What % of Limb-threatening Ischemia Patients Require Open Bypass?

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I have no conflicts of interest to disclose.

However, our group is BiVascular. We go both ways (Endo & Open) #IamBiVascular

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Gore (invited lecture – Vein Bypass: Surgical Bypass Summit 12/14)

National trends in lower extremity bypass surgery, endovascular interventions, and major amputations

Philip P. Goodney, MD, MS,1,2,* Adam W. Beck, MD,1 Jon Nagli, MS, BPh,* H. Gilbert Welch, MD, MPH,1,2,* Robert M. Zwerdling, MD, PhD,1,2,* Lehman and Bunnell, NH; White River Junction, VT; and Chicago, IL

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Fig. 1. Trends in endovascular interventions, major amputation, and lower extremity bypass surgery, 1996-2006. RR, Risk ratio; CI, confidence interval.
Critical Limb Ischemia and “CLI” Therapy:
Results depend predominantly upon:
1. Which patients are included
2. How one looks at them

SVS WfI Consensus Process
- Class I - Very Low
- Class 2 - Low
- Class 3 - Moderate
- Class 4 - High

Very Low = VL = Class or Clinical Stage 1
Low = L = Class or Clinical Stage 2
Moderate = M = Class or Clinical Stage 3
High = H = Class or Clinical Stage 4

Risk of Amputation

Benefit of Revascularization

By SVS WfI Class
**Results**

<table>
<thead>
<tr>
<th>Wifi Clinical Stage</th>
<th>Predicted Amputation</th>
<th>Observed Amputation</th>
<th>Observed Non-Healing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 1 (n= 40)</td>
<td>3%</td>
<td>3%</td>
<td>8%</td>
</tr>
<tr>
<td>Stage 2 (n= 64)</td>
<td>8%</td>
<td>10%</td>
<td>19%</td>
</tr>
<tr>
<td>Stage 3 (n= 46)</td>
<td>25%</td>
<td>23%</td>
<td>30%</td>
</tr>
<tr>
<td>Stage 4 (n= 8)</td>
<td>50%</td>
<td>40%</td>
<td>63%</td>
</tr>
</tbody>
</table>

**Wound Healing OR (95% CI)**

<table>
<thead>
<tr>
<th>Wifi Stage</th>
<th>Wound Healing OR (95% CI)</th>
<th>Amputation OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 1</td>
<td>1.00 (Referent)</td>
<td>1.00 (Referent)</td>
</tr>
<tr>
<td>Stage 2</td>
<td>.29 (0.08 -1.08)</td>
<td>4.8 (0.6-40.5)</td>
</tr>
<tr>
<td>Stage 3</td>
<td>.15 (0.04-0.57)</td>
<td>10.8 (1.3-88.8)</td>
</tr>
<tr>
<td>Stage 4</td>
<td>.05 (0.01-0.31)</td>
<td>23.4 (2.0-270.2)</td>
</tr>
</tbody>
</table>

**Critical Limb Ischemia is a broad disease spectrum and requires more than one treatment tool**

Critical Limb Ischemia (CLI) is a complex condition affecting millions of people worldwide. It is characterized by chronic or acute limb-threatening ischemia. The traditional approach to treating CLI has been surgical revascularization, typically involving bypass grafts or angioplasty. However, there is growing evidence that endovascular therapy, such as stenting and angioplasty, can be an effective alternative or adjunct to surgery. The choice of treatment depends on various factors, including the severity of ischemia, the presence of comorbidities, and the availability of resources. In some cases, a combination of surgical and endovascular procedures may be necessary to achieve optimal outcomes. The impact of various treatments on wound healing and amputation risk is an area of ongoing research and is crucial for improving patient outcomes.

**Unknown Factors:**

- Which specialists will treat the majority of CLI patients?
- Will these specialists have complete tool kits, or only hammers?
- Will the endovascular first approach predominate, or will subsets of patients (tissue loss, long segment disease, available vein conduit, good functional level, life expectancy >2 years) be offered bypass first?
- Is an endo first approach really a “free shot” without risk?
- Will patients really be offered bypass after endo failure or be consigned to major limb amputation?
**Endo versus Open for CLI:**

- *Faglia et al.* 564 consecutive patients with DM and CLI (1999-2003); 554 followed until 2007 (mean f/u 5.93+/-.128 years). Initial therapy:
  - PTA 74.5%, BYPASS 20.6%, Neither 4.9%
  - Restenosis or graft failure rate: 6.4-8.8%/year [94 pts clinical restenoses: 72 r-PTA, 9 BPG, 13 nil]
  - Contralateral CLI: 14.76%/year
  - Mortality: 12.53%/year

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**Best hedged estimates**

- 25-30% of CLI patients will eventually undergo surgery if endo first approach becomes uniformly accepted and no major prevention for intimal hyperplasia is uncovered
- 30-40% of CLI patients could require bypass if vein grafts are used when available in low - moderate risk candidates with long - segment disease and extensive tissue loss

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**BASIL Trial: long-term results**

- Bypass first group had better amputation free survival than angioplasty first group (RR .85)
- Bypass first arm had lower all cause mortality than angioplasty first (RR 0.65, p<0.009)
- Decreased survival associated with BMI, diabetes, age, serum creatinine level, and cigarette smoking

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**BASIL Trial: long-term results**

- No significant differences in health care costs at 5 years (30,000 pounds)
- Higher initial costs of surgery were counter-balanced by higher subsequent use of hospital services by angioplasty first group (Achilles heel of durability still remains for endovascular therapy in the first decade of the 21st century)
Does durability really matter for CLI patients?

- Intensive, ongoing medical and surgical interventions must be continued to achieve limb salvage
- Nearly half of patients required readmission within six months and >49% required repeat leg or foot procedures within three months
- More than half of patients failed to achieve complete wound healing within three months

Goshima et al. JVS 2004

What are data for tibial angioplasty for total occlusions?

- Scheinert et al (Leipzig): 104 consecutive tibial CTOs
  - Results at three months:
    - 33% patent without restenosis
    - 33% patent with restenosis (>50%)
    - 33% occluded
  - Whither (wither) the foot?
- To date, DEB and DES of minimal benefit BTK

Schmidt, Scheinert et al. Cath Cardiovasc Interv 2010 Dec 1;76(7):1047-1054

Conclusions:

- Potential factors which could further reduce number of bypasses for CLI:
  - Technical advances/prevention of myointimal hyperplasia
    - Pedal and arch angioplasty
    - Drug-eluting balloons
    - Drug-eluting stents
    - Absorbable stents
    - Debulking therapy
  - Treatment paradigm evolution
    - Changes in management paradigm (better treatment of diabetes and earlier treatment of ischemia); Cell-based wound therapy
    - Management models that lack participation by vascular surgeons and loss of skill set to perform complex distal bypass surgery

There are poor or no option endovascular cases whom open bypass can salvage

74 y/o diabetic woman. ABI 0.31. TP 0 mmHg with flat toe waveforms
Two prior angiograms. Not deemed to be endovascular or bypass candidate