A Foot Risk Classification System to Predict Diabetic Amputation in Pima Indians

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OBJECTIVE — To quantify the contribution of various risk factors to the risk of amputation in diabetic patients and to develop a foot risk scoring system based on clinical data.

RESEARCH DESIGN AND METHODS — A population-based case-control study was undertaken. Eligible subjects were *1*) 25–85 years of age, *2*) diabetic, *3*) 50% or more Pima or Tohono O'odham Indian, *4*) lived in the Gila River Indian Community, and 5) had had at least one National Institutes of Health research examination. Case patients had had an incident lower extremity amputation between 1983 and 1992; control subjects had no amputation by 1992. Medical records were reviewed to determine risk conditions and health status before the pivotal event that led to the amputation.

RESULTS — Sixty-one people with amputations were identified and compared with 183 control subjects. Men were more likely to suffer amputation than women (odds ratio [OR] 6.5, 95% CI 2.6–15), and people with diabetic eye, renal, or cardiovascular disease were more likely to undergo amputation than those without (OR 4.6, 95% CI 1.7–12). The risk of amputation was almost equally associated with these foot risk factors: peripheral neuropathy, peripheral vascular disease, bony deformities, and a history of foot ulcers. After controlling for demographic differences and diabetes severity, the ORs for amputation with one foot risk factor was 2.1 (95% CI 1.4–3.3), with two risk factors, 4.5 (95% CI 2.9–6.9), and with three or four risk factors, 9.7 (95% CI 6.3–14.8).

CONCLUSIONS — Male sex, end-organ complications of eye, heart, and kidney, and poor glucose control were associated with a higher amputation rate. Peripheral neuropathy, peripheral vascular disease, deformity, and a prior ulcer were similarly equally associated with an increased risk of lower extremity amputation.

Risk stratification systems have become commonplace in clinical practice. A risk stratification system may be defined as a formalized method of recognizing, documenting, and cumulating risk factors to predict later outcome. Examples include the Apgar score to assess newborns (1), the Duke classification system for staging colon cancer (2), and the New York Heart Association's classification system for heart disease (3). Providers use classification systems to inform patients about expected outcome and to select appropriate treatment. Researchers use these systems to evaluate treatment interventions on homogeneous groups of patients.

Several diabetic foot risk classification systems to predict amputation risk have recently been developed and widely disseminated (Table 1) (4–7). These classification systems usually include measures of neuropathy, bony deformities, and a history of prior foot ulceration, but they differ from each other in the definitions and relative importance of how each risk factor contributes to the overall risk score. Only one classification system includes vascular status (6), a well-known risk factor for poor wound healing and amputation (8). All of these classification systems, however, were developed from expert opinion, rather than from empiric data analysis, and only one prospective validation of a risk stratification system has been reported (9).

In the present study, the risk of amputation associated with various conditions was quantified, and a foot risk classification system was developed. The study was undertaken in the Pima Indians of Arizona, who have the highest reported prevalence of diabetes in the world and have a high rate of lower extremity amputation attributable to diabetes (10,11). A previous study of the Pima Indians identified a number of risk factors associated with amputation risk, including peripheral neuropathy, bony deformity, medial arterial calcification, peripheral vascular disease, and a history of prior foot ulcers (11,12).

RESEARCH DESIGN AND METHODS

— The Pima and the closely related Tohono O'odham Indians from the Gila River Indian Community have participated in a longitudinal study conducted by the National Institutes of Health (NIH) since 1965 (10). The Indian Health Service (IHS), a branch of the U.S. Public Health Service, provides medical care for this population and has conducted a model diabetes program in this community since 1979 (13). The model program provides culturally appropriate educational materials and staff for diabetes care, including a podiatrist.

The present case-control study includes 244 individuals who met the following criteria: *1*) 25–85 years of age; 2) 50% or more Pima or Tohono O'odham Indian; 3) lived in the Gila River Indian Community between 1 January 1983 and 31 December 1992; *4*) had a diagnosis of NIDDM by World Health Organization

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IHS, Indian Health Service; NIH, National Institutes of Health; OR, odds ratio; WHO, World Health Organization.

