Effectiveness of the Diabetic Foot Risk Classification System of the International Working Group on the Diabetic Foot

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OBJECTIVE — To evaluate the effectiveness of a diabetic foot risk classification system by the International Working Group on the Diabetic Foot to predict clinical outcomes.

RESEARCH DESIGN AND METHODS — A total of 225 diabetic patients were initially evaluated as part of a prospective case-control study at the University of Texas Health Science Center at San Antonio. Complete records were available for 213 patients for follow-up evaluation after 29 months. Upon enrollment, subjects were stratified into four risk groups based on the presence of risk factors according to the consensus of the International Working Group on the Diabetic Foot. Group 0 consisted of subjects without neuropathy, group 1 consisted of patients with neuropathy but without deformity or peripheral vascular disease (PVD), group 2 consisted of subjects with neuropathy and deformity or PVD, and group 3 consisted of patients with a history of foot ulceration or a lower-extremity amputation.

RESULTS — Upon enrollment, patients in higher-risk groups had longer duration of diabetes, worse glycemic control, vascular and neuropathic variables, and more systemic complications of diabetes. During 3 years of follow-up, ulceration occurred in 5.1, 14.3, 18.8, and 55.8% of the patients in groups 0, 1, 2, and 3, respectively (linear-by-linear association, $P < 0.001$). All amputations were found in Groups 2 and 3 (3.1 and 20.9%, $P < 0.001$).

CONCLUSIONS — The foot risk classification of the International Working Group on the Diabetic Foot predicts ulceration and amputation and can function as a tool to prevent lower-extremity complications of diabetes.

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The purpose of this study was to evaluate the effectiveness of a diabetic foot risk classification established by the International Working Group on the Diabetic Foot (1). There is some evidence that diabetic foot complications can be prevented. One of the keys to population-based screening and disease management is risk classification and stratification. The objective of the classification system developed by the International Working Group on the Diabetic Foot is to evaluate diabetic patients by using inexpensive readily available instruments in order to stratify them into risk groups that would be predictive of morbid outcomes. The tools were intended to be inexpensive and readily available to ensure worldwide implementation of the classification instrument. Resources such as therapeutic shoes, education, and clinical visits can then be allocated to patients at greatest risk of adverse events. In an international environment with an increasing prevalence of diabetes and dwindling medical resources, this type of tool can be used to help shift current treatment models to prevention models.

RESEARCH DESIGN AND METHODS

— A total of 236 diabetic patients were initially evaluated as part of a case-control study at the University of Texas Health Science Center at San Antonio in 1995 and 1996. After informed consent was obtained, the subjects were sequentially enrolled from the foot clinics. Complete records were available for 213 patients for follow-up evaluation after a mean period of 30 months. As part of standard care in the foot specialty clinic, we evaluated patients with diabetes and provided preventive care consisting of regular podiatry evaluation based on risk category and referral to the pedorthist, vascular surgery department, and diabetes education or other services as required. Patients with wounds received treatment based on well-accepted protocols including wound debridement, dewelghting the wound site with casts, removable walking boots or healing shoes, vascular testing, and lower-extremity revascularization and infection control as warranted (2).

Only data of subjects with follow-up were evaluated. Ulcers were defined as skin lesions distal to the ankle. Subjects who received an amputation as a direct result of their initial ulceration were disqualified from further analysis. These patients had a much higher a priori risk of amputation; inclusion may lead to selection bias.

All subjects had diabetes according to the criteria of the World Health Organization (3). The type of diabetes was based on the algorithm by Mogensen (4). Several variables previously reported to be risk factors for the development of diabetic foot ulcers and lower-extremity amputations were evaluated. These exposure variables are also shown in Tables 1 and 2.

