

Validation of the Infectious Diseases Society of America's Diabetic Foot Infection Classification System

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In this longitudinal study of 1666 persons with diabetes, there was an observed trend toward an increased risk for amputation (χ^2 test for trend, 108.0; $P < .001$), higher-level amputation (χ^2 test for trend, 113.3; $P < .001$), and lower extremity–related hospitalization (χ^2 test for trend, 118.6; $P < .001$) with increasing infection severity. The Infectious Diseases Society of America's foot infection classification system may be a useful tool for grading foot infections.

Foot wounds are among the most common and severe complications of diabetes and are now the most frequent cause for diabetes-associated hospitalization [1–3]. About one-half of these wounds become clinically infected during the course of therapy [4]. The severity of these infections ranges from mild and self-limited to limb- and even life threatening. Diabetes is the underlying cause of most lower extremity amputations in developed countries, and infection is the precipitating event for nearly 90% of these amputations [4–6]. Optimally, treating infection requires thoroughly evaluating the wound, appropriately prescribing antimicrobial therapy, and, often, considering hospitalization and surgical intervention. Ascertaining the severity of infection should help clinicians determine what treatments are needed, as well as in what environment and how urgently they must be provided.

Although many classification schemes have been offered for

diabetic foot wounds [7–13], and some include an assessment for infection [14, 15], until recently, there has been no widely accepted classification for infection severity. [16]. In 2004, the Infectious Diseases Society of America (IDSA) and the International Working Group on the Diabetic Foot (IWGDF) each published a comprehensive set of guidelines for the management of diabetic foot infections that included a classification scheme for infection severity (table 1). These systems, which are essentially identical, first divide wounds by whether they are clinically infected on the basis of the presence of purulent secretions or local or systemic signs of inflammation or infection. Infected wounds are further divided into those that are considered to be mild, moderate, or severe, on the basis of the size (especially of any cellulitis) and depth (or level of tissue involved) of the infection and presence of systemic manifestations of infection or metabolic instability (table 1) [7, 17]. These systems were developed by an international consensus of experts in various fields; however, to date, no studies have validated their ability to predict clinical outcomes of diabetic foot infection. Using a database developed for a prospective diabetes-related foot care management program, we evaluated the ability of the IDSA-IWGDF classification scheme to predict adverse clinical outcomes.

Methods. As part of a program to prevent diabetes-related lower extremity complications, we prospectively enrolled 1666 patients who were evaluated at baseline and then observed for an average of 27.2 months [4]. As a part of a systematic screening, we documented the patients' medical histories related to all potential foot complications and then examined them for the presence of sensory neuropathy, vascular disease, foot deformity, and limited joint mobility, using methods we have previously described [15, 18]. On the basis of an assessment of their risks for foot complications, we scheduled patients for follow-up visits at regular intervals, but instructed each to return at the first sign of any foot-related complication. We tracked clinical outcomes related to foot complications for all patients during follow-up, verifying hospital admissions, lower extremity amputations, and other complications with claims data. For all enrolled patients, the diabetes management program's foot clinic was the primary source of foot care, referral, and consultation for lower extremity complications. Data collection for this study was performed and completed before the publication of the IDSA classification system.

We defined a foot wound as a full-skin-thickness lesion involving any portion of the foot or ankle, excluding blisters and minor lacerations or abrasions [15, 19, 20]. We defined a foot

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Table 1. Diabetic foot infection classification schemes.

