Validation of a Diabetic Wound Classification System

The contribution of depth, infection, and ischemia to risk of amputation

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OBJECTIVE — To validate a wound classification instrument that includes assessment of depth, infection, and ischemia based on the eventual outcome of the wound.

RESEARCH DESIGN AND METHODS — We evaluated the medical records of 360 diabetic patients presenting for care of foot wounds at a multidisciplinary tertiary care foot clinic. As per protocol, all patients had a standardized evaluation to assess wound depth, sensory neuropathy, vascular insufficiency, and infection. Patients were assessed at 6 months after their initial evaluation to see whether an amputation had been performed.

RESULTS — There was a significant overall trend toward increased prevalence of amputations as wounds increased in both depth (χ^2_{trend} = 143.1, $P < 0.001$) and stage (χ^2_{trend} = 91.0, $P < 0.001$). This was true for every subcategory as well with the exception of noninfected, nonischemic ulcers. There were no amputations performed within this stage during the follow-up period. Patients were more than 11 times more likely to receive a midfoot or higher level amputation if their wound probed to bone (18.3 vs. 2.0%, $P < 0.001$, χ^2 = 31.5, odds ratio (OR) = 11.1, CI = 4.0–30.3). Patients with infection and ischemia were nearly 90 times more likely to receive a midfoot or higher amputation compared with patients in less advanced wound stages (76.5 vs. 3.5%, $P < 0.001$, χ^2 = 133.5, OR = 89.6, CI = 25–316).

CONCLUSIONS — Outcomes deteriorated with increasing grade and stage of wounds when measured using the University of Texas Wound Classification System.

Diabetes continues to be one of the most common underlying factors associated with lower-extremity amputation in postindustrialized and developing countries. Amputations are perhaps the most feared and well-recognized complication of diabetes by the general public. For most patients, amputation is a pivotal event that alters their quality and duration of life. Amputations have been associated with an increased risk of reamputation of the same extremity (1–3), amputation of the contralateral leg (4), an elevated mortality rate in the first 3–5 years after amputation (5), and placement in nursing homes or extended care facilities (6,7).

There are several well-accepted predisposing factors that place patients with diabetes at high risk for a lower-extremity amputation. The most common components in the causal pathway to limb loss include peripheral neuropathy, ulceration, infection, and peripheral vascular disease. Ulceration is the most common single precursor to amputation and has been identified as a component in 85% of lower- extremity amputations (8). Systematically recording the characteristics of ulcerations is critical to planning treatment strategies, monitoring treatment effectiveness, predicting clinical outcomes, and improving communication among health care providers. The wound classification systems that have previously been described in the medical literature to accomplish these tasks either do not provide information about some of the most important parameters that would be expected to dictate treatment and predict outcome, or these parameters are incompletely used in the grading scheme.

Most classification systems previously reported in the medical literature have primarily focused on the depth of the ulceration and have neglected or inconsistently included infection and peripheral arterial occlusive disease (9–16). These factors have been widely discussed in the literature (17–21). However, we are unaware of any diabetic wound classification systems that have been validated or demonstrated to predict outcome. Empirically, it seems that poor outcomes are generally associated with infection, peripheral vascular disease, and wounds of increasing depth, and that the cumulative effect of these comorbidities would progressively contribute to a greater likelihood of amputation. Therefore, the purpose of this study was to validate a wound assessment instrument based on the eventual outcome of the wound.

RESEARCH DESIGN AND METHODS

We evaluated the medical records of 360 diabetic patients presenting for care of a complicated foot wound to a multidisciplinary tertiary care diabetic foot clinic between 1 January 1994 and 1 July 1996. All subjects presented with a wound below the ankle. As part of the protocol, patients treated for foot complications in the high-risk diabetic foot clinic have a standardized evaluation to assess wound depth, sensory neuropathy, vascular insufficiency, and infection.

The diagnosis of diabetes was verified for all patients using the criteria set forth by the World Health Organization, which include treatment with insulin or an oral hypoglycemic agent, two random glucose measurements >200 mg/dl, or a fasting glucose >140 mg/dl (22). Sensory neuropathy was evaluated with a 10-g Semmes-Weinstein monofilament wire and a biothesiometer (Biomedical Instrument,

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Abbreviations: ABI, ankle-brachial index; OR, odds ratio.

