INTERVENTIONAL RADIOLOGY
Official journal of the Japanese Society of Interventional Radiology and Asia Pacific Society of Cardiovascular and Interventional Radiology

PICTORIAL ESSAY

Role of Percutaneous Deep Venous Arterialization for Patients with Chronic Limb-threatening Ischemia

Shigeo Ichihashi[1], Shinichi Iwakoshi[1], Takahiro Nakai[1], Yuji Yamamoto[1], Tomoaki Hirose[2], Kinya Furuichi[3], Yamato Tamura[4] and Toshihiro Tanaka[1]

1) Department of Diagnostic and Interventional Radiology, Nara Medical University, Japan
2) Department of Thoracic and Cardiovascular Surgery, Nara Medical University, Japan
3) Department of Radiology, Saiseikai Suita Hospital, Japan
4) Department of Cardiovascular Surgery, Nara Prefecture Seiwa Medical Center, Japan

Abstract:
Efficacy of percutaneous deep venous arterialization (pDVA) has been reported for patients with no-option chronic limb-threatening ischemia (CLTI). In the countries where a manufactured device dedicated for pDVA has not been reimbursed, pDVA using the off-the-shelf technique has alternatively spread. The off-the-shelf techniques for arteriovenous fistula (AVF) creation reported are as follows: AV spear technique, venous arterialization simplified technique (VAST), and a use of penetration guidewire or a reentry device. Technical success rates of the procedures are similar to those using the dedicated device. pDVA could be a last resort for the patients with no-option CLTI, including those suffering from stump ulcer after major limb amputation or those with occluded surgical bypass.

Keywords:
critical limb ischemia, peripheral arterial disease, endovascular procedures, percutaneous deep venous arterialization, chronic limb-threatening ischemia

Interventional Radiology 2023; 8(2): 97-104
https://doi.org/10.22575/interventionalradiology.2022-0025
https://ir-journal.jp/

Introduction

Revascularization plays a major role in chronic limb-threatening ischemia (CLTI). However, it has been reported that the so-called no-option CLTI patients at a rate of 14%-20% technically demand to be revascularized and cannot otherwise avoid major amputation of the lower limbs [1]. In 1912, the deep venous arterialization (DVA), in which deep veins were surgically anastomosed with the artery to create arteriovenous fistula (AVF), was reported for such patients [2]. After DVA, a retrograde flow via venous network can theoretically perfuse an ischemic wound. However, it was never widely adopted as outcomes significantly varied most likely due to the complexity of the procedures and lack of standardization. In recent years, advancement of the endovascular technologies and skills enable the creation of DVA endovascularly, and researchers from western countries where a manufactured device for pDVA is available have reported the usefulness of percutaneous deep venous arterialization (pDVA) [3, 4]. In the countries where the device has not been reimbursed, pDVA using the off-the-shelf technique has alternatively spread (**Fig. 1**) [5, 6]. This article outlines the indications for and details of the procedures using off-the-shelf technique and the clinical outcomes.

Indication of pDVA

CLTI patients who are not indicated for endovascular treatment and bypass surgery due to poor vessel runoff are potential candidates for pDVA. The poor vessel runoff compromises a successful distal puncture to establish a bidirectional approach or lacks the vessel site suitable for distal anastomosis at surgical bypass procedure (**Fig. 2**). Ferraresi et al. reported that diffuse distribution of medial arterial calcification in the foot is highly relevant with "below-the-ankle" occlusive disease and is a strong predictor of major adverse limb events including major amputation and repeated revascularization [7]. Such patients could be good candidates for

Corresponding author: Shigeo Ichihashi, shigeoichivasc@gmail.com
Received: July 14, 2022, Accepted: December 4, 2022

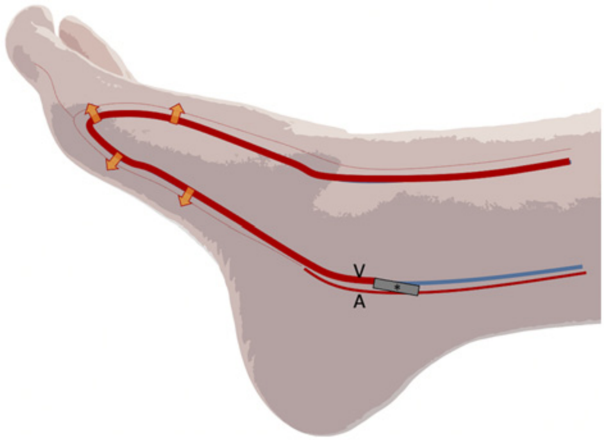

Figure 1. Concept of pDVA
AV shunt is created endovascularly. Ischemic wound is perfused with retrograde flow (yellow arrows) via venous capillaries. *stent
AV, arteriovenous; pDVA, percutaneous deep venous arterialization