BMI (Quetelet index) was calculated as weight in kilograms divided by the square of the height. Glycemic control was evaluated with HbA_{1c}. Plantar peak pressures were measured with the Novel

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Abbreviations: ABI, ankle-brachial index; OR, odds ratio; PVD, peripheral vascular disease; SWM, Semmes-Weinstein monofilament; VPT, vibration perception threshold.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Table 1—*Distribution of descriptive characteristics and demographics of continuous variables among the four groups of consensus classification*

	Group					
	0 (no neuropathy)	1 (neuropathy)	3 (neuropathy and/or vascular disease and/or deformity)	4 (previous ulcer)	Total	*P*
n	79	21	51	62	213	
Age (years)	49.8 ± 10.3	54.1 ± 7.5	55.3 ± 10.8	53.4 ± 10.2	52.6 ± 10.4	0.017
Diabetes duration (years)	7.7 ± 6.7	10.9 ± 8.3	13.2 ± 12.7	13.5 ± 8.0	11.0 ± 9.3	0.001
Follow-up (months)	29.1 ± 6.6	30.6 ± 4.5	29.7 ± 5.9	29.3 ± 7.2	29.4 ± 6.4	NS
BMI (kg/m^2)	31.4 ± 5.6	32.1 ± 7.2	33.1 ± 7.2	30.4 ± 5.7	31.6 ± 6.2	NS
HbA_{1c} (%)	8.7 ± 2.0	8.8 ± 2.0	8.6 ± 1.8	9.7 ± 2.3	9.0 ± 2.1	0.020
Plantar peak pressure (N/cm^2)	62.3 ± 20.9	65.1 ± 27.0	63.9 ± 20.7	83.1 ± 25.7	68.2 ± 24.2	<0.001
ABI	1.2 ± 0.3	1.2 ± 0.2	1.1 ± 0.4	1.33 ± 0.42	1.23 ± 0.35	0.036
VPT (V)	10.2 ± 4.1	24.3 ± 13.6	20.4 ± 11.9	37.0 ± 13.2	21.7 ± 15.0	<0.001
$TcPO_2$	40.5 ± 13.3	40.0 ± 10.5	38.2 ± 14.6	40.3 ± 19.5	39.8 ± 15.2	NS

Data are means ± SD.

EMED-SF platform system (Novel Electronics, St. Paul, MN). An average of three steps was used for analysis. Elevated plantar pressures were defined as a peak plantar pressure of >70 N/cm^2 (5). Several vascular parameters were evaluated. The data consisted of $TcPO_2$ on the dorsal first intermetatarsal space ($TcPO_2$, <40 mmHg, probe temperature of 45°C) (6), an ankle-brachial index (ABI) of <0.8 (7), absence of dorsal pedal and posterior tibial artery pulsations, and incompressibility of pedal arteries (ABI >1.2). Peripheral vascular disease (PVD) was defined as an ABI of <0.8 or any non-

Table 2—*Distribution of descriptive characteristics and demographics of dichotomous variables among the four groups of the consensus classification*

