Diagnosis and Management of Limb Tissue Loss

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Diagnosis and management of limb tissue loss
Diagnosis and management of limb tissue loss

Evaluation

Patient Health profile

Functional Profile

Limb Wound
Ischemia (Perfusion assessment)
Infection

Anatomy Burden & distribution of PAD
Venous conduit
Diagnosis and management of limb tissue loss

Patient Health profile

Functional Profile

Limb: Wound

Ischemia (Perfusion assessment)

Foot Infection

0: noninfected
1: mild (<2 cm cellulitis)
2: moderate (>2 cm cellulitis / purulence)
3: severe (systemic response / sepsis)

Toe Pressure / TCPO2
0: > 60 mmHg
1: 40-59
2: 30-39
3: < 30

Loma Linda University
Limb Preservation Program
Diagnosis and management of limb tissue loss

-Assessment of Infected Lower extremity wound
   (Regardless of ischemic profile)

 1) Degree of systemic response: mild- moderate- severe
 2) Soft tissue involvement?
 3) Bone involvement?

-Management
  Antibiotic selection
  Surgical management
    Debridement
    Open Amputation
2012 Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections

Clinical Infectious Diseases 2012;54(12):132–173
<table>
<thead>
<tr>
<th>Clinical Manifestation of Infection</th>
<th>PEDIS Grade</th>
<th>IDSA Infection Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>No symptoms or signs of infection</td>
<td>1</td>
<td>Uninfected</td>
</tr>
<tr>
<td>Infection present, as defined by the presence of at least 2 of the following items:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Local swelling or induration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Erythema</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Local tenderness or pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Local warmth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Purulent discharge (thick, opaque to white or sanguineous secretion)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local infection involving only the skin and the subcutaneous tissue (without involvement of deeper</td>
<td>2</td>
<td>Mild</td>
</tr>
<tr>
<td>tissues and without systemic signs as described below). If erythema, must be &gt;0.5 cm to ≤2 cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>around the ulcer. Exclude other causes of an inflammatory response of the skin (eg, trauma, gout,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>acute Charcot neuro-osteoarthropathy, fracture, thrombosis, venous stasis).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local infection (as described above) with erythema &gt; 2 cm, or involving structures deeper than skin</td>
<td>3</td>
<td>Moderate</td>
</tr>
<tr>
<td>and subcutaneous tissues (eg, abscess, osteomyelitis, septic arthritis, fasciitis), and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No systemic inflammatory response signs (as described below)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local infection (as described above) with the signs of SIRS, as manifested by ≥2 of the following:</td>
<td>4</td>
<td>Severe</td>
</tr>
<tr>
<td>• Temperature &gt;38°C or &lt;36°C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Heart rate &gt;90 beats/min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Respiratory rate &gt;20 breaths/min or PaCO₂ &lt;32 mm Hg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• White blood cell count &gt;12,000 or &lt;4000 cells/μL or ≥10% immature (band) forms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site of Infection, by Severity or Extent</td>
<td>Route of Administration</td>
<td>Setting</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Soft-tissue only</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>Topical or oral</td>
<td>Outpatient</td>
</tr>
<tr>
<td>Moderate</td>
<td>Oral (or initial parenteral)</td>
<td>Outpatient/inpatient</td>
</tr>
<tr>
<td>Severe</td>
<td>Initial parenteral, switch to oral when possible</td>
<td>Inpatient, then outpatient</td>
</tr>
</tbody>
</table>

**Figure 1.** Schematic diagram of cross-section of the foot. Numbers 1–5 indicate metatarsal bones. A, central plantar space; B, deep interosseous space; C, lateral plantar space; D, medial plantar space (255, 256).
**Do**

- Obtain an appropriate specimen for culture from almost all infected wounds
- Cleanse and debride the wound before obtaining specimen(s) for culture
- Obtain a tissue specimen for culture by scraping with a sterile scalpel or dermal curette (curettage) or biopsy from the base of a debrided ulcer
- Aspirate any purulent secretions using a sterile needle and syringe
- Promptly send specimens, in a sterile container or appropriate transport media, for aerobic and anaerobic culture (and Gram stain, if possible)

