What Factors predict success after Open and Endo revascularization for patients with wounds?

Joseph L. Mills, Sr., M.D.
Professor of Surgery, Chief, Vascular & Endovascular Surgery
University of Arizona Health Sciences Center
Co-Director, SALSA

I have no conflicts of interest to disclose.

However, I do admit to being Bivascular. I like Open and Endo!

Three spheres influence outcome:

- **Limb status:**
  - Wound, Wound, Ischemia and foot infection
  - Disease burden: Ancestral/TNM

- **Patient status:**
  - Current risk factor/Comorbidity index

- **Anatomic status:**
  - Based on length, type, multiplicity of arterial lesions
  - Need a simplified version of
  - Grading of stenosis or
  - Boiling score
  - Need to be presented in a matrix & not side-by-side

Figure 2: Adjusted prevalence rate of diabetes mellitus in adults in selected countries of the Americas (1)
Diabetic Foot Complications

- Diabetes is diagnosed once every 17 seconds!
- Up to 70% of the lower extremity amputations in the world are associated with diabetes
- Every 20 seconds, somewhere in the world, a lower extremity is amputated in a patient with diabetes

Demography is Destiny

- Fontaine and Rutherford are pure ischemia models; the concept of CLI was never intended to be applied to diabetics
- Global epidemic of diabetes; emerging evidence that etiology of foot ulcers in these patients has changed over the last 2 decades from primarily neuropathic to neuroischemic and purely ischemic
- Neuropathy, wound characteristics and infection complicate management
- Eurodiale: PAD + infection TRIPLES amputation risk
- Our patients have changed but our classification system has not

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LIMB status
What is critical limb ischemia and how should it be treated?

“The International Working Group on the Diabetic Foot (IWDF) therefore established a multidisciplinary working group, including specialists in vascular surgery, interventional radiology, internal medicine and epidemiology to evaluate the effectiveness of revascularization of the ulcerated foot in patients with diabetes and PAD. The aim of this multidisciplinary working group was to produce a systematic review on the efficacy of (endovascular and surgical) revascularization procedures and medical therapies in diabetic patients with a foot ulcer and PAD.”

Unanswered Questions?

- What factors determine the risk of amputation once a patient with diabetes gets a foot ulcer?
- Does revascularization reduce the risk of major limb amputation in patients with diabetes?
- If so, which method of revascularization is most effective and in what settings?
Unanswerable Questions!

- These questions are unanswerable due to the lack of an adequate classification system.
- Vascular classification systems (TASC, Bollinger, and Graziani) myopically focus only on the vascular anatomy, encouraging lesionology.
- Rutherford and Fontaine classifications are inadequate for the diabetic foot.
- “Critical Limb Ischemia” is a flawed concept with limited utility and applicability to the diabetic foot.

“Critical Limb Ischemia”

- Ischemic rest pain and absolute systolic ankle pressure of less than 40 mm Hg.
- Ankle pressure < 60 mm Hg systolic in the presence of superficial necrosis of the foot or digital gangrene involving the base of the phalanx.
- “It was generally agreed that diabetic patients who have a varied clinical picture of neuropathy, ischaemia and sepsis make a definition even more difficult . . . and these patients should be excluded.”
- “Diabetic patients should not be included, or should be clearly defined as a separate category to allow analysis of the results in non-diabetic . . .”

Useful, validated but incomplete classifications

- Wound Depth/Extent
- Wagner Grades
- PEDIS (1-3 scale)
- Texas Wound Classification System
- Ischemia
- Rutherford 4, 5 and 6
- Fontaine 3, 4
- Foot Infection: IDSA (1-4 scale)
SVS Lower Extremity Threatened Limb Classification WIFI Index

- **Wound**: extent and depth
- **Ischemia**: perfusion/flow
- **Foot Infection**: presence and extent

WIFI Classification

- Based upon existing validated systems or best available data with 4 point scales where
  - 0 = none
  - 1 = mild-moderate
  - 2 = moderate-severe
  - 3 = severe

### Wound – Clinical Category

<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 &gt; 10 cm² not involving calcaneus – (Pedis or UT Classes 2 and 3); gangrenous changes limited to digits. Salvageable with multiple digital amputs 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 -

<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>&gt; 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>

ABI=ankle brachial index; SP= systolic pressure; TP= toe pressure; TcpO2=transcutaneous oximetry
WIFI index is intended to be analogous to the TNM staging system for cancer

- A patient with diabetes, a shallow superficial foot ulcer, early cellulitis and an ABI of 0.43 with a TP of 35 mm Hg would be classified as follows:
  - W-1 I-2 FI-1 or WIFI 121
- Utilization of this proposed system would produce a grid of 64 possible combinations of Wound, Ischemia and Infection
- Members of the SVS LE Guidelines Committee and selected experts were asked to classify each possible presentation into one of four classes based on two considerations:

  **Two Distinct Questions**
  - What is the one-year risk of amputation if this limb status were treated with medical therapy alone (i.e., natural history of the condition)?
  - What is the likelihood the patient would benefit from or require revascularization in order to heal?