Table 1—*Comparison of foot risk classification systems by risk level*

Condition	Foot risk classification system				
	Birke and Sims (4)	Sims et al. (5)	Duffy and Patout (6)	Rith-Najarian et al. (9)	Brill et al. (7)
Sensation intact	0	0	0	0*	0
Loss of sensation alone	1	1	1	1	
Deformity alone					1
Loss of sensation and deformity		2	2†	2	2†
Loss of sensation and history of ulcer	2	3		3‖	
Plantar ulceration			3§		
Loss of sensation, ulcer history, and deformity	3	4¶			
Neuropathic fracture, Charcot foot	4	5			

*May have deformity. †Deformity may be replaced by weakness or preulcer or callus. ‡Loss of sensation or possible deformity or prior ulcer. §Or ischemic index <0.045. ‖Ulcer history, with or without other changes. ¶Deformity could be replaced by high plantar pressure.

(WHO) criteria (14,15); and 5) had undergone at least one NIH research examination. Cases were defined as people who met the above eligibility criteria and underwent a first diabetic amputation (i.e., not due to trauma or neoplasia) of the lower extremity during the study period. Controls were defined as people who met the above eligibility criteria, but had no lower extremity amputation by 31 December 1992. Three controls were selected randomly for each case. Medical records from Hu Hu Kam Memorial Hospital and the Phoenix Indian Medical Center and the home health records of the Gila River Indian Community Health Services were abstracted by a trained nurse chart abstractor. The chart abstractor was not blinded to which patients were cases and which were controls.

The concept of a pivotal or initiating event that leads to an amputation has been described previously (16). The pivotal event may be an acute traumatic event, such as stepping on a tack, or repetitive minor trauma, such as wearing new shoes that cause a blister. This event, imposed upon a susceptible individual with other pathophysiological conditions, provides the critical factor that culminates in a lower extremity amputation. The date and type of pivotal event were determined from the medical record and confirmed by a staff podiatrist. This pivotal event date was then assigned to the three controls selected for the case to fix a similar point in time for chart abstraction for cases and controls.

Data on health status, foot conditions, and diabetes complications documented before the pivotal event date for cases (or assigned pivotal event for controls) were assessed. These included diabetic retinopathy, renal failure (creatinine >4 mg/dl or dialysis or renal transplant), cardiovascular disease (e.g., myocardial infarct, angina, congestive heart failure, or stroke), peripheral neuropathy (e.g., loss of pain or light touch sensation using the Semmes-Weinstein monofilament (4) or paresthesia), peripheral vascular disease (diagnosis or absent pulses or claudication), and bony deformities (e.g., hammertoes, rigid hallux, bunions, Charcot foot, or other deformity). A history of foot ulcers was defined as a foot wound that took longer than 4 weeks to heal. The first three values of blood glucose determinations, when available, were collected for each of the 3 years before the pivotal event. Information on the urinary protein to creatinine ratio was obtained from the NIH research examination that corresponded most closely with the pivotal event date. Any data on alcohol-related conditions noted during the 3-year interval were identified and classified using a standard system (17,18). In addition, the tribal alcohol treatment program identified the cases and controls who had been in treatment before the pivotal event date.

Continuous variables were compared with Student's t tests and categorical variables with χ^2 tests. A logit model using STATA (1992) was built to assess the association of foot risk conditions with amputation risk in two stages. In the first stage, a diabetes severity variable was created, while controlling for demographic variables known to influence amputation risk. In the second stage, foot risk variables were entered into the model, while controlling for demographic and diabetes severity.

RESULTS— Among eligible diabetic people between 1983 and 1992, 61 first diabetic amputations occurred, and 183 controls were randomly selected for comparison. Table 2 describes the pivotal event and incident amputation level for the cases. Of the pivotal events, 44% were linked to a trauma (e.g., cuts, wounds, shoe trauma, thermal injury, or iatrogenic injury—surgery by a medical provider or patient), and 39% were new ulcers with no history of trauma. Over half of the incident amputations were of toes; 10% were transmetatarsal amputations; and one-third were major amputations (e.g., Symes, below-the-knee, or above-the-knee amputations).

