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ORIGINAL RESEARCH

Outcomes of Preventative Care in a Diabetic Foot Specialty Clinic

David G. Armstrong, DPM, and Lawrence B. Harkless, DPM

The purpose of the study was to report the incidence of ulceration, reulceration, and amputation in 341 patients treated in a multidisciplinary clinic over the course of 3 years. Patients enrolled were 57.8% male, with a mean age of 53.2 ± 11.8 years. All were assessed using the University of Texas Diabetic Foot Classification System. Of these patients, 118 fell into category 0 (protective sensation intact), 98 into category 1 (loss of protective sensation, LOPS), 77 into category 2 (LOPS with deformity), and 48 into category 3 (LOPS, deformity, previous history of ulcer or amputation). Outcomes assessed included any incident ulcerations or amputations. The authors stratified patients based on their compliance to follow up appointments. Non compliance was defined as missing >50% of scheduled appointments in any calendar year. Thirty of the above subjects were classified as noncompliant. Prior to analysis, the authors initially stratified subjects into compliant and noncompliant groups. If further stratified by foot category, the incidence of ulceration in the compliant group was 0 for diabetic foot categories 0 and 1, 3.5/1,000/ year for category 2, and 18/1,000/year for category 3. One category 3 patient required a partial first-ray amputation. The yearly incidence of amputation for the entire cohort was therefore 1.1/1,000/year. For categories 0–2 the incidence was 0, and for category 3, it was 9/1,000/year. Patients stratified into the noncompliant group were approximately 54 times more likely to ulcerate than patients who returned regularly for their scheduled care (81.8% ulcer prevalence vs. 5.4%, $p < .0001$, $OR = 54.0$, $CI = 7.5–1,425.0$). Additionally, noncompliant category 3 patients were over 20 times more likely to receive an amputation than their compliant counterparts (45.5% amputation prevalence vs. 2.7%, $p < .002$, $OR = 2.5–819.0$). The study concluded that multidisciplinary diabetes care team, which includes aggressive foot care and consistent treatment-based risk classification, may be effective in profoundly mitigating the occurrence and recurrence of diabetic foot sequelae, including ulceration and amputation. Furthermore, patient noncompliance to routine preventative care appears to be associated with a significantly higher prevalence of ulceration and amputation. (The Journal of Foot & Ankle Surgery 37(6):460–466, 1998)

Key words: amputation, classification, diabetes mellitus, foot, multidisciplinary, prevention, ulceration

Diabetes mellitus is the most common underlying cause of lower extremity amputations in the United States and Europe. Of the approximately 125,000 lower extremity amputations that are performed each year in the United States, 50%–83% are diabetes related (1, 2). Persons with diabetes have an up to 46-fold greater risk of lower extremity amputation than those without diabetes (2, 3). Diabetic foot infections are the most common reason for hospital admission among persons with diabetes, accounting for one-quarter of all diabetic admissions in the United States and Britain (4–7).

The multidisciplinary approach to diabetic foot care has been widely advocated (8–13). When utilized, this approach has, in many cases, reportedly reduced the incidence of lower extremity amputation and has reduced hospital stay by one-third (14). However, even at these centers, the rate of recurrence of neuropathic ulceration has been reported to be between 28% and 56% per annum (15). However, we are unaware of any reports in the medical literature that have recorded the incidence and

From the Department of Orthopaedics, University of Texas Health Science Center at San Antonio, The Texas Diabetes Institute and the Diabetic Foot Research Group, San Antonio, TX. Address correspondence to: David G. Armstrong, DPM, Department of Orthopaedics, University of Texas Health Science Center, San Antonio, 7703 Floyd Curl Drive, San Antonio, TX 78284-7776.

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TABLE 1 Patient characteristics on enrollment: compliant group

Group	*n*	Time with DM (years)	VPT	HbA1c on Enrollment	Incidence of Ulceration/ 1,000/year	Incidence of Amputation/ 1,000/year
Foot category 0 (protective sensation intact)	108	5.8 ± 5.1	11.9 ± 5.3	9.0 ± 2.0	0	0
Foot category 1 (LOPS)	94	6.7 ± 5.8	37.9 ± 5.4	9.2 ± 1.8	0	0
Foot category 2 (LOPS, deformity)	72	7.8 ± 6.1	39.9 ± 5.4	9.0 ± 1.9	3.5	0
Foot category 3 (LOPS, deformity, history of ulcer or amputation)	37	14.2 ± 7.1	41.0 ± 6.4	9.2 ± 1.9	18.0	9.0
Total	311	7.5 ± 6.3	29.7 ± 14.2	9.1 ± 1.9	3.1	1.1

HbA1c, hemoglobin A1C; VPT, vibration perception threshold; DM, diabetes mellitus; LOPS, loss of protective sensation.

prevalence of ulceration and amputation in a center using an evidence and treatment-based risk classification system to guide preventative and acute care, while dichotomizing patients by level of compliance. Therefore, the purpose of this study was to report the incidence of ulceration, reulceration, and amputation in patients treated in a multidisciplinary diabetes clinic over the course of 3 years (16–20).

