catheter that is introduced after removal of the arterial probe. The next step is to wire the plantar vein and the deep venous arch to facilitate the positioning of a 0.018-inch supportive wire into the marginal vein. Over this wire, a valvulotome is advanced and is used to destroy valves from the level of the crossing point up to the most distal valve in the lateral plantar vein (Figure 3).

Although cutting balloons were previously used before the availability of the LimFlow device (LimFlow SA), it is hypothesized that the barotrauma of high-pressure balloons and/or the use of cutting balloons may lead to excessive damage of the intima of the vein and predispose the vessel to future restenosis, as seen in cadaver angioscopic studies.[6] Predilatation of tibial veins with a 5-mm balloon is performed to facilitate the placement of covered stents. Next, 5-mm covered stents are placed from the level of the distal PTV extending into the proximal PTA. The DVA is finally created by placing a dedicated tapered covered stent (3.5–5.5 X 40 mm) over the crossing point (Figure 4).

Hybrid Approach

Another possible approach is the hybrid approach, in which a bypass is combined with an endovascular procedure. A conduit is made between the donor artery and the vein through which the distal valves are destroyed, and side branches are coiled or covered. A hybrid technique may be considered at any level but is mainly reserved for cases in which the popliteal artery is occluded and the patent donor artery is the superficial or common femoral artery.

POSTPROCEDURAL CHANGES

There are several mechanisms that are thought to contribute to limb salvage after DVA.[7] Early experiences demonstrate that complete wound healing can be achieved but that it takes more time compared with successful arterial revascularization. This is possibly related to the mechanisms involved in DVA that take time to develop and sort effect. Other than direct nutritional improvement by reversal of flow through venules, it is thought that there is also a beneficial effect by stimulation of angiogenesis and recruitment of hibernating collaterals. A prerequisite for successful limb salvage is early primary patency of the DVA, which is achieved by performing a successful DVA procedure in which optimal inflow and outflow are achieved. In addition, oral anticoagulation in combination with antiplatelet therapy is prescribed for at least 3 months. Duplex flow measurements can be helpful for identifying flow decrease or a flow ≤ 100 mL/min that put the DVA at risk for thrombosis.

The clinical status of the foot may undergo some changes immediately postprocedure. Bluish discoloration and swelling may become apparent. Clinical improvement, as manifested by granulation and wound healing, occurs at approximately 6 weeks postprocedure. Over several days to weeks after DVA, the physiology of the foot perfusion changes. Although the mechanisms are not yet clear, the swelling disappears while the tissue perfusion increases, as demonstrated by a rise in transcutaneous oxygen pressure ($TcPO_2$). In case of insufficient improvement, the possibility of outflow shunting or inflow stenosis needs to be considered. Blood can be shunted away from the ischemic tissue, thereby not contributing to the oxygenation of the forefoot. In these cases, collateral veins and perforating branches in the foot can be occluded through either embolization or ligation of the great saphenous vein in an attempt to pressurize the forefoot. In case of an inflow stenosis, a simple angioplasty procedure can be performed.

The selected site for the creation of the percutaneous arteriovenous fistula (AVF) is important as well. Care must taken not to cover significant collaterals. Shunting via the AVF should also not be excessive, as to not cause steal syndrome. Conversely, it is our opinion that the formation of a distal AVF does not provide sufficient shunting to heal wounds.

RESULTS

Early experiences show that results after DVA are promising. In a pilot study by Kum et al, all seven patients demonstrated symptomatic improvement with formation of granulation tissue, resolution of rest pain, or both. Complete wound healing was achieved in four (57%) patients at 6 months and five (71%) patients at 12 months, with a median healing time of 4.6 months (95% confidence interval, 84–192 days). Median postprocedure peak $TcPO_2$ was 61 mm Hg compared to a preprocedure level of 8 mm Hg (P = .046). At the time of wound healing, four of five (80%) patients achieved $TcPO_2$ levels > 40 mm Hg.[8] There were no periprocedural deaths or amputations. Figure 5 demonstrates the course of wound healing in a representative case patient after DVA.

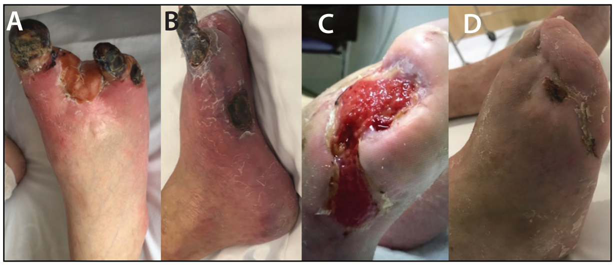

Figure 5. Wound photographs of a patient with dry gangrene and progressive rest pain nonresponsive to conservative management (A). After DVA, there was a temporary purple discoloration of the foot caused by a worsening of the ischemic state (B). Three months after DVA, the wounds show granulation tissue (C). At 9 months, complete wound healing was achieved (D).

CONCLUSION

Venous arterialization is technically feasible and can prevent major amputation in no-option patients with CLI. Additional research is necessary to better understand the physiologic mechanisms involved in tissue perfusion and thereby improve clinical outcomes in this challenging patient group. ■

1. Dua A, Lee CJ. Epidemiology of peripheral arterial disease and critical limb ischemia. Tech Vasc Interv Radiol. 2016;19:91-95.
2. Nehler MR, Duval S, Diao L, et al. Epidemiology of peripheral arterial disease and critical limb ischemia in an insured national population. J Vasc Surg. 2014;60:686-695.
3. Santema TB, Stoekenbroek RM, van Loon J, et al. Not all patients with critical limb ischemia require revascularization. Eur J Vasc Endovasc Surg. 2017;53:371-379.
4. White JV, Katz ML, Cisek P, Kreithen J. Venous outflow of the leg: anatomy and physiologic mechanisms of the plantar venous plexus. J Vasc Surg. 1996;24:819-824.
5. Schreve MA, Vos CG, Vahl AC, et al. Venous arterialization for salvage of critically ischaemic limbs: a systematic review and meta-analysis. Eur J Vasc Endovasc Surg. 2017;53:387-402.
6. Kum S. DVA – endo or open. Presented at: Critical Limb Ischemia Course (CLIC); March 22–23, 2018; Venice, Italy.
7. Houlind K, Christensen JK, Jepsen JM. Vein arterialization for lower limb revascularization. J Cardiovasc Surg (Torino). 2016;57:266-272.
8. Kum S, Tan YK, Schreve MA, et al. Midterm outcomes from a pilot study of percutaneous deep vein arterialization for the treatment of no-option critical limb ischemia. J Endovasc Ther. 2017;24:619-626.

Daniel A.F. van den Heuvel, MD
Department of Interventional Radiology
St. Antonius Hospital
Nieuwegein, the Netherlands
Disclosures: Consultant to LimFlow SA.

Michiel A. Schreve, MD
Department of Vascular Surgery
Noordwest Ziekenhuisgroep
Alkmaar, the Netherlands
Disclosures: Consultant to LimFlow SA.

Steven Kum, MD
Department of Vascular Surgery
Changi General Hospital
Simei, Singapore
Disclosures: Consultant to LimFlow SA.