**Do not**

- Culture a clinically uninfected lesion, unless for specific epidemiological purposes
- Obtain a specimen for culture without first cleansing or debriding the wound
- Obtain a specimen for culture by swabbing the wound or wound drainage
<table>
<thead>
<tr>
<th>Infection Severity</th>
<th>Probable Pathogen(s)</th>
<th>Antibiotic Agent</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild (usually treated with oral agent(s))</td>
<td><em>Staphylococcus aureus</em> (MSSA); <em>Streptococcus spp</em></td>
<td>Dicloxacillin</td>
<td>Requires QID dosing; narrow-spectrum; inexpensive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clindamycin&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Usually active against community-associated MRSA, but check macrolide sensitivity and consider ordering a “D-test” before using for MRSA. Inhibits protein synthesis of some bacterial toxins</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cephalexin&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Requires QID dosing; inexpensive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Levofloxacin&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Once-daily dosing; suboptimal against <em>S. aureus</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Amoxicillin-clavulanate&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Relatively broad-spectrum oral agent that includes anaerobic coverage</td>
</tr>
<tr>
<td></td>
<td>Methicillin-resistant <em>S. aureus</em> (MRSA)</td>
<td>Doxycycline</td>
<td>Active against many MRSA &amp; some gram-negatives; uncertain against streptococcus species</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Trimethoprim/sulfamethoxazole</td>
<td>Active against many MRSA &amp; some gram-negatives; uncertain activity against streptococci</td>
</tr>
<tr>
<td>Classification</td>
<td>Pathogens</td>
<td>Treatment Options</td>
<td>Dosing Strategy</td>
</tr>
<tr>
<td>----------------</td>
<td>-----------</td>
<td>------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Moderate (may be treated with oral or initial parenteral agent[s]) or severe (usually treated with parenteral agent[s])</td>
<td>MSSA; Streptococcus spp; Enterobacteriaceae; obligate anaerobes</td>
<td>Levofloxacin&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Once-daily dosing; suboptimal against <em>S. aureus</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cefoxitin&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Second-generation cephalosporin with anaerobic coverage</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ceftriaxone</td>
<td>Once-daily dosing, third-generation cephalosporin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ampicillin-sulbactam&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Adequate if low suspicion of <em>P. aeruginosa</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moxifloxacin&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Once-daily oral dosing. Relatively broad-spectrum, including most obligate anaerobic organisms</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ertapenem&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Once-daily dosing. Relatively broad-spectrum including anaerobes, but not active against <em>P. aeruginosa</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tigecycline&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Active against MRSA. Spectrum may be excessively broad. High rates of nausea and vomiting and increased mortality warning. Nonequivalent to ertapenem + vancomycin in 1 randomized clinical trial</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Levofloxacin&lt;sup&gt;b&lt;/sup&gt; or ciprofloxacin&lt;sup&gt;b&lt;/sup&gt; with clindamycin&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Limited evidence supporting clindamycin for severe <em>S. aureus</em> infections; PO &amp; IV formulations for both drugs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Imipenem-cilastatin&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Very broad-spectrum (but not against MRSA); use only when this is required. Consider when ESBL-producing pathogens suspected</td>
</tr>
<tr>
<td>Infection Severity</td>
<td>Probable Pathogen(s)</td>
<td>Antibiotic Agent</td>
<td>Comments</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>-----------------------------------------------------------</td>
<td>-----------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>MRSA, Enterobacteriaceae, <em>Pseudomonas</em>, and obligate anaerobes</td>
<td>MRSA</td>
<td>Vancomycin&lt;sup&gt;a&lt;/sup&gt;, ceftazidime, cefepime, <em>piperacillin-tazobactam</em>&lt;sup&gt;b&lt;/sup&gt;, aztreonam&lt;sup&gt;b&lt;/sup&gt; or a carbapenem&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Very broad-spectrum coverage; usually only used for empiric therapy of severe infection. Consider addition of obligate anaerobe coverage if ceftazidime, cefepime, or aztreonam selected. Expensive; increased risk of toxicities when used &gt;2 wk.</td>
</tr>
<tr>
<td>MRSA</td>
<td>Linezolid&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Daptomycin&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td>Once-daily dosing. Requires serial monitoring of CPK</td>
</tr>
<tr>
<td></td>
<td>Vancomycin&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td>Vancomycin MICs for MRSA are gradually increasing</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td><em>Pseudomonas aeruginosa</em></td>
<td><em>Piperacillin-tazobactam</em>&lt;sup&gt;b&lt;/sup&gt;</td>
<td>TID/QID dosing. Useful for broad-spectrum coverage. <em>P. aeruginosa</em> is an uncommon pathogen in diabetic foot infections except in special circumstances (2).</td>
</tr>
</tbody>
</table>
DIABETIC FOOT OSTEOMYELITIS (DFO)
Table 9. In Which Situations Is Diagnostic Bone Biopsy Most Recommended?