Clinical description	Infectious Diseases Society of America	International Working Group on the Diabetic Foot
Wound without purulence or any manifestations of inflammation	Uninfected	1
≥2 Manifestations of inflammation (purulence or erythema, pain, tenderness, warmth, or induration); any cellulitis or erythema extends ≤2 cm around ulcer, and infection is limited to skin or superficial subcutaneous tissues; no local complications or systemic illness	Mild	2
Infection in a patient who is systemically well and metabolically stable but has ≥1 of the following: cellulitis extending >2 cm; lymphangitis; spread beneath fascia; deep tissue abscess; gangrene; muscle, tendon, joint, or bone involvement	Moderate	3
Infection in a patient with systemic toxicity or metabolic instability (e.g., fever, chills, tachycardia, hypotension, confusion, vomiting, leukocytosis, acidosis, hyperglycemia, or azotemia)	Severe	4

infection clinically, using criteria consistent with the IDSA-IWGDF guidelines (i.e., the presence of purulent secretions or at least 2 local signs or symptoms of inflammation [21]). We also documented the presence or absence of systemic findings of infection, including fever, chills, leukocytosis, or metabolic aberrations. In addition, we evaluated all wounds for the extent and depth of soft tissue involvement and for any evidence (by clinical examination, imaging, and, when appropriate, bone biopsy) of bone infection (osteomyelitis) [22–24].

We assessed whether there was an association between an increasing IDSA infection severity class and any lower extremity complication, including foot-related hospitalization or lower extremity amputation. We used a χ^2 test for trend (χ^2_{trend}) and performed calculations using SPSS software, version 11.0 for Macintosh (SPSS), and Diagnostic and Agreement Statistics DAG Software (Mental Health Research Institute).

Results. The demographic and clinical characteristics of the patient population are shown in table 2. The enrolled patients

Table 2. Level of lower extremity amputation required among 247 patients with a foot wound, based on the foot infection severity classification of the Infectious Diseases Society of America and the International Working Group on the Diabetic Foot.

Characteristic	No infection (n = 97)	Mild infection (n = 71)	Moderate infection (n = 52)	Severe infection (n = 27)
Age >65 years	59.8	63.4	50.0	51.9
Male sex	53.6	53.5	48.1	63.0
Diabetes duration, mean years ± SD	12.8 ± 9.6	13.2 ± 9.3	16.3 ± 10.8	14.4 ± 12.0
Ethnicity				
Mexican American	57.8	50.7	61.5	44.4
White	36.1	47.9	34.6	51.9
African American	6.2	1.4	38.5	3.7
Body mass index >30 ^a	57.8	59.2	63.5	59.3
Peripheral neuropathy ^b	77.3	62.0	73.1	92.6
Peripheral vascular disease ^b	26.8	36.6	55.8	48.1
History of lower extremity disease				
Amputation ^b	13.4	11.3	30.8	44.4
Charcot arthropathy	3.1	5.6	3.8	3.7
Arterial bypass ^b	7.2	11.3	26.9	25.9
Wound depth				
Full thickness ^b	88.7	76.1	30.8	22.2
Fascia-tendon	7.2	21.1	25.0	11.1
Bone-joint ^b	4.1	2.8	44.2	66.7
Bone infection ^b	0	0	38.5	37.0
Multiple infections during evaluation period ^b	0	19.7	17.3	44.4
Hospitalization for infection ^b	0	4.2	51.9	88.9
Multiple hospitalizations ^b	0	0	0	14.8
Amputation level ^b				
No amputation	96.9	97.2	53.8	22.2
Foot	3.1	2.8	23.1	48.1
Leg	0	0	23.1	29.6

NOTE. Data are percentage of patients, unless otherwise indicated.

^a Body mass index calculated as weight in kilograms divided by the square of height in meters.

^b χ^2 Score for trend, $P < .05$.

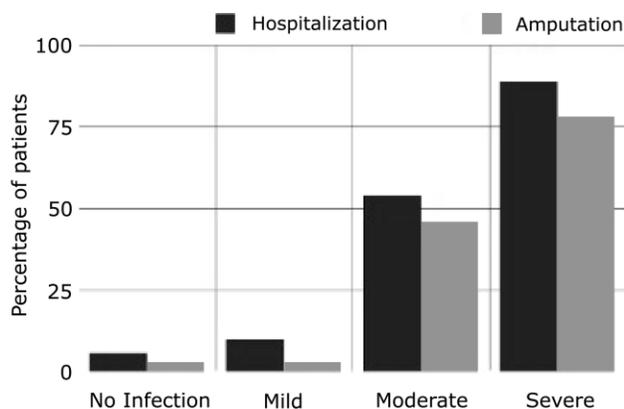


Figure 1. Hospitalization and amputation based on the Infectious Diseases Society of America and the International Working Group on the Diabetic Foot infection severity classification.