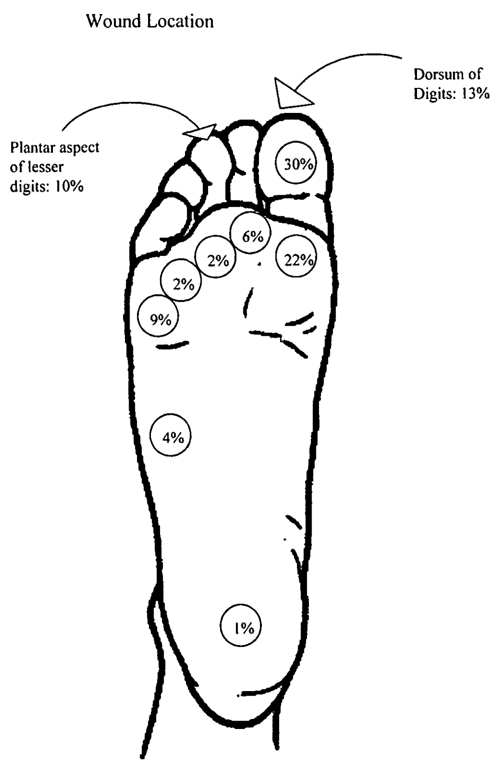

Figure 1—*Wound location.*

Newbury, OH) using the method and criteria described by Armstrong et al. (23,24).

The diagnosis of infection was made using clinical criteria. Wounds with frank purulence and/or two or more of the following local signs were classified as "infected." These signs include warmth, erythema, lymphangitis, lymphadenopathy, edema, pain, and loss of function. For all wounds, depth was evaluated using a sterile blunt nasal probe (25). If a wound probed to bone or joint, with the presence of local or systemic infection, a bone biopsy was performed with both microbiologic and histologic analysis to diagnose or exclude osteomyelitis. A working diagnosis of lower-extremity ischemia was made by a combination of clinical and noninvasive vascular studies. Clinical signs were based on the absence of one or more foot pulses of the involved foot. Noninvasive criteria included an ankle-brachial index (ABI) of <0.80 (19,26). Clinical signs and/or the presence of abnormal noninvasive values provided a diagnosis of lower-extremity vascular insufficiency.

Wounds were graded and staged by one of the principal investigators using the University of Texas Diabetic Wound Classification System (27). The location of wounds is illustrated in Fig. 1. The classification uses a matrix of wound grade on the horizontal axis and wound stage on the vertical axis to categorize wounds by severity. Wounds were graded by depth according to the following criteria: grade 0, a pre- or postulcerative site that had healed; grade 1, superficial wounds through the epidermis or epidermis and dermis that did not penetrate to tendon, capsule, or bone; grade 2, wounds that penetrated to tendon or capsule; and grade 3, wounds that penetrated to bone or into the joint. Within each wound grade there are four stages: clean wounds (A), nonischemic infected wounds (B), ischemic noninfected wounds (C), and infected ischemic wounds (D). Patients were assessed at 6 months after their initial evaluation to see whether an amputation had been performed. This classification is further illustrated in Figs. 2 and 3. If an ulceration increased in either grade or stage, the most severe classification was used for the purpose of analysis.

Descriptive statistics for this patient population are outlined in Table 1. To assess the association between increasing grade or stage of ulceration and prevalence of lower-extremity amputation, we used a χ^2 test for trend (χ^2_{trend}). To compare the level of amputation by stage and grade, we stratified all lower-extremity amputations into three levels: digit or ray amputation, midfoot-level amputation, and transfemoral/transtibial amputation. We used a χ^2 analysis with odds ratio (OR) and 95% CI to assess the potential association between high grade and stage wounds and the prevalence of high-level amputation. We classified amputations as "high-level" if they were performed at the midfoot level or more proximally. Furthermore, for all analyses, we used an α of 0.05 (28).

RESULTS — The prevalence of wound severity by ulcer grade and stage are outlined in Fig. 2. There was a significant overall trend toward an increased prevalence of amputations as wounds increased in both depth (χ^2_{trend} = 143.1, $P < 0.001$) and stage (χ^2_{trend} = 91.0, $P < 0.001$). This was true for every subcategory as well, with the exception of all stage A (noninfected, nonischemic) ulcers. There were no lower-extremity amputations performed within this stage during the follow-up period. These data are outlined in Fig. 3. As would be expected, patients placed into stages C and D had significantly lower ABIs than those in nonischemic stages (A and B) (0.69 ± 0.18 vs. 1.02 ± 0.14, $P < 0.001$). Furthermore, significantly more of the patients in ischemic stages had nonpalpable pulses (80.7 vs. 10.5%, χ^2 = 85.7, $P < 0.001$, OR = 35.7, CI = 12.5–100.0).

