A Review of Revascularization Procedures in the No-Option Critical Limb Ischemia Patient

Steve Mathew, MD[1] Deepak Kesani, DO[2]

1. Creighton University School of Medicine, Department of Radiology, Omaha, NE
2. Sunrise Health GME Consortium, Las Vegas, NV

Introduction & Rationale

- Peripheral arterial disease is an epidemic due to increased population age, disease factors such as T2DM, HTN, HLD, CKD, and lifestyle factors such as smoking.
- Symptomatic classification (Rutherford)

Category	Symptoms
0	Asymptomatic
1	Mild claudication
2	Moderate claudication
3	Severe claudication
4	Ischemic Rest Pain
5	Minor tissue loss from nonhealing ulcer or focal ulcer in the setting of pedal ischemia
6	Major tissue loss above transmetatarsal level without salvageable foot

adapted from Dave and Shah 2018 (2).

- Critical limb ischemia (CLI): defined as Rutherford 4-6
  - Diagnostics: ABI <0.4, toe pressure < 40mmHg, systolic ankle pressure < 60mmHg, flat pulse volume waveform, and absent pedal pulses (3).
  - Lack of treatment/intervention leads to limb loss, gangrene, sepsis, myocardial infarction, and death (4).
- In PAD, problems can be based on poor inflow from the larger vessels termed "big artery disease," which includes vessels from the iliacs to the dorsalis pedis and posterior tibial arteries or "small artery disease" from poor distribution of blood to tissues with diseased plantar arch and distal branches (tarsals, metatarsals, digital, etc.) (5).
  - Small artery disease was independently associated with CLI
  - T2DM and dialysis was strongly associated.
- A small group of patients are not candidates for surgical or endovascular revascularization and are termed "No-Option" because of their anatomy preventing interventions, or multiple failed interventions or have failed interventions (6).
- Given the recent proliferation of innovation in this field, this poster aims to look at the most recent endovascular and surgical options for venous arterialization.

Methods

- PubMed database review of literature for "venous arterialization" or "vein arterialization" from 2020 onwards.
- Included studies: Clinical trials, prospective and retrospective reviews
- Excluded studies: Case reports and reviews except when they were referred by primary included studies for description of technique.
- Focus on intervention type and technique.
- Focus on outcome including wound healing, limb salvage, amputation free survival

Results

- Endovascular approaches
  - Common elements: arterial access, balloon angioplasty at site that will become AVF followed by stent graft or interwoven stent for creating the AVF, valve incompetence (valvulotome, POBA, cutting balloon, or stent deployment) (6, 7, 8, 9, 10, 12, 13).
  - Re-entry device (6, 7)
    - Device positioned at tibial artery via femoral access through 6/7F sheath, and snare placed through lateral plantar vein with alignment of both elements.
    - Wire deployed through re-entry device into vein, which was snared and retrieved through venous access site. Can use IVUS for guidance.
  - Venous Arterialization Simplified Technique (8)
    - 2.5-3 mm balloon catheter in tibial artery prior to lesion/area of interest, with inflated balloon, and snare placed through tibial or foot vein through 4F sheath that are aligned.
    - Vein anterior to artery:
      - Percutaneous 22g needle puncture and venous puncture through snare
      - Wire advanced into balloon catheter that is retracted into the femoral access.
      - 4F support catheter advanced over wire into vein with advancement of a 0.014 wire into vein with angiography to confirm position.
    - Artery anterior to vein:
      - 22 g needle percutaneous puncture and arterial puncture through inflated balloon and through snare which is tightened followed by insertion of 0.018 wire.
      - Snare released and snared around 0.018 wire, while the needle is withdrawn to just beyond skin.
      - Snare used retrieve 0.018 wire, followed by introduction of 4F support catheter over wire into the arterial lumen.
  - Modified Venous Arterialization Simplified Technique (9):
    - 4F Angled tip catheter advanced through the artery, while a 3-5 mm balloon inflated in vein that are aligned.
    - Percutaneous 20g needle puncture through skin into balloon and tip of needle directly into angled catheter
    - Advancement of a 0.014 penetration wire through angled catheter into needle, with wire slowly withdrawn until it is within vein and needle is withdrawn.
  - AV spear technique (10)
    - Ultrasound guided visualization of PTA and PTV at the level of the ankle, where PTV superficial to PTA.
    - Snare advanced to PTV, and percutaneous puncture of PTV and PTA under US guidance, with advancement of a 0.014 hydrophilic wire that was captured using a snare and pulled back to femoral access.
    - A microcatheter was advanced over the 0.014 wire until it terminated at the skin of the ankle puncture site and the wire was removed.
    - A second hydrophilic 0.014 wire was advanced as the microcatheter was slowly retracted to obtain venous access.
    - After angiographic confirmation and angioplasty, only interwoven stent was required instead of a usual stent graft.
- Surgical Approaches (6, 11):
  - Common elements were the proximal parachute anastomosis, and distal vein valvulotomy prior to anastomosis.
  - Superficial vein arterialization: GSV is the bypass conduit of choice (6)
    - Standard technique: Following preparation of GSV, end-to-side anastomosis using parachute technique to the artery was performed. Then, the target vessel was exposed.
    - Single incision technique: Single incision at site of anastomosis of artery of choice. The GSV next to that location was freed and anastomosed end-to-side. Any large branches were ligated. Percutaneous US guided medial marginal vein access was obtained to perform valvulotomy. Branches were ligated operation vs staged coiling of perforators.
  - Deep Venous Arterialization (11):
    - Proximal end-to-side anastomosis with parachute technique.
    - Distal target tibial or pedal vein and adjacent artery was exposed.
    - Longitudinal incisions were performed prior to anastomosis of the posterior arterial and venous walls with 7-0 prolene.
    - The patient's patent vein was used to make the anterior wall of the distal AVF fistula producing a vein cuff.
    - A longitudinal incision was made through the cuff, and a valvulotome was inserted to render the distal valves incompetent prior to anastomosis of the PTFE graft to the vein cuff.
- Outcomes

