



Percutaneous Deep Vein Arterialization: How Long is the Way to Establish its Role in CLTI Patients?

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At the beginning of the twentieth century, in the absence of any possible revascularization technique, all critical limb threatening ischemia (CLTI) patients were considered to be “no option.” Nowadays, percutaneous deep vein arterialization (p-DVA) has the potential to represent a turning point in terms of limb salvage, amputation-free survival, and ultimately, life expectancy in patients who are currently classified as “no option.”

The first attempts to create a functional proximal arteriovenous fistula for CLTI patients were described between 1881 and 1916.¹ In the period between 1916 and 1948, this technique was slowly abandoned and never cited again in the literature. In 1951, Szilagyi et al¹ used the newly born angiography to better understand the flow dynamics after having created an anastomosis between the proximal superficial femoral artery and the concomitant vein in 9 CLTI patients. In all cases, they found that no contrast was reaching the below-the-knee veins because of the valve contenance; a clinical improvement was demonstrated in none of the subjects and all patients underwent major amputation. The modern concept of surgical p-DVA was created by Lengua² and Sheil³ in the mid 1970s, who were the first two clinicians to understand that the key to success was to perform a distal rather than proximal arterialization at the level of the veins of the foot, mechanically disrupting the resistance coming from their valves. Since then, the anastomosis technique slowly shifted toward a less invasive approach.^{4,5} The benefits are related to the lack of extensive surgical wounds, which are particularly difficult to heal in cases of edema secondary to the increased venous return, and to the possible cost savings related to the shortening of hospitalization. In the last few years, multiple different new techniques have been described,⁶⁻⁹ together with what nowadays is considered the “gold standard” approach, which benefits from the Limflow technology.⁵

A recent publication in the *Journal of Critical Limb Ischemia* by Pietzsch et al¹⁰ represents the first cost-effectiveness analysis regarding p-DVA. It is based on clinical data obtained from the PROMISE I study,¹¹ which enrolled 32 patients in 7 high-volume centers in the United States. Even though the described economic model looks convincingly promising, I personally think that it is still probably too early to come to any conclusion on the cost-effectiveness of p-DVA based on current medical evidence.

A pinch of scepticism is needed;¹² the good rate of limb salvage described in the few small case series published is possibly biased by the fact that the authors are all operators with recognized experience in limb salvage and working within strong multidisciplinary groups, where the current literature stresses the need for good patient selection and close collegial follow-up.

A better knowledge of the still-unclear mechanisms of action of p-DVA, a more structured standardization of the technique (where experts are currently still debating about possible different treatment options as the perfect site for the fistula creation or the need for reaching the below-the-ankle veins with covered stents), and a more-solid follow-up on a larger number of patients are urgently needed.

On the contrary, the too-hasty widespread use of p-DVA, potentially putting any vascular specialist in a situation to perform p-DVA as adequately reimbursed, could lead to less-rigid patient selection and possibly less-stringent follow-up. This would ultimately jeopardize the recognition of p-DVA as a high-value intervention for “no-option” CLTI patients.

Generally speaking, the balance to be struck in order to develop a technique/procedure in a timely manner is one of the biggest challenges of our era.¹³ Many innovative medical studies are directly sponsored by ambitious medical companies, which naturally need a return on the investments made in technology and clinical studies within a reasonable timeline, in order to please their stockholders. On the other hand, a too-rigidly regulated adoption of potentially promising techniques/devices based only on costly randomized controlled trials would easily freeze the enthusiasm of industry and clinicians for innovation and negatively impact the lives of many patients.

How long will it take to establish the role of p-DVA in CLTI patients? I am sure that the next five years will be crucial to come to some conclusions. Studies such as PROMISE International (ClinicalTrials.gov identifier NCT03321552), PROMISE II trial (ClinicalTrials.gov identifier NCT03970538), and the United Kingdom multicenter prospective study will surely help in developing a better understanding of the potential of p-DVA. Will all of the PROMISEs be fulfilled? We all definitely hope so. Stay tuned...

References

1. Szilagyi DE, Jay GD 3rd, Munnell ER, et al. Femoral arteriovenous anastomosis in the treatment of occlusive arterial disease. *AMA Arch Surg*. 1951;63:435-451.
2. Lengua F. Arterialization technic of the venous network in the foot. *Nouv Presse Med*. 1975;4:1309-1342.
3. Sheil GR. Treatment of critical ischaemia of the lower limb by venous arterialization: an interim report. *Br J Surg*. 1977;64:197-199.
4. 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.
5. Kum S, Huizing E, Schreve MA, et al. Percutaneous deep venous arterialization in patients with critical limb ischemia. *J Cardiovasc Surg (Torino)*. 2018;59:665-669.
6. Ichihashi S, Shimohara Y, Bolstad F, et al. Simplified endovascular deep venous arterialization for non-option CLI patients by percutaneous direct needle puncture of tibial artery and vein under ultrasound guidance (AV spear technique). *Cardiovasc Intervent Radiol*. 2020;43:339-343.
7. Ysa A, Lobato M, Mikelarena E, et al. Homemade device to facilitate percutaneous venous arterialization in patients with no-option critical limb ischemia. *J Endovasc Ther*. 2019;26:213-218.
8. 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.
9. Migliara B, Cappellari TF, Mirandola M, et al. Percutaneous saphenous vein arterialization. *J Endovasc Ther*. Epub 2021 Jul 7.
10. Pietszch JB, Ederhof M, Geisler BP, Schneider PA. Cost-effectiveness of percutaneous deep vein arterialization for patients with no-option chronic limb-threatening ischemia: an exploratory analysis based on the PROMISE I study. *J Crit Limb Ischem*. Epub 2021 Jul 26.
11. Clair DG, Shishebor MH, Schneider PA, Henao S, Bernardo NN, Deaton DH. 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*. Epub 2021 May 18.
12. Ysa A. Commentary: percutaneous venous arterialization: should we contain our enthusiasm? *J Endovasc Ther*. 2020;27:666-668. Epub 2020 May 19.
13. Reekers JA. For the times they are a-changin'? *CVIR Endovasc* 2, 5 (2019). Available at <https://doi.org/10.1186/s42155-018-0045-x>. Accessed on October 6, 2021.

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