Tibial bypass with vein vs HePTFE; current indications and new developments

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Disclosures

• WL Gore
• Vascular Flow Technologies
• Cormatrix
• Graftworxs

Current indications for bypass

• Indication for revascularization
  – Significant tissue loss (> 2cm)
• Patient comorbidity
  – Good medical risk
  – Reasonable life expectancy and level of function
• Arterial anatomy
  – TASC D lesions
• Angiosome revascularization
  – To revascularize the appropriate angiosome
• History of failed endovascular therapy

Bypasses in a limb preservation practice

Endovascular 72%
Surgical bypass 28%

50% patients without saphenous vein conduit

Heparin bonded ePTFE with DVP
Lack of saphenous conduit

N=290 tibial bypasses

Tibial bypass; GSV vs HePTFE

• Retrospective analysis of prospectively collected data
• 112 bypasses
  • Complete data set at 3, 6, 12 months
  • Pulse examination, ABI,
  • Duplex graft surveillance
• Bypass procedures
  • 62 HePTFE grafts (Prolene, WL Gore)
  • 50 GSV grafts
    • 80% TSV
    • 20% RSV

Tibial bypass; GSV vs HePTFE

Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>HePTFE</th>
<th>Vein</th>
<th>P</th>
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</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>72.6%</td>
<td>62.4%</td>
<td>0.377</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>46.1%</td>
<td>46.0%</td>
<td>0.925</td>
</tr>
<tr>
<td>ESRD</td>
<td>12.5%</td>
<td>18.8%</td>
<td>0.654</td>
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<tr>
<td>Classification</td>
<td>7.1%</td>
<td>18.8%</td>
<td>0.013</td>
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<tr>
<td>Rest pain</td>
<td>17.7%</td>
<td>29.8%</td>
<td>0.001</td>
</tr>
<tr>
<td>Non-healing ulcer</td>
<td>64.9%</td>
<td>57.6%</td>
<td>0.273</td>
</tr>
<tr>
<td>Gangrene</td>
<td>18.9%</td>
<td>28.9%</td>
<td>0.095</td>
</tr>
<tr>
<td>Limb loss</td>
<td>44.5%</td>
<td>70.8%</td>
<td>0.025</td>
</tr>
<tr>
<td>Other bypasses</td>
<td>43.5%</td>
<td>18.8%</td>
<td>0.004</td>
</tr>
</tbody>
</table>

More patients with gangrene in GSV group
More reoperative bypasses in HePTFE graft group

Bypass anatomy

Predominantly tibial bypass

HePTFE – more External Iliac proximal anastomosis

Summary

• There remains a role for surgical bypass (25%)
  – Significant tissue loss, good life expectancy
• GSV remains the ideal conduit
• There is a role for prosthetic bypass to tibial arteries
  – Patients with absent or poor quality GSV
• Techniques for prosthetic bypass
  – Distal vein patch technique
  – Heparin bonded ePTFE (Propaten)

New development

Extracellular Matrix (ECM)

• Derived from porcine small intestinal submucosa
  – Structural proteins (collagen, elastin)
  – Adhesive glycoproteins (fibronectin, laminin)
  – Glycosaminoglycans and proteoglycans
  – Matricellular proteins
• Bio-scaffold for stem cell population
• Differentiation into tissue specific regenerative, reparative tissue

ECM current clinical use
(Cormatrix, Atlanta, GA)

Pericardium Reconstruction
Cardiac Valve Repair
Carotid Endarterectomy

European CE mark and USA FDA clearance
ECM for lower extremity revascularization

- N = 40
- 15 month time period
- Trial with institutional IRB approval

Claudication: 13%
Rest Pain: 35%
Tissue Loss: 37%
Bypass stenosis: 15%

Iliofemoral Thromboendarterectomy with ECM Patch

Follow-up arteriogram

Vein Bypass Graft Revision

Prosthetic Bypass Graft Revision

Proximal anastomosis
Distal anastomosis

Results

- Follow up
  - Range of 1 to 15 months
  - Mean follow-up of 6.3 months
  - 92% Primary patency
- No acute anastomotic dehiscence, thrombosis, or infection
- Complications
  - 3 thromboses; 2 DVP bypasses; 1 IF TE
  - 1 anastomotic pseudoaneurysm; DVP bypass
  - 1 wound dehiscence
  - 2 mortalities during follow-up
DVP bypass with ECM
*Three month follow up*

Anastomotic pseudoaneurysm
*Three months post op*

Anastomotic histology
*Graft thrombosis at four months*

Vimentin stain; fibroblasts, endothelial cells, smooth muscle

CD34 stain; endothelial cells

Media

No inflammation

Adventitial granulation tissue

The future?
*Stem cell technology*

Conclusion

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  – Significant tissue loss, good life expectancy
• There is a role for prosthetic bypass to tibial arteries
  – Patients with absent or poor quality GSV
• Techniques for prosthetic bypass
  – Distal vein patch technique
  – Heparin bonded ePTFE (Proparen)
• New developments
  – ECM
  – “Smart graft technology”