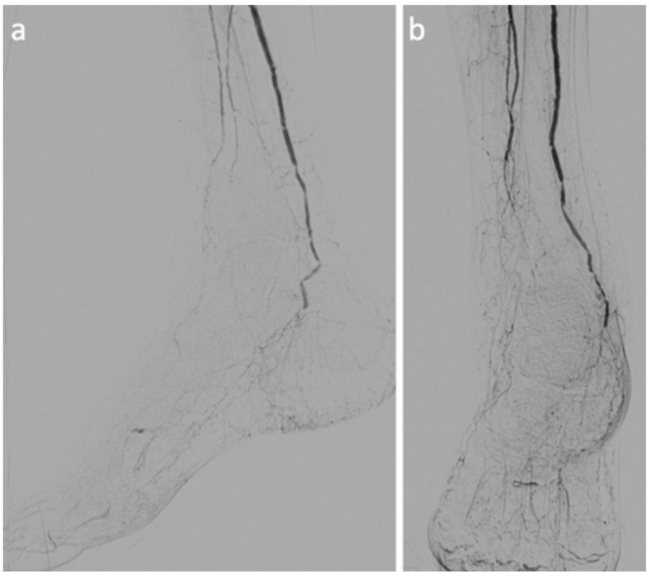

Figure 2. Angiogram in the patients with no-option CLTI
No visualization of dorsalis pedis and plantar arteries (a: lateral view, b: frontal view)
CLTI, chronic limb-threatening ischemia

pDVA. Patients with deep vein thrombosis and severe heart failure are generally excluded from the indications for pDVA as pDVA could exacerbate the symptoms.

Off-the-shelf Technique

Various endovascular methods have been reported as off-the-shelf techniques for AVF creation, AV spear technique [5], venous arterialization simplified technique (VAST) [6], and a use of penetration guidewire with a heavy tip load or a reentry device to puncture a vein from an artery [8]. The difficulty in using the penetration wire or reentry device is that the wire tip or the needle cannot penetrate when the vessel wall is heavily calcified. In that case, an expansion of PTA balloon in the vein, which is used for a target to be punctured, can reinforce the backup support of the reentry device, improving the success rate of venous puncture.

The AV spear technique is a method of creating AV connection by puncturing the tibial artery and vein simultaneously (**Fig. 3** and **4**) [5]. The vein and artery should be visualized at the same plane by duplex ultrasound. The tibial vein is first punctured, and then the tibial artery is penetrated. A guidewire is inserted into the artery. A through-and-through wire between a groin and foot can be established by retracting the guidewire from the sheath inserted into the common femoral artery (CFA). A microcatheter is advanced over the through-and-through wire from the CFA sheath until it appears from the skin surface of the foot. The microcatheter is carefully pulled back and a hydrophilic wire is guided into the tibial vein. Navigation of the guidewire to the plantar veins is occasionally difficult due to the blockage by venous valves. Use of a hydrophilic wire is effective to pass through the valves using the dancing wire technique [9]. After the navigation of the wire to dorsal and plantar venous arch, balloon dilation of the arteriovenous anastomosis is performed. Thereafter, the venous valves are destroyed by balloon dilatation. Insufficient valve destruction can result in impaired venous outflow and consequent obstruction of the arteriovenous shunt (**Fig. 5**). After sufficient blood flow is secured from the artery to the foot vein, stent placement at the arteriovenous anastomosis site is performed. The reason for the stent placement is that in the early cases, AVF without stent placement occluded due to the recoil of the shunt. In our cases, SUPERA stents (Abbott, IL, USA) were preferably used due to its stent design. The diameter of the interwoven stent can change flexibly. If used in the small artery, it can be deployed in the elongated manner without infolding of the stent. The interwoven stent is used for bridging the vein and artery where a caliber change between the vessels is seen. Direct endoluminal observation of the stented segment by an angioscopy showed a complete coverage of the stent struts by neointima (**Fig. 6**), which can serve as a barrier against thrombus formation. When creating an AVF at proximal portion of the tibial artery, blood stealing could occur from the venous branches to the central vein; therefore, it is common to use a covered stent. In most cases, the shunt is created in the posterior tibial artery and vein; however, it is also possibly created in the anterior tibial artery and vein. In the arteriovenous puncture by the AV spear technique, the tibial artery does not always run deeper compared to the tibial vein, and selection of the puncture site is restricted. Technical uncertainty exists with the puncture because only the artery can be punctured even if it is supposed to have penetrated the vein.

