Identifying Diabetic Patients at High Risk for Lower-Extremity Amputation in a Primary Health Care Setting

A prospective evaluation of simple screening criteria

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OBJECTIVE — To evaluate prospectively a risk categorization scheme for lower-extremity problems that incorporates the Semmes-Weinstein 5.07 monofilament and a simple exam to stratify patients who were followed in a primary-care setting into risk groups for plantar ulceration and lower-extremity amputation.

RESEARCH DESIGN AND METHODS — Patients with diabetes in a well-defined American-Indian population were stratified into four risk categories based on sensation status to the 5.07 monofilament, the presence of foot deformity, and a history of lower-extremity events (amputation or ulceration): category 0, sensate; category 1, insensate; category 2, insensate with deformity; and category 3, history of lower extremity events. Patients were followed prospectively for lower extremity events and changes in sensation status.

RESULTS — We gave screening exams to 358 (88%) of 406 individuals with diabetes in the community. The distribution of patients for risk categories 0, 1, 2, and 3 was 74.3, 8.4, 4.5, and 13%, respectively. Over a 32-mo follow-up period, 41 patients developed ulcerations, and incidence rates correlated positively with increasing risk category ($P < 0.00001$). All 14 amputations occurred in risk groups 2 and 3.

CONCLUSIONS — These data suggest that the risk categorization described here may have a role in identifying patients at risk for lower extremity events who are followed in a primary-care setting.

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RECEIVED FOR PUBLICATION 10 OCTOBER 1991 AND ACCEPTED IN REVISED FORM 30 APRIL 1992.

IHS, INDIAN HEALTH SERVICES; CI, CONFIDENCE INTERVAL.

The reduction of amputations in diabetic patients has become a major objective for the year 2000 in the U.S. (1). To achieve this goal, simple strategies are needed to identify high-risk patients followed in primary-care settings, so that services such as protective footwear (2) and intensive patient education (3) can be targeted to individuals at risk before irreversible damage occurs. Two basic pathophysiological processes contribute to lower extremity amputations in diabetic patients: neuropathy and vascular insufficiency (4,5). The relative contribution of each process may vary in different groups of diabetic patients (4–7). Simple strategies to quantify vascular insufficiency have not predicted reliably the necessity for amputation (8,9). In recent years, several retrospective studies have correlated neuropathic ulcerations in diabetic patients with the lack of protective sensation, defined as insensitivity to the Semmes-Weinstein 5.07 monofilament (10–13). Using this screening method for neuropathy combined with a brief history and physical exam, we categorized diabetic patients at high risk in a primary health-care setting and followed them prospectively.

RESEARCH DESIGN AND METHODS

— This study was conducted at Red Lake, MN, where primary care is provided to the 4500 Red Lake Indian Reservation residents by the IHS. The reservation is isolated geographically, and surveillance activities indicate that ~95% of the community regularly seeks their care at the IHS hospital. Diabetes prevalence rates among Red Lake Chippewa Indians (14.8% age-sex adjusted) were almost four times the U.S. rate (14). Cases and major complications were identified through active clinic and community screenings and followed with a diabetes registry as previously described (14).

From 1 July 1988 to 28 February 1991, individuals on the diabetes regis-

Table 1—*Risk category criteria*

Risk category	Sensate to 5.07 monofilament	Deformity present	History of lower extremity event
0	+	+/−	−
1	−	−	−
2	−	+	−
3	+/−	+/−	+

(+), criteria present; (−), criteria absent.
Adapted from criteria developed at National Hansen's Disease Center (15).

try had a foot exam at least annually and were assigned to one of four categories based on the presence of a foot deformity, history of lower extremity events (i.e., ulceration or amputation), and the ability to perceive the 5.07-U monofilament (15) (Table 1). Sensation status was determined by applying the 5.07 monofilament to eight points on the plantar surface of each foot at time A or time B while the patient was blinded, a method whose reproducibility has been described previously (11). Patients were considered sensate if they correctly identified the time at which the monofilament was applied to all areas on both feet. Patients who failed to perceive the monofilament on one or more areas of either foot were retested twice before they were classified as insensate. The monofilaments were checked on a scale periodically throughout the study and remained within 10% of their calculated buckling force. Deformities, identified on clinical examination, included hallux varus or valgus, claw and hammer toes, bony prominence, or Charcot foot on either foot. History of ulceration and amputation was determined by interview, medical record review, and examination. Ulcerations were defined as any full-thickness penetration of the dermis on the plantar aspect of the foot. A subset of patients had an ankle-arm ischemic index calculated from measurements of the right brachial artery and both posterior tibial arteries, which were obtained with a mercury manometer and a 2-MHz portable doppler. Analysis was based on the extremity with the lower index.