- Patient or provider prefers definitive diagnosis to justify choice of early surgery in favor of prolonged treatment
- Cultures of soft tissue or blood suggest high risk of osteomyelitis with antibiotic-resistant organism(s)
- There is progressive bony deterioration or persistently elevated inflammatory markers during empiric or culture-directed therapy (should consider surgical resection)
- Suspect bone is a planned target for insertion of orthopaedic metalware
<table>
<thead>
<tr>
<th>Bone or joint</th>
<th>Parenteral or oral</th>
<th>...</th>
<th>2–5 d</th>
</tr>
</thead>
<tbody>
<tr>
<td>No residual infected tissue (eg, postamputation)</td>
<td>Parenteral or oral</td>
<td>...</td>
<td>1–3 wk</td>
</tr>
<tr>
<td>Residual infected soft tissue (but not bone)</td>
<td>Initial parenteral, then consider oral switch</td>
<td>...</td>
<td>4–6 wk</td>
</tr>
<tr>
<td>Residual infected (but viable) bone</td>
<td>Initial parenteral, then consider oral switch</td>
<td>...</td>
<td>≥3 mo</td>
</tr>
<tr>
<td>No surgery, or residual dead bone postoperatively</td>
<td>Initial parenteral, then consider oral switch</td>
<td>...</td>
<td></td>
</tr>
</tbody>
</table>
Assessment Non-Infected Lower Extremity Wound

- Off loading
- Edema control
- Metabolic Control
- Nutrition
- Biopsy?

**Non Ischemic**
- DFU
- VLU
- PU

**Ischemic**
- Arterial ulcer
- DFU + Arterial ischemia
- VLU + Arterial ischemia
- PU + Arterial ischemia
- Surgical wound /Trauma + Arterial ischemia

Surgical wound /Trauma

Non Loma Linda Health
Limb Preservation Program
Clinical Services
<table>
<thead>
<tr>
<th>Origin</th>
<th>Cause</th>
<th>Location</th>
<th>Pain</th>
<th>Appearance</th>
<th>Role of revascularization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial</td>
<td>Severe PAD, Buerger’s disease, Venous insufficiency</td>
<td>Toes, foot, ankle</td>
<td>Severe</td>
<td>Various shape, pale base, dry Irregular, pink base, moist</td>
<td>Important</td>
</tr>
<tr>
<td>Venous</td>
<td>Venous insufficiency</td>
<td>Malleolar, esp. medial</td>
<td>Mild</td>
<td>Irregular, pink base</td>
<td>None</td>
</tr>
<tr>
<td>Mixed venous/arterial</td>
<td>Venous insufficiency + PAD</td>
<td>Usually malleolar</td>
<td>Mild</td>
<td>Irregular, pink base</td>
<td>If non-healing</td>
</tr>
<tr>
<td>Skin infarct</td>
<td>Systemic disease, embolism</td>
<td>Lower third of leg, malleolar</td>
<td>Severe</td>
<td>Small, often multiple</td>
<td>None</td>
</tr>
<tr>
<td>Neuropathic</td>
<td>Neuropathy from diabetes, vitamin deficiency, etc</td>
<td>Foot/plantar surface (weight-bearing), associated deformity</td>
<td>None</td>
<td>Surrounding callus, often deep, infected</td>
<td>None</td>
</tr>
<tr>
<td>Neuroischemic</td>
<td>Diabetic neuropathy + ischemia</td>
<td>Locations common to both ischemic and neuroischemic As arterial</td>
<td>Reduced due to neuropathy</td>
<td>As arterial</td>
<td>As arterial</td>
</tr>
</tbody>
</table>
Above Foot Ulcers

