LIMB SALVAGE
IN THE DIABETIC PATIENT

WHO?
HOW?
BEST?

DISCLOSURES

- Educational grant from
  Cook Inc
OBJECTIVES

➢ Review risk stratification and staging schemes for the threatened limb
➢ Discuss current concepts of revascularization and areas of controversy
➢ Provide available diabetes-specific data

DIABETES AND PAD—GLOBAL EPIDEMIC

➢ >23 million diabetics in US; 300+ million worldwide
➢ 1 in 3 diabetics older than 50 have PAD
➢ Nearly 70% of amputations in US affect diabetic patients
➢ Age-adjusted risk for amputation is 28-fold higher
➢ Estimated that a diabetic person undergoes lower extremity amputation every 20-30 seconds around the globe
➢ Diabetic foot ulcer (DFU) is a strong predictor for limb loss
➢ Among patients with a DFU that heals 28-83% will recur within one year
➢ Diabetics with PAD are at significantly increased risk of death and limb loss
➢ Major public health expenditures and growing rapidly
Lower level of awareness
- Broad clinical spectrum of disease
- Poor classification and staging systems complicate management and communication between providers
- Multiple providers, often fragmented and delayed care
- Diagnostic and therapeutic approaches highly variable
- Recognition and treatment of advanced stages critical
- “Time is Tissue”
DIABETES UPDATE 2018

OPTIMAL MANAGEMENT STRATEGY

➢ ASSESS LIMB THREAT
  • SVS Threatened Limb (WIfI) Stage

➢ ASSESS PATIENT RISK
  • Perioperative: < 5% mortality
  • Long-term survival: > 50% 2-year survival

➢ ASSESS ANATOMIC PATTERN OF ARTERIAL DISEASE AND TISSUE IMPAIRMENT
  • Feasibility
  • Revascularization option

Fontaine and Rutherford Classifications:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Category</th>
<th>Clinical description</th>
<th>Objective criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>Asymptomatic—no hemodynamically significant exclusive disease</td>
<td>Normal treadmill or reactive hyperemia test</td>
</tr>
<tr>
<td>1</td>
<td>M1 classification</td>
<td>Complete treadmill exercise; AP after exercise &gt;50 mm Hg but at least 20 mm Hg lower than resting value</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>M2 classification</td>
<td>Complete treadmill exercise; AP after exercise &lt;50 mm Hg</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>M3 classification</td>
<td>Complete treadmill exercise; AP after exercise &lt;50 mm Hg, but significantly lower than resting value</td>
<td></td>
</tr>
<tr>
<td></td>
<td>I</td>
<td>Ischemic rest pain</td>
<td>Resting AP &lt;60 mm Hg, flat or hardy pulse, ankle or temporal PVR, TP &lt; 60 mm Hg</td>
</tr>
<tr>
<td></td>
<td>II*</td>
<td>Minor tissue loss—necrotizing ulcers, focal gangrene with diffuse pedal ischemia</td>
<td>Resting AP &lt;60 mm Hg, ankle or temporal PVR, flat or hardy pulse, TP &lt; 60 mm Hg</td>
</tr>
<tr>
<td></td>
<td>III*</td>
<td>Major tissue loss—extending above TM level, functional foot no longer salvageable</td>
<td>Same as category II *</td>
</tr>
</tbody>
</table>

AP, Ankle pressure; PVR, pulse volume recording; TP, toe pressure; TM, transmetatarsal.
*Grades II and III, categories 4, 5, and 6, are embraced by the term chronic critical ischemia.
†Five minutes at 2 mph on a 12% incline.
OPTIMAL MANAGEMENT STRATEGY

➢ ASSESS LIMB THREAT
  • SVS Threatened Limb (WIfI) Stage

➢ Wound: extent and depth
➢ Ischemia: perfusion / flow
➢ Foot Infection: presence and extent
## ASSESS LIMB THREAT