	Group 0 (no neuropathy)	OR (groups 1–3)	Group 1 (neuropathy)	OR (groups 1–3)	Group 2 (neuropathy, vascular disease and/or deformity	OR (groups 2–3)	Group 3 (previous ulcer)	Total	*P*
Female	70.9	7.0 (3.3–14.7)	85.7	17.2 (4.5–66.7)	47.1	2.6 (1.2–5.6)	25.8	53.5	<0.001
Type 2 diabetes	94.2	NS	100	1.1 (1.0–1.1)	94.1	NS	93.4	93.8	NS
Previous or present drinker	45.6	2.3 (1.1–4.5)	47.6	NS	60.8	NS	65.6	55.2	0.011
Present or previous tobacco use	55.7	NS	57.1	NS	52.9	NS	60.7	56.6	NS
Nephropathy	25.3	3.1 (1.5–6.4)	33.3	NS	27.5	2.8 (1.3–6.2)	51.6	34.3	0.004
Retinopathy	33.8	8.9 (3.7–21.5)	50.0	4.6 (1.4–14.7)	44.4	5.7 (2.2–14.4)	82.0	51.4	<0.001
HbA_{1c} >9%	42.7	2.5 (1.2–5.0)	57.9	NS	40.9	2.7 (1.2–6.0)	65.0	50.5	0.033
Amputation history	0	2.8 (2.2–3.6)	0	1.4 (1.2–1.7)	0	2.2 (1.8–2.7)	30.6	8.9	<0.001
Elevated plantar peak pressures	33.3	4.4 (2.0–9.6)	47.1	NS	36.2	3.9 (1.7–9.1)	68.8	44.4	0.001
ABI <0.8	0	2.7 (2.0–3.6)	0	NS	21.2	NS	10.3	8.5	0.015
Any missing pulse	0	3.0 (2.3–3.9)	0	1.6 (1.3–1.9)	52.9	NS	36.1	23.1	<0.001
Incompressible ankle pressure (>1.2)	40.5	NS	42.1	NS	34.0	NS	47.3	43.0	NS
$TcPO_2$ <40 mmHg	47.2	NS	60.0	NS	62.5	NS	48.1	52.6	NS
VPT >25 V	0	8.9 (5.0–15.9)	42.9	6.7 (2.2–20.0)	27.5	13.2 (5.3–33.0)	83.3	34.6	<0.001
Abnormal SWM test	0	62.5 (9.2–500)	89.5	NS	67.4	15.0 (1.8–121.1)	96.9	49.0	<0.001
Deformity	36.7	3.3 (1.7–6.8)	0	2.0 (1.5–2.7)	68.6	NS	66.1	49.3	<0.001
Hallux limitus	5.1	7.1 (2.4–22.4)	9.5	NS	11.8	2.8 (1.0–7.8)	27.4	13.6	<0.001
Pes equinus	17.7	NS	14.3	NS	29.4	NS	29.0	23.5	NS
Limited ROM subtalar joint	29.1	2.4 (1.2–4.9)	14.3	6.0 (1.6–22.5)	14.3	NS	50	36.2	0.006

Data are % or OR (95% CI) unless otherwise indicated. For VPT, abnormal SWM test, deformity, and hallux limitus, $P < 0.001$; for limited ROM subtalar joint, $P = 0.006$. ROM, range of motion.

Table 3—*Distribution of adverse outcomes after 3 years among the four groups of the consensus classification*

	Group 0 (no neuropathy)	OR (groups 1–3)	Group 1 (neuropathy)	OR (groups 1–3)	Group 2 (neuropathy, vascular disease and/or deformity	OR (groups 2–3)	Group 3 (previous ulcer)	Total	*P*
Follow-up ulcer	4 (5.1)	34.1 (11.0–105.8)	3 (14.3)	10.9 (2.9–41.2)	7 (13.3)	11.4 (4.4–29.6)	40 (64.5)	54 (25.4)	<0.001
Follow-up amputation	0	2.7 (2.2–3.4)	0	1.4 (1.2–1.6)	1 (2.0)	17.4 (2.2–136.4)	16 (25.8)	17 (8.0)	<0.001
Toe/ray	0	—	0	—	1 (2.0)	—	7 (11.3)	8 (3.8)	<0.001
Transmetatarsal	0	—	0	—	0	—	5 (8.1)	5 (2.3)	
Transtibial or higher	0	—	0	—	0	—	4 (6.5)	4 (1.9)	
Reamputations	0	2.4 (2.0–3.0)	0	1.4 (1.2–1.6)	0	1.9 (1.6–2.3)	7 (43.8)	7 (41.1)	0.001
Follow-up bypass	0	2.4 (2.0–2.9)	0	1.4 (1.2–1.6)	1 (2.0)	NS	5 (8.1)	6 (2.8)	0.006

Data are *n* (%) and OR (95% CI) unless otherwise indicated. For follow-up ulcer, follow-up amputation, and for all amputations, $P < 0.001$; for reamputations, $P = 0.001$; and for follow-up bypass, $P = 0.006$.

palpable pedal pulsation. Peripheral neurological deficits were assessed with vibration perception threshold (VPT) and Semmes-Weinstein monofilament (SWM). The VPT was measured with a Biothesiometer (Biomedical Instrument, Newbury, OH) at the tip of the hallux (8). A voltage of >25 V was defined as a loss of protective sensation (9). The 10-g SWM was applied to 10 areas of the foot. Impaired sensation was defined as one or more unnoticed pinpricks with the SWM or a VPT of >25 V (10).

