The WIfI System for Threatened Limbs

Let’s take a closer look at SVS’ lower extremity threatened limb classification.

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**Introduction**

Classification systems typically rely on critical limb ischemia (CLI) as the primary criterion to determine the prognosis of threatened lower extremities, to lead clinical decision-making, and to define the disease burden from these conditions. However, existing classification systems, which rely heavily on critical limb ischemia criteria, are not sufficient in addressing all patient populations and presentations, such as patients with type II diabetes mellitus (T2DM). While perfusion is an important consideration, other components such as the presence and severity of infection must be assessed to adequately classify and stratify threatened lower extremities.

Current practices prioritize anatomic characteristics over disease severity. The Society for Vascular Surgery (SVS) Lower Extremity Guidelines Committee created a new framework that includes three main factors: Wound, Ischemia and Foot Infection (WIfI). This system incorporates perfusion along with wound extent and the severity of infection, because current major classification systems, such as the Wagner Grading System, do not include the degree of such characteristics (Figure 2). The WIfI system is not intended to be used as the sole decision-making tool; rather, it aids clinical decision-making by stratifying amputation risk. In addition, this grading system allows for comparison between similar patient populations in order to determine the relative effectiveness of alternative therapies.

Historically, traditional definitions of ischemia have not easily translated for patients with T2DM.

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Figure 1: Ring of dominance to determine the patient’s most pressing condition: infection, ischemia, tissue loss or a combination.

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Wound Grades

Classification from 0 to 3 depends on the size, depth, severity and wound-healing ability. Grade 0 indicates lack of wounds. Grades from 1 to 3 are assigned by increasing level of tissue loss as well as increased complexity of the treatment procedure required. Grade 1 includes small ulcers with no indication of gangrene, while grade 3 includes extensive ulcers and gangrene. Gangrene cases that would prevent salvage of limbs are excluded from this classification.1

Ischemia Grades

Grading for ischemia is based on the ankle-brachial index (ABI). Patients with ABI > 0.8 would be considered grade 0 for ischemia. Patients

Based on the cumulative scores from each category, patients are stratified into one of four clinical stages.

TABLE I:
The University of Texas Classification Combines Grades and Stages for Wounds

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>I</th>
<th>II</th>
<th>III</th>
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</thead>
<tbody>
<tr>
<td>A</td>
<td>areas of pressure which are sometimes called pre-ulcerative lesion</td>
<td>superficial ulcer not including tendon, capsule or bone</td>
<td>deep ulcer including tendon, capsule but not bone</td>
<td>deep ulcer including bone and articulation</td>
</tr>
<tr>
<td>B</td>
<td>infection</td>
<td>infection</td>
<td>infection</td>
<td>infection</td>
</tr>
<tr>
<td>C</td>
<td>ischemia</td>
<td>ischemia</td>
<td>ischemia</td>
<td>ischemia</td>
</tr>
<tr>
<td>D</td>
<td>infection + ischemia</td>
<td>infection + ischemia</td>
<td>infection + ischemia</td>
<td>infection + ischemia</td>
</tr>
</tbody>
</table>

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with ABI < 0.4 would be considered grade 3. Grades 1 and 2 are reserved for patients with intermediate perfusion deficits (between 0.4 and 0.8). TP or TcPO2 measurements may also be used when ABI may not be reliable such as with diabetics or the elderly.1

Infection Grades

Grades for infection severity would be based on clinical observations where grade 3 refers to infections causing systemic or metabolic toxicity.1 Figure 3 provides an example of a non-infected wound, whereas Figure 4 provides an example of a wound with both infection and ischemia. One accepted classification system that outlines such ischemia and infection grades is the University of Texas Classification System (Table 1).

Results

The goal of the WIfI classification system has been to define a more accurate representation of disease conditions, through assigned grades and stages, in order to better inform patient care decisions.1 A variety of studies have evaluated the WIfI criteria and clinical stages since the system’s development to assess its correlation with relevant clinical markers and its predictive ability for major outcomes; thus far, a majority of studies have affirmed and validated the WIfI classification system as an effective and precise tool for assessing many aspects of lower extremity threatened limbs including risk of major amputation, wound healing time (WHT), and one-year amputation free survival (AFS) rate.

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A number of studies have sought to determine if the WIfI system is predictive of and correlates undergoing any revascularization procedures and the percentage of limbs undergoing minor amputation increased significantly with each increasing WIfI stage; more specifically, the use of endovascular and open revascularization procedures increased significantly by stage in addition to the mean number of minor amputation procedures required per limb.1 Moreover, the percentage of limbs which achieved complete wound healing decreased significantly with each increasing WIfI clinical stage, highlighting a decreased rate of healing and an increase in WIfI stage.

This study also performed Kaplan-Meier analyses of the one-year AFS rate decreased, and WHT is prolonged.4 These two studies confirmed that the WIfI clinical stage predictions parallel the outcomes of the actual patients. A final clinical study stratified limbs according to WIfI stage and concluded with the following results. The percentage of limbs undergoing any revascularization procedures and the percentage of limbs undergoing minor amputation increased significantly with each increasing WIfI stage; more specifically, the use of endovascular and open revascularization procedures increased significantly by stage in addition to the mean number of minor amputation procedures required per limb.1 Moreover, the percentage of limbs which achieved complete wound healing decreased significantly with each increasing WIfI clinical stage, highlighting a decreased rate of healing and an increase in WIfI stage.

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Wound Management

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Year limb salvage rates and found significant differences between the stages (Stage 1: 96%, stage 2: 84%, stage 3: 90% and stage 4: 78%). Finally, an increased WIfI stage was associated with a decreased one-year AFS rate for comparing different treatment and therapy options and outcomes, including limb treatment procedures and the likelihood of limb salvage.

**Numerous studies have demonstrated that WIfI is able to effectively stratify heterogeneous patient populations with limb-threatening conditions and predict major clinical outcomes in a standardized fashion.**

(Stage 1: 84%, stage 2: 75%, stage 3: 80%, and stage 4: 69%). Thus, this study affirmed that the different WIfI clinical stages correlate with distinctions in patient outcomes, including limb treatment procedures and the likelihood of limb salvage.

**Discussion**

An analysis of the WIfI system and review of recent literature assessing its merits strongly demonstrate that the tool is both effective at predicting major outcomes and correlates with relevant clinical outcomes. Numerous studies have demonstrated that WIfI is able to effectively stratify heterogeneous patient populations with limb-threatening conditions and predict major clinical outcomes in a standardized fashion.2,3,4

Early studies also indicate that the WIfI system may correlate with more patient-centered outcomes including ambulatory status, independent living status, and the likelihood of complete wound healing.5 Ultimately, these studies support WIfI as a promising tool not only for use in clinical decision-making to guide treatment decisions but also as a new framework to analyze clinical outcomes. This suggests that WIfI can and should be used for comparing different treatment and therapy options in clinical trials as this tool could facilitate the development of new therapies and analyses of existing treatments. Thus, the WIfI classification in uniquely poised to provide more comprehensive assessments of lower extremity threatened limbs and to address the current gaps in clinical tools available for broad, diverse patient populations, including those with T2DM.

**References**