Stage \ Grade	0	I	II	III
A	Pre or postulcerative lesion completely epithelialized-- **4.2%**	Superficial wound, not involving tendon, capsule, or bone-- **25.8%**	Wound penetrating to tendon or capsule-- **10.0%**	Wound penetrating to bone or joint-- **5.6%**
B	Infection-- **2.2%**	Infection-- **13.1%**	Infection-- **7.8%**	Infection-- **20.8%**
C	Ischemia-- **1.1%**	Ischemia-- **2.8%**	Ischemia-- **1.1%**	Ischemia-- **0.8%**
D	Infection and Ischemia- **0.6%**	Infection and Ischemia-- **0.6%**	Infection and Ischemia-- **0.6%**	Infection and Ischemia **- 3.1%**

Figure 2—*Wound prevalence by grade and stage.*

Stage	Grade 0	Grade I	Grade II	Grade III	p value (X2 Trend)
A	Pre or postulcerative lesion completely epithelialized– 0%	Superficial wound, not involving tendon, capsule, or bone– 0%	Wound penetrating to tendon or capsule– 0%	Wound penetrating to bone or joint– 0%	n/a
B	Infection– 12.5%	Infection– 8.5%	Infection– 28.6%	Infection– 92%	p< 0.0001, X2= 77.9
C	Ischemia– 25.0%	Ischemia– 20.0%	Ischemia– 25.0%	Ischemia– 100%	p< 0.002, X2= 11.3
D	Infection and Ischemia- 50.0%	Infection and Ischemia– 50%	Infection and Ischemia-100.0%	Infection and Ischemia– 100%	p< 0.02, X2 = 6.0
p value (X2 Trend)	p < 0.02, X2 = 5.7	p < 0.002, X2 = 11.5	p< 0.0001, X2 = 14.0	p < 0.0001, X2 = 36.7	

Figure 3—*Prevalence of amputations within each wound category.*

Of all patients presenting for care, 28.6% received some form of lower-extremity amputation. These included digital or ray-level amputations (75.7% of total amputations), midfoot-level amputations (18.4% of total), and transfemoral/transtibial amputations (5.8% of total). Patients were more than 11 times more likely to receive a midfoot or higher level amputation if their wound probed to bone (grade 3) (18.3 vs. 2.0%, $P < 0.001$, $\chi^2 = 31.5$, OR = 11.1, CI = 4.0–30.3). Similarly, patients with infection and ischemia (stage D) were nearly 90 times more likely to receive a midfoot or higher amputation compared with patients in less advanced wound stages (76.5 vs. 3.5%, $P < 0.001$, $\chi^2 = 133.5$, OR = 89.6, CI = 25–316). Figure 4 illustrates the overall contribution of grade and stage on the absolute number of high-level lower-extremity amputations.

CONCLUSIONS — The results of this study indicate that outcomes deteriorate with increasing grade and stage of wounds when measured using the University of Texas Wound Classification System. We are unaware of any other wound classification schemes in the medical literature that have shown a trend toward an increased prevalence of amputation with advancing depth, presence of infection, and ischemia. While there have been no previous reports of wound classification systems specifically linking many of these risk factors, several components of the classification have evidence in the medical literature that would suggest that the rationale for the system used in this project should work. For instance, wounds that probe to bone have been associated with a high prevalence of osteomyelitis (25,29). Furthermore, osteomyelitis is a frequent cause of lower-extremity amputation in high-risk diabetic patients. Likewise, infection is clearly a prime cause of lower-extremity morbidity and frequently eventuates into wet gangrene and subsequent amputation. The data collected in this study suggest that, with depth held constant, patients with infections were at a higher risk for lower-extremity amputation than those without infection (30). Furthermore, since ischemia is the only single disease process that can, by itself, necessitate an amputation (8), it comes as no surprise that the data reported in this study suggest a higher prevalence of amputations in ischemic patients, and that the prevalence of amputation increases considerably more in the presence of both ischemia and infection. Other reports have suggested a cumulative effect of risk factors that contribute to increased risk of ulceration (31,32) and amputation (33).

The rationale for the criteria used in this classification system was based on the risk scoring systems described in these previous reports. In a retrospective case-control study, Mayfield et al. (33) suggested that the risk of lower-extremity amputation increases with the presence of sensory neuropathy and peripheral vascular disease. Pecoraro and colleagues (17) indicated that peripheral vascular disease and infection were significantly associated with an increased prevalence of lower-extremity amputation. Additionally, infection, gangrene, and ischemia were the most common component causes of lower-extremity amputation (8). In our study, both within- and between-grade and -stage evaluations support these previous observations.