- Diabetic (neuropathic or neuroischemic)
- Multifactorial
- Mixed arterial venous
- Arterial
- Venous
- Other
Ischemic

Lower extremity wound

Revascularization

Conservative

Primary Amputation

Palliative Limb Care
### Treatment Pathways Selection Criteria

<table>
<thead>
<tr>
<th>Revascularization</th>
<th>Conservative</th>
<th>Primary Amputation</th>
<th>Palliative Limb Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI &lt; 0.9</td>
<td>ABI &lt; 0.9</td>
<td>ABI &lt; 0.9</td>
<td>ABI &lt; 0.9</td>
</tr>
<tr>
<td>TcPO$_2$ &lt; 30mmHg</td>
<td>TcPO$_2$ &gt; 30mmHg</td>
<td>Major non salvageable tissue loss</td>
<td>Co-morbidity expected to lead to mortality prior to need for amputation</td>
</tr>
<tr>
<td>Fit</td>
<td>Active pedal sepsis</td>
<td>No anatomical targets vessel</td>
<td>Not candidate revascularization</td>
</tr>
<tr>
<td>Suitable target vessel</td>
<td>No rest pain</td>
<td>Low maintenance wound</td>
<td></td>
</tr>
</tbody>
</table>

Stratification

Intention to Treat Pathway

**Revascularization**
Expectation of healing after correcting ischemia

**Conservative**
Expectation of healing without correcting ischemia (ischemia deemed mild)

**Primary Amputation**
Non-salvageable extremity due to extensive tissue loss with or without pedal sepsis

**Palliative Limb Care**
No expectation of healing due to major comorbidities, High predicted mortality Wound does not affect QoL

Loma Linda Health
Limb Preservation Program
Clinical Services
Clinical Research

Long-Term Outcome of Patients with Peripheral Arterial Disease and Tissue Loss Stratified to a Nonrevascularization Approach

Isabella Possagnoli, Christian Bianchi, Jason Chiriano, Theodore Teruya, Vicki Bishop, and Ahmed Abou-Zamzam, Loma Linda, California

Seminars in Vascular Surgery
Volume 28, Issues 3–4, September–December 2015, Pages 184–189
SI: Wound Care in the Vascular Surgery Patient

Clinical outcomes of patients with peripheral artery disease and lower extremity wounds based on a predetermined intention-to-treat strategy

