A New Wound-Based Severity Score for Diabetic Foot Ulcers

A prospective analysis of 1,000 patients

STEFAN BECKERT, MD
MARIA WITTE, MD
CORINNA WICKE, MD
ALFRED KÖNIGSRAINER, MD
STEPHAN COERPER, MD

OBJECTIVE — Several well-accepted classification systems are available for diabetic foot ulcers. However, there are only a few and scientifically not validated severity scores. The aim of this study was to establish a new wound-based clinical scoring system for diabetic foot ulcers suitable for daily clinical practice anticipating chances for healing and risk of amputation.

RESEARCH DESIGN AND METHODS — Four clinically defined parameters, namely palpable pedal pulses, probing to bone, ulcer location, and presence of multiple ulcerations, were prospectively assessed in 1,000 consecutive patients. In the next step, a new diabetic ulcer severity score (DUSS) was created from these parameters. Palpable pedal pulses were categorized by the absence (scored as 1) or presence (scored as 0) of pedal pulses, while probing to bone was defined as yes (scored as 1) or no (scored as 0). The site of ulceration was defined as toe (scored as 0) or foot (scored as 1) ulcer. Patients with multiple ulcerations were graded as 1 compared with those with single ulcers (scored as 0). The DUSS was calculated by adding these separate gradings to a theoretical maximum of 4. Wounds were followed-up for 365 days or until healing or amputation if earlier. Probability of healing and risk of amputation were calculated by the Kaplan-Meier method.

RESULTS — Uni- and multivariate analyses showed a significantly higher probability of healing for patients with palpable pulses, no probing to bone, toe ulcers, and absence of multiple ulcerations. When patients were divided into subgroups with the same DUSS, we found significantly different probabilities for healing. We showed a decreasing probability of healing for ulcers with a high DUSS, concurrent with increasing amputation rates. An increase in the DUSS by one score point reduced the chance for healing by 35%. Similarly, the higher the ulcer score, the larger the initial wound area, the longer the wound history, and the more likely the need for surgery or hospitalization.

CONCLUSIONS — The DUSS categorizes different ulcers into subgroups with specific severity and similar clinical outcome. Using this score, the probabilities for healing, amputation, need for surgery, and hospitalization are predictable with high accuracy. This might be useful for the anticipation of health care costs and for comparison of subgroups of patients in clinical studies.

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Approximately 15% of all diabetic patients are at risk for foot ulcerations during their lifetime, and 70% of healed ulcers are estimated to recur within 5 years (1,2). Peripheral neuropathy, peripheral vascular disease, abnormal plantar pressure load, and infection are accepted as the main risk factors for the development of diabetic foot ulcers and amputations (3,4). Since diabetic foot wounds and amputations account for a significant part of diabetes-related health care costs (5,6), several attempts have been made to establish classification systems that help assess the severity of disease. According to the International Working Group on the Diabetic Foot, a classification system appropriate for clinical practice should facilitate communication between health care providers, influence daily management, and provide information about the healing potential of an ulcer (7). In 1976, Meggitt (8) described one of the most commonly cited wound classification systems that was further popularized by Wagner (9) in 1981. However, the Meggitt-Wagner classification exclusively assessed ulcer depth without comorbidities such as ischemia or pressure load (2). More recently, the University of Texas system improved ulcer classification by including the parameters ischemia and infection (10,11). A classification system using simple clinical methods was recently published by Treece et al. (12) consisting of the five parameters ulcer area, ulcer depth, sepsis, arteriopathy, and denervation.

In contrast to classification systems, a clinical severity score should be based on a standardized clinical assessment of wound-based parameters facilitating the categorization of wounds into specific severity subgroups for comparison of outcome with respect to the clinical course of wound repair. So far, only one scoring system has been prospectively evaluated, i.e., the wound severity score by Knighton et al. (13). However, this score ranging from 0 to 97 has neither been widely used for clinical routine nor for clinical trials. In our study, we categorized diabetic foot ulcers according to a severity score ranging from 0 to 4 using four wound-based clinical parameters: palpable pedal pulses, probing to bone, ulcer location (foot or toe ulcer), and the presence of multiple ulcers. The aim of this study was to describe the impact of this scoring system on prediction of clinical outcome defined as probability of healing and risk for amputation.