The VAST is a method of inserting a snare catheter or balloon into both the artery and vein, which are punctured percutaneously (**Fig. 7** and **8**) [6]. Since two snares are targeted under fluoroscopy, vessel puncture is easier than the

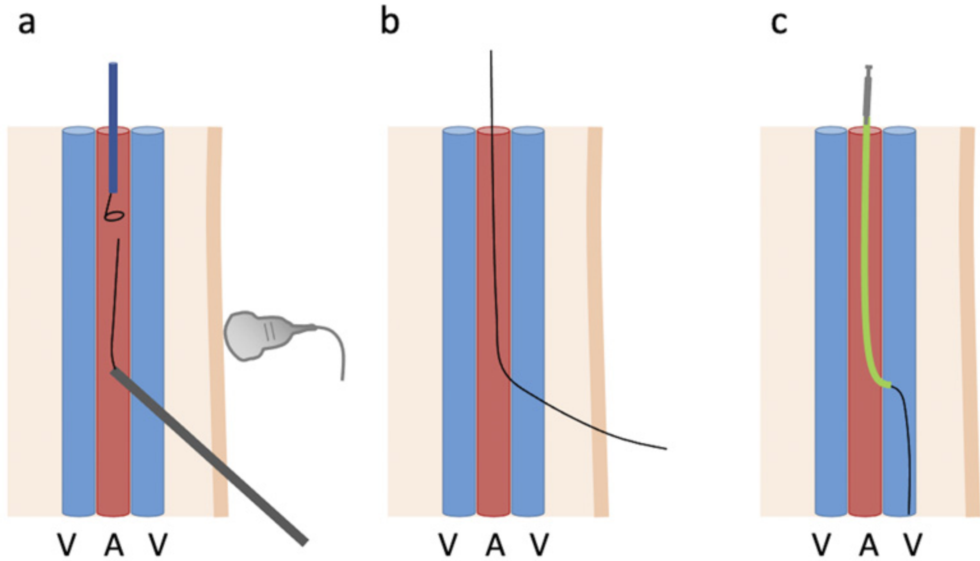

Figure 3. Schema of the AV spear technique. (Reused from the reference #5)
a: Percutaneous puncture of the vein and artery under ultrasound guidance. b: Establishing the through-and-through wire. c: Navigating a guidewire into the tibial vein
AV, arteriovenous

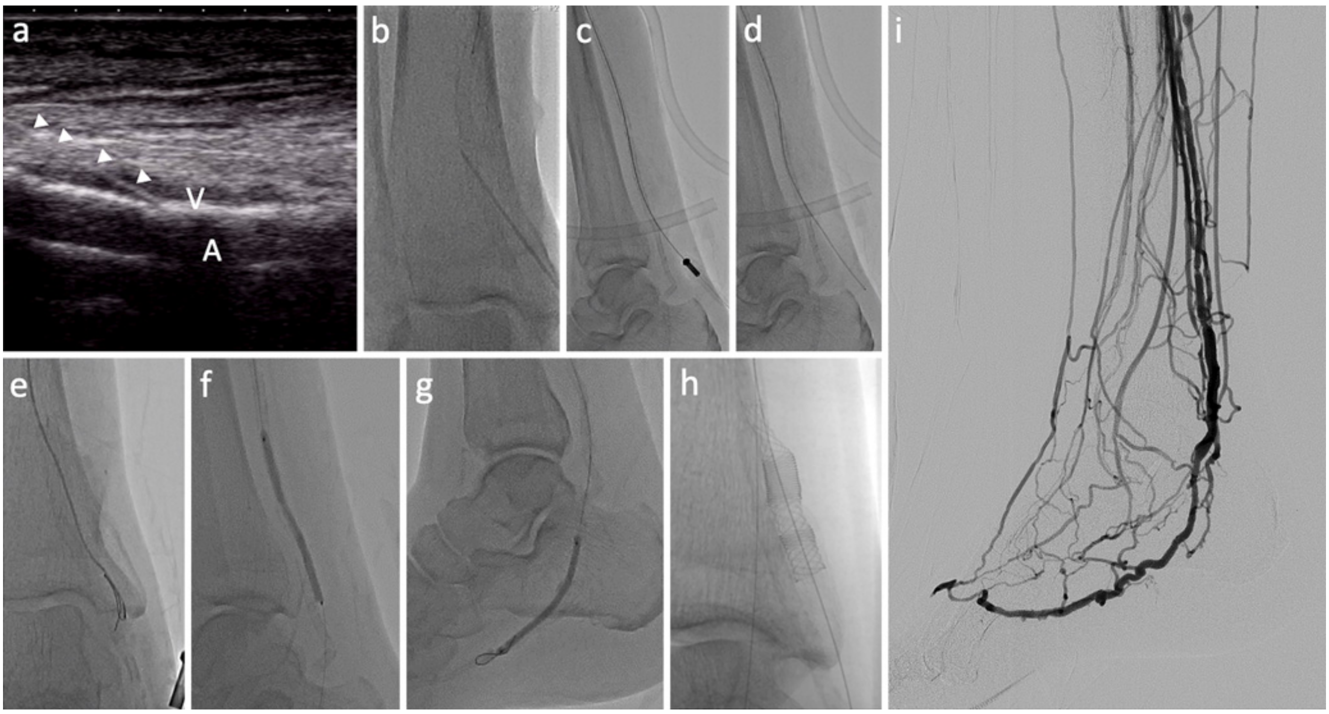

Figure 4. Procedure details of AV spear technique (same patient with Figure 2, reused from the reference #5).
a: Percutaneous penetration of the artery and vein under ultrasound guidance, arrow heads: needle. b: Percutaneous penetration of the artery and vein, the needle tip is located in the posterior tibial artery. c: A through-and-through wire was established. d: Microcatheter was advanced from the common femoral access over the through-and-through wire until the microcatheter exited the skin at the distal puncture point. e: Successful navigation of the guidewire into the tibial vein. f: A balloon angioplasty was performed to create the AV fistula. g: An angioplasty of plantar vein. h: A Supera stent was deployed at the AV fistula. i: Completion angiogram after pDVA.
AV, arteriovenous; pDVA, percutaneous deep venous arterialization