Table 1 – Baseline characteristics by intention to treat.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Revascularization</th>
<th>Medical</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y, mean ± SD</td>
<td>66.3 ± 7.9</td>
<td>67.5 ± 8.6</td>
<td>.04</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td>.05</td>
</tr>
<tr>
<td>Male</td>
<td>193 (98)</td>
<td>183 (100)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>4 (2)</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>140 (71.1)</td>
<td>130 (71)</td>
<td>.99</td>
</tr>
<tr>
<td>Hispanic</td>
<td>27 (13.7)</td>
<td>30 (16.4)</td>
<td>.46</td>
</tr>
<tr>
<td>African American</td>
<td>27 (13.7)</td>
<td>17 (9.3)</td>
<td>.17</td>
</tr>
<tr>
<td>Other</td>
<td>3 (1.5)</td>
<td>6 (3.3)</td>
<td>.26</td>
</tr>
<tr>
<td>Comorbidities, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HTN</td>
<td>180 (91.4)</td>
<td>174 (95)</td>
<td>.15</td>
</tr>
<tr>
<td>DM</td>
<td>153 (77.7)</td>
<td>151 (82.5)</td>
<td>.23</td>
</tr>
<tr>
<td>Lipids</td>
<td>171 (86.8)</td>
<td>150 (82)</td>
<td>.19</td>
</tr>
<tr>
<td>Active tobacco</td>
<td>70 (35.5)</td>
<td>38 (20.8)</td>
<td>.01</td>
</tr>
<tr>
<td>ESRD</td>
<td>26 (13.2)</td>
<td>24 (13.1)</td>
<td>.98</td>
</tr>
<tr>
<td>CKD</td>
<td>46 (23.4)</td>
<td>48 (26.2)</td>
<td>.51</td>
</tr>
<tr>
<td>Noninvasive test, mean ± SD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABI</td>
<td>0.64 ± 0.24</td>
<td>0.77 ± 0.20</td>
<td>.001</td>
</tr>
<tr>
<td>TcPO₂</td>
<td>36 ± 20</td>
<td>48 ± 16.1</td>
<td>.001</td>
</tr>
<tr>
<td>Ankle pressure</td>
<td>90 ± 39</td>
<td>112 ± 38</td>
<td>.001</td>
</tr>
</tbody>
</table>

Abbreviations: ABI, ankle-brachial index; CKD, chronic kidney disease; DM, diabetes mellitus; ESRD, end-stage renal disease; HTN, hypertension; SD, standard deviation.
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Revascularization, n (%)</th>
<th>Medical, n (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound location</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forefoot</td>
<td>205 (77.1)</td>
<td>175 (75.8)</td>
<td>.73</td>
</tr>
<tr>
<td>Heel</td>
<td>39 (14.7)</td>
<td>47 (20.3)</td>
<td>.09</td>
</tr>
<tr>
<td>Leg</td>
<td>22 (8.3)</td>
<td>9 (3.9)</td>
<td>.04</td>
</tr>
<tr>
<td>Wound type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ulcer</td>
<td>143 (53.8)</td>
<td>185 (80.1)</td>
<td>.001</td>
</tr>
<tr>
<td>SSW</td>
<td>16 (6)</td>
<td>15 (6.5)</td>
<td>.8</td>
</tr>
<tr>
<td>Wet gangrene</td>
<td>96 (36.1)</td>
<td>22 (9.5)</td>
<td>.001</td>
</tr>
<tr>
<td>Dry gangrene</td>
<td>11 (4.1)</td>
<td>9 (3.9)</td>
<td>.89</td>
</tr>
</tbody>
</table>
### Table 4 - Comparative analysis of outcomes by treatment strategy.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Revascularization</th>
<th>Medical</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healed, n (%)</td>
<td>178 (67)</td>
<td>165 (71)</td>
<td>.52</td>
</tr>
<tr>
<td>Time to heal, mo, mean ± SD</td>
<td>6.8 ± 6.3</td>
<td>4.1 ± 3.9</td>
<td>.0001</td>
</tr>
<tr>
<td>Failed, n (%)</td>
<td>62 (23.3)</td>
<td>50 (21.6)</td>
<td>.52</td>
</tr>
<tr>
<td>Active, n (%)</td>
<td>26 (9.8)</td>
<td>16 (6.9)</td>
<td>—</td>
</tr>
<tr>
<td>Recurrence, n (%)</td>
<td>47 (32)</td>
<td>64 (43)</td>
<td>.041</td>
</tr>
</tbody>
</table>
Comprehensive follow up

Wound Protocol

Environment
- Mechanical: Proper Edema-Bioburden control- Proper Off loading
- Metabolic: HbA1c, anemia, Alb > 3.5 mg/dl, Vitamines

Basic wound care
- Debridement
- Dressings
  Bi-Weekly trajectory monitoring (Goal: 50 Percent reduction @ 4 weeks)

Advanced wound care
- DHACM/NPW/Others
• Long term Vascular Surveillance

• DUS 1 mo, 3 Mo, 6mo, 12mo, 18 mo, 24 mo, 36 mo, 48 mo

Guidelines of re interventions:

- High – low velocities after Venous bypass: Regardless clinical status => Re-intervention

- Occluded bypass: If clinical no resolution or recurrence => Re intervention.
  No clinical recurrence => No re intervention.