Table 3 compares the demographic features of cases and controls. Cases were more likely to be men (53 vs. 37%, $P < 0.05$), were older than 55 years of age (54 vs. 31%, $P < 0.001$), and have had diabetes 20 or more years (51 vs. 18%, $P < 0.001$). Cases had significantly more comorbidity, as shown in Table 4. Cases were more likely to have background and proliferative diabetic retinopathy (OR 5.6, 95% CI 2.1–15 and OR 21, 95% CI 5.8–80, respectively), end-stage cardiovascular disease (OR 8.4, 95% CI 2.9–25), or renal failure (OR 5.1, 95% CI 1.4–18). The mean glucose level was significantly higher in cases than in controls (246 vs. 216 mg/dl, $P < 0.005$).

The first-stage logistic model incorporated demographic variables associated with amputation plus variables for diabetes severity. A dichotomous diabetes severity variable was constructed indicating the presence of diabetic retinopathy, cardiovascular disease, or renal failure. After controlling for demographic factors and diabetes severity, alcohol-related medical problems, alcohol treatment history, and tobacco use were not associated with amputation risk (data not shown).

Table 5 shows that cases were more likely to have one of the four major foot conditions associated with risk of amputation: peripheral neuropathy (OR 4.7, 95% CI 2.3–9.7), peripheral vascular disease (OR 6.9, 95% CI 2.6–18.3), foot deformity (OR 3.8, 95% CI, 1.4–10.5), or

Table 2—*Description of cases*

	No.	%
Total no. patients	61	
Pivotal event		
Trauma		
Cuts, puncture wounds	16	26
Thermal injury	3	5
Shoe trauma	5	8
Iatrogenic injury	3	5
New onset ulcer without mention of trauma		
Sole of foot	9	15
Hallux only	8	13
Other toes	6	10
Heel (decubiti)	1	1
Dermatological abnormalities	4	7
Vascular etiology	4	7
Unknown event	2	3
Amputation level of incident amputation		
Toe	35	57
Transmetatarsal	6	10
Symes	1	2
Below the knee	16	26
Above the knee	3	5

a history of prior foot ulcer (OR 5.5, 95% CI 2.4–12.5). Controlled for demographic factors and diabetes severity, the adjusted ORs for these conditions ranged from 2.2 to 3.4. No significant interaction among these four risk conditions was observed.

Two models of foot risk stratification were developed as shown in Table 5. The first model used a dichotomous definition of risk, defined as having one or more high-risk foot conditions. Almost three-quarters of the cases had one or more of these high-risk conditions, compared with only 25% of the controls (adjusted OR of 3.6 (95% CI 1.7–7.8)).

The second model of risk stratification was developed using the sum of foot risk factors. The crude OR of this risk stratification system showed an increasing risk with increasing number of risk factors. When adjusted for age, sex, duration of diabetes, and severity of diabetes, the adjusted OR for amputation was 2.1 (95% CI 1.4–3.3). There was no interaction between foot risk factors and demographic or disease severity factors.

Table 6 provides the final logistic model incorporating demographic, disease severity, and foot risk factors. The strongest predictor of amputation risk was male sex (OR 6.5, 95% CI 2.6–15.8), followed by the presence of one or more end-organ diseases (retinopathy, cardiovascular disease, or renal disease) (OR 4.6, 95% CI 1.7–12.2). Even when the model was controlled for age, male sex, and duration of diabetes, end-organ disease and poor glucose control were associated with an increased risk of amputation. After controlling for demographic differences and diabetes severity, the OR for amputation risk with one foot risk factor was 2.1 (95% CI 1.4–3.3), with two risk factors was 4.5 (95% CI 2.9–6.9), and with three or four risk factors was 9.7 (95% CI 6.3–14.8) (Table 7).