From the Department of General and Transplant Surgery, University of Tübingen, Tübingen, Germany.
Address correspondence and reprint requests to Stephan Coerper, MD, Department of General and Transplant Surgery, Hoppe-Seyler-Strasse 3, 72076 Tübingen, Germany. E-mail: stephan.coerper@med.uni-tuebingen.de.
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A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.
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RESEARCH DESIGN AND METHODS

— Between December 1997 and April 2004, a total of 1,000 consecutive patients was prospectively followed-up in our outpatient wound care unit. All subjects suffered from diabetes according to the criteria of the World Health Organization (14). Prospective documentation was followed-up for 365 days or until healing or amputation if earlier. Patients with less than two visits during the observation period were excluded from the investigation.

Wounds

All ulcers were located below the ankle and assessed by a physician at the initial visit. Wounds were graded by measuring wound depth with a sterile blunt probe, and the deepest tissue involved was documented (dermis as grade 1, subcutaneous as grade 2, fascia as grade 3, muscle as grade 4, and bone as grade 5). Soft tissue infection was diagnosed if a purulent discharge was present combined with two other local signs (warmth, erythema, lymphangitis, lymphadenopathy, edema, or pain) (15). Peripheral vascular disease was clinically defined by the absence of both pedal pulses. Location was categorized as toe or foot. Additionally, patients were categorized as having single or multiple ulcerations on the same foot.

In patients with multiple ulcers, the wound with the highest grading was selected for analysis. For wounds with identical grading, the larger wound was chosen. Healing was defined as complete epithelization, minor amputation such as toe or forefoot amputation, or major amputation such as below- or above-knee amputation. Amputation rate was defined as the percentage of patients undergoing minor or major amputation within the observation period.

Local wound therapy

Wounds were treated according to a comprehensive wound care protocol as previously described (16). In brief, wound care consisted of sharp debridement, advanced local surgical procedures such as limited bone resections, moist wound therapy, and adequate pressure offloading. Toe ulcers were off-loaded with half-shoes (Thanner, Höchstädt, Germany), while foot ulcers were off-loaded by individually modified handcrafted orthotic devices (Brillinger, Tübingen, Germany). Effectiveness of standardized offloading was ensured for every device by pedography assessed by a specially trained orthotist. Treatment was performed by an interdisciplinary team of a general and vascular surgeon, a radiologist, a diabetologist, an orthotist, and a specially trained wound care nurse.

Wound documentation

Documentation was performed as previously described (16). A special software program was created on the basis of a commercially available database (Windows Data Access Objects). Hardware requirements were a personal computer with 64 MB RAM (greater than a Pentium 200 processor), a digital photocamera (>2 million pixels), a port for a Smart Media Card, and a digitizer pad (Wacom, Krefeld, Germany) for planimetric measurements.

Diabetic ulcer severity score

Ulcers were classified by the above-mentioned variables. Absent pedal pulses were scored as 1 while present pedal pulses were scored as 0. Bone involvement was defined as probing to bone (yes = 1 or no = 0). The site of ulceration was defined as toe (scored as 0) or foot (scored as 1) ulcer. Patients with multiple ulcerations were graded as 1 compared with those with single ulcers (scored as 0). Diabetic ulcer severity score (DUSS) was calculated by adding these separate gradings to a theoretical maximum of 4.

Statistics

For statistical analysis, data were entered into an SPSS database (SPSS, Chicago, IL) to calculate probability of healing by Kaplan-Meier method. The single dichotomous parameters of the DUSS that influence healing were analyzed with the log-rank test. A multivariate analysis using Cox regression was performed to investigate the overall influence of these parameters on time to healing. Additionally, Cox regression was used to show correlation between the DUSS and healing. A $P < 0.05$ was considered significant. Results are expressed as median (minimum-maximum), unless otherwise stated.