### WOUND GRADE — Clinical Assessment

<table>
<thead>
<tr>
<th>Grade</th>
<th>Clinical Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Ischemic rest pain; Pre-gangrenous skin change, without frank ulcer or gangrene (Pedis or UT Class 0)</td>
</tr>
<tr>
<td>1</td>
<td>Minor tissue loss: small shallow ulceration &lt; 5 cm² on foot or distal leg (Pedis or UT Class 1); no exposed bone unless limited to distal phalanx</td>
</tr>
<tr>
<td>2</td>
<td>Major tissue loss: deeper ulceration(s) with exposed bone, joint or tendon, ulcer 5-10 cm² not involving calcaneus – (Pedis or UT Classes 2 and 3); gangrenous changes limited to digits. Salvageable with multiple digital amps or standard TMA ± skin coverage</td>
</tr>
<tr>
<td>3</td>
<td>Extensive ulcer/gangrene &gt; 10 cm² involving forefoot or midfoot; full thickness heel ulcer &gt; 5 cm² + calcaneal involvement. Salvageable only with complex foot reconstruction, nontraditional TMA (Chopart/Lisfranc); flap coverage or complex wound management needed</td>
</tr>
</tbody>
</table>

### ISCHEMIA GRADE — Noninvasive Assessment

<table>
<thead>
<tr>
<th>Grade</th>
<th>ABI</th>
<th>Ankle SP</th>
<th>TP, TcpO2</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>≥ 0.80</td>
<td>≥ 100 mm Hg</td>
<td>≥ 60 mm Hg</td>
</tr>
<tr>
<td>1</td>
<td>0.60-0.79</td>
<td>70-99 mmHg</td>
<td>40-59 mm Hg</td>
</tr>
<tr>
<td>2</td>
<td>0.40-0.59</td>
<td>50-69 mm Hg</td>
<td>30-39 mm Hg</td>
</tr>
<tr>
<td>3</td>
<td>&lt; 0.40</td>
<td>&lt; 50 mm Hg</td>
<td>&lt; 30 mm Hg</td>
</tr>
</tbody>
</table>
### ASSESS LIMB THREAT

**INFECTION GRADE — Clinical Assessment**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Clinical Description</th>
<th>EDSA</th>
<th>IWGDF Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>wound without purulence or manifestations of infection</td>
<td>uninfected</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>&gt;2 manifestations of infection: erythema or purulence, pain (tenderess, warmth or induration) or cellulitis or erythema extends &lt; 2cm around ulcer; infection is limited to skin or subcutaneous tissues; no local complications or systemic illness</td>
<td>mild</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>Infection in patient who is systemically and metabolically stable but has ≥1 of the following: cellulitis extending ≥2cm, lymphangitis; spread beneath fascia; deep tissue abscess; gangrene; muscle, tendon, joint or bone involvement</td>
<td>moderate</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>Infection in patient with systemic or metabolic toxicity</td>
<td>severe</td>
<td>4</td>
</tr>
</tbody>
</table>

**FOOT INFECTION: SVS Grades**

- W-0: VL, VL, L, M, VL, L, M, H
- W-1: VL, VL, L, M, VL, L, M, H

### ASSESS LIMB THREAT

**AMPUTATION RISK**

<table>
<thead>
<tr>
<th>Ischemia – 0</th>
<th>Ischemia – 1</th>
<th>H</th>
<th>Ischemia – 2</th>
<th>Ischemia – 3</th>
</tr>
</thead>
</table>

UCSF
**Assess Limb Threat**

**Amputation Risk**

<table>
<thead>
<tr>
<th>Ischemia – 0</th>
<th>Ischemia – 1</th>
<th>H</th>
<th>Ischemia – 2</th>
<th>Ischemia – 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>W-0</td>
<td>VL</td>
<td>L</td>
<td>M</td>
<td>L</td>
</tr>
<tr>
<td>W-1</td>
<td>VL</td>
<td>L</td>
<td>M</td>
<td>L</td>
</tr>
<tr>
<td>W-2</td>
<td>L</td>
<td>M</td>
<td>H</td>
<td>M</td>
</tr>
<tr>
<td>W-3</td>
<td>M</td>
<td>H</td>
<td>H</td>
<td>M</td>
</tr>
</tbody>
</table>