Materials and Methods

In this study, 341 diabetic patients were enrolled at the Texas Diabetes Institute at the University of Texas Health Science Center at San Antonio; 57.8% were male, with a mean age of 53.2 ± 11.8 years. The Texas Diabetes Institute is a state-supported program for multidisciplinary diabetes care and includes core participation of general internal medicine, podiatry, endocrinology, ophthalmology, diabetes nurse education, and nutritional and social services with an active vascular surgery consultancy. All subjects met the following criteria: 1) the presence of diabetes mellitus, 2) evaluation by medicine service within the past 3 months at the time of enrollment, 3) glycosylated hemoglobin performed in the past 3 months, and 4) age 18–80 years of age. Descriptive statistics for this population are summarized in Table 1.

The diagnosis of diabetes mellitus was verified for all patients using the criteria set forth by the World Health Organization, which include treatment with insulin or an oral hypoglycemic agent, and two random glucose measurements greater than 200 mg/dl or a fasting glucose greater than 140 mg/dl (21). Sensory neuropathy was evaluated with a 10-g Semmes-Weinstein monofilament and a Biothesiometer[1] using the method and criteria described by Armstrong and co-workers (18, 22). These criteria included a vibration perception threshold (VPT) greater than 25 volts using the Biothesiometer or greater than 4 imperceptible sites out of 10 using a yes–no method of administration with a 10-g monofilament.

On musculoskeletal examination, the subjects were evaluated for deformity or limited joint mobility based on the criteria defined by Lavery and co-workers (< 50° hallux dorsiflexion or any nonreducible sagittal or transverse plane contracture of the digits) (23–25).

In this clinical setting, the authors stratified all patients' risk according to the University of Texas (UT) Diabetic Foot Classification System (16–18). In addition to a baseline (category 0), this classification system is divided into risk factors for ulceration (categories 1–3) and risk factors for amputation (categories 4–6). This classification scheme is detailed in Figure 1. In this study, all subjects were included in categories 0–3 (23): intact protective sensation (category 0); loss of protective sensation, no deformity, and no history of ulceration or amputation (category 1); loss of protective sensation, deformity, but no history of ulceration or amputation (category 2); loss of protective sensation, deformity, plus a history of ulceration, amputation, or acute Charcot arthropathy (17, 26). Of these patients, 108 fell into category 0, 94 into category 1, 72 into category 2, and 37 into category 3. All subjects were consecutively enrolled between March 15 and August 31, 1995 as they were matriculated into the clinic. Interim data were collected yearly, with the final data collected at the end of July 1998. Subjects were stratified by compliance. Those missing more than half of their scheduled appointments in any 1-year period were classified as "noncompliant" ($n = 30$). Outcomes assessed included any incident ulcerations or amputations during this period of assessment.

All subjects in categories 2 and 3 received depth inlay shoes. Subjects in category 3 received additional outsole

[1] Biomedical Instrument Co., Newbury, OH.

