Diabetic Foot Syndrome

Evaluating the prevalence and incidence of foot pathology in Mexican Americans and non-Hispanic whites from a diabetes disease management cohort

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OBJECTIVE — To report the incidence of diabetes-related lower-extremity complications in a cohort of patients enrolled in a diabetes disease management program.

RESEARCH DESIGN AND METHODS — We evaluated screening results and clinical outcomes for the first 1,666 patients enrolled in a disease management program for a period of 24 months (50.3% men, aged 69.1 ± 11.1 years).

RESULTS — The incidence of ulceration, infection, amputation, and lower-extremity bypass was 68.4, 36.5, 5.9, and 7.7 per 1,000 persons with diabetes per year. Amputation incidence was higher in Mexican Americans than in non-Hispanic whites (7.4/1,000 vs. 4.1/1,000; $P = 0.003$, odds ratio [OR] 1.8, 95% CI 1.2–2.7). The amputation-to-ulcer ratio was 8.7%. The incidence of Charcot arthropathy was 8.5/1,000 per year. Charcot was more common in non-Hispanic whites than in Mexican Americans (11.7/1,000 vs. 6.4/1,000; $P = 0.0001$, 1.8, 1.3–2.5). The prevalence of peripheral vascular disease was 13.5%, with no significant difference based on ethnicity ($P = 0.3$). There was not a significant difference in incidence of foot infection ($P = 0.9$), lower-extremity bypass ($P = 0.3$), or ulceration ($P = 0.1$) based on ethnicity. However, there were more failed bypasses in Mexican Americans (33%) than in non-Hispanic whites (7.1%). Mexican Americans were 3.8 times more likely to have a failed bypass (leading to an amputation) or be diagnosed as "nonbypassable" than non-Hispanic whites (75.0 vs. 44.0%; $P = 0.01$, 3.8, 1.2–11.8).

CONCLUSIONS — The incidence of amputation is higher in Mexican Americans, despite rates of ulceration, infection, vascular disease, and lower-extremity bypass similar to those of non-Hispanic whites. There may be factors associated with failed or failure to bypass that mandate further investigation.

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Diabetes continues to be the single most common underlying factor related to lower-extremity amputation in the U.S. and Europe (1–4). The incidence of lower-extremity amputation increases with age (5). Amputations are significantly more common in men than in women (6,7), and the incidence and proportion of lower-extremity amputations is significantly higher in minorities. In addition, in Mexican and African American communities, 75–83% of all amputations occur in those with diabetes (7,8). In contrast, among non-Hispanic whites, approximately half of amputations occur in those with diabetes (7,8).

There are a number of diabetes-related complications, such as peripheral sensory neuropathy, peripheral vascular disease, ulceration, Charcot arthropathy, and infection, that contribute to lower-extremity amputation (9–14). However, there is little published information concerning the incidence of these complications in minorities. The purpose of this article was to identify the incidence of diabetes-related lower-extremity complications and amputations in a cohort of Mexican Americans and non-Hispanic whites with diabetes. We hypothesized that higher incidence of lower-extremity amputations would be associated with a higher prevalence of peripheral vascular disease and peripheral sensory neuropathy and a greater severity of "diabetic foot risk" as well as a higher incidence of ulceration, infection, and Charcot arthropathy.

RESEARCH DESIGN AND METHODS

— In conjunction with two large physician groups, we implemented a diabetes disease management program in San Antonio, Texas, to prevent lower-extremity complications. Members with diabetes were identified from inpatient and outpatient administrative databases to identify patients with any 250 code from *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM). The diagnosis of diabetes was confirmed by review of medical records or laboratory data or by communication with the primary care physician. This report includes data from a cohort of the first 1,666 patients consecutively screened and followed for an average of 24 months (range 20–28 months). A database was constructed as part of the disease management program to record screening information and track clinical outcomes.

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

Table 1—*Population descriptive characteristics*

	Total	Non-Hispanic white	Mexican Americans	Other
n	1,666	733	866	67
Age (years)	69.1 ± 11.1	70.6 ± 10.5	67.9 ± 11.3	67.5 ± 13.2
Male (%)	50.3	55.2	53.1	60.9
Weight (kg)	83.8 ± 19.7	85.8 ± 19.9	81.7 ± 19.1	89.9 ± 22.5
Duration of diabetes (years)	11.2 ± 9.5	10.3 ± 9.7	11.7 ± 9.2	13.1 ± 11.7
Peak plantar pressure (N/cm^2)	86.6 ± 27.4	89.9 ± 27.5	84.0 ± 26.7	84.2 ± 31.4
One or more foot deformities (%)	63.1	62.2	63.1	73.4
History of ulceration (%)	7.3	7.1	7.5	6.0
History of amputation (%)	3.5	2.2	4.6	3.0
History of lower-extremity bypass (%)	2.3	2.5	2.0	4.5

Data are means ± SE.