Patients contributed a maximum of one ulceration and amputation to the numerators of complication rates. Denominators were based on the person-years of the cohort at risk during the follow-up period. Individual contributions to the denominator were truncated when a patient died or was lost to follow-up. Statistical significance was determined by χ^2 analysis (16).

RESULTS — The distribution by risk category, clinical characteristics, and fate of all community members with known diabetes is summarized in Table 2. Of the 406 individuals on the diabetes registry, 358 (88%) were screened and assigned to risk categories; 13% of those screened fell into the highest risk category. All amputations occurred in high-risk patients, whereas ulceration rates increased progressively by category. ($P < 0.00001$ for trend) (Table 3). Nineteen patients died, and 2 patients were lost to follow-up.

Insensitivity to the 5.07 monofilament occurred in 19% of the patients screened. Among this group, the odds ratio of subsequent ulceration was 9.9 (95% CI 4.8–21.0), and amputation was 17 (95% CI 4.5–95.0) compared with those who retained sensation. These relationships were maintained when con-

Table 3—*Incidence of lower extremity events by risk category*

Category	Plantar ulceration N	Plantar ulceration Rate	Plantar ulceration Odds ratio*	Amputation N	Amputation Rate
0	4	6	1.0	0	—
1	7	89	15	0	—
2	6	170	32	1	28
3	24	330	78	13	180

Rates per 1000 diabetic person-yr. *n*, number of patients.
*$P < 0.00001$ for trend.

Table 2—*Distribution, characteristics, and fate of patients with diabetes*

	N	Screened subjects (%)	Age (yr)*	Duration of diabetes (yr)*	Men (%)	Women (%)	Died (N)	Lower extremity amputation (N)	Ulcer (N)
Category									
0	266	74.3	53.6 ± 12.4	6.1 ± 4.1	38	62	7	0	4
1	30	8.4	58.2 ± 12.1	11.6 ± 5.6	63	37	1	0	7
2	16	4.5	61.8 ± 8.4	12.6 ± 4.8	69	31	3	1	6
3	46	12.8	58.7 ± 13.0	14.1 ± 7.3	57	43	8	13	24
0–3	358	100	55.0 ± 12.3	12.3 ± 6.7	44	56	19	14	41
3 (sensate)	22	6.1	60.0 ± 13.3	13.5 ± 7.9	50	50	4	3	10
3 (insensate)	24	7.7	57.1 ± 12.6	14.7 ± 6.8	62	38	4	10	14
No exam	48		51.2 ± 18.0	6.3 ± 6.6	60	40	9	1	1

*Values are means ± SD. *n*, number of patients.

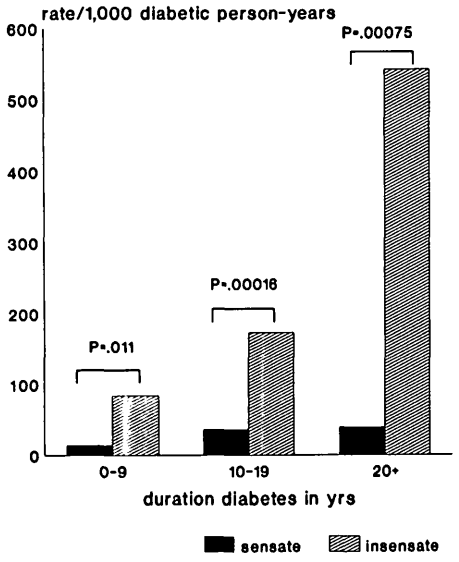

Figure 1—*Incidence of plantar ulceration by duration of diabetes and sensitivity to 5.07 monofilament (n = 41).*

trolling for duration of diabetes (Fig. 1, Fig. 2).

