Revascularization of Patients with Critical Limb Ischemia

Endovascular Should Be Considered First Line Therapy

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Revised Presentation Title

A Selective Approach to Revascularization Works Best...

...But Endovascular Should be Considered First Line Therapy

Disclosures

• Consultant, speaker, or researcher
  – Abbott Vascular
  – Medtronic
  – Boston Scientific

• No commercial content or discussion of devices

• Vascular surgeon
Key Questions

- What are the results of lower extremity bypass in surgical candidates?
  - Excluding highest risk for adverse outcomes
- Why not surgery first?
- What are the results from an “endovascular first” vascular surgery practice for CLI
- Does “endovascular first” burn bridges?
- What to do in real world vascular surgery practice?

Lower Extremity Bypass Graft for CLI

- SVS Objective Performance Goals
  - OPGs calculated from surgical arms of five multi-center randomized trials for CLI
  - only included patients with autologous vein available for bypass conduit
  - excluded end-stage renal disease on dialysis were eliminated from the analysis...“given the disproportionately poor outcomes achieved in these patients”
- Vascular Study Group of New England
  - Self-reported data on 2899 lower extremity bypass procedures between 2003 and 2009
  - Excluded claudication (21%), prosthetic conduit (20%), operations for aneurysm (7%), ESRD (6%), lost to follow up (3%)

Patients Undergoing Vein Bypass for CLI

<table>
<thead>
<tr>
<th></th>
<th>VSGNE cohort (n = 1039)</th>
<th>SVS OPG cohort (n = 838)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>58%</td>
<td>57%</td>
</tr>
<tr>
<td>Previous ipsilateral leg surgical interventions</td>
<td>14%</td>
<td>12%</td>
</tr>
<tr>
<td>Previous ipsilateral leg surgical/endovascular intervention</td>
<td>29%</td>
<td>16%</td>
</tr>
<tr>
<td>Clinical high risk (age over 80 and tissue loss)</td>
<td>15%</td>
<td>16%</td>
</tr>
<tr>
<td>Anatomic high risk (infraoppliteal target)</td>
<td>58%</td>
<td>60%</td>
</tr>
<tr>
<td>Conduit high risk (absence of adequate single-segment great saphenous vein)</td>
<td>10%</td>
<td>27%</td>
</tr>
</tbody>
</table>

1-year Outcomes of Lower Extremity Bypass with Autologous Vein

<table>
<thead>
<tr>
<th>Major Adverse Limb Events or Post-Operative Death</th>
<th>VSGNE</th>
<th>SVS OPG</th>
</tr>
</thead>
<tbody>
<tr>
<td>26%</td>
<td></td>
<td>23%</td>
</tr>
</tbody>
</table>

| Limb loss | 9% | 11% |
| Death     | 8% | 14% |
| Re-intervention, amputation, or graft stenosis | 33% | 54% |

Contemporary Outcomes

- Data confirm CLI is a bad problem with less than optimal outcomes for many
- Surgical bypass may be option of choice for those who:
  - Have good quality autologous conduit
  - Are suitable candidates for operation
- Bypass provides reasonably effective and durable revascularization for CLI in those patients selected for surgical treatment

CLI Recommendations Less Certain

- Renal failure
- Absent or poor autologous conduit
- Poor functional status
- Limited life expectancy
Optimum Outcomes Rare with Surgery

- OHSU experience with bypass for CLI
  - Mean postoperative follow-up 42 months
  - 88% independent at home
- Wound complications common
- Repeat operations required in 54%
- Only 14.3% had the “ideal surgical result”
  - Uncomplicated operation
  - Long-term symptom relief
  - Maintenance of functional status
  - No recurrence or repeat operations


Some Never Benefit

- Outcomes from VSGNE (2003 to 2007) evaluated for 1012 patients who underwent infrainguinal bypasses for CLI
- 10% had clinical failure one year after bypass, despite a patent graft
  - Amputation
  - Persistent or worsened ischemic symptoms
- Concluded “further emphasis needs to be placed on functional outcomes in addition to traditional surgical end points.”


Limitations of Surgical Revascularization

- 50% to 60% 5-year survival reported in surgical literature of CLI, lower in other series
- Surgical care considered palliative
- Outcomes data from published series lack generalizability
- Functional impact of surgical complications
- Dr. John Porter: “The last...decades in limb salvage surgery we discovered what we could do. Now it is time to learn what we should do.”