The screening process involved review of the patient's medical history and a lower-extremity physical examination. Using previously published methods (3), a staff podiatrist examined each patient to identify lower-extremity complications and risk factors, such as history of lower-extremity pathology (previous foot ulceration and amputation), peripheral sensory neuropathy, peripheral vascular disease, foot deformities, and abnormal foot pressures. Peripheral neuropathy was evaluated with a 10-g Semmes-Weinstein monofilament (Touch-Test Sensory Evaluator; North Coast Medical, Morgan Hill, CA) and vibration perception threshold testing (VPT Tester; Salix Medical, San Antonio, TX) using methods previously described by Armstrong et al. (15). Neuropathy with loss of protective sensation was based on either a vibration perception threshold level >25 volts or the inability to accurately detect the Semmes-Weinstein monofilament. Lower-extremity vascular disease was defined as a nonpalpable foot pulse (dorsalis pedis or posterior tibial arterial pulse) and ankle brachial index <0.80 in either foot.

The staff podiatrist evaluated patients for the presence of structural and functional foot deformity such as hallux valgus, hammer toes or claw toes, hallux rigidus (dorsiflexion of the first metatarsophalangeal joint <50 degrees), and ankle equinus (dorsiflexion <0 degrees) (14,16–19). We assessed foot pressures with a force-plate (EMED; Novell, Minneapolis, MN). Foot pressures were identified using a two-step method according to previously described criteria (20–22).

Based on the results from screening, we stratified patients into risk groups for either yearly rescreening or preventive care. We used the International Diabetic Foot Classification System to facilitate risk group assignment (23–25). Low-risk patients (foot risk category 0) were rescreened annually. High-risk patients were defined as risk groups 1, 2, or 3 (Table 2). Patients in these risk groups were seen at least every 12 weeks for foot care and evaluation, fitted by a certified pedorthist for shoes and insoles, scheduled for group diabetes education, and provided referrals to subspecialists as needed.

Two staff podiatrists evaluated and treated foot complications. Foot infections were based on the presence of clinical signs of cellulitis, purulence, exposed bone, or bone biopsy when appropriate (26–28). Foot ulcers were defined as full-thickness wounds involving the lower extremity (29–31). Charcot arthropathy was defined as lower-extremity fracture or dislocation in the presence of sensory neuropathy with loss of protective sensation.

We used a normal test (z statistic) to compare incidence rates and a Mantel-Haenszel χ^2 test to compare differences in the proportion of lower-extremity complications associated with diabetes between racial/ethnic groups. To calculate a 95% CI for the relative risk, we used the formula described by Miettinen (32). We used a χ^2 test for trend to compare the severity of lower-extremity risk based on the international risk classification system among Mexican Americans and non-Hispanic whites (33).

RESULTS — Patient demographics and severity of diabetic foot risk using the Diabetic Foot Risk Classification at the time of screening are presented in Tables 1 and 2. There was no significant difference in the severity of diabetic foot risk among Mexican Americans and non-Hispanic whites when we compared the proportion of patients according to the

Table 2—*International consensus on the diabetic foot: Diabetic Foot Risk Classification*

Category	Risk factors	Total	Non-Hispanic white	Mexican American	Other
0	No sensory neuropathy	58.6	57.8	59.1	62.5
1	Sensory neuropathy, no foot deformity, no PVD	5.9	7.0	5.3	3.0
2	Sensory neuropathy and foot deformity or PVD	24.7	25.9	23.5	25.5
3	Previous ulcer or amputations	10.8	9.3	12.1	9.0

The prevalence of foot pathology and severity of "diabetic foot risk" using the Diabetic Foot Risk Classification at the time of screening. The prevalence of persons in each risk group was not different based on race ($P = 0.17$, $P = 0.69$, $P = 0.47$, $P = 0.34$ for categories 0, 1, 2, and 3, respectively).

Table 3—*Lower extremity complications and clinical outcomes*

	Total	Non-Hispanic white	Mexican Americans	Other
n	1,666	733 (44.0%)	866 (52.0%)	67 (4.0%)
Neuropathy (%)	41.4%	42.2%	40.9%	37.5%
Peripheral vascular disease (%)	12.3	11.7	12.9	10.9
Ulcers treated for infection (%)	53.4	57.8	52.1	30.8
Neuropathy to ulcer ratio	38.6	35.3	40.6	52.0
Amputation incidence (per 1,000 person-years)	5.9	4.1	7.4	6.4
Ulcer incidence (per 1,000 person-years)	68.4	71.2	63.7	83.1
Ulcer to amputation ratio (%)	8.7	6.4	10.4	7.7
Incidence of Charcot arthropathy (per 1,000 person-years)	8.5	11.7	6.4	0

Data are means ± SD.

Diabetic Risk Classification. The prevalence of peripheral sensory neuropathy with loss of protective sensation was 40.9% in Mexican Americans and 42.2% in non-Hispanic whites ($P = 0.1$).

The prevalence and incidence of lower-extremity complications are presented in Table 3. For the entire population, the incidence of lower-extremity ulceration, infection, amputation, and lower-extremity bypass was 68.4, 36.5, 5.9, and 7.7 per 1,000 person years, respectively. The incidence of lower-extremity ulceration and infection was similar in Mexican Americans and non-Hispanic whites (Table 3). More than half (56.5%) of lower-extremity ulcerations were treated for infection during the evaluation period.

