Preventing Diabetic Foot Ulcer Recurrence in High-Risk Patients

Use of temperature monitoring as a self-assessment tool

LAWRENCE A. LAVERY, DPM, MPH[1]
KEVIN R. HIGGINS, DPM[2]
DAN R. LANCTOT, BS[2]
GEORGE P. CONSTANTINIDES, MS[2]
RUBEN G. ZAMORANO, MSW, MPH[2]
KYRIACOS A. ATHANASIOU, PHD, PE[3]
DAVID G. ARMSTRONG, DPM, PHD[4]
C. MAULI AGRAWAL, PHD, PE[5]

OBJECTIVE — The purpose of this study was to evaluate the effectiveness of a temperature monitoring instrument to reduce the incidence of foot ulcers in individuals with diabetes who have a high risk for lower extremity complications.

RESEARCH DESIGN AND METHODS — In this physician-blinded, randomized, 15-month, multicenter trial, 173 subjects with a previous history of diabetic foot ulceration were assigned to standard therapy, structured foot examination, or enhanced therapy groups. Each group received therapeutic footwear, diabetic foot education, and regular foot care. Subjects in the structured foot examination group performed a structured foot inspection daily and recorded their findings in a logbook. If standard therapy or structured foot examinations identified any foot abnormalities, subjects were instructed to contact the study nurse immediately. Subjects in the enhanced therapy group used an infrared skin thermometer to measure temperatures on six foot sites each day. Temperature differences >4°F (>2.2°C) between left and right corresponding sites triggered patients to contact the study nurse and reduce activity until temperatures normalized.

RESULTS — The enhanced therapy group had fewer foot ulcers than the standard therapy and structured foot examination groups (enhanced therapy 8.5 vs. standard therapy 29.3%, $P = 0.0046$ and enhanced therapy vs. structured foot examination 30.4%, $P = 0.0029$). Patients in the standard therapy and structured foot examination groups were 4.37 and 4.71 times more likely to develop ulcers than patients in the enhanced therapy group.

CONCLUSIONS — Infrared temperature home monitoring, in serving as an "early warning sign," appears to be a simple and useful adjunct in the prevention of diabetic foot ulcerations.

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Foot ulcers are among the most common complications of diabetes (1,2). Sensory neuropathy is often a major component in the critical pathway for the development of diabetic ulcers and amputations. Pain is one of the primary natural warning systems that alerts individuals to take action and seek medical care (3). Because this early warning system is faulty, individuals with diabetic neuropathy can sustain injuries that are not recognized until they are so severe that full-thickness wounds result (4). In the "diabetic foot" patient, involvement to identify early warning signs of the disease process is imperative to reduce the incidence of complications.

Inflammation is one of the earliest signs of tissue injury and ulceration (5–8). However, the clinical signs of inflammation are usually too subtle to be detected by patients or even by trained health care providers (9). We hypothesized that skin temperatures could be used as a surrogate measure of injury and localized inflammation. Skin temperature measurements can be easily performed and assessed by the lay public and have been used as a diagnostic tool for diabetic foot ulcerations, decubitus wounds, and Charcot arthropathy (10–20). Pilot work in this area suggests that high-risk patients can effectively use an infrared thermometer as a home monitoring tool to identify inflamed tissue and take action to prevent foot ulceration (21). The aim of the present study was to evaluate a home temperature monitoring tool to help high-risk individuals identify areas on their feet that are inflamed and prone to ulceration before a wound develops.

RESEARCH DESIGN AND METHODS

— This was a single (physician) blinded, multicenter, randomized trial with a 15-month evaluation period. We randomly assigned 173 individuals at high risk for diabetic foot ulceration to three treatment groups (Fig. 1). The three treatment arms involved a standard therapy group, a structured foot examination group, and an enhanced therapy group. The study was approved by the hospital institutional review board. We used a computer generated randomization list. The information was sealed in opaque envelopes and opened after randomization and verification that the subject met all of the inclusion criteria and had none of the exclusion criteria. Subjects were instructed not to discuss their group assignment with the treating physician.

Standard therapy

Standard therapy consisted of lower extremity evaluation by a physician every 8 weeks, an education program that fo-

From the [1]Department of Surgery, Scott & White Hospital, Texas A&M University Health Science Center, Temple, Texas; [2]Xilas Medical, San Antonio, Texas; the [3]Department of Bioengineering, Rice University, Houston, Texas; the [4]Dr. William M. Scholl College of Podiatric Medicine, Rosalind Franklin University of Medicine and Science, Chicago, Illinois; and the [5]Department of Engineering, University of Texas, San Antonio, San Antonio, Texas.

Address correspondence and reprint requests to Lawrence A. Lavery, DPM, MPH, 703 Highland Spring Ln., Georgetown, TX 78628. E-mail: llavery@swmail.org.