- Occluded ANY ENDO: No clinical recurrence: No reintervention.

- High – low velocities after ANY ENDO: If clinical no resolution or recurrence => Re-intervention.
  : No clinical recurrence: Stents => Consider ISR protocol
  Other => No Re-intervention
Role of Surgery in Critical Limb Ischemia

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Loma Linda VA Healthcare System
Role Of Surgery in CLI

Surgical Technique 101

Bypass
Endarterectomy
Remote Endarterectomy
Surgical Technique 101

Types of Conduits

Greater saphenous vein
Arm vein
Prosthetic Conduit
Allograft conduits
Surgical Technique 101

Vein Bypass

In-situ
Non reverse
Reverse
Why Vein?
- Autogenous vein is non-thrombogenic
- Active secretion of prostacyclin and nitrous oxide
Role Of Surgery in CLI

Surgical Technique

- Identifies bifurcated systems (~35% cases)
- Identifies major tributaries
Role Of Surgery in CLI

Surgical Technique
2) Cut First Valve Under Direct Vision

1. Dissect and control the CFA and GSV.
2. Cut any valves within 2-3cm under direct vision – the ELV will not.
3. Perform the proximal anastomosis after valves are cut.
3) Dilate the Saphenous Vein

Although not necessary, this step will reduce the chance of “sleeper valves” that get missed during the first pass.
4) Advance ELV in Closed Position

Holding the ELV straight (uncoiled), flush the ELV with heparinized saline and test that the blades can open and close prior to insertion.
Role Of Surgery in CLI

Surgical Technique

5) Open Blades 2cm Below Anastomosis

1. Pin Green

2. Pull White

CAUTION: Advancing the blades into the proximal anastomosis will cause damage.
Surgical Technique

6) Pull Back ELV Slowly Until Green Stripe

- Speed allows blood to engage valves before being cut.
- Closing blades after green stripe prevents damaging end of vein.
7) Identify & Tie Off Major Side Branches

1. Distal end of arterialized vein clamped
2. Doppler placed on vessel 4-6cm below proximal anastomosis
3. Finger compresses vessel, moving distally until flow detected
4. Only tie off side branches connecting to the deep vein system
8) Repeat a Second Pass with ELV

Valves downstream of side branches may not have been properly cut on the first pass. The second pass guarantees complete valvulotomy.
9) Complete Distal Anastomosis

A LeMills Valvulotome (included with all 1.5mm ELV’s) can be used to cut the final set of valves prior to completing the distal anastomosis.
Role Of Surgery in CLI

Surgical Technique
Reverse configuration
Tunneling issues
Mismatch
No valve lysis required
Remote SFA Endarterectomy

- Hybrid vascular procedure using both surgical and endovascular skills
- Adds another revascularization option to patients with limited conduit.
- Decreases chance for infection
Remote Endarterectomy Steps

Step 1: Identify the End Point (re-entry)
Remote Endarterectomy Steps

Step 2: Common femoral endarterectomy and Proximal SFA development

Core
Remote Endarterectomy Steps

Step 3: Dissection / Transection of SFA core

Vollmar Dissector
Remote Endarterectomy Steps

Step 3: Core Removal

*EndoHelix is not always necessary for core removal
Remote Endarterectomy

Atherectomy

366 mg

Remote Endarterectomy

9.3 grams
Remote Endarterectomy Steps

Step 4: End Point Management*

*Periscope is not always necessary for end point management
Partial vs. Complete Debulking