The prevalence of peripheral vascular disease at the time of screening was 12.3%, with no significant difference based on ethnicity (Mexican Americans 12.9% vs. non-Hispanic whites 11.7%; $P = 0.46$). Whereas the proportion of patients referred for angiography and vascular intervention was similar in Mexican Americans (3.7%) and non-Hispanic whites (3.4%) ($P = 0.8$), the incidence of lower-extremity bypass surgery was lower in Mexican Americans (6.4/1,000 person years vs. 9.4/1,000 person years in non-Hispanic whites; $P = 0.03$, odds ratio [OR] 1.7, 95% CI 1.2–2.4). Mexican Americans were nearly four times more likely to have a failed bypass (leading to an amputation) or to be categorized as "not a bypass candidate" at the time of angiography and evaluation than were non-Hispanic whites (75.0 vs. 44.0%; $P = 0.01$, 3.8, 1.2–11.8).

The incidence of Charcot arthropathy was 8.5/1,000 person years. Charcot arthropathy was more common in non-Hispanic whites than in Mexican Americans (11.7/1,000 vs. 6.4/1,000; $P = 0.0001$, OR 1.8, 95% CI 1.3–2.5).

Mexican Americans were more than two times as likely to have had a history of lower-extremity amputation before enrollment into this cohort than non-Hispanic whites (4.6 vs. 2.2%; $P = 0.01$, OR = 2.1, CI = 1.2–3.9), despite similar histories of ulceration and lower-extremity bypass (Table 1). The trend continued after enrollment and during the period of follow-up. The incidence of lower-extremity amputation was higher in Mexican Americans than in non-Hispanic whites (7.4/1,000 vs. 4.1/1,000; $P = 0.003$, 1.8, 1.2–2.7). The amputation-to-ulcer ratio was 8.7%. There was no significant difference in this ratio between non-Hispanic whites and Mexican Americans (0.06 vs. 0.10; $P = 0.4$).

CONCLUSIONS — The results of this study support previously published data that identified a disproportionately higher incidence of diabetes-related lower-extremity amputations in Mexican Americans in Texas (7). There is little information in the medical literature that describes the prevalence or incidence of lower-extremity complications that are part of the syndrome that leads to amputation in this population. Our a priori hypothesis was that the higher amputation incidence rate in Mexican Americans would be explained by a higher prevalence of vascular disease, neuropathy, and history of lower-extremity complications. In fact, this hypothesis was not supported by the data. Mexican Americans had similar rates of sensory neuropathy, vascular disease, and "diabetic foot risk" as well as similar ulcer and infection incidence, and non-Hispanic whites had a higher incidence of Charcot arthropathy. One important difference, however, lies with the significantly disproportionate prevalence of Mexican Americans identified as "failed bypass" or "poor bypass candidates." In our study, Mexican Americans were at ~4 times greater risk for having a failed bypass or being identified as a poor bypass candidate than non-Hispanic whites. This correlates well with the hypothesis of Toursarkissian et al. (34). In a review of 144 patients undergoing revascularization of distal vessels, they were unable to identify a difference in failed bypass based on ethnicity, but rather suggested that it might be preoperative factors, such as prevalence of nonreconstructible distal vessels, that account for the high incidence of lower-extremity amputation among Mexican Americans.

A higher amputation risk in Mexican Americans could also be attributed to differences in access to specialty medical care, patient education, self-care practices, patient compliance, disease severity, or cultural issues. Patients in this study were assessed as part of a diabetes disease management protocol that allowed open access to therapeutic shoes and insoles, foot care, patient education, and medical or surgical consultation. However, we were unable to measure the patient's ability to perform routine prevention tasks, their level of "foot knowledge," or their compliance with therapeutic footwear or other recommendations. It is interesting to note that Mexican Americans were more than two times more likely to have had a history of amputation before entry into this program. This is despite similar histories of foot ulceration and bypass.

Reports in the medical literature identify a wide range of prevalence and inci-

dence rates for diabetic foot pathology (35,36). It is difficult to interpret the reason for the variation in pathology since reports are from different regions, countries, ethnic populations, and health care delivery systems. In addition, reports use different techniques and operational definitions to identify pathology and the population at risk. Few of these reports provide a comprehensive evaluation of diabetic foot disease (35).

In conclusion, the data reported in this study suggest that incidence of amputation is higher in Mexican Americans, despite similar rates of ulceration, infection, vascular disease, and lower-extremity bypass. There may be factors associated with failed or failure to perform lower-extremity bypass on these patients. These issues clearly call for further investigation in subsequent studies. Additionally, this is the first study in the literature to report the incidence of Charcot arthropathy in a large cohort of U.S. patients followed prospectively. We believe that these data may provide further information for clinicians and researchers to identify and treat this relatively common malady. Further work in this area should identify explanatory variables for ethnic differences in incidence of Charcot arthropathy.

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