**Grid Consensus Process**

- **Class I - Very Low**
- **Class 2 - Low**
- **Class 3 - Moderate**
- **Class 4 - High**

**Risk of Amputation**

<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>L</td>
<td>M</td>
<td>H</td>
</tr>
<tr>
<td>W-1</td>
<td>M</td>
<td>L</td>
<td>H</td>
</tr>
<tr>
<td>W-2</td>
<td>H</td>
<td>M</td>
<td>L</td>
</tr>
<tr>
<td>W-3</td>
<td>H</td>
<td>H</td>
<td>M</td>
</tr>
</tbody>
</table>

**Very Low = VL = Class or Clinical Stage 1**
**Low = L = Class or Clinical Stage 2**
**Moderate = M = Class or Clinical Stage 3**
**High = H = Class or Clinical Stage 4**
**Benefit of Revascularization**

1. Produces only 11 scenarios where revascularization may benefit
2. Allows examination of interaction of foot infection and ischemia

**Table W I fl Simplified**

<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>V I L L M</td>
<td>L</td>
<td>L M M H M</td>
<td>L L L M H</td>
</tr>
<tr>
<td>W-1</td>
<td>V I L L M</td>
<td>M</td>
<td>L M M H M</td>
<td>L L M M H</td>
</tr>
<tr>
<td>W-2</td>
<td>L L M M H</td>
<td>M</td>
<td>L M M H M</td>
<td>L L M M H</td>
</tr>
<tr>
<td>W-3</td>
<td>M M H H H</td>
<td>M</td>
<td>L M M H M</td>
<td>L L M M H</td>
</tr>
</tbody>
</table>

**PATIENT status**

**Table 1: COMORBIDITY INDEX**

<table>
<thead>
<tr>
<th>Major</th>
<th>Minor</th>
<th>Uncertain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt; 75 years</td>
<td>CHF</td>
<td>Diabetes</td>
</tr>
<tr>
<td>Dialysis (CKD 5)</td>
<td>Multiple ulcers</td>
<td>Smoking</td>
</tr>
<tr>
<td>CAD</td>
<td>AP &lt; 50 (Ischemia 3)</td>
<td>Serum albumin</td>
</tr>
<tr>
<td>Gangrene (W2, W3)</td>
<td>&quot;urgent operation&quot;</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2: MARKERS OF IMPAIRED FUNCTION AND FRAILTY**

<table>
<thead>
<tr>
<th>Marker</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Body Mass Index (BMI)</td>
<td>Body (2010)</td>
</tr>
<tr>
<td>Hematocrit &lt; 30</td>
<td>Prevent III</td>
</tr>
<tr>
<td>Dementia</td>
<td>Taylor (JVS 2006)</td>
</tr>
<tr>
<td>Impaired ambulation (homebound; transfer only)</td>
<td>Taylor (JVS 2006)</td>
</tr>
</tbody>
</table>
Risk Factor – Comorbidity Index

Table 3: RISK STRATIFICATION BY CATEGORY

<table>
<thead>
<tr>
<th>SYSTEMIC</th>
<th>WOUND</th>
<th>HEMODYNAMIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Gangrene (W2 and W3)</td>
<td>Ache pressure &gt;50 mmHg</td>
</tr>
<tr>
<td>CAD</td>
<td>Ulcers, multiple (&gt;2)</td>
<td></td>
</tr>
<tr>
<td>CHF</td>
<td>Number of accessible ulcers</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dementia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impaired ambulation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RCI = Risk Comorbidity Index

1. RCI: RISK/COMORBIDITY INDEX: (Prevent III, Finversd, LEGS, BASIL)
- 1 point each: CAD (MI, angina, PTCA, CABG)
- Age > 75 years
- HCT < 30
- 2 points: Diabetic mellitus
- 3 points: Ulcer
- 4 points each: Gangrene, CKD Stage 5, dialysis dependent
- Systemic toxicity, urgent foot surgery

Low risk (≤ 2 points), Moderate risk (3–5 points), High risk (> 6 points)

Arterial ANATOMY

- TASC I and II mix too many segments, lack sufficient detail
- Bollinger and Graziani classifications are on the right track, but need to be simplified for broader clinical use
- Factors that should be considered include:
  - Occlusion versus stenosis
  - Lesion length
  - Multiplicity of lesions and pattern of disease
  - Degree of Calcification
  - Runoff including pedal circulation for selected cases

Table III. Factors related to critical limb ischemia

<table>
<thead>
<tr>
<th>G1 (%)</th>
<th>G2 (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nerve crush injury grade</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ankle pressure &lt;60 mmHg</td>
<td>0.10</td>
<td>≤0.001</td>
</tr>
<tr>
<td>No congestive heart failure</td>
<td>0.83</td>
<td>0.009</td>
</tr>
<tr>
<td>Stenosis vs multiple stenosis</td>
<td>2.75</td>
<td>≤0.001</td>
</tr>
<tr>
<td>Ulcer or higher grade &gt;1</td>
<td>2.06</td>
<td>≤0.001</td>
</tr>
<tr>
<td>PTA</td>
<td>1.77</td>
<td>≤0.001</td>
</tr>
<tr>
<td>Reconstructive vascular surgery</td>
<td>2.01</td>
<td>≤0.001</td>
</tr>
</tbody>
</table>

G1, evidence graded; G2, evidence class IIa; PTA, percutaneous transluminal angioplasty.
Conclusions:

- The goals of treatment for most patients are relief of ischemic pain, healing of ischemic lesions, and maintenance of ambulatory and independent living status.
- Improvements in percutaneous techniques allow an increasing subset of patients to be treated with minimally-invasive therapy and less attendant morbidity.

Conclusions

- We won’t be able to assess outcomes and relative efficacy of interventions intended to prevent limb amputation in patients with PAD and diabetes without a uniform classification system.
- Wound depth, Ischemia, Foot Infection (WIFI-Index) are the critical factors that need to be considered and graded, much like TNM staging for cancer.
- The WIFI Index is intended to allow assessment, comparison and improvement of outcomes, not to dictate therapy, since therapies change over time.
- A simple Risk Comorbidity Index (RCI) and an Updated practical arterial anatomic classification system will be of added value.