PTA, Laser, Atherectomy = plaque burden remains

EndoRE = Debulking, complete plaque removal
Remote Endarterectomy Steps
Step 5: Arteriotomy closure
Remote Endarterectomy Postoperative management

- Dual Anti-platelet therapy (ASA & Plavix) 3 months (single for life)
- Statins (Life long)
- Duplex ultrasound surveillance (similar Vein bypass)
- Pletal?
Role Of Surgery in CLI
## Impact

<table>
<thead>
<tr>
<th>Survival</th>
<th>Limb</th>
<th>QoL</th>
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<tbody>
<tr>
<td>Hemodynamic</td>
<td>Amputation</td>
<td>Wound</td>
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<tr>
<td>Primary</td>
<td>Free survival</td>
<td>Percentage Healing</td>
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<tr>
<td>Patency</td>
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<td>Pain reduction, Infection</td>
</tr>
<tr>
<td>TLR</td>
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<td>Reintervention</td>
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<td>Recurrence prevention</td>
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<tr>
<td>Free survival</td>
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<td>Minor amputation reduction</td>
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<tr>
<td></td>
<td></td>
<td>Economic burden</td>
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<tr>
<td></td>
<td></td>
<td>Improved function</td>
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</tbody>
</table>
A thoughtful but aggressive approach to care of patients with critical limb ischemia (CLI) is required to alleviate lower-extremity pain/tissue injury and achieve durable limb salvage.

The approach to the treatment of critical limb ischemia (CLI) has evolved with many opting to perform revascularization using an “endovascular first” philosophy.

There is definite role for infrainguinal arterial surgery

Preferred approach after failed endovascular therapy

Who benefits from an “open first” approach.
Evidence of Bypass first (n = 228 BPS vs. 224 BAP)

- Bypass versus angioplasty in severe ischemia of the leg (BASIL): multicentre, randomized controlled trial
  

- Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial: An intention-to-treat analysis of amputation-free and overall survival in patients randomized to a bypass surgery-first or a balloon angioplasty-first revascularization strategy
  
BASIL trial

- Bypass Surgery vs. BAP at 2.5 years lead similar short term clinical outcomes.
- Although Bypass surgery was one third more expensive and the morbidity was higher.

- No significant difference in Amputation Free survival or Overall survival

- However, in patients who survive >2 years after randomization, Bypass Surgery first was associated with a significant increased in Overall survival and a trend towards improved Amputation Free survival
A total of 104 patients with BTK pattern. 56 randomized to BTK Vein Bypass, and 48 to BTK POBA.

There were no statistically significant differences in Amputation Free Survival or OS.

Patients allocated to Vein Bypass demonstrated significantly quicker relief of rest pain when compared with POBA ($p = .005$), but no significant differences in improved tissue healing.

Median length of index hospital admission was significantly greater in the Vein Bypass than in the POBA group (18 vs. 10 days, $p < .0001$).
Evidence of Bypass first

Loma Linda University
Limb Preservation Program

Role Of Surgery in CLI

Health

From the Society for Clinical Vascular Surgery

Results for primary bypass versus primary angioplasty/stent for lower extremity chronic limb-threatening ischemia

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective nonrandomized single-institution study
- **Take Home Message:** Among 1336 first-time lower extremity revascularizations, open bypass had improved wound healing and fewer restenoses and reinterventions, and it had increased survival at 3 years compared with endovascular treatment.
- **Recommendation:** The authors suggest consideration of open bypass first in patients with critical limb ischemia and not endovascular repair.

![Graph 1](image1)

**Fig 6.** Freedom from reintervention, major amputation, or stenosis (RAS events) after any first-time revascularization.

![Graph 2](image2)

**Fig 7.** Overall survival after any first-time revascularization.
The trial will enroll 1,620 patients single-segment GVS & 480 who do not. Randomized in a 1:1 fashion to either endovascular therapy or surgical bypass.

**Primary endpoint** is major adverse limb event–free survival, an endpoint that includes both above-ankle amputation and major reintervention.