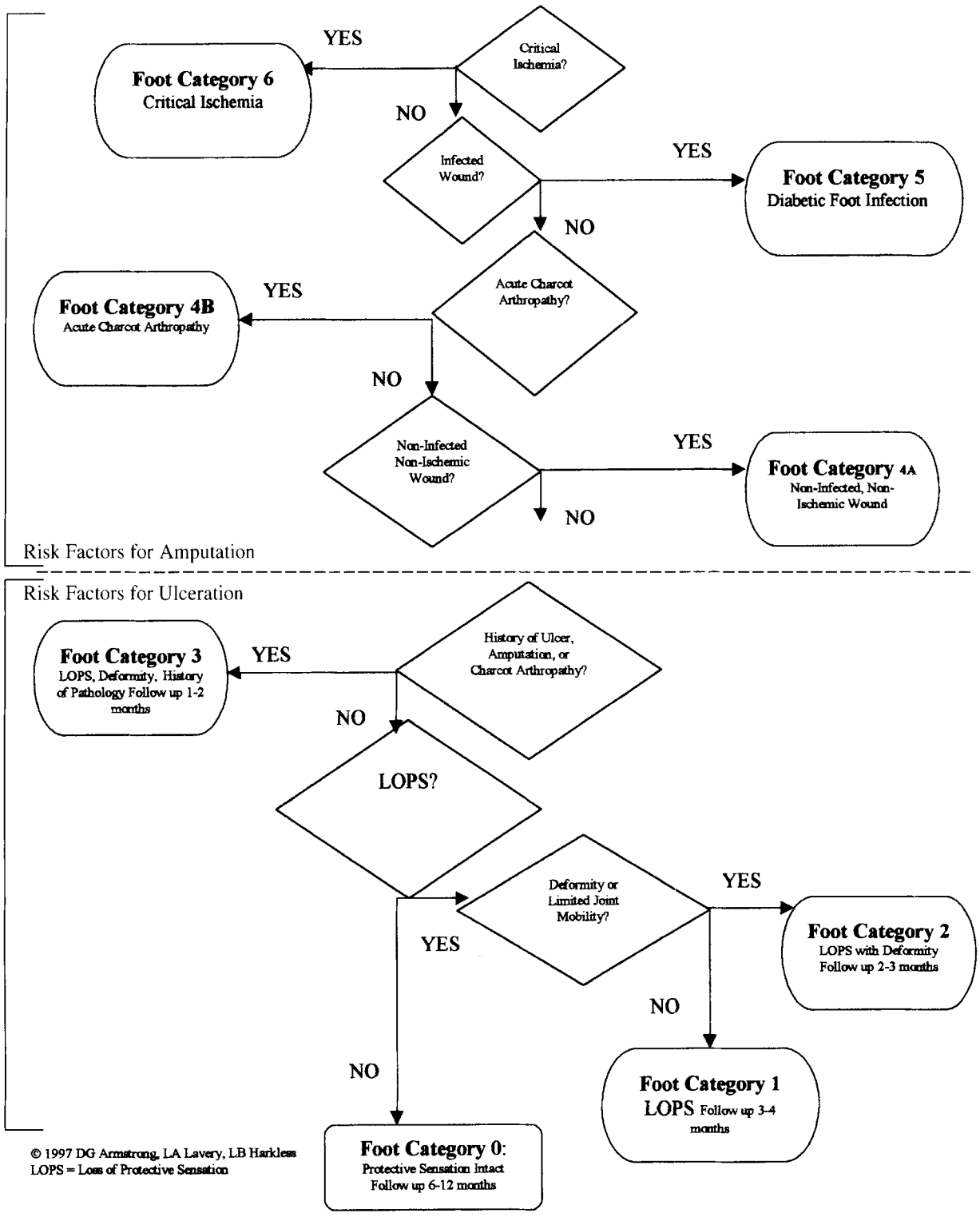

FIGURE 1 University of Texas Treatment-Based Diabetic Foot Classification System.

modifications that corresponded with the site of ulceration. Subjects in categories 0 and 1 were advised to purchase comfort-type, blucher-design, lace-up shoes. Follow-up was determined by foot category. Category 0 patients were followed between 1 and 3 times, annually, depending on their ability to inspect and care for their own feet. Category 1 patients were evaluated every 3–4 months. Those falling into category 2 were evaluated every 2–3 months. Category 3 patients were evaluated every 1–2 months.

A working diagnosis of lower extremity ischemia was made by a combination of clinical and noninvasive vascular studies. Clinical signs were based on the absence of one or more foot pulses of the involved foot. Noninvasive criteria included ankle-brachial index (ABI) of <0.80 (27, 28). Clinical signs and/or presence of abnormal noninvasive values provided a diagnosis of lower extremity vascular insufficiency. Of the cohort followed, 10 patients were initially diagnosed with significant lower extremity ischemia (UT diabetic foot category 6). All of these patients received a lower extremity arterial bypass graft. Following improvement of their ischemia, all were reassigned to a corresponding lower foot risk classification (four to foot category 3, five to foot category 2, one to foot category 1). As this was an outcomes study evaluating preventative care, no subjects were initially enrolled who fell into category 4 (noninfected ulcer/Charcot) or 5 (infection).

To assess the differences between the four groups based on descriptive continuous statistics, a multivariate analysis of variance procedure was used. After it was determined whether there were significant differences, a post hoc Tukey's studentized range test for multiple comparisons was used to compare differences between risk groups simultaneously. A chi-square test with odds ratio (OR) and 95% confidence interval (CI) was used to assess differences between dichotomous variables. For all analyses, an alpha of 0.05 was used (29).

