An early validation of the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System

David L. Cull, MD, Ginger Manos, MD, Michael C. Hartley, MD, Spence M. Taylor, MD, Eugene M. Langan, MD, John F. Eidt, MD, and **Brent L. Johnson, MS,** *Greenville, SC*

Objective: **The Society for Vascular Surgery (SVS) recently established the Lower Extremity Threatened Limb Classification System, a staging system using Wound characteristic, Ischemia, and foot Infection (WIfI) to stratify the risk for limb amputation at 1 year. Although intuitive in nature, this new system has not been validated. The purpose of the following study was to determine whether the WIfI system is predictive of limb amputation and wound healing.**

Methods: **Between 2007 and 2010, we prospectively obtained data related to wound characteristics, extent of infection, and degree of postrevascularization ischemia in 139 patients with foot wounds who presented for lower extremity revascularization (158 revascularization procedures). After adapting those data to the WIfI classifications, we analyzed the influence of wound characteristics, extent of infection, and degree of ischemia on time to wound healing; empirical Kaplan-Meier survival curves were compared with theoretical outcomes predicted by WIfI expert consensus opinion.**

Results: **Of the 158 foot wounds, 125 (79%) healed. The median time to wound healing was 2.7 months (range, 1-18 months). Factors associated with wound healing included presence of diabetes mellitus ($P = .013$), wound location ($P = .049$), wound size ($P = .007$), wound depth ($P = .004$), and degree of ischemia ($P < .001$). The WIfI clinical stage was predictive of 1-year limb amputation (stage 1, 3%; stage 2, 10%; stage 3, 23%; stage 4, 40%) and wound nonhealing (stage 1, 8%; stage 2, 10%; stage 3, 23%; stage 4, 40%) and correlated with the theoretical outcome estimated by the SVS expert panel.**

Conclusions: **The theoretical framework for risk stratification among patients with critical limb ischemia provided by the SVS expert panel appears valid. Further validation of the WIfI classification system with multicenter data is justified. (J Vasc Surg 2014;60:1535-42.)**

The Society for Vascular Surgery (SVS) Lower Extremity Guidelines Committee recently created the Lower Extremity Threatened Limb (Wound Ischemia foot Infection [WIfI]) Classification System, to stratify the risk of limb amputation in the heterogeneous population of patients presenting with critical limb ischemia (CLI).[1] The SVS WIfI classification system was developed by merging the existing CLI and diabetic foot ulcer (DFU) classification systems.[2-8]

The purpose of this classification system was not meant to function as a stand-alone clinical decision-making tool but to allow for better patient stratification in clinical trials designed to compare new strategies for treating CLI. The classification system predicts limb amputation risk based on three graded factors: wound characteristics, the degree of pedal perfusion, and the extent of infection. Owing to a paucity of natural history studies in patients with CLI, the risks of limb amputation within the categories of this new classification system were estimated by a panel of experts using a Delphi consensus process. The theoretical assumptions developed by this panel still await clinical validation.

Our group has long sought to develop a CLI classification system that would help vascular surgeons predict the likelihood of wound healing in patients with CLI and assist them in evaluating patients for possible revascularization.[9] In 2007, borrowing from the same literature used to develop the SVS WIfI classification system, we began collecting data related to wound characteristics, degree of ischemia, and extent of infection on patients presenting with foot wounds; we also monitored them prospectively The similarity of our collected data and the factors used by the SVS WIfI classification system provided a unique opportunity to use our study population to score patients according to the SVS WIfI and to compare actual patient outcomes with those predicted by the SVS panel of experts. Thus, the purpose of this study was to provide early clinical validation of the SVS WIfI classification system.

METHODS

The Greenville Health System Institutional Review Board for the study of human subjects approved this study (IRB #14947). Patient consent was deemed unnecessary.

From the Department of Surgery, University of South Carolina School of Medicine-Greenville, Greenville Health System/University Medical Center.

Author conflict of interest: none.

Presented at the 2014 Vascular Annual Meeting of the Society for Vascular Surgery, Boston, Mass, June 5-7, 2014.