**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**
- unsalvageable foot

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**Assess Limb Threat**

**Revascularization Benefit**

<table>
<thead>
<tr>
<th>Ischemia – 0</th>
<th>Ischemia – 1</th>
<th>Ischemia – 2</th>
<th>Ischemia – 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>W-0</td>
<td>VL</td>
<td>L</td>
<td>M</td>
</tr>
<tr>
<td>W-1</td>
<td>VL</td>
<td>L</td>
<td>M</td>
</tr>
<tr>
<td>W-2</td>
<td>L</td>
<td>M</td>
<td>H</td>
</tr>
<tr>
<td>W-3</td>
<td>M</td>
<td>H</td>
<td>H</td>
</tr>
</tbody>
</table>

**Stage 1**
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- Advanced in one or more categories

**Stage 5**
- unsalvageable foot
ASSESS LIMB THREAT
Estimated Amputation Risk by Stage


An early validation of the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System

Table VI. Comparison of expert predicted and data derived 1-year outcomes (limb amputation, wound nonhealing) by Wound characteristic, Ischemia, and foot Infection (WIF) clinical stage from Kaplan-Meier life table analysis

<table>
<thead>
<tr>
<th>Estimated WIF classification</th>
<th>No.</th>
<th>Predicted outcome, %</th>
<th>Observed outcome, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Limb amputation</td>
<td>Limb amputation</td>
</tr>
<tr>
<td>Stage 1—very low risk</td>
<td>40</td>
<td>~3</td>
<td>3.0 ± 3</td>
</tr>
<tr>
<td>Stage 2—low risk</td>
<td>64</td>
<td>~8</td>
<td>10.0 ± 4</td>
</tr>
<tr>
<td>Stage 3—moderate risk</td>
<td>46</td>
<td>~25</td>
<td>23.0 ± 6</td>
</tr>
<tr>
<td>Stage 4—high risk</td>
<td>8</td>
<td>~50</td>
<td>40.0 ± 22</td>
</tr>
</tbody>
</table>

### ASSESS LIMB THREAT

#### AMPUTATION VS WIFI STAGE

<table>
<thead>
<tr>
<th>Study (year): # Limbs at Risk</th>
<th>Stage 1</th>
<th>Stage 2</th>
<th>Stage 3</th>
<th>Stage 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cull (2014): 151</td>
<td>37 (3%)</td>
<td>63 (10%)</td>
<td>43 (23%)</td>
<td>8 (40%)</td>
</tr>
<tr>
<td>Zhan (2015): 201</td>
<td>39 (0%)</td>
<td>50 (0%)</td>
<td>53 (8%)</td>
<td>59 (64%)*</td>
</tr>
<tr>
<td>Darling (2015): 551</td>
<td>5 (0%)</td>
<td>111 (10%)</td>
<td>222 (11%)</td>
<td>213 (24%)</td>
</tr>
<tr>
<td>Causey (2016): 160</td>
<td>21 (0%)</td>
<td>48 (8%)</td>
<td>42 (5%)</td>
<td>49 (20%)</td>
</tr>
<tr>
<td>Beropoulis (2016): 126</td>
<td>29 (0%)</td>
<td>42 (2%)</td>
<td>29 (3%)</td>
<td>26 (12%)</td>
</tr>
<tr>
<td>Ward (2016): 98</td>
<td>5 (0%)</td>
<td>21 (14%)</td>
<td>14 (21%)</td>
<td>58 (34%)</td>
</tr>
<tr>
<td>Darling (2017): 992</td>
<td>12 (0%)</td>
<td>293 (4%)</td>
<td>249 (4%)</td>
<td>438 (21%)</td>
</tr>
<tr>
<td>Robinson (2017): 262</td>
<td>48 (4%)</td>
<td>67 (16%)</td>
<td>64 (10%)</td>
<td>83 (22%)</td>
</tr>
<tr>
<td>Mathioudakis (2017): 279</td>
<td>95 (6.5%)</td>
<td>33 (6%)</td>
<td>87 (8%)**</td>
<td>64 (6%)***</td>
</tr>
<tr>
<td>N = 2820 (weighted mean)</td>
<td>291 (3.2%)</td>
<td>728 (6.8%)</td>
<td>803 (8.5%)</td>
<td>998 (24%)</td>
</tr>
<tr>
<td>Median (% 1 year amputation)</td>
<td>0%</td>
<td>8%</td>
<td>8%</td>
<td>22%</td>
</tr>
</tbody>
</table>