Of the 288 patients who demonstrated protective sensation to the 5.07 monofilament on the first screening, 229 (76%) were retested during the follow-up period: 27 of those lost sensation on a subsequent exam. In addition, 68% of those with insensitivity to the 5.07 monofilament on the first test were retested, and 8 could perceive the monofilament on the second exam.

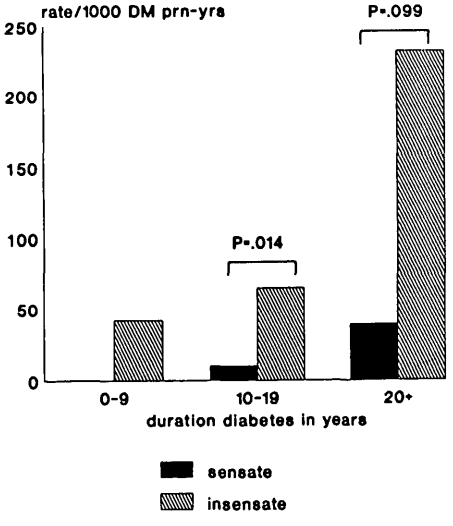

Figure 2—*Incidence of lower-extremity amputation by duration of diabetes and sensitivity to 5.07 monofilament (n = 14).*

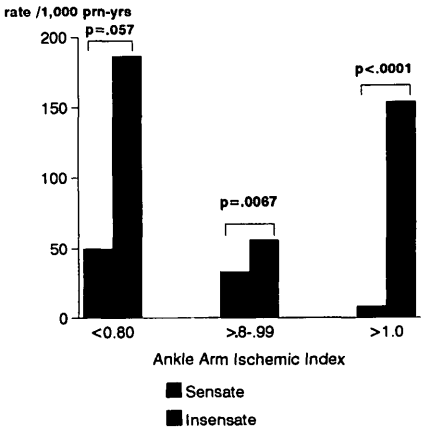

Figure 3—*Incidence of plantar ulceration by ankle-arm ischemic index and sensation status to 5.07 monofilament (n = 35).*

Of the 358 (86%) patients, 308 also had measurements for an ankle-brachial ischemic index. Incidence of ulceration was higher among insensate subjects compared with sensate subjects in all ranges of vascular indexes (Fig. 3).

CONCLUSIONS— This study represents one of the few prospective attempts to evaluate risk for lower extremity amputation in a defined diabetic population. Despite the lack of sophisticated measures of neuropathy and vascular insufficiency, the ability of the screening process used in this study to define high-risk individuals was remarkable. The risk of a previous amputation has long been described, and the importance of deformity is gaining recognition (4,9,17). Both of these factors are easy to ascertain in a primary-care setting. The preliminary data on the ischemic index suggest that the addition of a low index (<0.80) to the high-risk criteria may enhance the ability of categorization schemes to identify high-risk patients for ulceration.

The screening methods used in this study have obvious weaknesses. Sensitivity testing with monofilaments is semiquantitative (18). Although efforts were made to perform the technique carefully and to check the filament characteristics periodically, we cannot confirm whether changes in status at the subsequent exam represented true changes in underlying neuropathy or were variations in the method. Ulcers did occur in sensate patients, some of whom could be expected to incur sufficient trauma to ulcerate during the period of follow-up. During follow-up, amputations occurred in patients who retained protective sensation and possibly were attributable to various other causal pathways, such as a combination of minor trauma and vascular insufficiency (6). Although we did not incorporate all known risk factors in the screening strategy, the categorizations still can identify high-risk patients. Simple screening strategies can be used in conjunction with more sophisticated techniques when available. Reducing lower extremity amputations in diabetic patients will require the development, refinement, and testing of simple strategies to identify high-risk patients for intensive intervention. The system described herein represents a beginning.

Acknowledgments— We thank the Red Lake Tribal Council for support of the Diabetes Program; the people of the Red Lake community for regular participation in the Diabetes Clinic; Mary Winegardner, for meticulous maintenance of the Red Lake Diabetes Registry; and the Red Lake Hospital for its commitment; and the Comprehensive Health Services staff of the Diabetic Foot Program. We appreciate the assistance of Celeste Beaulieu and Drs. Carlene McIntyre and Fred Ness in data abstraction. We also thank Dr. Gayle Reiber for constructive suggestions in preparing this manuscript.

The opinions expressed in this report represent those of the authors and are not necessarily those of the Indian Health Service.

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