Figure 5. Insufficient valve destruction
Arrows show residual stenoses corresponding to venous valves. AV shunt occluded next day. a: pre-pDVA, b: post-pDVA, arrowhead corresponds to the shunt point
AV, arteriovenous; pDVA, percutaneous deep venous arterialization

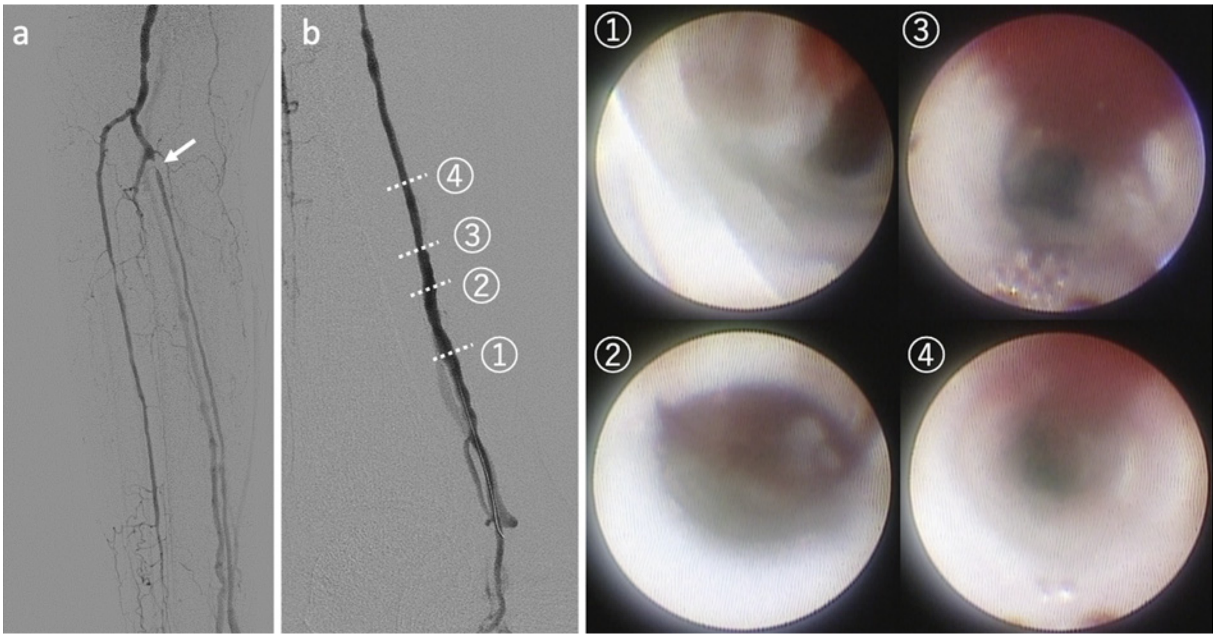

Figure 6. Angioscopic findings after pDVA
Direct endoluminal observation of the stented segment was obtained by an angioscopy (VISIBLE, FiberTech Co., Ltd., Chiba, Japan) 2 months after pDVA; stent struts were fully covered by neointima but transparently visible in the venous side (①): stent struts were not visible in the AV junction (②, ③) and arterial side (④). Neither a thrombus formation nor a restenosis was found throughout the stent.
a: Angiogram taken 2 months after pDVA, the white arrow shows ostial stenosis of the posterior tibial artery
b: Angiogram at the arteriovenous fistula
pDVA, percutaneous deep venous arterialization

AV spear technique and its success rate is much higher. Another important consideration is that the AVF can occlude if AVF does not directly connect with plantar or dorsal vein that serves as the primary outflow of the shunt (**Fig. 9**). It is recommended to check the continuity of the outflow vessel and the vein where the AVF is being created.

