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Commentary

A Contemporary Review of Transcatheter Arterialization of Deep Veins by a Vascular Surgeon with A Decade of Experience Treating "No Option" CLTI

Patrick Carroll, Julia Cochrane, Morgan Petersen, Jay Patel, Brianna-Marie Hollister, Aldin Malkoc, Samuel Lee, Samuel Schwartz*

Department of Surgery, Arrowhead Regional Medical Center, California University of Science and Medicine, Colton, USA

DESCRIPTION

General outcomes

Transcatheter Arterialization of Deep Veins (TADV) is an endovascular procedure that artificially creates an arterial to deep venous pathway to treat patients with no option or end-stage Chronic Limb-Threatening Ischemia (CLTI) [1]. Successful Arteriovenous (AV) shunting promotes antegrade flow *via* the deep venous system to revascularize malperfused areas to improve wound healing [2]. There are in general three key steps in performing a successful TADV, the first is to create the AV shunt, the second step is to ablate any venous valves, and the final step is to block shunted arterial blood flow from entering venous collaterals that divert blood flow away from the affected target in the limb [1]. The only registered device that is capable of performing these three general steps of TADV is the LimFlow system [1]. To assess the efficacy of TADV, there are three primary outcomes described by multiple international and domestic trials. The first is Limb Salvage (LS), which is defined as preservation of an affected limb without amputation [3-5]. The second is Amputation Free Survival (AFS), which is characterized by freedom from above-knee amputation or all-cause mortality. Lastly, Complete Wound Healing (CWH) refers to complete epithelialization of damaged tissue [4].

Several key domestic and international trials have proven efficacy of the limflow system in no option CLTI with promising results. The PROMISE I trial is a United States (US) domestic trial that enrolled thirty-two patients and reported AFS rates at 30 days, 6 months, and 12 months of 91%, 74%, and 70% respectively [6]. The total percentage of CWH or in the process of healing was 67% at 6 months and 75% at 12 months. The outcome of limb salvage was not reported in this trial. An expansion of the PROMISE I trial was the PROMISE II trial, which included dialysis patients and included LS, AFS and WH as outcomes. At 6 months, the reported AFS was 66.1% [3]. LS was achieved in 67 patients (76% by Kaplan-Meier analysis) and CWH was attained in 25% of patients. Along the international front, a prominent study that studied TADV was the ALPS study. They reported 3 primary outcomes at 6, 12, and 24 months, estimates were 83.9%, 71.0%, and 67.2% for AFS, 86.8%, 79.8% and 79.8% for limb salvage, and 36.6%, 68.2%, and 72.7% for complete wound healing, respectively [4]. The PROMISE III, PROMISE International, and PROMISE UK trials are currently ongoing and have yet to publish their results. Nonetheless, compiling the outcomes of these three monumental trials, patients with "No Option CLTI" should be evaluated as candidates for TADV in order to prevent major amputation [3,4,6]. These results allow physicians to provide a last resort treatment option when all other surgical and interventional options have failed.

Proximal *versus* distal TADV

The location of the TADV refers to the site of the AV anastomosis. A proximal TADV procedure is generally considered to be closer to the origin of the Posterior Tibial (PT) artery, while the distal TADV is closer to the ankle [7]. The PT artery is the most commonly selected location for AV crossing (75.2%), followed by the peroneal artery (19.0%), and lastly the tibioperoneal trunk (5.7%) [3]. Regardless of which location is used, this procedure involves using arteriography and venography to identify an area with the shortest distance between the vessels that will be anastomosed [8]. An important consideration in determining the crossing point for the anastomosis is that venous arterialization requires 6-12 weeks to improve blood flow to the foot. In other words, pre-existing arterial perfusion to the foot must be maintained. Therefore, the crossover point should ideally be performed in an artery that is not critical for the perfusion of the foot [9].

Patients often have other high resistance arteries with limited flow in the calf, so it is important to consider that high blood flow through the TADV circuit can create a "steal" effect, which can result in retrograde flow through the other arteries causing severe ischemia. This effect can be mitigated by occluding some

Correspondence to: Samuel Schwartz, Department of Surgery, Arrowhead Regional Medical Center, California University of Science and Medicine, Colton, USA, E-mail: schwartzsa@armc.sbcounty.gov

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of the outflow veins branching early in the foot, which prevents blood flow to the distal parts of the foot or by extending the stent graft more distally [10]. While Migliaria B states that a "typical storm" of varying degrees of cyanosis, edema, and superficial necrosis over the weeks following the procedure is expected due to the reversal of flow in the venous system. So et al states that lower limb edema and high output cardiac failure are relatively infrequent with TADV, and much less common when compared to open venous arterialization [11,12]. While there seems to be no clear agreement on whether a proximal or distal TADV is more beneficial, Zaman et al takes a preferential stance on distal DVAs, citing a more cost effective approach due to a shorter stent graft requirement, and less pain and edema resulting in the ability to perform transmetatarsal amputation sooner (2 weeks after TADV *vs.* recommended 8+ weeks) and the ability to create plantar flaps instead of guillotine amputations due to decreased suture line stress [7].

