A New Classification System for the Threatened Lower Limb: SVS WIfI

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I have no conflicts of interest to disclose.

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

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

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Critical limb ischemia, first defined in 1982, is intended to delineate a subgroup of patients with a threatened lower extremity primarily because of chronic ischemia. It was the intent of the original authors that patients with diabetes be excluded or analyzed separately. The Fontaine and Rutherford Systems have been used to classify risk of amputation and likelihood of benefit from revascularization by reclassifying patients into two groups: ischemic rest pain and tissue loss. Due to demographic shifts over the last 40 years, especially a dramatic rise in the incidence of diabetes mellitus and rapidly expanding techniques of revascularization, it has become increasingly difficult to perform meaningful outcomes analysis for patients with threatened limbs using these existing classification systems. Particularly in patients with diabetes, limb threat is part of a broad disease spectrum. Perfusion is only one determinant of outcome; wound extent and the presence and severity of infection also greatly impact the threat to a limb. Therefore, the Society for Vascular Surgery Lower Extremity Guidelines Committee undertook the task of creating a new classification of the threatened lower extremity that reflects these important considerations. We term this new framework, the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System. Risk stratification is based on three major factors that impact amputation risk and clinical management: Wound, Ischemia, and foot Infection (WIfI). The implementation of this classification system is intended to permit more meaningful analysis of outcomes for various forms of therapy in this challenging, but heterogeneous population. (J Vasc Surg 2014;59:220-24.)

http://download.journals.elsevierhealth.com/pdfs/journals/0741-5214/PIIS0741521413015152.pdf
Therapy for “CLI”:
The results all depend on:
1. Which patients are included;
2. How you look at them

Three spheres influence outcome:
- **Limb** status:
  - WII: Wound, Ischemia and foot Infection
  - Disease burden: Analogous to TNM
- **Patient** status:
  - Patient Risk Factor/Comorbidity Index
- **Anatomic** status:
  - Based on length, type, multiplicity of arterial lesions
  - Need a simplified version of
    - Graziani classification or
    - Bollinger score
  - TASC I and II are useless clinically & should be forgotten

Diabetes and Prediabetes—42% of the U.S. Adult Population

Approximately 24 to 27 million U.S. citizens ages 20 and older currently suffer from diabetes. In addition to the 13% who already have diabetes, 29% of the population has prediabetes. Refer to Figure 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
- EVERY 20 SECONDS!

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
LIMB status

Rutherford Classification

<table>
<thead>
<tr>
<th>Grade</th>
<th>Category</th>
<th>Clinical diagnosis</th>
<th>Objective criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>Anterior—no hemodynamically significant occlusive disease</td>
<td>Normal treadmill or reactive hyperemia test</td>
</tr>
<tr>
<td>1</td>
<td>Mild classification</td>
<td>Complete tandem duplex, 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>Moderate classification</td>
<td>Complete tandem duplex, endovascular procedures possible</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Severe classification</td>
<td>Complete tandem duplex, endovascular procedures not possible</td>
<td></td>
</tr>
<tr>
<td>II*</td>
<td>4</td>
<td>Ischemic rest pain</td>
<td>Resting AP &lt;40 mm Hg, pain or barely palpable pulses or minimal TcPO2 &lt;15 mm Hg, nonhealing TBI, ulceration or gangrene</td>
</tr>
<tr>
<td>III*</td>
<td>5</td>
<td>Major tissue loss—wandering shin, fixed gangrene, with diffuse cold pulse and TBI &gt;40%</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Major tissue loss—extensive above TM level, necrotic tissue no longer palpable</td>
<td>Same as category 5</td>
<td></td>
</tr>
</tbody>
</table>

AF: Ablation; PVR: pulse volume recording; TBI: toe pressure; TcPO2: transcutaneous oxyhemoglobin.

*Grades II and III: Categories 4, 5, and 6, are considered by the term chronic critical ischemia.

In the management of chronic limb ischemia, a multidisciplinary approach is essential, involving vascular surgeons, internists, and interventional radiologists. The Rutherford Classification provides a framework for grading disease severity, guiding treatment decisions.
What is critical limb ischemia and how should it be treated?

“The International Working Group on the Diabetic Foot (IWDGF) 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)

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SVS

Lower Extremity Threatened Limb Classification

WIFI Index

- Wound: extent and depth
- Ischemia: perfusion/flow
- Foot Infection: presence and extent
The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIFI)

Joseph L. Mills, Sr, MD; Michael S. Conte, MD; David G. Armstrong, DPM, MD, PhD; Frank B. Pomporelli, MD; Andrea Schanzer, MD; Anton N. Sidawy, MD, MPH; and George Andreas, MD, on behalf of the Society for Vascular Surgery Lower Extremity Guidelines Committee, Tacoma, Wash; San Francisco and Van Nuys, Calif; Brighton and Worchester, Mass and Washington, D.C.

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### 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

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### 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 5-10 cm² not involving calcaneus – (Pedis or UT Classes 2 and 3); gangrenous changes limited to digits. Salvageable with multiple digital amputation 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>

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### 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>≥ 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 mm Hg</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 1 - Very Low
- Class 2 - Low
- Class 3 - Moderate
- Class 4 - High

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
Anatomic Classification

- 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

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.

For more information:

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http://Twitter.com/jmills1955