Reevaluating the Way We Classify the Diabetic Foot

Restructuring the diabetic foot risk classification system of the International Working Group on the Diabetic Foot

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OBJECTIVE — To separately evaluate peripheral arterial occlusive disease (PAOD) and foot ulcer and amputation history in a diabetic foot risk classification to predict foot complications.

RESEARCH DESIGN AND METHODS — We evaluated 1,666 diabetic patients for 27.2 ± 4.2 months. Patients underwent a detailed foot assessment and were followed at regular intervals. We used a modified version of the International Working Group on the Diabetic Foot's (IWGDF's) risk classification to assess complications during the follow-up period.

RESULTS — There were more ulcerations, infections, amputations, and hospitalizations as risk group increased (χ^2 for trend $P < 0.001$). When risk category 2 (neuropathy and deformity and/or PAOD) was stratified by PAOD, there were more complications in PAOD patients ($P < 0.01$). When risk group 3 patients (ulceration or amputation history) were separately stratified, there were more complications in subjects with previous amputation ($P < 0.01$).

CONCLUSIONS — We propose a new risk classification that predicts future foot complications better than that currently used by the IWGDF.

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Several risk classification schemes have been developed to facilitate diabetic foot assessment and to prioritize high-risk patients for prevention services (1–6). The risk assessment instrument developed by the International Working Group on the Diabetic Foot (IWGDF) has been shown to predict diabetic foot complications (1). However, it may undervalue the impact of peripheral arterial occlusive disease (PAOD) and history of amputation. The purpose of this study was to evaluate the role of these variables in risk assessment within the context of a global risk evaluation instrument to predict lower-extremity complications.

RESEARCH DESIGN AND METHODS

— We evaluated 1,666 consecutive diabetic patients enrolled in a managed care–based diabetes disease management program for an average of 27.2 ± 4.2 months. At enrollment, patients underwent a standardized general medical examination and detailed foot assessment (7,8). The screening process involved a review of the patient's past medical history and a lower-extremity physical examination. A staff podiatrist examined each patient to identify lower-extremity complications and risk factors, such as history of lower-extremity ulcerations and amputation, peripheral sensory neuropathy, peripheral vascular disease, foot deformities, limited joint mobility, and abnormal foot pressures using previously published methods (5,9–11).

Neuropathy was evaluated with a 10-g Semmes-Weinstein monofilament (Touch-Test Sensory Evaluator; North Coast Medical, Morgan Hill, CA) and vibration perception threshold tester (Salix Medical, San Antonio, TX) (12). PAOD was defined as a nonpalpable dorsalis pedis or posterior tibial arterial pulse and ankle brachial index in either foot <0.80. We defined deformity as any contracture that could not be fully corrected manually, such as hallux valgus, hammer toes or claw toes, hallux rigidus (dorsiflexion of the first metatarsophalangeal joint <50°), and ankle equinus (dorsiflexion <0°). Foot ulcers were defined as full-thickness wounds involving the foot or ankle. Infection was defined by criteria consistent with the International Working Group and Infectious Diseases Society of America guidelines (13).

Statistical analysis

For analysis for this report, we modified the IWGDF risk classification. Risk group 2 was divided into subgroups hypothesized to provide a more refined explanation of increasing risk. In this modified risk classification, risk group 2A included subjects with sensory neuropathy and foot deformity, and 2B included subjects with PAOD. Risk group 3 was subdivided into subjects with a history of ulceration (3A) and a history of amputation (3B). In an earlier study the two groups were suggested to have different risk profiles (1).

Counts for ulcers, infections, amputations, and hospitalizations were broken down by six risk groups based on modification of the IWGDF risk classification (Table 1). The risk groups are a type of qualitative ranking or ordering of risk.

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Abbreviations: PAOD, peripheral arterial occlusive disease; IWGDF, International Working Group on the Diabetic Foot.

We then compared the proportion of outcomes for each risk group using a procedure described by Bartholomew (14). Tests for all outcomes (ulcers, infections, amputations, and hospitalizations) were highly significant ($P < 0.005$) for the hypothesis that the proportion of patients in increasing risk groups were qualitatively ordered from smallest to largest proportions in the groups. Odds ratios (ORs) for risk groups 1, 2A, 2B, 3A, and 3B were calculated compared with risk group 0, and 95% CIs were calculated for each OR using the method developed by Wolf as described by Schlesselman (15).

RESULTS — There was a significant trend for more ulcerations, infections, amputations, and hospitalizations as risk group increased (χ^2 for trend $P < 0.001$). When the original IWGDF risk category 2 was split into modified risk group 2A (neuropathy and deformity) and modified risk group 2B (peripheral vascular disease), there were more foot complications in subjects with PAOD ($P < 0.01$). In addition, when we stratified patients with a previous ulcer or a previous amputation, there were significantly more infections, amputations, and hospitalizations among patients with a previous amputation ($P < 0.01$). There was no difference in the frequency of ulcers, infections, or hospitalizations in IWGDF risk category 1 (neuropathy, no deformity, no PAOD) versus 2A (neuropathy with deformity, no PAOD) ($P > 0.05$). ORs comparing IWGDF risk group 0 with risk groups 1 and 2A were as follows: ulcer, OR 1.7 (95% CI 1.03–2.9); infection, 2.2 (1.1–4.2); amputation, 8.0 (1.1–251.9); and hospitalization, 11.7 (1.9–359.5).