One of the difficulties in establishing classifications, such as the one described in this study, is the development of operational definitions for comorbid conditions that are practical and yet still predictive of outcome. Unfortunately, infection and peripheral vascular insufficiency in people with diabetes are often defined by subtle parameters. In people with diabetes, elevated glucose levels have been associated with leukocyte dysfunction (34–37). Often, patients with severe foot infections are afebrile (38), have normal white blood cell counts (38–40), and do not mount robust local or systemic inflammatory responses. Similarly, patients with critical ischemia often have deceptively normal noninvasive studies due to medial arterial calcinosis and a normal clinical appearance of the foot (41,42). There does not seem to be widespread agreement concerning specific criteria, and in many situations, the definitions require clinical interpretation that is difficult to quantify (42–44). Therefore, the operational definitions used in this study were broadly defined and perhaps erred on the side of a conservative diagnosis. Even considering this potential shortcoming, the trends identified in this project strongly suggest that the risk of amputation increases with wound depth, and that there is an additive effect of infection and vascular insufficiency.

Table 1—*Descriptive characteristics of patient population*

Stage	*n*	Age (years)	% men	Duration of diabetes (years)	Race (MA/W/AA/A)	ABI	One or more palpable pedal pulses? (%)
Total	360	53.9 ± 10.4	68.6	14.0 ± 9.2	79.2/12.5/6.7/1.6	0.99 ± 0.18	73.3
A	164	54.3 ± 10.2	67.1	14.0 ± 9.5	81.7/11.0/5.5/1.2	1.03 ± 0.15	78.0
B	158	53.5 ± 10.4	69.6	14.2 ± 9.2	77.2/13.3/7.6/0.6	1.02 ± 0.14	83.5
C	21	55.8 ± 11.3	66.7	16.3 ± 8.1	66.7/23.8/9.5/0	0.71 ± 0.18	14.3
D	17	51.9 ± 10.8	76.5	11.0 ± 9.0	88.2/5.9/5.9/0	0.66 ± 0.19	5.9

Data are means ± SEM, *n*, or %. A, Asian; AA, African-American; MA, Mexican-American; W, non-Hispanic white.

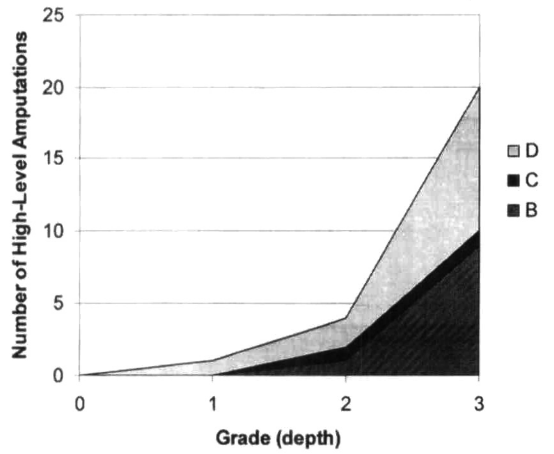

Figure 4—*Contribution of grade and stage to prevalence of lower-extremity amputations. The prevalence of high-level lower-extremity amputations (proximal to the forefoot) increased by grade and stage. As the depth of the wound increased according to grade (0–3), the proportion of high-level amputations increased. There were no lower-extremity amputations of any level in stage "A" (noninfected, nonischemic) wounds, regardless of depth.*

Another limitation of this study may involve the referral patterns and treatment strategies within our community. The patients predominantly served by the clinics involved in this study were ambulatory. This certainly would impact the prevalence of patients with decubitus heel wounds compared with wounds of the forefoot. Forefoot wounds have generally been associated with repetitive moderate pressure from walking rather than constant exposure to pressure (as is exemplified in decubitus wounds) (45–50). Our results may well reflect the experience of other centers. However, we are unaware of existing published work in the medical literature that has described and classified the location, depth, presence of infection, peripheral vascular disease, and outcomes in a large population of patients with diabetic foot wounds.

When a multidisciplinary approach is implemented in the treatment of high-risk diabetic patients, dramatic reductions in overall amputation rates and hospital lengths of stay have been realized (51–53). A central element of this type of approach is a common language to facilitate communication concerning a patient's location along the spectrum of risk. There are a number of other criteria that might be considered in wound classification. Other classification systems have included items such as location, color, presence of granulation tissue, quality of drainage, and etiology (10,13–16,21). However, these indexes are quite subjective and do not have a strong association with outcome. Furthermore, the addition of numerous classifiers eventually makes a system cumbersome and impractical in a busy clinical setting. To make a classification system clinically relevant, it should be easy to use and effective to communicate the status of wounds in people with diabetes. Only through a validated clinically practical system can we endeavor to educate primary care and specialty providers to appropriately describe the depth and associated morbidity of diabetic foot wounds, thereby limiting their progression toward infection and surgical ablation. In achieving these goals, we will undoubtedly make great progress in reducing the unconscionably high prevalence of diabetes-related lower-extremity amputations.

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