Endovascular First

- Outpatient procedure
- Avoids surgical morbidities of incision, nerve injury, lymphedema, pain
- Choice of most patients and referring providers
Results with “Endovascular First”

- Bypass versus Angioplasty in Severe Ischemia of the Limb (BASIL) trial
  - “Endovascular first” approach for patients with CLI compared to bypass surgery
  - similar amputation-free survival
- Approach adopted at UC Davis
- Reviewed peripheral interventions for CLI (Rutherford grades 4, 5, 6) over a 24-month period (2006-2007)

UC Davis Review

- Study performed to evaluate whether duplex scan findings after infrainguinal endovascular interventions for critical limb ischemia (CLI) were predictive of need for reintervention or amputation
- Provided insight on the overall safety and efficacy of treatment strategy

### Results

**LIMBS WITH CRITICAL LIMB ISCHEMIA**

Analysis per limb treated:
Outcomes at 12 months for patients with DUS within 30 days

<table>
<thead>
<tr>
<th></th>
<th>Lost to follow-up ($n = 6$)</th>
<th>Primary patency (%)</th>
<th>Reinterventions ($n$)</th>
<th>Secondary patency (%)</th>
<th>Open revascularization ($n$)</th>
<th>Amputation ($n$) (%)</th>
<th>Death ($n$) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Normal DUS ($n = 40$)</strong></td>
<td>4</td>
<td>26 (65)</td>
<td>4</td>
<td>30 (75)</td>
<td>2</td>
<td>2 (5.6)</td>
<td>8 (20)</td>
</tr>
<tr>
<td><strong>Abnormal DUS ($n = 50$)</strong></td>
<td>2</td>
<td>23 (46)</td>
<td>9</td>
<td>32 (64)</td>
<td>2</td>
<td>10 (20.1)</td>
<td>8 (16)</td>
</tr>
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</table>

**Compare to VSGNE Data for Lower Extremity Bypass**

- Limb salvage: 46.5%
- Freedom from reintervention, amputation, graft stenosis: 85.9%
Surgical Revascularization Outcomes Impacted by Prior Therapy

• VSGNE retrospective analysis of infrainguinal lower extremity bypass (LEB)
  • 1880 LEBs performed (2003 through 2009)
    – 32% (n = 603) had a prior infrainguinal revascularization procedure
    • Ipsilateral endovascular, 7%; ipsilateral bypass, 15%
    • Contralateral endovascular, 3%; contralateral bypass, 17%
  • Patients with prior ipsilateral endovascular treatment (compared to without prior intervention)
    – More female (32 vs 41%)
    – Less likely to have tissue loss (52% vs 63%)
    – More likely to require arm vein conduit (16% vs 5%)
  • Prior intervention or bypass did not alter 30-day MAE and 1-year mortality after the index bypass


Surgical Revascularization Outcomes After Prior Endovascular Therapy

• 1-year major amputation and 1-year graft occlusion rates were higher in patients who had prior intervention than those without (31% vs 20%; P = .046 and 28% vs 18%; P = .009)
• Independent multivariate predictors of higher 1-year amputation and graft occlusion rates were prior ipsilateral intervention, prior ipsilateral bypass, dialysis dependence, prosthetic conduit and distal (tibial and pedal) bypass target
• Any failure of prior revascularization (or renal failure) predictive of poorer outcome


Specific Risks of Endovascular First Strategy

• Embolization
  – Risk varies with endovascular techniques
• Occlusion of outflow artery that could be used as graft target

Beware of “burning your bridges”
Preserve Collaterals

- Profunda femoris is the “lifeline” of the lower limb
- Covered stents may be associated with increased risk of severe acute ischemia
- Important for treating physician to be aware of current and future revascularization options

Bypass only?  Endovascular only?

Preserving critical collaterals and gradual restenosis may save the limb from immediate loss with revascularization failures

What Would a Vascular Surgeon Choose?

- Consider the basic data underlying clinical decision making
- Choose a trusted treatment strategy
- Seek care from the best surgeons in the best centers
- Individualize treatment to the situation of the individual patient

Today’s vascular surgeon