CONCLUSIONS — The results of this study suggest that a modified IWGDF diabetic foot classification is more effective at predicting diabetic foot complications than the original risk scheme. Based on our results modifying the IWGDF classification, we proposed a five-tiered risk classification identified in Table 1 as the Texas Foot Risk Classification. The original IWGDF classification grouped neuropathy without PAOD and without deformity (Texas risk group 1) and subjects with PAOD and/or peripheral neuropathy with foot deformity together (Texas risk group 2). When we compared neuropathy and deformity and PAOD

Table 1—*Outcomes by modified IWGDF risk classification*

Modified IWGDF Risk Classification	Texas Foot Risk Classification	Ulcer	Multiple ulcers	Infection	Multiple infections	Amputation	Hospital admission
Group 0 (no PN, no PAOD)	Group 0 (no PN, no PAOD)	45 (2.0%)	5 (0.2%)	23 (1.2%)	1 (0.04%)	1 (0.04%)	1 (0.10%)
Group 1 (PN, no PAOD, no deformity)	Group 1 (PN)	10 (4.5%)	1 (0.4%)	4 (1.8%)	0	0	1 (10.0%)
		2.4 (1.1–5.0)	2.7 (0.1–17.8)	1.9 (0.6–5.5)			10 (0.3–370.5)
Group 2A (PN and deformity, no PAOD)		18 (3.0%)	8 (1.2%)	14 (2.3%)	4 (0.7%)	4 (0.7%)	5 (5.1%)
		1.2 (0.8–2.7)	5.8 (1.8–21.3)	2.3 (1.1–4.7)	11.1 (1.5–349.9)	10.9 (1.5–344.6)	13.6 (2.13–427.8)
Group 2B (PAOD)	Group 2 PAOD)	45 (13.8%)	11 (3.4%)	36 (11.0%)	6 (1.8%)	12 (3.7%)	23 (15.9%)
		9.3 (5.7–15.2)	15.1 (5.0–53.5)	13.5 (7.6–24.9)	30.3 (5.0–934.8)	60.9 (11.8–1826.5)	124.8 (26.1–3690.7)
Group 3A (ulcer history)	Group 3 (ulcer history)	87 (31.7%)	21 (16.1%)	39 (14.2%)	12 (4.4%)	6 (2.2%)	10 (8.2%)
		50.5 (30.5–87.0)	80.5 (32.0–261.3)	19.2 (10.7–35.5)	73.6 (14.2–2211.6)	36.3 (6.6–1126.5)	60.7 (11.4–276.6)
Group 3B (amputation history)	Group 4 (amputation history)	42 (32.2%)	21 (16.1%)	35 (26.8%)	12 (9.2%)	27 (20.7%)	29 (50.0%)
		52.7 (27.2–09.8)	102.3 (36.6–55.5)	62.3 (30.7–30.6)	174.8 (33.2–350.3)	567.9 (136.3–2439.0)	650.3 (156.4–2795.1)

$N = 976$. Data are *n* (IR) and OR (95% CI). IR, incidence rate per year; PN, peripheral neuropathy. The original IWGDF classification paper consists of four groups: group 0, patients without risk factors; group 1, patients with neuropathy; group 2, patients with neuropathy and a deformity of vascular disease; group 3, patients with a history of ulcer or amputation.

separately, there were significantly more ulcers, infections, amputations, and hospitalizations in subjects with PAOD. There was no difference in outcomes in subjects with neuropathy compared with those with neuropathy and foot and ankle deformity. Therefore, we combined patients with neuropathy and without PAOD into a single risk group (Texas risk group 1) (Table 1). We did not include deformity as a decisive factor in risk group assignment. In addition, we provided separate risk tiers for PAOD (Texas risk group 2), history of foot ulcer (Texas risk group 3), and history of amputation (Texas risk group 4).

The 80/20 effect

The results are a classic example of the Pareto effect (sometime called the 80/20 effect in economics) (16–19). According to the Pareto Principle, when multiple factors contribute to a common outcome, relatively few factors account for the majority of the effect (17–19). Ordering of the most important factors helps identify the "most important few"—the factors that warrant the most attention. In this study, subjects in Texas risk groups 2, 3, and 4 accounted for <20% of the study population but 70% of ulcers and 90% of amputations and hospitalizations. Understanding this concept should help health care providers concentrate on risk groups that have the greatest morbidity and health care costs. Prevention in these populations may provide the most health care improvements for society for the lowest costs. This is a departure from simply focusing on a specific risk factor, such as neuropathy.

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