Results

In the compliant group, there was not a significant difference in the prevalence of males or females, age, or degree of glucose control between foot categories. Patients in foot category 0 had a significantly lower VPT compared with the other foot categories ($p < .001$ for all comparisons). Additionally, foot category 3 patients had a significantly longer duration of diabetes compared to all other groups ($p < .001$ for all comparisons).

The authors reviewed the incidence of lower extremity ulceration in the period studied and analyzed subjects based on compliance. For the compliant group ($n = 311$), the yearly incidence of ulceration was 3.1/1,000/year. Prior to ulceration, two of these patients fell into diabetic foot category 3 (previous history of ulceration) and one had neuropathy and deformity but no history of ulceration or amputation (foot category 2). If stratified by foot category, the yearly incidence of ulceration was 0 for diabetic foot categories 0 and 1, 3.5/1,000/year for category 2, and 18/1,000/year for category 3. One of the ulcerated patients in category 3 ultimately became infected and required a partial first-ray amputation. Therefore, the overall yearly incidence of amputation for the entire cohort was 1.1/1,000/year. For categories 0–2 the incidence was 0, and for category 3, it was 9/1,000/year. These data are summarized in Table 1.

Prophylactic surgery was performed on 20 compliant foot category 2 patients at a mean 3.2 ± 6.1 months into the follow-up period. Of these, 13 were lesser digital arthroplasties and seven were first metatarsophalangeal joint arthroplasties. None of these patients ulcerated or developed postoperative infections in the time reviewed.

As stated in the methods, 10 patients were diagnosed on initial screening with significant lower extremity ischemia (category 6) and subsequently received vascular intervention. All of these subjects fell into the compliant group. One of these patients (reassigned to foot category 3 after bypass) was among the compliant patients who ulcerated in the postoperative period. However, there were no incident amputations in this subclassification.

Thirty patients missed more than half of their appointments and were classified as noncompliant with their preventative care regimen (Table 2). This group was 80.0% male with an average age of 51.3 ± 8.9 years

TABLE 2 Patient characteristics on enrollment: Noncompliant group

Group	*n*	Time with DM (years)	VPT	HbA1c on Enrollment	Incidence of Ulceration/ 1,000/year	Incidence of Amputation/ 1,000/year
Foot category 0 (protective sensation intact)	10	4.4 ± 3.5	12.2 ± 5.7	8.9 ± 1.6	0	0
Foot category 1 (LOPS)	4	7.0 ± 3.6	34.3 ± 5.6	9.3 ± 1.9	83.3	0
Foot category 2 (LOPS, deformity)	5	11.8 ± 5.8	36.5 ± 8.8	8.6 ± 1.9	66.6	0
Foot category 3 (LOPS, deformity, history of ulcer or amputation)	11	12.7 ± 6.2	38.1 ± 9.5	10.4 ± 1.4	272.7	151.5
Total	30	9.0 ± 6.1	28.6 ± 4.0	9.2 ± 1.7	122.2	5.5

and a mean 9.0 ± 6.1 years of diabetes duration. This population included 10 diabetic foot category 0 patients, four category 1, five category 2, and eleven category 3 patients. Of these patients, 11 (36.7% of all noncompliant patients) presented with an ulceration a mean 14.2 ± 5.1 months following their initial visit. One of these patients fell into category 1 and one into category 2, and nine had a previous history of ulceration (category 3). Five patients (16.6% of all noncompliant patients), all category 3, received lower extremity amputations in this cohort at a mean 13.0 ± 5.0 months from initial evaluation. These included two lesser ray resections, one transmetatarsal amputation, and two below-knee amputations. The prevalence of male gender ($p < .02$, OR = 3.2, CI = 1.3–8.0), ulceration ($p < .0001$, OR = 52.0, CI = 13.7–296.8), and amputation ($p < .0001$, OR = 44.6, CI = 6.6–1,459.7) were all significantly larger in the noncompliant group than the cohort receiving consistent care. When comparing the highest risk patients in each cohort (category 3), those in the noncompliant group were approximately 54 times more likely to ulcerate than patients who returned regularly for their scheduled care (81.8% ulcer prevalence vs. 5.4%, $p < .0001$, OR = 54.0, CI = 7.5–1,425.0). Additionally, noncompliant category 3 patients were over 20 times more likely to receive an amputation than their compliant counterparts (45.5% amputation prevalence vs. 2.7%, $p < .002$, OR = 2.5–819.0).

