

**In The Endovascular Era, What Is The Current Role Of Open Bypasses In A Limb Salvage Program: What Percentage Of CLTI Patients Will Need One At Some Time In Their Course And What Percentage Of Those Will Require A PTFE Graft**

**VEITH SYMPOSIUM™**  
Connecting The Vascular Community

Niten Singh, MD  
Professor of Surgery  
University of Washington

**Disclosures**

- None

**Background**

- Multidisciplinary Limb Preservation Service (LPS)
  - Improve limb salvage in patients with advanced vascular disease
  - Cost-effective
  - The procedures performed for CLTI in each center will vary depending on the composition and expertise of the team

*Clinical Research*  
The Impact of a Limb Preservation Service on the Incidence of Major Amputations for All Indications at a Level I Trauma Center  
*Adar Khanna, MD, PhD; Robert Hoffman, Benjamin Sannes, Ellen Olinaga, Naveen Tane, and Niten Singh, Seattle, Washington*

**LPS Program**

- Vascular Specialist
  - What options can you offer a patient?
    - Endovascular therapy
      - Cutting edge technology
      - DES, DCB, bioresorbable scaffolds, etc.
    - Open surgical bypass
      - No significant advancement (inflow, outflow, and conduit)
      - It is the workhorse for limb salvage!

Using Multidisciplinary Teams to Improve Outcomes for Treating Chronic-Limb Threatening Ischemia  
*Hannah Wolf, MD, and Niten Singh, MD, Seattle, Washington*

**BEST-CLI Two Cohorts**


- Cohort 1- Suitable single segment saphenous vein
  - 1434 patients
    - 718 underwent surgery
    - 716 underwent endovascular treatment
- Cohort 2- No suitable single segment saphenous vein
  - 396 patients
    - 197 assigned to surgery
    - 199 assigned to endovascular therapy

*Surgery or Endovascular Therapy for Chronic-Limb-Threatening Ischemia*  
*Adar Khanna, MD, PhD; Robert Hoffman, Benjamin Sannes, Ellen Olinaga, Naveen Tane, and Niten Singh, Seattle, Washington*


**Cohort 1 Outcomes**

**Table 2. Efficacy and Safety Outcomes in Cohort 1.<sup>10</sup>**


| Outcome  | Surgery        | Endovascular Therapy | Hazard Ratio (95% CI) <sup>†</sup> | P Value |
|--|----------------|----------------------|------------------------------------|---------|
| <b>Efficacy</b>  |                |                      |                                    |         |
| Primary outcome: major adverse limb event or death from any cause — no./total no. (%) <sup>‡</sup> | 302/709 (42.6) | 408/711 (57.4)       | 0.68 (0.59–0.79)                   | <0.001  |
| Secondary outcomes — no./total no. (%)   |                |                      |                                    |         |
| Death from any cause   | 234/709 (33.0) | 267/711 (37.6)       | 0.98 (0.82–1.17)                   |         |
| Above-ankle amputation of the index limb   | 74/709 (10.4)  | 106/711 (14.9)       | 0.73 (0.54–0.98)                   |         |
| Intervention in index limb   |                |                      |                                    |         |
| Major  | 65/709 (9.2)   | 167/711 (23.5)       | 0.35 (0.27–0.47)                   |         |
| Minor  | 205/718 (28.6) | 237/716 (33.1)       | 0.85 (0.70–1.02)                   |         |
| Perioperative death <sup>§</sup>   | 12/687 (1.7)   | 9/708 (1.3)          | 1.54 (0.64–3.68)                   |         |
| Major adverse limb event or perioperative death  | 139/687 (20.2) | 246/708 (34.7)       | 0.53 (0.43–0.65)                   |         |
| Myocardial infarction  | 75/718 (10.4)  | 85/716 (11.9)        | 0.97 (0.71–1.33)                   |         |
| Stroke   | 39/718 (5.4)   | 44/716 (6.1)         | 0.93 (0.60–1.43)                   |         |




## Cohort 2 Outcomes




- Primary outcomes (MALE/Death)
  - 83 of 194 (42.8%) patients in surgical group
  - 95 of 199 (47.7%) patients of endovascular group
- Surgical group
  - 105 fem-pop, 86 fem-tibial, 18 pop-tibial
  - 119 bypasses were with prosthetic conduit (PC)
  - 48 with alternative autogenous conduit (AAC)
- No difference in outcomes between groups




## Bypass



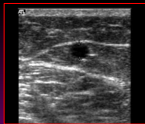

- Single segment saphenous should be the primary revascularization strategy among those eligible
- Potential Barrier
  - Patient autonomy- should they have a say?
  - Suitable anatomy
  - Surgical availability?
  - Surgical proficiency – *can they do it?*




## Suitable Vein




- What is considered suitable veins?
  - Are we standardizing vein mapping protocols?
  - Ideal is 3.0 mm
- Questionable vein 2.0-2.5mm
  - POCUS in OR prior to abandoning it?
  - Routine exploration?