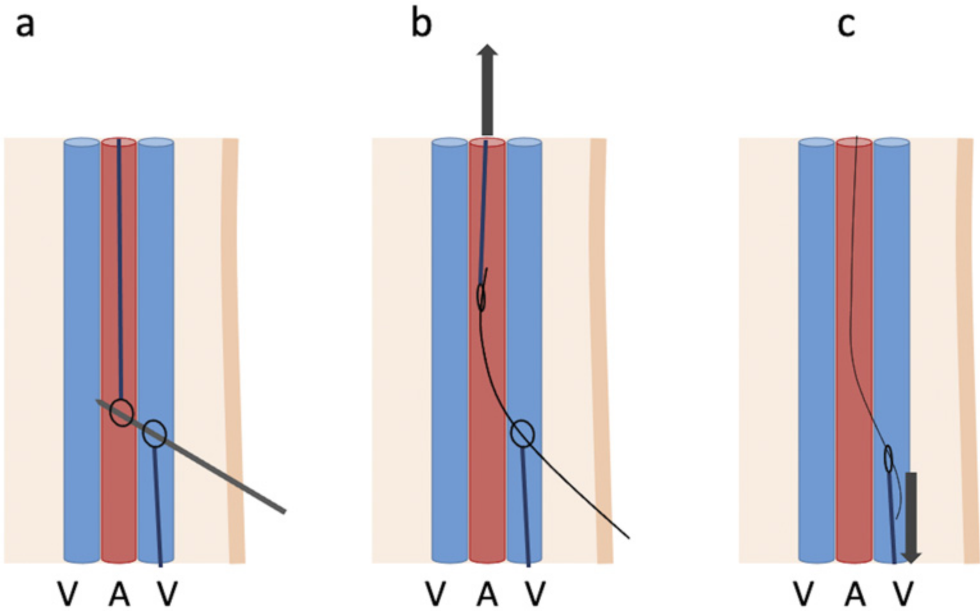

Figure 7. Schema of the VAST
a: Percutaneous puncture of double snare catheters, each inserted from the artery and vein. b: After insertion of a guidewire via the needle, the guidewire is withdrawn by a snare located in the artery. c: The guidewire is withdrawn by the other snare in the vein.

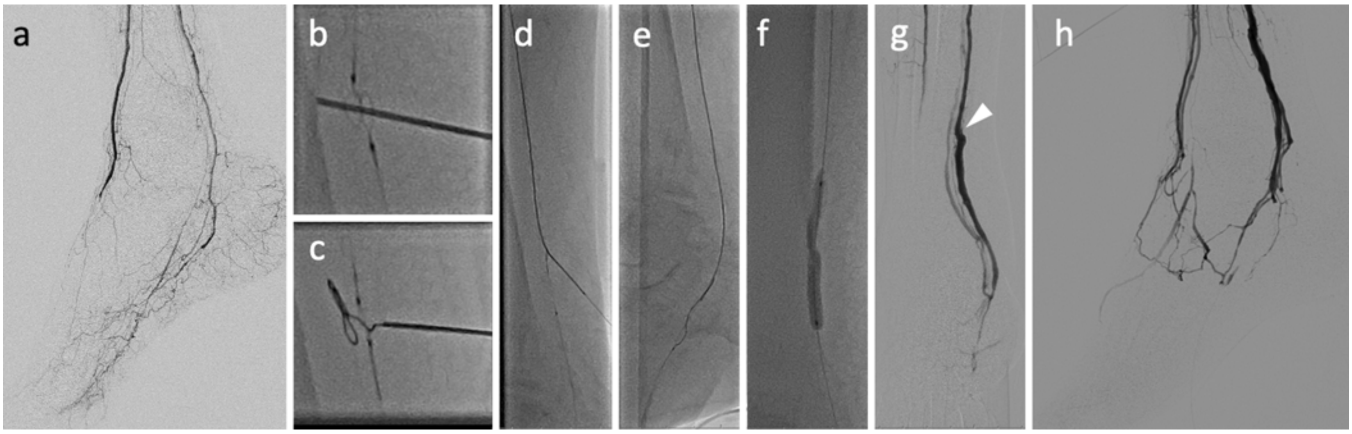

Figure 8. pDVA procedure using VAST
a: Arteriogram before pDVA. b: Percutaneous puncture of double snare catheters, each inserted from the artery and vein. c: Insertion of guidewire. d: Withdrawing the guidewire by snare catheters. e: Guidewire from the artery to vein. f: Balloon dilatation at the fistula. g: Angiogram after stent placement (arrowhead: fistula point). h: Completion angiogram
pDVA, percutaneous deep venous arterialization

Clinical Results of pDVA

Results of pDVA using manufactured LimFlow devices (LimFlow Inc., San Jose, CA, USA) have been reported. The prospective PROMISE I trial was conducted in the United States and enrolled 32 no-option CLTI patients [3]. Among them, 97% succeeded in pDVA, and the rates of freedom from major amputation at 6 and 12 months were 75% and 70%, respectively. Wound healing or improvement rates were 67% and 75% at 6 and 12 months, respectively. The ALPS study was conducted in Europe and Singapore, and 32 people were enrolled [4]. The success rate of the procedure was 96.9%, and the rate of freedom from major amputation and wound healing rate at 6, 12, and 24 months after pDVA were 83.9%, 71.0%, and 67.2% and 36.6%, 68.2%, and 72.7%, respectively. DEPARTURE JAPAN, a multicenter retrospective study in Japan, reports the results of pDVA using the off-the-shelf technique. The VAST was used in 83.3% of the cases. The technical success rate is 88.9%, and the rate of freedom from major amputation and wound healing rate at 6 and 12 months were 55.6% and 49.4% and 23.0% and 53.2%, respectively [10]. Considering the severity of the limb circumstances, the avoidance rate of major amputation and wound healing rate are acceptable. However, obstruction of the arteriovenous shunt exacerbates ischemia and greatly increases the likelihood of major am-