RESULTS

Patients

In total, 1,000 diabetic patients were included in this study, with 675 (67.5%) being male and 325 (32.5%) being female. Median age was 69 (26–95) years. Median initial wound area was calculated to be 0.9 cm^2 (0.1–123), with a median wound history of 31 days (1–18,708). Throughout the observation period, median number of visits was 5 (2–60). Median time of follow-up was calculated to be 68 days (3–365). A total of 40.4% of the patients had more than one ulcer at the initial visit. For 621 (62.1%) patients, an additional inpatient treatment period was necessary for reasons such as invasive diagnostics, local or major surgery, or control of infection (Table 1).

Wound classification and outcome

Initially, ulcers were graded with 29 (2.9%) ulcers classified as grade 1, 635 (63.5%) as grade 2, 20 (2.0%) as grade 3, 47 (4.7%) as grade 4, and 269 (26.9%) as grade five (Table 1). There was a significantly lower probability of healing with respect to nonpalpable pulses ($P <$ 0.0009), probing to bone ($P < 0.0019$), multiple ulcerations ($P < 0.00001$), and foot versus toe ulcerations ($P < 0.00001$). Multivariate analysis demonstrated these parameters as independent variables with significant impact on healing (Table 2). However, local soft tissue infection, when diagnosed at the initial visit, did not influence probability of healing ($P = 0.5324$).

In the next step, the new DUSS was calculated from the above-mentioned parameters, which have been shown as independent variables for healing. Dividing patients into subgroups with the same DUSS, we found significantly different probabilities for healing. There was a 93% probability of healing for uncomplicated ulcers (score 0), decreasing to 57% for ulcers with a severity score of 4 ($P <$ 0.0001) (Fig. 1). In addition, influence of the DUSS on healing was analyzed using a Cox regression model, confirming a high correlation between the new severity score and time to healing, resulting in a risk ratio of 0.648 (95% CI 0.589–0.714; $P < 0.001$). An increase in the DUSS by one score point reduced the chance for healing by 35%.

In total, 99 minor amputations were performed. However, the incidence of minor amputations did not significantly increase concurrent with the DUSS ($P =$ 0.671). The overall major amputation rate was found to be 2.6%. Wounds demonstrated a trend of increasing probability for major amputation along with increasing DUSS shown by Kaplan-Meier analysis: patients with a score of 0 had no risk of major amputation, while patients with a score of 1 had a 2.4%, patients with a score of 2 had a 7.7%, patients with a score of 3 had an 11.2%, and patients with a score of 4 had a 3.8% probability to

Table 1—*Baseline demographic details*

Details	
Patients	
Sex	Male: 675 (67.5); female: 325 (32.5)
Age (years)	69 (26–95)
Number of visits	5 (2–60)
Multiple ulcers	404 (40.4)
Time of follow-up (days)	68 (3–365)
Hospitalization	621 (62.1)
Wounds	
Wound history (days)	31 (1–18,708)
Wound area (cm^2)	0.9 (0.1–123)
Soft tissue infection at initial visit	354 (35.4)
Probing to bone	269 (26.9)
Ulcer location	Toe: 356 (35.6); foot: 644 (64.4)
Palpable peripheral pulses	656 (65.6)
Wound grading	
Grade 1	29 (2.9)
Grade 2	635 (63.5)
Grade 3	20 (2.0)
Grade 4	47 (4.7)
Grade 5	269 (26.9)
Surgery	
Sharp debridement	1,000 (100)
Bone resection	136 (13.6)
Minor amputation	99 (9.9)
Major amputation	26 (2.6)

Data are median (range) or *n* (%).

lose their limb. However, this difference did not reach statistical significance ($P = 0.524$).

There was a continuous increase of wound size from 0.3 to 2.7 cm^2 and of wound duration from 29 to 61 days dependent on ulcer severity score. Hospitalization and the need for surgery were more likely in patients with high severity scores: patients with ulcers of grade 0 had a likelihood of hospitalization of 38% and of surgery of 10%. In contrast, an ulcer score of 4 meant subsequent surgery in 50% and admission to the hospital in almost 100% (Table 3).

