Managing R6 wounds - the utility of multi-vessel revascularization and inflow strategies

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Disclosure

Peter A. Schneider

Potential conflicts of interest to report:

Enter patients in studies sponsored by: Gore, Cordis, Medtronic, Silk Road, Bard, NIH, Limflow

Modest royalty: Cook

Scientific Advisory Board (non-compensated): Abbott, Medtronic, Boston Scientific

Chief Medical Officer: Intact Vascular, Cagent
Critical Limb Ischemia

**Rutherford 4**
Rest pain

**Rutherford 5**
Minor tissue loss

**Rutherford 6**
Major tissue loss
Managing Rutherford 6
More likely to....

• Have undrained infection
• Present as an emergency
• Have uncontrolled medical co-morbidities
• Be malnourished
• Require multiple local foot procedures
• Benefit from multi-vessel revascularization
• Have tissue damage threatening vital structures
• Die or loose the leg
Rutherford 6
General Principles

• Severity of foot damage determines salvage much more so than method of revascularization.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Category</th>
<th>Clinical Description</th>
<th>Objective Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>0</td>
<td>Asymptomatic</td>
<td>Normal treadmill or reactive hyperemia test</td>
</tr>
<tr>
<td>I</td>
<td>1</td>
<td>Mild intermittent claudication</td>
<td>Treadmill exercise limited to 5 min; ankle pressure after exercise &gt;50 mmHg but at least 20 mmHg lower than at rest</td>
</tr>
<tr>
<td>I</td>
<td>2</td>
<td>Moderate intermittent claudication</td>
<td>Between Rutherford 1 and 3 disease</td>
</tr>
<tr>
<td>I</td>
<td>3</td>
<td>Severe intermittent claudication</td>
<td>Treadmill exercise limited to &lt;5 min; ankle pressure after exercise &lt;50 mmHg</td>
</tr>
<tr>
<td>II</td>
<td>4</td>
<td>Ischemic rest pain</td>
<td>Resting ankle pressure &lt;40 mmHg and/or great toe pressure &lt;30 mmHg; pulse volume recording barely pulsatile or flat</td>
</tr>
<tr>
<td>III</td>
<td>5</td>
<td>Minor tissue loss — nonhealing ulcer, focal gangrene with diffuse pedal ischemia</td>
<td>Resting ankle pressure &lt;60 mmHg and/or great toe pressure &lt;30 mmHg; pulse volume recording barely pulsatile or flat</td>
</tr>
<tr>
<td>III</td>
<td>6</td>
<td>Major tissue loss — extending above transmetatarsal level, functional foot no longer salvageable</td>
<td>Resting ankle pressure &lt;60 mmHg and/or great toe pressure &lt;30 mmHg; pulse volume recording barely pulsatile or flat</td>
</tr>
</tbody>
</table>
The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIfI)

## Risk of leg amputation at 1 year

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

### Foot infection

**Grade 3 wound has a high risk of leg amputation.**

VL=very low, L=low, M=moderate, H=high

The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIfI)

Wound Grading System

<table>
<thead>
<tr>
<th>Grade</th>
<th>Ulcer</th>
<th>Gangrene</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No ulcer</td>
<td>No gangrene</td>
</tr>
<tr>
<td></td>
<td>Clinical description: ischemic rest pain (requires typical symptoms + ischemia grade 3); no wound.</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Small, shallow ulcer(s) on distal leg or foot; no exposed bone, unless limited to distal phalanx</td>
<td>No gangrene</td>
</tr>
<tr>
<td></td>
<td>Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Deeper ulcer with exposed bone, joint or tendon; generally not involving the heel; shallow heel ulcer, without calcaneal involvement</td>
<td>Gangrenous changes limited to digits</td>
</tr>
<tr>
<td></td>
<td>Clinical description: major tissue loss salvageable with multiple (≥3) digital amputations or standard TMA ± skin coverage.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Extensive, deep ulcer involving forefoot and/or midfoot; deep, full thickness heel ulcer ± calcaneal involvement</td>
<td>Extensive gangrene involving forefoot and/or midfoot; full thickness heel necrosis ± calcaneal involvement</td>
</tr>
<tr>
<td></td>
<td>Clinical description: extensive tissue loss salvageable only with a complex foot reconstruction or nontraditional TMA (Chopart or Lisfranc); flap coverage or complex wound management needed for large soft tissue defect</td>
<td></td>
</tr>
</tbody>
</table>

TMA, Transmetatarsal amputation.