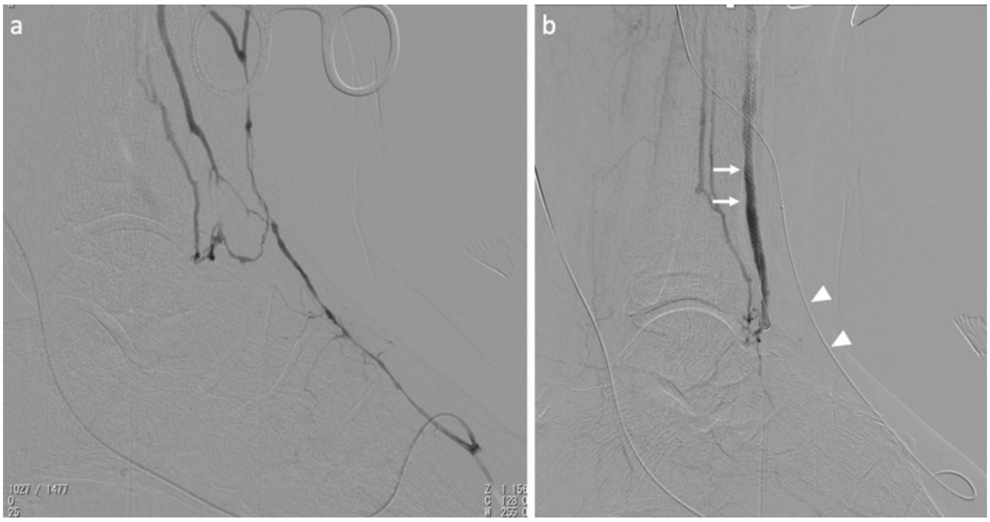

Figure 9. No continuity between superficial dorsal vein and anterior tibial vein
a: Angiogram of the superficial dorsal vein. b: No direct connection between superficial dorsal vein (arrowheads) and anterior tibial vein (arrows) where shunt was created.