CONCLUSIONS— In the past, many classification systems for diabetic foot ulcers have been proposed (9,10,13,17). Some were characterized by an extensive diagnostic work up and complex grading or scoring schedules, while others were exclusively based on clinical parameters. However, these well-established classification systems were not capable of predicting long-term outcome. The impact of these classification systems is primarily based on the improvement of communication between health care providers and on facilitating selecting the appropriate treatment schedule in respect to ulcer grading. However, scoring systems that are necessary to predict the outcome of diabetic foot ulcers in a stratified patient population are not available so far. Our new severity score, named the DUSS, might represent the first severity score for diabetic foot ulcers evaluated in 1,000 patients that is capable of predicting clinical outcome.

This new prognostic scoring system was established summarizing a set of already-known prognostic factors for diabetic foot ulcers. Each parameter was exclusively assessed by clinical examination. Since the aim of our scoring system was to create an easy wound-based score, we did not investigate disease-based parameters such as duration of diabetes, type of diabetes, and comorbid illness. To that end, we included only four parameters: nonpalpable pulses, ulcer location, probing to bone, and the presence of multiple ulcers. Even with this limitation, we were able to create a scoring system discriminating patients with ulcerations of different outcome.

In a first step, we demonstrated in our patient population by univariate analysis that previously described prognostic parameters such as nonpalpable pulses, probing to bone, and the presence of multiple ulcers (17,18) had an influence on healing even when assessed exclusively by clinical examination. Categorizing diabetic ulcers as toe and foot ulcers is a new approach for the description of diabetic ulcer location. Nevertheless, toe ulcers were seen to heal faster compared with foot ulcers. However, this was not the result of noncritical toe amputations, since Kaplan-Meier analysis was utilized to test healing versus nonhealing or amputation. Our data demonstrated faster healing of toe ulcers independently of the incidence of toe amputation. An explanation might be consequent off-loading, which is a major factor in proper healing (18,19). Even though the effectiveness of all the off-loading devices used in this study was controlled by standardized pedography, off-loading is still technically much easier to achieve in toe ulcers by using half-shoes compared with complex Charcot feet with ulceration on the midfoot or heel where complete off-loading can only be achieved by complex handcrafted off-loading devices. It was initially surprising that soft tissue infection when diagnosed only at the initial visit had no significant influence on outcome. However, in our surgical patient population, sharp surgical debridement and immediate use of antibiotics characterize the treatment protocol of soft tissue infection. We assume that the immediate and adequate therapy of wound infection is the reason

Table 2—*Multivariate analysis of parameters reducing chances for healing*

			95% CI	
	Significance	Odds ratio	Lower	Upper
Multiple ulcers	0.0001	0.648	0.540	0.778
Probing to bone	0.025	0.777	0.623	0.968
Location (foot ulcers)	0.0001	0.483	0.402	0.580
Nonpalpable pulses	0.0001	0.723	0.603	0.868

Cox regression analysis was used with a $P < 0.05$ considered significant.