I: Ischemia
Hemodynamics/perfusion: Measure TP or TcPO2 if ABI incompressible (>1.3)
SVS grades 0 (none), 1 (mild), 2 (moderate), and 3 (severe).
## Risk of Amputation vs SVS WIfI Stage: Compilation of Published Data

<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 (37%)</td>
</tr>
<tr>
<td>Darling (2015): 551</td>
<td>5 (0%)</td>
<td>111 (2%)</td>
<td>222 (6%)</td>
<td>213 (28%)</td>
</tr>
<tr>
<td>Causey (2016): 160</td>
<td>21 (0%)</td>
<td>48 (25%)</td>
<td>42 (21%)</td>
<td>49 (31%)</td>
</tr>
<tr>
<td>Beropoulis (2016): 126</td>
<td>29 (13%)</td>
<td>42 (19%)</td>
<td>29 (19%)</td>
<td>26 (38%)</td>
</tr>
<tr>
<td>N = 1189 (weighted average)</td>
<td>131 (4%)</td>
<td>314 (9%)</td>
<td>389 (11%)</td>
<td>355 (31%)</td>
</tr>
</tbody>
</table>

Number of limbs at risk in each WIfI stage with % amputation at 1 year in parentheses averages in total in bottom row (in parentheses) are weighted average. Courtesy: J Mills
Rutherford 6

45 year old man with full thickness left heel gangrene

- Toe/brachial index 0.10
- GFR-20ml/min
- MRI shows fluid over calcaneus but no overt clinical signs of infection.
Occlusion of distal PT and common plantar arteries
Distal SFA stent.
Treat inflow aggressively.
Primary runoff is posterior tibial artery.
Attempt to cross not successful

Total contrast 13ml
Dorsiflexion
Below knee popliteal to pedal bypass next day
58 year old diabetic man on dialysis with deep left foot abscess

- L toe pressure undetectable
- HgbA1C=15
- Right popliteal to distal posterior artery bypass in 1998 for forefoot gangrene
  - Stabilize
  - Drain infection
  - Revascularize
Left SFA and popliteal a.

Occluded posterior tibial artery.

Severely diseased ant. tibial a.
Anterior tibial artery reconstitutes but is diffusely diseased

Posterior tibial a. reconstitutes
Place sheath close to treatment site

Anterior tibial artery
Long balloon used from distal to proximal to treat anterior tibial artery

Fair result after AT angioplasty
Origin of posterior tibial a.
Guidewire in posterior tibial artery

Balloon angioplasty

Patent anterior tibial and posterior tibial arteries
Patent anterior tibial and posterior tibial arteries to the foot.
Worse Tissue Loss = Higher Likelihood of Limb Loss

Kaplan-Meier 12 Month Freedom from All Cause Death or Major Amputation by Baseline Rutherford Criteria

- Rutherford 4
- Rutherford 5
- Rutherford 6
Rutherford 6 Crosses Angiosomes

**Fig 1.** Angiosome concept. Six angiosomes of the foot and ankle are supplied by three main arteries. **Left,** The anterior tibial artery (ATA) becomes the dorsalis pedis artery that supplies the dorsum of the foot and dorsum side of the toes. **Middle,** Three main branches of the posterior tibial artery (PTA) supply distinct portions of the sole: the calcaneal branch to the heel, the medial plantar artery to the medial, and the lateral plantar artery to the lateral midfoot and the forefoot. The PTA supplies the plantar side of the toes, the web spaces between the toes, the sole of the foot, and the inside of the heel. **Right,** The peroneal artery (PA) supplies the lateral border of the ankle and the outside of the heel.
IN.PACT DEEP Trial
Randomized DEB vs PTA for BTK Revascularization in CLI

Freedom from amputation at 1 year >90%

358 subjects in 13 centers
Randomized 2:1-DEB to PTA

Rutherford 6
4% PTA group
2% DCB group

Most “endo first” data is in Rutherford 4 and 5 patients

Zeller et al. JACC 2014;64:1568
Most “endo first” data is in Rutherford 4 and 5 patients

Endovascular-first approach is not associated with worse amputation-free survival in appropriately selected patients with critical limb ischemia

302 patients
62% Endo first
35% Open first
3% Hybrid

**Endo first**
Focal disease BTK
SFA TASC A-C
No impending limb loss

Management of Rutherford 6

• CRITISCH Study-1200 CLI patients, 27 centers
• Natural history snapshot of current practice
• 23% of CLI was R6
• More likely to get bypass and less likely to get endo treatment.
• Primary amputation more likely (10% vs <1%)

Managing Rutherford 6

• Sickest patients at highest risk but less available data about management.
• Urgent: drain infection/control medical status
• Aggressive management of foot
• Multi-vessel revascularization
• More likely to require bypass surgery
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