Table 3—*Demographics of cases and controls*

	P value	Patients		Controls	
		No.	%	No.	%
Sex	0.05				
Men		32	53	68	37
Women		29	47	115	63
Age (years)	0.001				
25–34		1	2	23	12
35–44		9	15	51	28
45–54		18	29	53	29
55–64		21	34	38	21
≥65		12	20	18	10
Duration of diabetes (years)	<0.001				
<5		2	3	38	21
5–9		2	3	36	20
10–14		9	15	40	22
15–19		17	28	34	19
20–24		16	26	24	13
>25		15	25	9	5

CONCLUSIONS— In the present study, peripheral neuropathy, peripheral vascular disease, bony deformity, and a history of foot ulcers were almost equally associated with the risk of amputation. Each additional risk factor increased the risk of amputation, as shown in Table 7.

Our risk classification system differs from previously published risk classification systems in six important ways: *1*) it is based upon data rather than clinical impressions; *2*) it links specific foot conditions with outcomes; *3*) it is population-based rather than referral-based; *4*) it incorporates vascular status; *5*) it includes all four risk factors simultaneously; and *6*) it controls for confounding demographic factors and diabetes severity.

Studies in other populations have also noted an association between sex and amputation risk (19,20), but the basis of this association has not been explained. The association of amputation with the clinical diagnosis of diabetic complications (diabetic retinopathy, cardiovascular disease, and renal failure) has previously been described in this population and others (11,21). Our findings suggest that among people with diabetes, those with end-organ disease should receive in-

Table 4—*Comorbid conditions of cases and controls*

	Cases		Controls			
	n	%	n	%	R	95% CI
Total number	61		183			
Diabetic retinopathy						
None	7	12	78	43	1.00	—
Background	26	43	52	29	5.6	2.1–15
Proliferative	15	25	8	4	21	5.8–80
Unknown	13	21	43	24	3.4	1.1–10
Hypertension	43	71	85	47	2.8	1.4–5.4
Hyperlipidemia	33	54	61	34	2.4	1.3–4.4
Coronary artery disease	10	16	5	3	6.9	2.1–25
Myocardial infarct	4	7	5	3	2.5	0.5–11
Congestive heart failure	7	12	5	3	4.6	1.3–18
Transient ischemic attacks	2	3	0	0	—	—
Stroke	4	7	6	3	2.1	0.5–8.7
Cardiovascular disease						
None	10	13	70	88	1.00	—
Hypertension and/or hyperlipidemia	33	25	98	75	2.4	1.03–5.5
End stage CVD: CAD, MI, CVA, TIA	18	30	15	8	8.4	2.9–25
Renal status						
No renal disease	24	39	122	67	1.00	—
Proteinuria	30	49	43	30	2.8	1.4–5.5
Renal failure: end-stage renal disease, transplant, Cr > 4	7	12	7	4	5.1	1.4–18
Mean glucose (mg/dl)	246	(SD 62)	216	(SD 68)		$P < 0.005$

Data for proteinuria were obtained from the NIH data set.

tensive surveillance and preventive care to decrease their risk of amputation.

In the general population, tobacco use has been associated with peripheral vascular disease and with peripheral neuropathy, which are both risk factors for amputation (20). Our findings of no association between amputation risk and tobacco use could be due to the low prevalence and light usage of tobacco among Pima Indians (11), although previous studies have shown little or no association between tobacco use and risk of amputation in diabetic patients (21,22). The lack of association of alcohol use with amputation risk in our study may have been due to methodological problems inherent in retrospective chart review, including misclassification, missing data for a large proportion of both cases and controls, and the lack of information on the total amount of alcohol consumed. An association of foot ulcers with greater alcohol consumption has been reported previously in a diabetic white male population (22).