#### REvascularization Benefit vs WIFI Stage

- **High benefit**
- **Low/Nil benefit**
OPTIMAL MANAGEMENT STRATEGY

ASSESS ANATOMIC PATTERN OF DISEASE AND TISSUE IMPAIRMENT

➢ Feasibility
  • Non-functional limb
  • Limited life-span
  • High-risk comorbidities
  • Poor overall functional status

➢ Revascularization option
  • Location  inflow vs outflow
  • Extent  single vs multilevel; focal vs diffuse
  • Severity  occlusion vs stenosis
  • Features  calcification
  • Conduit
OPTIMAL MANAGEMENT STRATEGY

ASSESS ANATOMIC PATTERN OF DISEASE AND TISSUE INVOLVEMENT

➢ Common
  • outflow disease
  • multilevel involvement
  • long segment involvement
  • chronic occlusions
  • extensive calcification
➢ Reversing tissue loss increases perfusion requirements
  • support healing (large defects, complex foot reconstruction)
  • offset comorbid conditions that may impair wound healing
  • support weight-bearing
  • concomitant infection
➢ TIME IS TISSUE
➢ TREATMENT FAILURES OFTEN POORLY TOLERATED

OPTIMAL REVASCULARIZATION STRATEGY

ENDOVASCULAR VS OPEN
**DIABETES UPDATE 2018**

**OPTIMAL REVASCULARIZATION STRATEGY**

- Restore in-line flow to the tissue bed in need
  - Especially with tissue loss
  - Pulsatile flow
  - Treating proximal lesions in the setting of a distal occlusion or even stenosis will be inadequate for wound healing

- Vigilant surveillance
  - Clinical examination
  - Non-invasive imaging (Duplex ultrasound)
  - Low threshold for re-intervention

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**DIABETES UPDATE 2018**

**ENDOVASCULAR THERAPY FOR LIMB SALVAGE**

**ADVANCES**

- Crossing lesions and occlusions
  - wires, catheters, re-entry devices

- Balloon technology
  - profile, length, diameter, cutting, lower pressure, drug elution

- Stent technology
  - profile, length, durability, flexibility, drug-eluting, bioresorbables

- Atherectomy devices

- Techniques
  - retrograde access, subintimal, crack & pave
ENDOVASCULAR THERAPY FOR LIMB SALVAGE

➢ Potential advantages
  • Less invasive; ↓ mortality and morbidity (?)
  • Fast recovery

➢ Potential disadvantages
  • Reduced efficacy: hemodynamics, durability
  • Risk of limb deterioration
  • May affect surgical options
  • Cost: repeated treatments, ↓ symptom-free intervals
  • Techniques are not standardized
  • Results are mostly modest sized observational series or registries with heterogeneous cohorts, variable follow-up quality and intervals

DIABETES UPDATE 2018

➢ Greatest impact has been on femoropopliteal disease mostly tested in claudicants

➢ Improvements in treatment of BTK disease have been modest
ENDOVASCULAR THERAPY FOR LIMB SALVAGE

• 136 limbs / 123 patients
• 54 isolated tibial
• Primary patency < 40% at one year
• Secondary patency 63% at one year


UCSF
ENDOVASCULAR THERAPY FOR LIMB SALVAGE

Iida O et al. JACC Cardiovasc Interv 2015 8(11): 1493-1502

Neupane et al. Catheter Cardiovasc Interv 2018; 00:1-7
ENDOVASCULAR THERAPY FOR LIMB SALVAGE

Infrainguinal angioplasty  N = 777
All diabetic patients
• 1 year survival  93%
• 1 year limb salvage  88%

Endovascular failure  OR
• Toe pressure < 50 mmHg  2.15
• Infrainguinal TASC II C/D  1.99
• Indirect angiosome revase2.03

Table 1. Randomized Controlled Trials of Drug-Eluting Stents in Infrapopliteal Disease.