were similar to those in most diabetic populations. During a mean of 27.2 months of follow-up, 247 (14.8%) of the 1666 patients developed a lower extremity wound, and 151 (9.1%) developed a foot infection. Using the IDSA-IWGDF system, we classified 71 (47.0%) of the infections as mild, 52 (34%) as moderate, and 27 (17.9%) as severe. One patient with a mild infection (0.6%) did not have a recognizable portal of entry and was not included in the analysis.

With an increasing IDSA-IWGDF classification system infection severity (i.e., going from uninfected to severe infection), there was a statistically significant trend toward an increased risk for amputation (χ^2_{trend} , 108.0; $P < .001$), an increased anatomic level of amputation (χ^2_{trend} , 113.3; $P < .001$) (table 2), and an increased need for lower-extremity-related hospitalizations (χ^2_{trend} , 118.6; $P < .001$). These data are shown graphically in figure 1. Furthermore, as shown in table 2, with increasing IDSA-IWGDF infection severity there was a significant trend toward increasing risk for experiencing other diabetic foot-related complications, such as neuropathy, vascular disease, and history of amputation. Additionally, there was a trend toward a deeper wound, a higher prevalence of osteomyelitis, and more frequent occurrence of multiple infections during the evaluation period with increasing infection severity.

Discussion. Clinicians and researchers have used classification schemes for the foot-related complications of diabetes for 30 years [12, 13]. The usefulness of these systems is attested to by the fact that over a dozen have been devised since the original Meggitt-Wagner grading system [8]. Previously published diabetic foot classification systems either did not specifically define infection or, if they did, only noted its presence or absence. Determining the severity of a foot infection in a patient with diabetes may help the clinician with several important tasks. These include deciding whether the patient should be hospitalized, whether to use parenteral or oral an-

tibiotic therapy, and how urgently surgery or other treatments need to be performed. The IDSA and IWGDF developed infection severity classifications that were designed to be simple to apply and easy to remember, but they were based on expert consensus, not study data. We believe the results of this study are the first to validate these new guidelines. We found that an increasing severity of infection is associated with more-frequent lower-extremity comorbidities, such as peripheral neuropathy and arterial vascular disease, and, not surprisingly, with deeper infection-related disease (especially bone and joint disease). Of most interest is that increasing IDSA-IWGDF severity is associated with a significantly increased need for hospitalization and more-frequent (and higher level) lower extremity amputation.

Considering that these patients were screened for foot disorders at enrollment in the study, were educated about proper foot care, and had ready access to a foot clinic, we observed a higher incidence of foot infection than expected. As would be expected from an ambulatory population, most of the infections were mild or moderate, and were treated with oral antibiotic therapy on an outpatient basis. Surprisingly, 27 (18%) of all infections were severe, and 50 patients required a lower-extremity amputation of some type. Of note is that the mild and moderate infections were also associated with a high risk for hospitalization and, too often, a poor outcome.

The most important finding of this study is that it supports the clinical value of the IDSA-IWGDF diabetic foot infection classification in predicting clinical outcomes. It suggests that persons with mildly infected or noninfected wounds are highly unlikely to require hospitalization, develop osteomyelitis, or undergo amputation. This likely would have a significant impact on the use of resources in this population. We believe that the simplicity of determining the components of this system, coupled with the strong suggestion of its clinical utility, may make it a useful instrument in helping clinicians determine which of their patients are at the highest risk for adverse outcomes from a diabetic foot infection. Perhaps more aggressive medical, surgical, and adjunctive measures could be directed at these patients, with the hope that this would improve their foot salvaging outcome. This system should also be useful for clinical research studies, to allow for comparisons among patients enrolled in various investigations.

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