Need for secondary interventions

The types of secondary interventions can be broken down into two major categories: Moderation of blood flow and recanalization. Moderation of blood flow includes procedures such as coil embolization of venous collaterals that may steal blood flow or banding the system to reduce excessive blood flow. More data is needed to adequately assess desired blood flow, but current literature suggests a rate between 150 to 450 mL/min to prevent both ischemic steal on the high end and thrombosis of the system on the low end [10]. This can be evaluated perioperatively, assessing the need for secondary intervention before complications develop, likely improving outcomes, although research into this topic is not yet robust. On the other hand, similar to other forms of arteriovenous system creation, the TADV circuit needs time to arterialize and mature emphasizing the need for close monitoring and postprocedural care even after the patient is discharged [13]. Recanalization procedures include percutaneous transluminal angioplasty or drug-coated balloon and additional stenting. The clinical decision to perform secondary intervention depends on the potential complications experienced by the patient such as steal of blood flow or inadequate perfusion [14-17]. This poses a significant challenge to assessment of the impact of secondary interventions on long-term outcomes as patients requiring these procedures were likely already experiencing complications.

REFERENCES

1. Spiliopoulos S, Davoutis E, Arkoudis NA, Sritharan K, Lechareas S. Percutaneous deep venous arterialization for limb salvage in no option patients with chronic limb-threatening ischemia. J Clin Med. 2023;12(23):7324.
2. Mutirangura P, Ruangsetakit C, Wongwanit C, Sermsathanasawadi N, Chinsakchai K. Pedal bypass with deep venous arterialization: The therapeutic option in critical limb ischemia and unreconstructable distal arteries. Vascular. 2011;19(6):313-319.
3. Shishehbor MH, Powell RJ, Montero-Baker MF, Dua A, Martínez-Trabal JL, Bunte MC, et al. Transcatheter arterialization of deep veins in chronic limb-threatening ischemia. N Engl J Med. 2023;388(13):1171-1180.
4. Schmidt A, Schreve MA, Huizing E, Del Giudice C, Branzan D, Ünlü Ç, et al. Midterm outcomes of percutaneous deep venous arterialization with a dedicated system for patients with no-option chronic limb-threatening ischemia: The ALPS multicenter study. J Endovasc Ther. 2020;27(4):658-665.
5. Schreve MA, Vos CG, Vahl AC, de Vries JP, Kum S, de Borst GJ, et al. Venous arterialisation for salvage of critically ischaemic limbs: A systematic review and meta-analysis. Eur J Vasc Endovasc Surg. 2017;53(3):387-402.
6. Clair DG, Mustapha JA, Shishehbor MH, Schneider PA, Henao S, Bernardo NN, 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(5):1626-1635.
7. Zaman N, Rundback J. Deep venous arterialization: Background, patient selection, technique, outcomes and follow-up, and future implementation. Semin Intervent Radiol. 2023;40(2):183-192.
8. Ho VT, Gologorsky R, Kibrik P, Chandra V, Prent A, Lee J, et al. Open, percutaneous, and hybrid deep venous arterialization technique for no-option foot salvage. J Vasc Surg. 2020;71(6):2152-2160.
9. Janda L, Clair D. Transcatheter arterialization of the deep veins for limb salvage. Ann Vasc Surg. 2024.
10. Clair D, Gibbons M. A review of percutaneous deep vein arterialization for the treatment of nonreconstructable chronic limb threatening ischemia. Semin Vasc Surg. 2021;34(4):188-194.
11. Migliara B. Totally percutaneous deep foot vein arterialization in no-option CLTI patients anatomical and technical key points. J Vasc Endovasc Ther. 2020;5(2):3-4.
12. So SE, Chan YC, Cheng SW. Efficacy and durability of percutaneous deep vein arterialization: A systematic review. Ann Vasc Surg. 2024;105:89-98.
13. Huizing E, Schreve MA, Kum S, de Borst GJ, de Vries JPM, Ünlü Ç. Postprocedural management in patients after percutaneous deep venous arterialization: An expert opinion. J Endovasc Ther. 2023:15266028231158946.
14. Zaman NS, Shackles C, Moriarty KT, Herman K, Rundback JH. Patterns of failure in deep venous arterialization and implications for management. J Crit Limb Ischem. 2022;2(3):58-63.
15. Schreve MA, Huizing E, Kum S, de Vries JP, de Borst GJ, Ünlü Ç. Volume flow and peak systolic velocity of the arteriovenous circuit in patients after percutaneous deep venous arterialization. Diagnostics. 2020;10(10):760.
16. Dua A, Rose-Sauld S, Ferraro L, Sweeney E, Editors. The Massachusetts general hospital approach to transcatheter arterialization of the deep veins for advanced limb salvage: Protocols and procedures. Springer Nat; 2023.
17. Huizing E, Schreve MA, Kum S, Papageorgiou G, de Vries JP, de Borst GJ, et al. Development of a prediction model for the occurrence of stenosis or occlusion after percutaneous deep venous arterialization. Diagnostics. 2021;11(6):1008.