**Secondary endpoints** include evaluation of minor reinterventions, hemodynamic success, and clinical success, cost-effectiveness component, functional status and quality of life.
BASIL-2

- Launched in spring 2014
- Randomize 600 pts with below knee disease and severe limb ischemia
- Best endovascular therapy vs vein graft bypass
- Primary endpoint – rate of amputation-free survival at 33 months
Remote Endarterectomy Versus Supragenicular Bypass Surgery for Long Occlusions of the Superficial Femoral Artery: Medium-Term Results of a Randomized Controlled Trial (The REVAS Trial)

**Conclusion:** RSFAE is a minimally invasive option for surgical repair of TASC C and D superficial femoral artery obstructions, with assisted primary and secondary patency rates comparable with bypass surgery. Venous bypass grafting is superior to both RSFAE and polytetrafluoroethylene grafting, but only 45% of patients had a sufficient saphenous vein available. If the saphenous vein is not applicable, RSFAE should be considered because it is less invasive and prosthetic graft material can be avoided.
Randomized controlled trial of remote endarterectomy versus endovascular intervention for TransAtlantic Inter-Society Consensus II D femoropopliteal lesions

Robertato Gabrielli, MD, PhD,a Maria Sofia Rosati, MD, PhD,b Silvio Vitale, MD,a Giulia Baciarello, MD,b Andrea Siani, MD, PhD,a Roberto Chiappa, MD,a Giovanni Caselli, MD,a and Luisa Irace, MD, PhD,a Rome, Italy.

Conclusions: RE is a safe, effective, and durable procedure for TASC-II D lesions. Our data demonstrate a significantly higher primary, assisted primary, and secondary patency of RE vs ENDO procedures. Furthermore, overall secondary patency rates remain within the standard limits, although preoperative CLI and dyslipidemia continue to be associated with worse outcomes. Taken together, these data suggest that RE should be considered better than an endovascular procedure in SFA long-segment occlusion treatment. (J Vasc Surg 2012;56:1598-605.)
Prior failed ipsilateral percutaneous endovascular intervention in patients with critical limb ischemia predicts poor outcome after lower extremity bypass.

Conclusions: Prior iPVI is highly predictive for poor outcome in patients undergoing LEB for CLI with higher 1-year amputation and graft occlusion rates than those without prior revascularization, similar to prior ipsilateral bypass. These findings provide information, which may help with the complex decisions surrounding revascularization options in patients with CLI. (J Vasc Surg 2011;54:730-6.)
Impact of femoropopliteal endovascular interventions on subsequent open bypass.

Amputation-free survival of bypass grafts after failed endovascular intervention.

Primary patency of bypass grafts after failed endovascular intervention.

CONCLUSIONS

The endovascular-first approach to treat patients with claudication and CLI has been adopted with widespread acceptance. Subsequent conversion to an OBP operation is necessary in a low number of patients. Nevertheless, these interventions are complicated with more distal bypass targets in nearly half of patients and ultimately complicate lower limb salvage and primary patency rates. Although current data on this subject are not entirely conclusive, it is prudent to take this into consideration during the decision-making process when treating patients with chronic atherosclerotic peripheral arterial disease.
In relatively fit patients expected to live > 2 years the apparent improved durability and reduced reintervention rate of open surgical bypass could outweigh the short-term considerations of increase of morbidity especially in those with an available and suitable single segment greater saphenous vein conduit.
Factors Leaning toward Open Bypass

Life expectancy of 2 years

Major Tissue loss

Anatomic Pattern consistent with multilevel disease with large burden per segment (Tasc C or D)

Good quality venous conduit

Failed endovascular intervention
Most of us, are biased towards endovascular approach, but we need to continue to support it scientific application while treating today’s patients.
“To preserve limb integrity, to heal and improve our patients’ life and health”
Loma Linda Health
Limb Preservation Program
Clinical Services
Interventional Branch

• Access LLUMC, HSH

• Equipment (toll box)

• RN/Tech support
To preserve limb integrity, to heal and improve our patients' life and health
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Loma Linda Health
Limb Preservation Program
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