## Cohort 2- Suitable Vein?



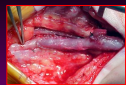

In the surgical group, 105 femoral–popliteal, 86 femoral–tibial or pedal, and 18 popliteal–tibial or pedal bypasses were performed. There were 48 bypasses involving alternative autogenous veins and 119 bypasses involving a prosthetic conduit. In 19% of cases, the surgeon unexpectedly identified a single segment of great saphenous vein that was suitable for bypass surgery. Among the endovascular interventions, 133 were performed on the superficial femoral artery, 114 on the popliteal artery, and 86 on the tibial or pedal arteries (Table S6).




## Who Will Perform Bypasses?



- We do not have enough vascular surgeons to treat all patients with bypass
  - A total of 3500 vascular surgeons in the country
  - Until we increase that number, we will need to understand that other specialties are treating these patients to the best of their ability
- Are all current vascular trainees technically proficient to do complex bypass?





## What percentage of CLTI patients will need a bypass at some point?




- Reviewed our experience with patients not enrolled in BEST-CLI
  - 2014-2019
  - 17 patients enrolled in BEST-CLI
    - 10 randomized to open
    - 7 randomized to endovascular
  - 142 patients not enrolled in BEST-CLI
    - 31 underwent open bypass as index procedure
    - 111 underwent endovascular as index procedure
      - 32 required a bypass after endovascular

**– 44% underwent open bypass in our LPS**  
Schwarz et al. presented at WVS annual meeting 2024




## Role of PTFE Bypass




- The landmark trial by Veith et al
  - PTFE patency rates were the same as saphenous vein up to 2 years with significantly lower 4-year patency rates
- Samson et al
  - Heparin bonded PTFE (HePTFE) had higher patency rates than standard PTFE
    - 3-year primary patency
      - Above knee popliteal artery-85%
      - Below knee popliteal artery-72%


Veith et al. *J Vasc Surg* 1986; 3:104-14 Samson et al *J Vasc Surg* 206:64638-47




## PTFE bypass making a comeback?




- Neville et al
- Described the trend in their LPS program
  - 103 surgical bypasses for CLTI from 2018-2022
    - Instituted a formal LPS program in 2018
    - Prior to creating LPS open surgical bypass decreasing with endovascular therapy increasing
    - Increasing trend of bypasses from 21% in 2018 to 37% in 2022
    - GSV-21% and **HePTFE in 79%**
    - Anastomotic adjuncts used in 88%



Gerling KA et al. *J Crti Limb Ischem*. 2024;4:E29-E33




## PTFE Outcomes




- VQI study
  - 22,671 LE bypass procedures for CLTI
    - GSV
    - Alternative autogenous conduits (AAC)
    - Nonautogenous biologic conduits (NABC)
    - Prosthetic conduit (PC)
  - AAC and NABC lower primary patency vs GSV and PC
  - PC with superior primary patency and MALE-free survival versus AAC and NABC


Addul-Malak et al. *J Vasc Surg* 2022; 76:188-195.




## Discussion



- *Role of Open Bypass*
  - Randomized data associated with better outcomes with GSV
  - Dependent on surgeon availability and willingness
- *Role of PTFE bypass*
  - *Known* outcomes from numerous studies
  - Adjunctive maneuvers with improved outcomes for tibial artery bypass



## Conclusion



- A Limb Salvage Program should be capable of offering all aspects of care
  - Role of open bypass surgery
    - Essential and should be increasing in percentage following the results of BEST-CLI
  - In our LPS 44% required bypass but will increase to 55-60%
  - HePTFE and HePTFE with adjunctive maneuvers are effective in this patient population as well
    - Percentage of patients requiring PTFE bypass should increase and likely be in the 10-15%