Reprint requests: David L. Cull, MD, Department of Surgery, University of South Carolina School of Medicine-Greenville, Greenville Health System/University Medical Center, 701 Grove Rd, Greenville, SC 29605 (e-mail: dcull@ghs.org).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

http://dx.doi.org/10.1016/j.jvs.2014.08.107

Table I. Comparison of study data categories with the Wound characteristic, Ischemia, and foot Infection (*WIfI*) grades

Study data categories		*WIfI*
Wound characteristics[a]		Wound grade[b]
Wound size		0 No rest pain
1	<1 cm^2	1 Small, shallow ulcer
2	1-3 cm^2	No exposed bone, unless limited to distal phalanx
3	>3 cm^2	No gangrene
Wound depth		2 Deeper ulcer with exposed bone joint, or tendon, not involving the tissue heel
1	Ulcer not extending to SQ	Shallow heel ulcer without calcaneal involvement
2	Ulcer extending to SQ tissue	Gangrenous changes limited to digits
3	Ulcer extending to bone or joint space	3 Extensive, deep ulcer involving forefoot/midfoot
Wound type		Deep, full thickness heel ulcer + calcaneal involvement
1	Ulcer	Extensive gangrene involving forefoot/midfoot
2	Gangrene	Full thickness heel necrosis + calcaneal involvement
Location		Infection grade
1	Forefoot	0 No symptoms or signs of infection
2	Midfoot	1 Local infection involving only skin, SQ tissue
3	Heel	2 Local infection with erythema >2 cm, or involving structures deeper than skin, SQ (eg, abscess, osteomyelitis)
Infection categories		3 Local infection with signs of SIRS
1	None	Ischemia grade
2	Erythema	0 TP >60 mm Hg
3	Purulence	ABI >0.8
4	Systemic evidence of infection	AP >100 mm Hg
Ischemia categories[c]		1 TP 40-59 mm Hg
1	TP >60 mm Hg	ABI 0.6-0.79
	ABI >0.9	AP 70-100 mm Hg
	Palpable pulse	2 TP 30-39 mm Hg
	AP >80 mm Hg	ABI 0.4-0.59
2	TP 30-60 mm Hg	AP 50-70 mm Hg
	ABI 0.5-0.9	3 TP <30 mm Hg
	AP 50-79 mm Hg	ABI <0.39
3	TP <30 mm Hg	AP <30 mm Hg
	ABI <0.5	
	AP <50 mm Hg	

ABI, Ankle-brachial index; *AP,* systolic ankle pressure; *SIRS,* systemic inflammatory response syndrome; *SQ,* subcutaneous tissue; *TP,* toe pressure.
[a]Study only included patients with foot wounds.
[b]WIfI classification dictates that wound depth take priority over wound size.
[c]If ABI and TP resulted in different grades in patients with diabetes mellitus, TP was used to determine grade.

Description and application of the SVS WIfI Classification System. Developed in 2013, the SVS WIfI system provides an objective classification for wound nonhealing and limb amputation based on three independent risk factors: wound extent (eg, size, depth, presence of gangrene), degree of ischemia, and extent of foot infection. All three factors are individually graded on a scale of 0 to 3. For example, a shallow, small foot ulcer would be classed as a grade 1 wound (W-1), whereas a large wound extending to the joint space with gangrene would be classed as a grade 3 wound (W-3). Severity of ischemia and extent of infection are likewise graded on scales from 0 to 3. A detailed description of the SVS WIfI grading is presented in Table I.

After a patient has been graded on each of the three categories, the grades are combined to create a WIfI spectrum score. The expert consensus panel evaluated each WIfI spectrum score to predict the risk of limb amputation at 1 year and in a separate analysis, the likelihood that the patient would benefit from limb revascularization. A grid of potential WIfI spectrum scores, including the predictions of the consensus panel regarding the risk of limb amputation at 1 year (very low risk, low risk, moderate risk, high risk) for each score, is provided in Table II. The risk category of a WIfI spectrum score determines the clinical stage of disease. WIfI spectrum scores deemed to be very low risk for limb amputation at 1 year are categorized as clinical stage 1 disease. Spectrum scores deemed low risk, moderate risk, and high risk for limb amputation at 1 year are categorized as clinical stage 2, stage 3, and stage 4 disease, respectively.

Patients. All patients presenting to our tertiary referral center between June 2007 and March 2011 with CLI (Rutherford class V or VI) scheduled to undergo a revascularization procedure were prospectively collected in a database. Data related to foot wound characteristics, extent of infection, and degree of ischemia were entered into the database according to specific categories. Those categories were similar but not identical to the grades used by the WIfI classification system.