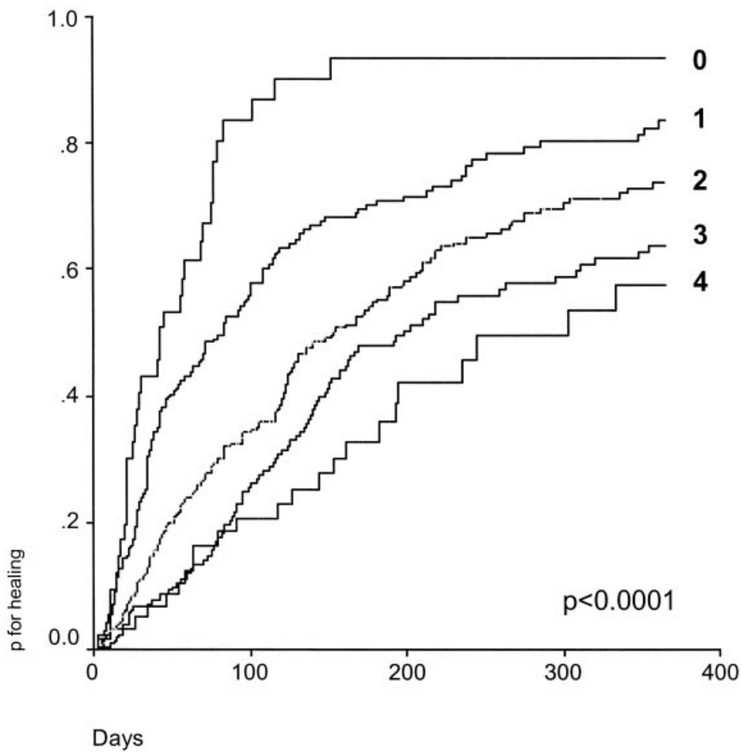

Figure 1—*Probability of healing according to the DUSS. Patients were divided into subgroups having the same DUSS (0–4). Data are given as probability of healing calculated by Kaplan-Meier analysis for a follow-up period of 365 days.*

for the strong healing response. On the other hand, we found that recurrent soft tissue infection during follow-up had a major impact on healing (data not shown). Since ulcer assessment was performed at the initial visit we did not include soft tissue infection as a parameter for the DUSS.

In the next step, we were able to show by multivariate analysis that all four parameters had an independent impact on wound healing. Therefore, there was no need for weighting these parameters, which further simplified our new scoring system. We generated a DUSS by adding the grading of each parameter (given as 1 or 0) to a theoretical maximum score of 4. Dividing patients into subgroups with the same DUSS, we were able to demonstrate significant differences for probability of healing.

Additionally, other parameters known for their impact on wound healing were distributed in concordance with our severity score. Ulcers with a higher DUSS were associated with a longer wound history and larger ulcer area. Probability of healing was strongly decreasing with an increasing DUSS, meaning that an increase in the DUSS by one score point reduced the chance for healing by 35% each. Similarly, probability of hospitalization and surgical procedures could be anticipated. Patients with a high DUSS were more likely to undergo surgery and hospitalization. Since the need for surgery and hospitalization are important economic issues, this new score might also be helpful for future economic calculations.

Surprisingly, major amputation rate was low in our study (2.6%). On the other hand, there was a relatively high minor amputation rate of 9.9%. We strongly believe that adequate local surgery and, if necessary, even minor amputation may prevent major amputations. This is in concordance with Holstein et al. (20) and Margolis et al. (21) who could show increasing minor amputation rates concurrent with decreasing major amputation rates. Concerning the impact of the DUSS on the risk for major amputation, we found an increasing major amputation rate concurrent with increasing ulcer severity score; the probability of major amputation was increasing from 0% (score 0) to 11.2% (score 3). However, this obvious trend did not reach statistical significance since there was an unexpected low major amputation rate of 3.8% associated with a DUSS score of 4. This can be explained by the low overall incidence of major amputations and by the low number of patients in this subgroup.

According to Krop et al. (22), more work is necessary to assure equitable risk adjustment in the calculation of capitation rates for health plans and practitioners who specialize in the care of individuals with diabetes. We believe that the establishment of the DUSS may contribute to a better and realistic calculation of health care costs in patients with diabetic foot ulcers.

This new severity scoring system provides an easy diagnostic tool for anticipating probability of healing, hospital admission, and local surgery by combining four clinically assessable wound-based parameters, namely presence/absence of pedal pulses, probing to bone, wound location, and presence/absence of multiple ulcerations to an ulcer severity score. Since this scoring system can be easily applied in daily clinical practice, it may be suitable estimating putative health care costs. On the other side, this score

Table 3—*Subgroup analysis with respect to ulcer severity score*

Score	Wounds (n)	Wound size (cm^2)	Wound duration (days)	Surgery (%)	Hospitalization (%)
0	44	0.3 (0.1–11.2)	29 (2–597)	9	38.6
1	284	0.5 (0.1–99)	26.5 (1–2,922)	17	48.6
2	387	1.0 (0.1–123)	31 (1–4,018)	27	62.5
3	225	2.4 (0.1–98)	42 (1–18,708)	37	71.6
4	60	2.7 (0.1–41)	61 (3–1,516)	50	91.7

Data are n, percent, or median (range).

may be very helpful for the stratification of study groups to guarantee comparable patient subgroups. However, we would like to emphasize that subsequent adequate and standardized wound care is an indispensable prerequisite to the DUSS being a valid diagnostic tool.

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