Joint mobility of the first metatarsal phalangeal joint, the subtalar joint, and the ankle was assessed by averaging three measurements. Limited joint mobility of the forefoot was determined by the presence of hallux limitus, which is dorsiflexion of the hallux of <50 degrees (10–12). Limited range of motion of the subtalar joint was determined by <20 degrees total range of motion, and pes equinus was defined as <0 degrees of dorsiflexion at the ankle (10). Deformity of the forefoot was defined as hallux valgus, rigid toe contractures (such as hammer or claw toes), and prominent metatarsal heads (10).

All subjects completed a CAGE (cut-down, annoyed, guilty, and eye-opener) questionnaire. Alcohol abuse was defined as a positive CAGE (≥3) (13). Previous alcohol abuse was also noted if it was stated in the medical record. Nephropathy was defined as creatinine >4.0 mg/dl, current renal dialysis, and history of renal transplantation (14,15). Retinopathy was defined as presence of at least background changes. The retinal pictures had been taken as part of the routine diabetes care of the subjects (Cannon CR6-45NM Non-Mydratic Retinal Camera; Cannon, Lake Success, NY).

During an average follow-up of 29 months, several outcomes were evaluated. These included occurrence of an ulcer or amputation, the level of such an amputation, reamputations of such an amputation, and necessity for a peripheral arterial bypass.

For continuous exposure variables, a one-way analysis of variation was used to detect any statistical differences among the groups. This test is used to test the hypothesis that several means are equal and function as an extension to the Student's *t* test. For dichotomous exposure variables and for detection of trends among the four and five groups of the classification and of the alternative classification, respectively, a linear-by-linear association (Mantel-Haenszel χ^2 test for trend) was calculated to evaluate trends from group 0 through group 3. This test calculates the linear association between row and column variables in a cross-tabulation. Odds ratios (ORs) of the data in groups 0, 1, and 2 were calculated independently from one another to the data in group 3 in a cross-tabulation. To evaluate the incidence of morbidity in the group of patients with a history of ulceration, the data of groups 0, 1, and 2 were combined and compared with the data of the patients in group 3 with a χ^2 test.

After this, the same procedure was followed for two subgroups within group 3. Group 3 was split into a group of patients without a history of amputation (group 3a) and one with a history of amputation (group 3b), thereby resulting in a total of five groups. $P < 0.05$ was considered statistically significant. All statistical analyses were performed with SPSS 8.0 software.

RESULTS — Of 236 initially enrolled patients, follow-up was available for 213 patients. As shown in Tables 1–3 , it appears that initial measurements for most of the factors assessed in the study are more often of a more severe nature in the higher-risk groups. The data of groups 0, 1, and 2 were combined and compared with the data of the patients in group 3 with a χ^2 test. Patients with a history of ulceration were 2.8 times (95% CI 1.5–5.3) more likely to have nephropathy, 6.9 times (3.1–15.4) more likely to have retinopathy, and 3.9 times (1.9–7.9) more likely to have elevated plantar peak pressures than patients in groups 0, 1, and 2.

Table 3 displays the incidence of ulcerations and amputations in the 3-year follow-up period. There were significantly more ulcerations and amputations ($P < 0.001$) as well as an increased proportion of proximal amputations in the higher-risk groups ($P < 0.001$). Patients in the highest-risk group were 34.1 times (95% CI 11.0–105.8) more likely to develop an ulceration in the follow-up period.

χ^2 Tests showed that patients with a history of an ulceration were 17.8 times (95% CI 8.3–37.9) more likely to develop an ulceration within the 3-year follow-up period than patients without an ulcer history (groups 0, 1, and 2 combined). Likewise, they were 52.2 times (6.7–404.1) more likely to receive a lower-extremity amputation and 13.2 times (1.5–115.1) more likely to undergo a peripheral arterial bypass.

