Global Vascular Guideline for the Management of Chronic Limb-Threatening Ischemia: Prelude

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• NO DISCLOSURES

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Rationale for a Global Vascular Guideline in CLTI
• Growing global prevalence of disease and risk factors
• High patient and public health costs
• Diverse specialties/providers and care settings
• Highly variable utilization of vascular interventions
• Wide disparity in outcomes, unclear standard of care
• Continuously evolving technology, shifting practice patterns
• Lack of consensus definitions and disease staging a major limitation to evidence-based medicine and clinical/outcomes research
• Define Key Research Questions
• Foster Evidence-Based Care and Quality Outcomes

Definitions: CLTI

The term critical limb ischemia (CLI) is outdated and fails to encompass the full spectrum of patients who are evaluated and treated for limb-threatening ischemia in modern practice.

Instead, the term chronic limb-threatening ischemia (CLTI) is proposed, in order to include a broader and more heterogeneous group of patients with varying degrees of ischemia that can often delay wound healing and increase amputation risk.
CLTI: spectrum of disease that includes patients with objectively documented PAD and any of the following:

- ischemic rest pain with confirmatory hemodynamic studies,
- diabetic foot ulcer,
- non-healing lower limb or foot ulceration of at least 2 weeks duration,
- gangrene involving any portion of the lower limb or foot

Patients with purely venous ulcers, acute limb ischemia, acute frostbite, ischemia due to emboli, acute trauma, mangled extremity, and those with wounds related to nonatherosclerotic conditions, such as vasculitis, collagen vascular disease, Buerger's disease, neoplastic disease, dermatoses, and radiation may have many underlying causes of their lower extremity disease and these are beyond the scope of these guidelines.

CLTI: criteria for diagnosis

<table>
<thead>
<tr>
<th>Objective documented atherosclerotic PAD</th>
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<tbody>
<tr>
<td>Ischemic rest pain typically described as pain in the mid- and forefoot at rest, often worse with recumbency and relieved by dependency, present for more than 2 weeks</td>
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<tr>
<td>Tissue Loss: diabetic foot ulcer, non-healing lower limb or foot ulceration of at least 2 weeks duration, any gangrene</td>
</tr>
<tr>
<td>ABPI &lt;0.4 (using higher of the DP/PT)</td>
</tr>
<tr>
<td>Absolute highest ankle pressure &lt;50 mmHg</td>
</tr>
<tr>
<td>Absolute toe pressure &lt;30 mmHg</td>
</tr>
<tr>
<td>ToP02 &lt;20 Torr</td>
</tr>
<tr>
<td>Flat pulse volume recording waveforms</td>
</tr>
<tr>
<td>WiFi ischemia score ≥1</td>
</tr>
</tbody>
</table>

Need for Structured Decision Making in CLTI

- PLAN:
  - Patient Risk
  - Limb threat severity: WiFi Staging
  - Anatomic pattern of disease: GLASS system

Limb staging: WiFi

- WiFi stratifies amputation risk according to the Wound, the degree of Ischemia, and presence and severity of foot Infection
- WiFi scores and clinical stages appear to strongly correlate with important clinical outcomes, including those included in SVS Objective Performance Goals (OPG): limb amputation, 1-year amputation free survival, and wound healing time
- WiFi is currently being evaluated in
  - Multi-center trials in the US
  - UK NHR HTA-funded BASIL-2 and BASIL-3 trial
  - SVS VQI (Vascular Quality Initiative) Registry of lower extremity interventions.

Rationale for a new anatomic staging system in CLTI

- Schemes focused on individual lesions (e.g. TASC) or overall burden of disease (e.g. Bollinger) are not useful for defining evidence-based revascularization in CLTI
- Restoration of in-line flow to the foot is a primary technical goal of revascularization in CLTI, particularly in patients with tissue loss
- Factors that determine clinical success for endovascular and open bypass surgery are intrinsically different
**GLASS: Target Artery Path and Limb-Based Patency**

- Restoration of in-line flow to the ankle and foot is a primary goal.
- Target artery path (TAP): the selected continuous route of in-line flow from groin to ankle.
- TAP usually involves the least diseased IP artery; may be angiosome-based.
- Limb-based patency (LBP): maintained patency of the TAP. Lost when:
  - Occlusion, critical stenosis, or re-intervention affecting any portion of the TAP (anatomical failure), and/or:
  - Fall in ABI (≥ 0.15) or TBI (≥ 0.10), or ≥ 50% stenosis in the TAP, in the presence of recurrent or unresolved clinical symptoms (e.g., rest pain, worsening/persistent tissue loss; signifying hemodynamic failure).

**GLASS: Grades and Stages**

- Determined by expert consensus supported by evidence reviews.
- Grade and Stage are based on lesion complexity for ENDO.
- Combinations of FP and IP Grades were assigned to 3 GLASS Stages for the limb based on the following TAP complexity scale:
  - **Stage I: Average Complexity Disease**
    - expected technical failure < 10% AND >70% 12-month LBP
  - **Stage II: Intermediate Complexity Disease**
    - expected technical failure < 20% AND 50-70% 12-month LBP
  - **Stage III: High Complexity Disease**
    - expected technical failure >20%; OR <50% 12-month LBP

**Benefit of revascularization varies with severity of limb threat and ischemia**

<table>
<thead>
<tr>
<th>Limb Severity (W/ Stage)</th>
<th>Infarct Grade</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>LOW/Nil</td>
</tr>
<tr>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>2</td>
<td>NA</td>
</tr>
<tr>
<td>3</td>
<td>HIGH</td>
</tr>
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**Questions or Comments?**