Open Surgical Treatment First is Best for Some CLI Patients: Which Ones and an Endo-First Policy Can Harm Such Patients

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Selecting the Optimal Revascularization Strategy

- Assess Patient Risk
  - Perioperative and long-term survival
  - Average risk: <5% op mortality, >70% 2 yr survival
- Assess Limb Severity
  - SVS Threatened Limb (WIfI) Stage
- Assess Anatomic Pattern of Disease
  - Endo: Likelihood of technical success and of patency
  - Bypass: Quality of available vein and target artery

Patient-Level Risk Scores


Disclosures

- Consultant: Medtronic, Cook
- Executive Committee- BEST trial (NIH)
- Honorarium- WL Gore

Risk Stratification: the PIII CLI Risk Score


Wound: extent and depth
Ischemia: perfusion/flow
Foot Infection: presence and extent

The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and Foot Infection (WIF)
• Stage 1
  - Minimal ischemia; no/minor TL
  - Not in strict ‘CLI’ definition
• Stage 2
  - Stage 1 with more infection
  - Rest pain without infection
  - Minor tissue loss/ mod infection
• Stage 3
  - Range of tissue loss/ischemia
  - Mild to mod infection
• Stage 4
  - Advanced in one or more categories
• Stage 5 is an unsalvageable foot

WIfI Stage 4: Outcomes of Infrainguinal Revascularization (UCSF Series)

Interventional Challenges in CLI

- Multi-level disease is COMMON
- Long-segment disease and CTOs are COMMON
- Extensive calcification is frequent
  - Diabetes and renal disease
- Advanced tissue loss requirements
  - Support healing of foot reconstructions e.g. TMA
  - Large defects may take weeks or months to heal
  - Comorbid conditions often slow wound healing
  - Weight bearing stresses
  - Concomitant infection

LEB: Dominant Impact of Vein Quality
**PREVENT III Trial: Impact of Vein Quality**

Patency by distal anastomosis (optimal conduit)

- Level of distal anastomosis is not an important limitation for a good quality vein
- SSGSV ≥ 3.5 mm

**BASIL:**

Impact of treatment received on Amputation-Free Survival

Association is not necessarily Causation, but the observation is consistent

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- VSGNE: N=1880 LEB for CLI
- Prior iPVI (134), iLEB (275)
- No diff in MAE or survival
- Prior failed iPVI and iLEB imparted similar increased risk for amputation, graft failure, and MALE following LEB

Growing impact of restenosis on the surgical treatment of peripheral arterial disease. Jones D et al; JAHA 2013

Propensity score adjustment included approximately 20 patient-level, anatomic and surgical variables

N.B. The difference in outcomes is increasing with observation time

What are the potential explanations for inferior bypass outcomes after PVI failure?

- Systemic Factors (i.e. Bad Patient- thrombophilia)
- Being a poor surgical candidate associates with “pushing the envelope” in PVI
- Change in DANA to more distal target
- Embolization of runoff vessels in calf and foot
- Target artery inflammation/injury from catheter manipulations
- Delay in effective revascularization— further tissue loss, infection worsens limb stage

Failure of Revascularization in CLI Has Negative Consequences

- Delayed healing, recurrent wounds, increased tissue loss, infection
- Recurrent pain, immobilization, inanition
- Additional hospitalizations, procedures, costs
- Altered subsequent treatment options
- Psychosocial stress for patient and family

Pick the right procedure first based on Patient Risk, Limb Stage, and Vascular Anatomy (PLAN for success)
Who Benefits More from Open Bypass?

- Average risk CLI patient
- More severe limb threat (e.g., WIfI score)
- Bad anatomy for endo:
  - Multilevel severe disease e.g., CTOs above and BTK
  - Long occlusions esp tibial, small caliber, heavy Ca2+
  - Severe CFA, popliteal/trifurcation disease
- Adequate quality vein available
- Runoff to foot intact
- Roughly 30-50% of pts referred with severe ischemia in my practice

CLI: A Selective Revascularization Strategy

<table>
<thead>
<tr>
<th>Surgical Risk</th>
<th>Average (&lt;5% mort)</th>
<th>High</th>
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<tbody>
<tr>
<td>Patients with poor functional status, multiple comorbidities/limited life expectancy and tissue loss should be considered for Primary Amputation or palliation</td>
<td></td>
<td></td>
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<tr>
<td>Anatomy</td>
<td>Multi-level, TASC C/D</td>
<td>Single level, TASC A-C</td>
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<tr>
<td>Vein availability</td>
<td>GSV or good alternate</td>
<td>Inadequate</td>
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</tbody>
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BYPASS FAVORED

ENDO FAVORED