Study	Pts	Limb salvage (%)	Healing wound (%)	AFS (%)	Techniques
Miranda et. al. (6)	41	81	46.30		endo using re-entry, surgical SVA
Lauria et. al. (11)	10	79	60	80 (6 mo)	Surgical DVA
DEPARTURE Japan (9)	18	72.2	53.20	55.6 (6 mo) 49.4 (12 mo)	endo using VAST, mVAST, AV spear, reentry device
ALPS (12)	32	79.8	68(12 mo) 73(24 mo)	83.9 (6 mo) 71 (12 mo) 67.2 (24 mo)	Limflow
Promise-1 (13)	32		75	74 (6 mo) 70 (12 mo)	Limflow
Cangiano et. al. (7)	14	78	79		endo using IVUS guided re-entry

  - Cross-comparison limited by heterogeneity in measurement.
  - No significant differences between endovascular and surgical approaches
  - Unifying patient characteristics between studies was that everyone had CLI and lack of anatomic revascularization targets or failure of surgical/endovascular therapy.

Discussion/Conclusion

- No-Option CLI patients have multiple surgical and endovascular options for treatment with SVA/DVA that can allow for improved limb salvage.
- Limitations include small sample sizes, heterogeneity in outcome measurements, some patient characteristics, and follow-up times.

References

1. AbuRahma AF. When are endovascular and open bypass treatments preferred for femoropopliteal occlusive disease? Ann Vasc Dis [Internet]. 2018 Mar 25 [cited 2022 Sep 14];11(1):25–40. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5882358/
2. Dave B, Shah R. Peripheral stent technology and current status for endovascular treatment of femoropopliteal artery disease: a clinical review. International Journal of Research in Medical Sciences [Internet]. 2018 Apr 25 [cited 2022 Sep 14];6(5):1474–83. Available from: https://www.msjonline.org/index.php/ijrms/article/view/4710
3. Stoner MC, Calligaro K, Chaer RA, Dietzek AM. Reporting standards of the Society for Vascular Surgery for endovascular treatment of chronic lower extremity peripheral artery disease. Journal of Vascular Surgery. 2016. < https://www.jvascsurg.org/action/showPdf?pii=S0741-5214%2816%2930002-7>
4. Nanjundappa A, Laird Jr J. Critical Limb Ischemia Understanding the scope of the problem. Endovascular today. July 2006. < https://evtoday.com/articles/2006-july/EVT0706_03.htm>
5. Ferraresi R, Mauri G, Losurdo F, Troisi N, Brancaccio D, Caravaggi C, et al. BAD transmission and SAD distribution: a new scenario for critical limb ischemia. J Cardiovasc Surg [Internet]. 2018 Aug [cited 2023 Jan 4];59(5). Available from: https://www.minervamedica.it/index2.php?show=R37Y2018N05A0655.
6. Miranda JA, Pallister Z, Sharath S, Ferrer L, Chung J, Lepow B, et al. Early experience with venous arterialization for limb salvage in no-option patients with chronic limb-threatening ischemia. Journal of Vascular Surgery [Internet]. 2022 Oct [cited 2023 Jan 4];76(4):987-996.e3. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0741521422016408.
7. Cangiano G, Corvino F, Giurazza F, De Feo EM, Fico F, Palumbo V, et al. Percutaneous deep foot vein arterialization ivus-guided in no-option critical limb ischemia diabetic patients. Vasc Endovascular Surg. 2021 Jan;55(1):58–63.
8. Ysa A, Lobato M, Mikelarena E, Arruabarrena A, Gómez R, Apodaka A, et al. Homemade device to facilitate percutaneous venous arterialization in patients with no-option critical limb ischemia. J Endovasc Ther [Internet]. 2019 Apr [cited 2023 Jan 4];26(2):213–8. Available from: http://journals.sagepub.com/doi/10.1177/1526602819830983.
9. Ichihashi S, Shimohara Y, Bolstad F, Iwakoshi S, Kichikawa K. 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 [Internet]. 2020 Feb [cited 2023 Jan 4];43(2):339–43. Available from: http://link.springer.com/10.1007/s00270-019-02388-2
10. Nakama T, Ichihashi S, Ogata K, Kojima S, Muraishi M, Obunai 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 [Internet]. 2022 May [cited 2023 Jan 4];45(5):622–32. Available from: https://link.springer.com/10.1007/s00270-022-03095-1
11. Lauria AL, Propper BW, Neville RF. Surgical deep vein arterialization: adding to the armamentarium of complex limb salvage. Annals of Vascular Surgery [Internet]. 2022 Nov [cited 2023 Jan 4];87:198–204. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0890509622001790
12. 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 [Internet]. 2020 Aug [cited 2023 Jan 4];27(4):658–65. Available from: http://journals.sagepub.com/doi/10.1177/1526602820922179
13. 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. Journal of Vascular Surgery [Internet]. 2021 Nov [cited 2023 Jan 4];74(5):1626–35. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0741521421007370