Discussion

The results of this study suggest that a multidisciplinary diabetes care team, which includes aggressive preventative foot care and consistent treatment-based risk classification, can be effective in mitigating the occurrence and recurrence of diabetic foot sequelae, including ulceration and amputation. Furthermore, it suggests that noncompliance with preventative care may be associated with poorer outcomes. This report corresponds well with a previous report by Rith-Najarian et al (30). who indicated progressive increases in ulcer and amputation incidence with increasing risk stratum and reported that approximately one in five patients in categories 2 and 3 received a lower extremity amputation in a 32-month follow-up.

As would be expected, the outcomes of the noncompliant group were significantly poorer than those of patients receiving regular diabetic foot care, with noncompliant patients being at over 50 times greater risk for ulceration and 20 times greater risk for amputation than the most high-risk members of the compliant group. There are numerous factors that may play a role in mitigating lower extremity morbidity. These may include gender activity level, level of denial, strength of social support mechanisms, and quality of education (31). However, the authors believe that, when risk category is held relatively constant, these data suggest that degree of compliance to a regimen centered around prevention may be one of the strongest determinants for morbidity in the population studied.

There are a number of descriptive studies that suggest that 40%–85% of amputations among diabetics can be prevented with a team approach (8–12, 14). To help accomplish this goal, an understanding of practical risk factors for ulceration could assist primary care providers to categorize patients by their risk status and schedule intervention resources accordingly. Previous studies of risk factors for ulcerations have identified peripheral neuropathy, limited joint mobility, foot deformities, abnormal foot pressures, and a history of ulceration or amputation as important factors (23, 32–35). Lavery and co-workers indicated that these risk factors, when combined, increased cumulative risk for ulceration (23). Patients with neuropathy alone were at approximately 2 times greater risk for ulceration compared with sensate individuals. Those with neuropathy and deformity/limited joint mobility were at 12 times greater risk. Lastly, patients with neuropathy, deformity, and a previous history of ulcer or amputation were at over 36 times increased risk for ulceration. This formed the basis for a cogent diabetic foot classification system.

The University of Texas Diabetic Foot Classification System (16, 17, 23) is divided into two halves. The first half is based on the screening systems first described Birke and colleagues (26) and Rith-Najarian and coworkers (30) and includes risk factors for ulceration. The second half includes risk factors for amputation. Each of these halves has three categories. The objective of treatment is both to convert a patient from a high-risk category into a lower risk category and to adequately communicate risk during the entire course of treatment. The classification system is outlined in flowchart format in Figure 1.

Goals of therapy while using the risk classification system are to reduce or maintain each patient at his or her lowest overall risk class. This is accomplished through a standardized treatment protocol. Patients in category 0, who have intact protective sensation, are evaluated one to three times per year for reinforcement of education as well as routine diabetic foot care. Treatment for the foot category 1 patient involves education about appropriate shoe gear selection. This typically involves comfort-type or athletic-type over-the-counter shoe gear which are often adequate to off-load the insensate foot without deformity (36). It should be advised that, while these shoes are normally reasonable for the category 1 patient, because of their lack of ample volume in the toebox they may not be well suited for higher risk subjects

with significant deformity. This patient is followed every 3–4 months. The category 2 patient should be immediately placed into well-fitting prescription depth inlay shoes to accommodate for the deformity and to protect against elevated plantar pressures which are commensurate with that deformity. These patients should be seen every 2–3 months by a diabetic foot specialist. The patient in diabetic foot category 3 typically has loss of protective sensation (LOPS) and deformity, but also has a history of previous ulceration, amputation, or acute Charcot's arthropathy. Because of this prior history, this patient clearly has all of the prerequisite ingredients necessary to develop another problem, and thus should be monitored very closely. Prescription shoes and visits every 1–2 months by a diabetic foot care professional are of critical importance to ensure that this patient remains free of recidivism. This may be coupled with frequent telephone contact by a nurse case manager. Patients in categories 4–6 are typically seen more frequently, with categories 5 or 6 often treated on an inpatient basis. ` While engaging in principle, the concept of "team approach" or "multidisciplinary care," if embarked upon without a common interdisciplinary language of risk, may actually in practice be somewhat detrimental to care. This is due in large part to differences in operational definitions of risk. The results of this study support the concept that use of a common language in the form of a classification system (16, 18, 19), if used consistently, may be effective in limiting the incidence of diabetes-related sequelae. However, not until we make widespread use of such parlance to communicate risk and predict outcome will we ultimately be able to substantially reduce the unnecessarily high prevalence of lower extremity amputations throughout the world.

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