Table 4 shows the result of the variant

Table 4—*Distribution of adverse outcomes after 3 years among the groups of the consensus classification*

	Group 0 (no neuropathy)	OR (groups 1–3b)	Group 1 (neuropathy)	OR (groups 1–3b)	Group 2 (neuropathy, PVD and/or deformity)	OR (groups 2–3b)	Group 3a (previous ulcer, no amputation)	OR (groups 3a–3b)	Group 3b (previous amputation)	Total	*P*
n	79		21		51		43		19	213	
Follow-up ulcer	4 (5.1)	100.0 (20.4–491.0)	3 (14.3)	32.0 (5.6–181.6)	7 (13.7)	33.5 (7.7–145.6)	24 (55.8)	4.2 (1.1–16.7)	16 (84.2)	54 (25.4)	<0.001
Follow-up amputation	0	7.6 (4.5–12.8)	0	1.6 (1.1–2.2)	1 (2.0)	29.2 (3.3–260.1)	9 (20.9)	NS	7 (36.8)	17 (18.1)	<0.001
Toe/ray	0	—	0	—	1 (2.0)	—	6 (14.0)	—	1 (5.3)	8 (3.8)	
Midfoot/TMA	0	—	0	—	0	—	2 (4.7)	—	3 (15.8)	5 (2.3)	<0.001
BKA or AKA	0	—	0	—	0	—	1 (2.3)	—	3 (15.8)	4 (1.9)	
Reamputations	0	—	0	—	0	4.2 (2.7–6.4)	4 (9.3)	NS	3 (15.8)	7 (41.1)	<0.001
Follow-up bypass	0	6.0 (3.8–9.3)	0	2.3 (1.6–3.3)	1 (2.0)	NS	2 (4.7)	NS	3 (15.8)	6 (2.8)	0.001

Data are *n* (%) or OR (95% CI) unless otherwise indicated. For follow-up ulcer, follow-up amputation, toe/ray, midfoot/transmetatarsal amputation (TMA), below-the-knee amputation (BKA), or above-the-knee amputation (AKA), and reamputations, $P < 0.001$; for follow-up bypass, $P = 0.001$.

of the consensus classification, in which the group of patients with a history of ulceration was split into a group of patients with and without a history of amputation. It appeared that the higher-risk groups had a significantly higher number of ulcerations, amputations, and a higher proportion of proximal amputations than patients in the lower-risk groups (<0.001). Patients in the highest-risk group (group 3b) were 100 times (95% CI 20.4–491.0) more likely to ulcerate than patients in the lowest-risk group (group 0).

CONCLUSIONS — This study evaluates the effectiveness of a classification system to predict diabetic foot complications. Our data suggests that the classification system proposed by the International Working Group is effective in predicting groups that are more likely to develop diabetes-related foot complications. There was a clear trend for increased morbid events in progressive stages of the classification scheme. Our results show that patients in a higher-risk group are 34 times more likely to ulcerate than patients in the lowest-risk group. Likewise, high-risk patients are a little over 17 times more likely to receive an amputation in a 3-year follow-up than patients in a lower-risk group. Patients with a history of amputation are even more likely to develop a foot complication. These patients are 100 times more likely to ulcerate and 32 times more likely to receive an additional amputation than patients in the lower-risk groups (Table 4). Overall, patients in higher-risk groups had a longer history of diabetes, worse glycemic control, more neuropathy, and increased plantar pressures. Furthermore, they were more likely to be male and to have a history of alcohol abuse and end-organ complications of diabetes, such as nephropathy and retinopathy. The stratification process easily explains these differences among the risk groups at enrollment of the patients; there is an increased prevalence of angiopathy, neuropathy, deformity, and earlier amputations in the higher risk groups. It seems only logical that these conditions are more often seen in certain groups of patients, such as men with a longer history of diabetes and worse glucose level control. It has been demonstrated that foot deformities and other ulcer risk factors are indeed exacerbated by poor glucose control and longer duration of diabetes (16).