Several factors in the present study may contribute to an underestimation of the association of foot risk factors with amputation. The definitions of pe-

Table 5—*Foot conditions of cases and controls associated with an increased risk of diabetic amputation*

	Patients (%)	Controls (%)	Crude OR	95% CI	Adjusted OR	95% CI
Peripheral neuropathy	43	14	4.7	2.3–9.7	3.1	1.3–7.0
Peripheral vascular disease	43	15	6.9	2.6–18.3	3.4	1.2–9.4
Foot deformity	19	6	3.8	1.4–10.5	3.0	1.02–8.7
Prior foot ulcer	33	8	5.5	2.4–12.5	2.2	0.95–5.3
Risk stratification I: peripheral neuropathy or peripheral vascular disease or foot deformity or prior foot ulcer	71	25	7.3	3.7–14.8	3.6	1.7–7.9
Risk stratification II: no. risk factors (peripheral neuropathy, peripheral vascular disease, foot deformity, and prior foot ulcer)						
None	30	75	1.00	—	1.0	—
One	39	19	5.3	2.4–11.5	2.1	1.4–3.3
Two	16	3	12.8	3.7–45	4.5	2.9–6.9
Three or four	15	2	17.3	4.2–76	9.7	6.3–14.8

Adjusted indicates adjustment for age, sex, duration of diabetes, and severity of diabetes.

Table 6—*Final logistic model predicting diabetic amputation risk*

	OR	*P* value	95% CI
Age, per 5 years	1.3	0.013	1.06–1.6
Male sex	6.5	<0.001	2.6–15.8
Duration of diabetes, per 5 years	1.4	0.022	1.05–1.9
Mean glucose per 50 mg/dl	1.6	0.007	1.1–2.3
Severe renal, retinal, or cardiovascular disease	4.6	0.002	1.7–12.2
Sum of foot risk conditions	2.1	<0.001	1.4–3.3

ripheral neuropathy, peripheral vascular disease, and bony deformity depend upon identification and documentation in the medical record by many different providers from a variety of disciplines. Patients without protective sensation may not note the loss, may fail to discuss the loss with the provider, may not be examined, or may not have the loss recorded. However, during the study time period, the IHS diabetes program conducted several educational programs for providers and an annual chart review of diabetes care, which included foot examinations (23). These efforts probably increased the identification and recording of important foot conditions and foot care. Finally, many of these patients with high-risk conditions received treatment aimed at decreasing their risk of amputation. All of these limitations may underestimate the association of foot risk factors with amputation.

This risk scoring system may give providers a more accurate appreciation of risk factors for lower extremity amputation in the diabetic patient. In one study, clinicians placed neuropathy and foot deformity as less important than cigarette smoking, but above nephropathy and retinopathy (24). Most providers already recognize the significance of a foot ulcer and are more likely to refer ulcer patients for education and specialty foot care compared with patients with foot deformities or neuropathy (25). Our study emphasizes the almost equal gravity of peripheral neuropathy, peripheral vascular disease, and bony deformities with that of foot ulcers.

Our findings also suggest additional opportunities for prevention of amputation. Almost half of the pivotal events were associated with trauma, and thus were potentially preventable: cuts and puncture wounds from walking barefoot, burns, shoe trauma from new or ill-fitting shoes, and decubitus ulcers in bedridden people. Education on foot care and footwear can reduce the incidence of traumatic events (26). Another third of the pivotal events were new-onset ulcers without a history of trauma. Many of these were probably mal perforant ulcers, which develop from the repetitive low-pressure stress of walking on an unprotected neuropathic foot. This injury is also amenable to preventive efforts to cushion and protect the insensitive foot (4,27).

We conclude that the presence of a bony deformity, peripheral neuropathy or peripheral vascular disease or a history of foot ulcers is equally associated with an increased risk of amputation in the diabetic Pima Indian. The presence of any of these four conditions should trigger increased surveillance, patient education, and referral to a foot care specialist (28). Providers should be encouraged to identify these foot risk conditions early, particularly in men and those with end-organ disease of the eye, heart, or kidney, and they should provide appropriate management to decrease the risk of amputation.

Table 7—*Pima diabetic foot risk classification system*

Sum of risk factors	OR for amputation
0	1.0
1	2.1
2	4.5
3 or 4	9.7

Peripheral neuropathy	0 or 1
Peripheral vascular disease	+0 or 1
Bony deformity	+0 or 1
History of foot ulcer >4 weeks	+0 or 1
Sum of risk factors	=0 to 4

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