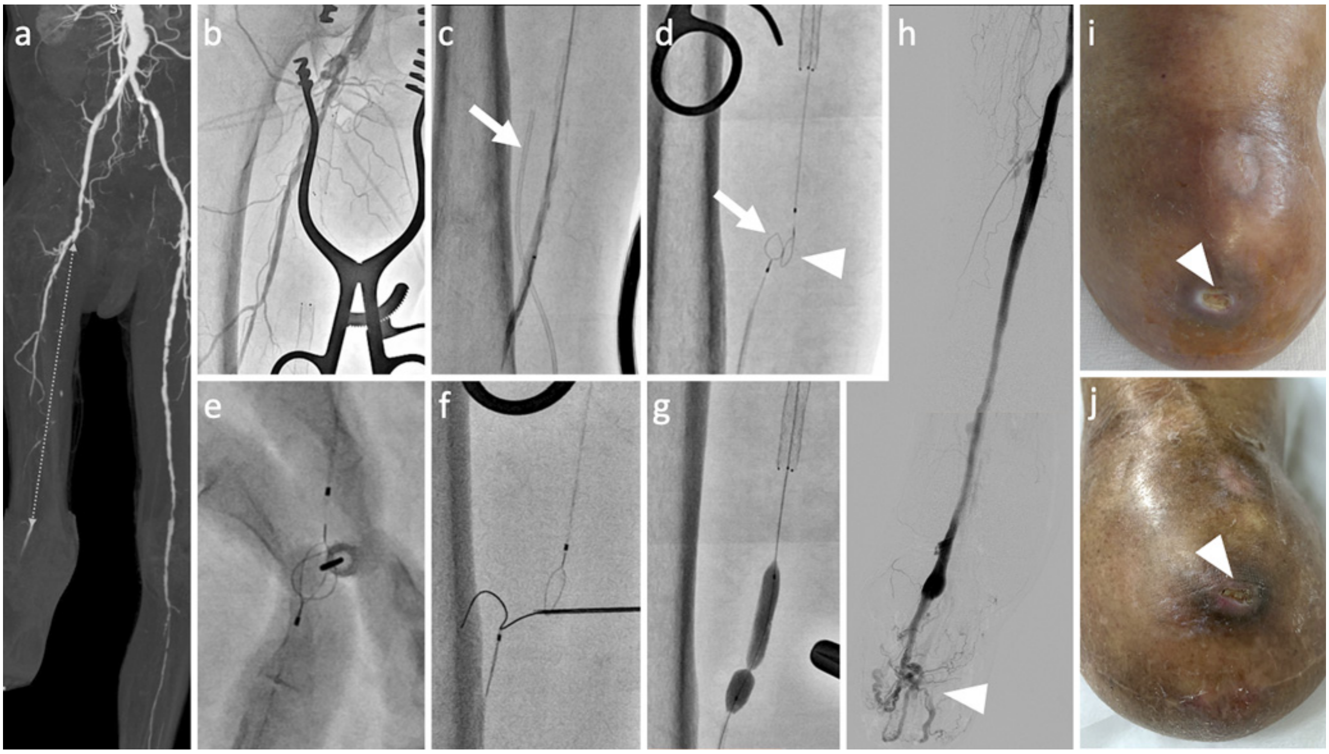

Figure 10. pDVA for unhealed amputated stump ulcer after below-the-knee amputation (reused from the reference #10)
a: CT angiography demonstrates right SFA long occlusion (dotted line) with poor vessel runoff. b: Angiogram after endarterectomy of CFA. c: 4F sheath was inserted into femoral vein in a proximal direction (arrow). d: Two snare catheters were positioned in a parallel fashion (arrow: snare in femoral vein, arrowhead: snare in SFA). e: Percutaneous penetration of the two snares. f: Retrieving the guidewire by snares, establishing a through-and-through wire from CFA to femoral vein. g: Balloon angioplasty of AV fistula. h: Angiogram after placement of VIABAHN prostheses shows good visualization of branches of the popliteal vein (arrowhead). i: Stump ulcer before pDVA (arrowhead). j: After pDVA, the wound (arrowhead) improved
AV, arteriovenous; CFA, common femoral artery; SFA, superficial femoral artery

putation. The patency of the AVF by pulsation of the plantar vein or duplex ultrasound should be regularly checked.

pDVA may also be useful for healing stump ulcer after major amputation of the lower extremities. Healing of stump ulcer is important in that stump infection will occur in the presence of delayed wound healing and residual ischemia, which can result in a revision to a higher level of amputation (**Fig. 10**) [11]. pDVA may also be useful for limb sal-