The goal of the study was not to assess the responsible cause or cluster of causes that lead to an ulceration or amputation but rather to determine if a classification system would predict an ulceration or amputation. By themselves, the risk factors have been shown to be possible causal factors in ulceration and amputation in diverse case-control studies. Neuropathy has been shown to be a pivotal risk factor by itself for both ulceration and amputation (6,10,12,17,18). Vascular disease has been strongly associated with amputations (19,20); its role as a risk factor for ulceration seems likely, but several studies provided mixed results. An ABI of <0.8, for instance, was not identified as a significant risk factor in previous studies (6,21). It has been suggested that vascular disease might be a more important risk factor for delayed wound healing and subsequent amputation than for ulceration (10). Deformities of the foot might contribute to ulceration because they can create areas of increased pressure on the foot. Likewise, amputations have been shown to increase the risk of additional ulceration (22).

Several authors have proposed classification systems in the past. Most of them incorporated neuropathy, bony foot deformity, history of ulceration or amputation, or various combinations of these (10,23–29). Three of them also included PVD (10,28,29). Although most early classification systems were solely based on expert clinicians' experiences, three of these systems were validated with patient data (10,26,29). Mayfield et al. (29) validated their classification for amputations, Lavery et al. (10) validated their classification for ulcerations, and Rith-Najarian et al. (26) validated their classification for both ulcers and amputations. The consensus classification differs from earlier classification systems because clinicians and researchers from various parts of the world and from various fields of work were involved in its conceptualization. Some of the authors of other classification systems were also members of the International Working Group on the Diabetic Foot (1).

One of the classifications, which resembles the international consensus, is the University of Texas Treatment-Based Diabetic Foot Classification System (10,30,31). It consists of two different

classifications. The first one stratifies patients into risk groups for ulceration, and the second one stratifies patients with an existing ulceration into risk groups for amputation (31). Although it is very logical and the first part for ulcerations has been validated, it is not the simplest of classifications. Incorporating this classification scheme in diabetes clinics that are not specialized in problems of the diabetic foot might be difficult and impractical. This is especially true because there are wide intercountry variations in health care resources and infrastructure. Even in the Western world, which is known for readily available medical care, the quality of diabetic foot examinations is often lacking (32,33). The complexity of most of the classification systems might make them hard to implement globally. The goal of the consensus was to achieve global consistency in adequate diagnostic, preventative, and therapeutic strategies. These strategies use simple diagnostic tools to help prevent diabetic foot problems from occurring. Therefore, a shift might take place from therapeutic medical and surgical treatment to preventative measures.

The International Working Group on the Diabetic Foot did not specifically describe the default methods to measure neuropathy or angiopathy. However, the instruments we used to define these methods are described in the Consensus (1). VPTs, SWMs, ABIs, and pedal pulses are widely accepted clinical measures (8 10,34,35). All of these techniques provide easily obtainable data. Only the VPT, measurable with a biothesiometer or neuroesthesiometer, could be expensive for some centers. It was used in this study because of its convenience and because all of the researchers involved were familiar with its use. As an alternative, a 128-Hz tuning fork could be used. The data collected with a tuning fork has been shown to correlate well with the data of the VPT (36).

The recommended check-up frequency for the group without neuropathy was once a year, for the group with neuropathy but without deformity or vascular disease wasonce every half year, for the group with neuropathy, deformity, and/or vascular disease was once every 3 months, and for the group of patients with a history of ulceration was once every 1–3 months (1). In general, patients in this study were not strictly seen according to the frequency recommended by the consensus. At the University of Texas, patients are often seen more frequently than the guidelines in the consensus. Therefore, the chance that diabetic foot ulcers occurred and healed outside of a patient's appointment schedule is small.

Even though several descriptive studies have reported the effectiveness of diabetic foot prevention programs, we still do not regularly inspect the foot or prescribe therapeutic shoes and insoles to protect high-risk patients from repetitive injuries. The International Working Group's Classification provides a simple and effective globally implementable framework for assessment and treatment. It can easily be used as a checklist in medical records to help health professionals allocate resources, such as therapeutic shoes and insoles, to determine the frequency of follow-up visits, and to document that foot screening is being performed on a regular basis.

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