<table>
<thead>
<tr>
<th>Study/Stent Type</th>
<th>N</th>
<th>CLJ / IC</th>
<th>Control Arm</th>
<th>Follow-up, mo</th>
<th>Outcome</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACHILLES Sirolimus-eluting</td>
<td>200</td>
<td>CLJ + IC</td>
<td>PTA</td>
<td>12</td>
<td>Primary patency 75% vs 57%</td>
<td>0.025</td>
</tr>
<tr>
<td>DESTINY Everolimus-eluting</td>
<td>140</td>
<td>CLJ</td>
<td>BMS</td>
<td>12</td>
<td>Primary patency 85% vs 54%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>YUKON-BTX Sirolimus-eluting</td>
<td>161</td>
<td>CLJ + IC</td>
<td>BMS</td>
<td>12</td>
<td>Primary patency 81% vs 56%</td>
<td>0.004</td>
</tr>
<tr>
<td>IDEAS Drug-eluting</td>
<td>50</td>
<td>CLJ + IC</td>
<td>PCB</td>
<td>6</td>
<td>Restenosis 28% vs 58%</td>
<td>0.046</td>
</tr>
</tbody>
</table>

Abbreviations: BMS, bare metal stent; CLJ, critical limb ischemia; IC, intermittent claudication; PCB, paclitaxel-coated balloon; PTA, percutaneous transluminal angioplasty.

ENDOVASCULAR THERAPY FOR LIMB SALVAGE

Olin et al. JACC 2016; 67(11):1338-57

<table>
<thead>
<tr>
<th>Clinical Trial Name (Ref. #)</th>
<th>Device</th>
<th>N</th>
<th>Lesion length (mm)</th>
<th>Restenosis (%)</th>
<th>IC/CLI (%)</th>
<th>TLR (%)</th>
<th>De Novo (%)</th>
<th>Occlusions (%)</th>
<th>RVD (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACHILLES (120)</td>
<td>PTA</td>
<td>101</td>
<td>27 ± 21</td>
<td>42.9</td>
<td>NR</td>
<td>16.5</td>
<td>98.2</td>
<td>75.4</td>
<td>2.6</td>
</tr>
<tr>
<td></td>
<td>DES</td>
<td>99</td>
<td>27 ± 21</td>
<td>22.4*</td>
<td>NR</td>
<td>10.0</td>
<td>94.7</td>
<td>83.3</td>
<td>2.6</td>
</tr>
<tr>
<td>DESTINY (121)</td>
<td>BMS</td>
<td>66</td>
<td>19 ± 10</td>
<td>36.0</td>
<td>O/100</td>
<td>35.0</td>
<td>100</td>
<td>17.0</td>
<td>2.9</td>
</tr>
<tr>
<td></td>
<td>DES</td>
<td>74</td>
<td>16 ± 10</td>
<td>17.0</td>
<td>O/100</td>
<td>8.0*</td>
<td>100</td>
<td>15.0</td>
<td>3.0</td>
</tr>
<tr>
<td>YUKON-BTX (122)</td>
<td>BMS</td>
<td>79</td>
<td>31 ± 9</td>
<td>44.4</td>
<td>58.2/41.8</td>
<td>17.5</td>
<td>100</td>
<td>21.5</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>DES</td>
<td>82</td>
<td>30 ± 8</td>
<td>19.4*</td>
<td>48.8/51.2</td>
<td>9.7</td>
<td>100</td>
<td>21.2</td>
<td>3.0</td>
</tr>
<tr>
<td>DEBATE-BTX (123)</td>
<td>PTA</td>
<td>67</td>
<td>131 ± 79</td>
<td>74.0</td>
<td>O/100</td>
<td>43.0</td>
<td>NR</td>
<td>82.1</td>
<td>2.9</td>
</tr>
<tr>
<td></td>
<td>DCB</td>
<td>65</td>
<td>128 ± 83</td>
<td>27.0*</td>
<td>O/100</td>
<td>18.0</td>
<td>NR</td>
<td>77.5</td>
<td>2.9</td>
</tr>
<tr>
<td>IMPACT DEEP CLI (124)</td>
<td>PTA</td>
<td>119</td>
<td>129 ± 95</td>
<td>35.5</td>
<td>0.8/99.2</td>
<td>13.1</td>
<td>NR</td>
<td>45.9</td>
<td>12.9</td>
</tr>
<tr>
<td></td>
<td>DCB</td>
<td>239</td>
<td>102 ± 91</td>
<td>41.0</td>
<td>O/100</td>
<td>9.2</td>
<td>77.2</td>
<td>38.6</td>
<td>10.2</td>
</tr>
<tr>
<td>IDEAS (125)</td>
<td>DCB</td>
<td>25</td>
<td>148 ± 57</td>
<td>57.9</td>
<td>NR</td>
<td>13.6</td>
<td>NR</td>
<td>12.0</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td>DES</td>
<td>27</td>
<td>127 ± 47</td>
<td>28.0*</td>
<td>NR</td>
<td>7.7</td>
<td>NR</td>
<td>23.0</td>
<td>NR</td>
</tr>
</tbody>
</table>