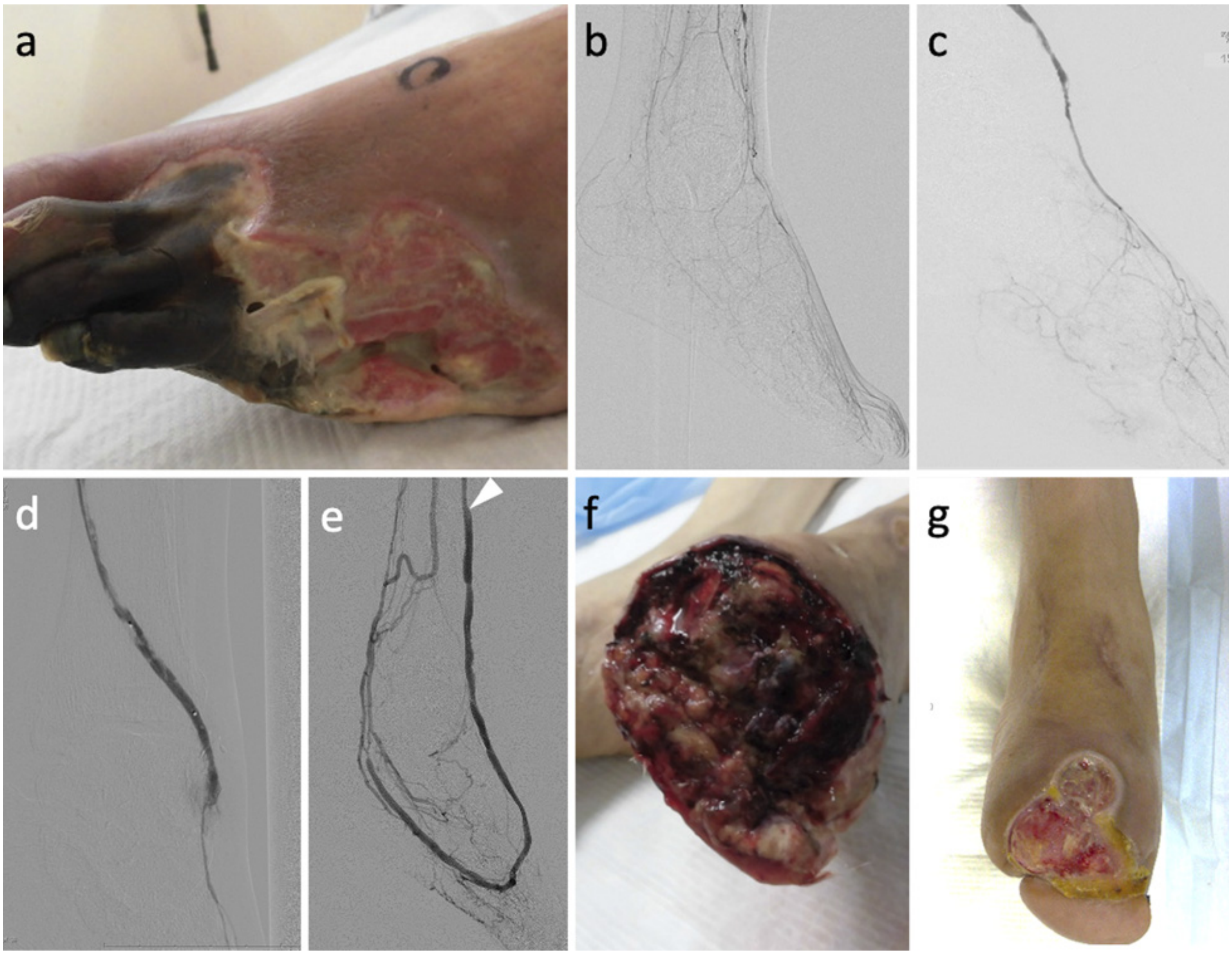

Figure 11. pDVA as a salvage for limb with failed distal bypass
a: Gangrene of left foot. b: Angiogram shows poor vessel runoff below the ankle. c: Distal bypass was performed using the saphenous vein anastomosed with dorsalis pedis artery. d: Repeated endovascular interventions were performed to restore the occluded bypass. e: pDVA was finally performed to salvage the foot; arrowhead indicates the shunt point. f: Lisfranc amputation was done. g: Wound was improving despite the wound infection
pDVA, percutaneous deep venous arterialization

vage for the patients with graft occlusion after bypass surgery (**Fig. 11**). These are the potential subjects of study.

Bleeding at the vessel puncture is a potential complication related with the pDVA procedure. Nakama et al. reported one case of bleeding due to the failed puncture of the artery and vein where VAST was used, leading to compartment syndrome [10]. No complication was reported in the studies evaluating the LimFlow device [3, 4].

Conclusion

The roles of pDVA in the patients with no-option CLTI are outlined. By using various off-the-shelf techniques, it is possible to perform pDVA with a high technical success rate compared to that using the manufactured device. Further data accumulation is awaited to clarify the indication for and long-term data of pDVA. pDVA could play a major role for stump wounds after major amputation of the lower limbs and limb salvage after bypass occlusion, which were previously considered difficult to tackle with.

Acknowledgement: none
Conflict of Interest: Shigeo Ichihashi is a consultant for Japan Lifeline and had a research funding from WL Gore and Associates and honorarium from Boston Scientific Japan, Terumo Co., Abbott Japan LLC, and BD.
Funding: This study was not supported by any funding.
Author Contribution: Substantial contributions to the conception or design of the research or the acquisition and analysis of data by all authors
Drafting the work or revising it critically for important intellectual content by all authors
Final approval of the version to be published by all authors
Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved by all authors
Consent for Publication: The consent for publication was obtained from all patients for the data, including photographs. As this was not a clinical research, an approval from IRB was not required.
Disclaimer: Shigeo Ichihashi and Toshihiro Tanaka are the

Editorial Board members of Interventional Radiology. They were not involved in the peer-review or decision-making process for this paper.

References

1. Faglia E, Clerici G, Clerissi J, et al. Longterm prognosis of diabetic patients with critical limb ischemia: a population-based cohort study. Diabetes Care. 2009; 32: 822-827.
2. Halstead AE, Vaughan RT. Arteriovenous anastomosis in the treatment of gangrene of the extremities. Surg Gynecol Obstet. 1912; 14: 1-19.
3. 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.
4. Schmidt A, Schreve MA, Huizing E, 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: 658-665.
5. 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.
6. 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.
7. Ferraresi R, Ucci A, Pizzuto A, et al. A novel scoring system for small artery disease and medial arterial calcification is strongly associated with major adverse limb events in patients with chronic limb-threatening ischemia. J Endovasc Ther. 2021; 28: 194-207.
8. Cangiano G, Corvino F, Giurazza F, et al. Percutaneous deep foot vein arterialization IVUS-guided in no-option critical limb ischemia diabetic patients. Vasc Endovascular Surg. 2021; 55: 58-63.
9. 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.
10. Nakama T, Ichihashi S, Ogata K, et al. Twelve-month clinical outcomes of percutaneous deep venous arterialization with alternative techniques and ordinary endovascular therapy devices for patients with chronic limb-threatening ischemia: results of the DEPARTURE Japan study. Cardiovasc Intervent Radiol. 2022; 45: 622-632.
11. Ichihashi S, Tamura Y, Maeda S, Kichikawa K. Percutaneous deep venous arterialization at femoropopliteal segment for unhealed amputated stump ulcer after below the knee amputation. Catheter Cardiovasc Interv. 2021; 98: E124-E126.