SURGICAL THERAPY FOR LIMB SALVAGE

- Bypass with autogenous vein is the “gold standard”
- Results well documented in hundreds of reports: anecdotal > retrospective > randomized trials
- Versatile: results in complex situations (anatomic, patient related) well established
- Low mortality, good durability
- BUT – there are limitations and risks:
  - Wound and other complications
  - Prolonged recovery
  - Vein quality and availability
  - Surveillance and reintervention
  - Technically demanding
- Risk scores may help select pts
SURGICAL THERAPY FOR LIMB SALVAGE

PLANNING
➢ High quality imaging
  • Digital subtraction angiography with dedicated, multiple views of ankle and foot
  • CTA and MRA are often inaccurate below the knee
➢ Ultrasound vein mapping preop and intraop
  • Ipsilateral extremity and contralateral limb, arms as needed
  • Vein caliber, quality, anatomic variants
➢ Skin and soft tissue integrity
  • Plan incisions and graft tunnels to minimize morbidity
➢ Baseline medical therapies
  • Antiplatelet, statin, b-blocker / anti-HTN, anticoagulation

SURGICAL THERAPY FOR LIMB SALVAGE

TECHNICAL
➢ Management of the arteries
  • Selection of sites for anastomoses
  • Dealing with calcification
➢ Conduit assessment and handling
➢ Incision and wound management
➢ Anticoagulation management
  • Antiplatelets, anticoagulants
➢ Completion assessment
➢ Always need Plan B (and C, D…)

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DIABETES UPDATE 2018

SURGICAL THERAPY FOR LIMB SALVAGE

➢ Average risk CLTI patient
➢ More severe limb threat (WIfI stage 3/4)
➢ Bad anatomy for endovascular intervention
  • multilevel severe disease (CTOs above and BTK)
  • long occlusions especially tibial
  • small caliber, heavy calcification
  • severe CFA or popliteal/trifurcation disease
➢ Adequate quality vein available
➢ Runoff to foot intact


DIABETES UPDATE 2018

SURGICAL THERAPY FOR LIMB SALVAGE

➢ N = 604 bypasses (43% of study population) with single segment GSV, diameter > 3.5 mm
➢ 30 day failure 1.7%
➢ One year results
  • PP 72%
  • SP 87%
  • Limb salvage 91%
➢ Importance of conduit assessment and quality
SURGICAL THERAPY FOR LIMB SALVAGE

Level of distal anastomosis is not an important limitation for a good quality vein

SSGSV ≥ 3.5 mm
DIABETES UPDATE 2018

SURGICAL THERAPY FOR LIMB SALVAGE


SURGICAL THERAPY FOR LIMB SALVAGE

Single center
N = 843
83% DM
92% CLI
Mortality
periop = 1.4%
DM = 0.9%
NDM = 4.2%
(p=0.005)


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**SURGICAL THERAPY FOR LIMB SALVAGE**

Single center  
N = 1310  
50% DM  
100% CLI  
Mortality periop = 0.0%


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**ENDO VS SURGERY FOR LIMB SALVAGE**

BASIL Trial

Adam DJ et al. Lancet 2005; 366:1925-34
ENDO VS SURGERY FOR LIMB SALVAGE

SPINACH Registry

Iida O et al. Circ Cardiovasc Interv 2017 10(12)
ENDO VS SURGERY FOR LIMB SALVAGE


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ANGIOSOME-BASED SURGICAL THERAPY

ANGIOSOME CONCEPT
DIRECT REVASCULARIZATION

Forsythe & Hinchliffe J Cardiovasc Med (Torino) 2016, 57(2):273-81
Our systemic review of available literature demonstrates that there is limited data available to substantiate an angiosome-based model of revascularization….
EVIDENCE BASED APPROACH

<table>
<thead>
<tr>
<th>Surgical Risk</th>
<th>Average (&lt;5% mort)</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life Expectancy</td>
<td>≥ 2 years</td>
<td>Limited</td>
</tr>
<tr>
<td>Limb Threat Stage</td>
<td>WfI Stage 3,4</td>
<td>WfI Stage 2,3</td>
</tr>
<tr>
<td>Anatomy</td>
<td>Multi-level, TASC C/D</td>
<td>Single level, TASC A-C</td>
</tr>
<tr>
<td>Vein availability</td>
<td>GSV or good alternate</td>
<td>Inadequate</td>
</tr>
</tbody>
</table>

BYPASS FAVORED

ENDO FAVORED

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OPTIMAL REvascularization STRATEGY

Recommendations on revascularization of infra-popliteal occlusive lesions

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Classa</th>
<th>Levelb</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the case of CLTI, infra-popliteal revascularization is indicated for limb salvage</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>For revascularization of infra-popliteal arteries:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• bypass using the great saphenous vein is indicated</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>• endovascular therapy should be considered</td>
<td>IIa</td>
<td>B</td>
</tr>
</tbody>
</table>

2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS)

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INITIAL REVASCULARIZATION PROCEDURE FOR CLI

- Recent VQI data (N = 38,470)
  - Endovascular: 63%
  - Bypass: 37%

- Bisdas et al CRITISCH Registry
  - Endovascular: 53%
  - Bypass: 24%

Proportion of all LEB (N=3,504) performed as secondary procedures, by indication and year

- 72% increase p < 0.001

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OPTIMAL REVASCULARIZATION STRATEGY

BASIL Trial


OPTIMAL REVASCULARIZATION STRATEGY

RAO-Free Survival (weighted)

HR 1.22
[95% CI: 1.09 – 1.37]
P<0.001 (Cox model)

MALE-Free Survival (weighted)

HR 1.23
[95% CI: 1.10 – 1.38]
P<0.001 (Cox model)

No. of patients at risk:
Primary bypass 2238 1242 691 371
Secondary bypass 1098 549 281 122

Jones DW et al. JAHA 2013
OPTIMAL REVASCULARIZATION STRATEGY

- Funded by NHLBI in 2013
- Compare initial Endo vs initial Bypass in CLI
- Target 2100 patients, approximately 120 centers
- Current enrollment approximately 1200

BASIL 2 (BTK) – Bypass versus Angioplasty / Stenting in Severe Ischaemia of the Leg due to BTK Disease Trial

Andrew W. Bradbury
Sampson Gamgee Professor of Vascular Surgery
University of Birmingham, UK
Heart of England NHS Foundation Trust