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

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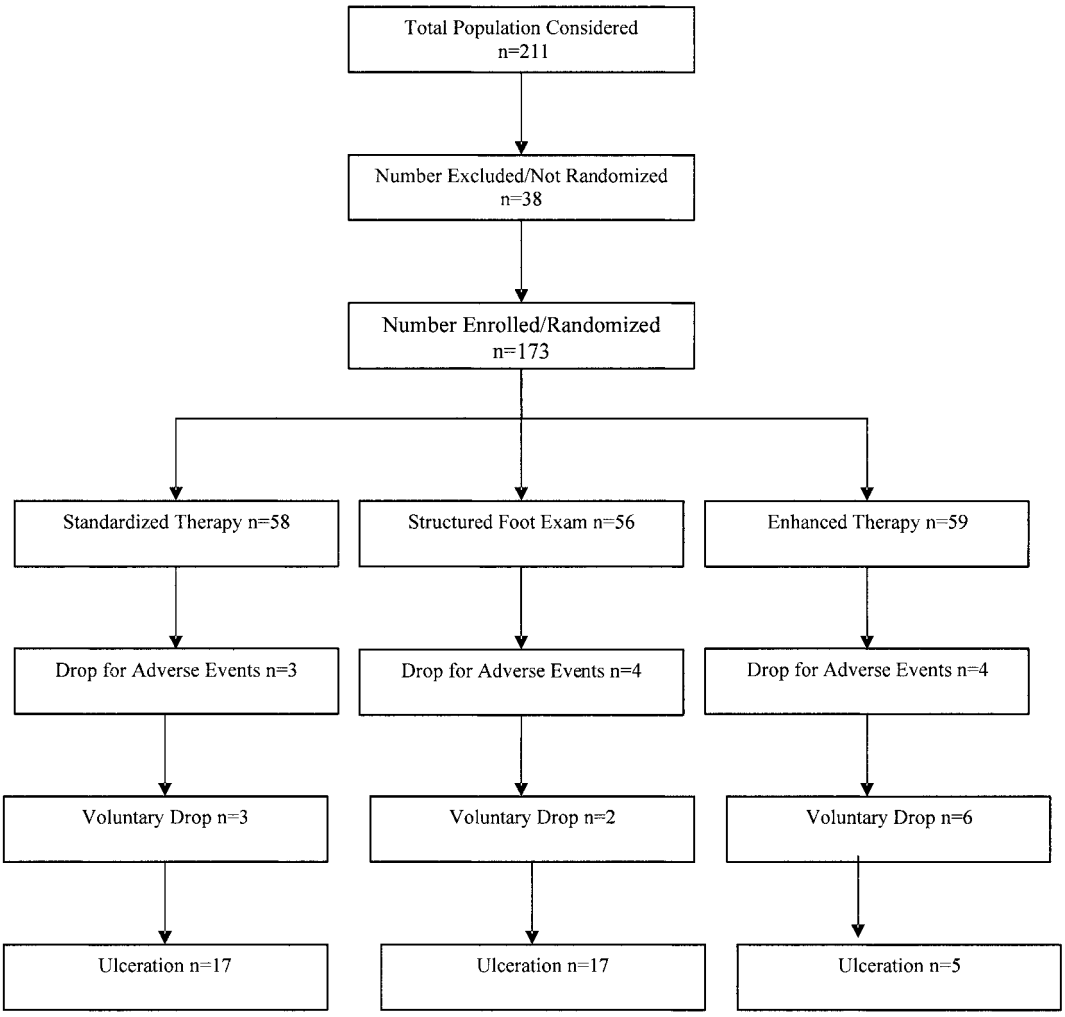

Figure 1—*Study enrollment schematic.*

cused on foot complications and self-care practices, and therapeutic insoles and footwear. The treating podiatrist evaluated the shoes and insoles during regularly scheduled clinic visits and determined whether any components of the shoes or insoles needed to be replaced or repaired. The education segment of training was provided by a videotape that addressed the etiology of diabetic foot ulcers, risk factors, self-care practices, and early warning signs of diabetic foot disease. In addition, all study participants were provided with a pedometer to record their daily activity in a logbook.

Patients were advised to inspect their feet daily. If patients identified an area of concern on their foot, they were instructed to contact the study nurse. The nurse then scheduled an appointment with a study investigator without divulging the treatment group assignment. Patients were asked not to discuss their treatment group assignment with the treating physician.

Structured foot examination

Patients assigned to this treatment group received standard therapy in addition to training to conduct a structured foot inspection twice a day with the assistance of a mirror to see the bottom of the foot. The objective of the examination was to identify redness, discoloration, swelling, and local warmth by palpation. Patients recorded normal and abnormal observations in a logbook with pictorial representations of both feet and a checklist of the elements to be included in the self-examination. The intent of the logbook was to go beyond customary education and recommendations for self-inspection and provide a structured protocol for evaluation. In addition, the logbook provided verification that the examination was performed. If the patient identified any abnormalities, he or she was instructed to contact the study nurse.

Enhanced therapy

In addition to measures implemented in the standard therapy group, patients assigned to the enhanced therapy group were taught to use a digital infrared thermometer (TempTouch; Xilas Medical, San Antonio, TX) to measure and record temperatures on each foot. To standardize training, a videotape was used to teach subjects how to use the infrared thermometer. The study nurse had each subject demonstrate the correct use of the temperature device. Subjects recorded foot temperatures in a logbook with pictorial representations of the top and bottom of both feet and six sites to measure temperatures: the great toe, the first, third, and fifth metatarsal head region, the midfoot, and the heel. Subjects who had undergone amputation at the standard evaluation sites were given alternative sites on the basis of the site of their previous amputation. If skin temperatures were elevated by >4°F (2.2°C) compared with the corresponding site on the

opposite foot for two consecutive days, subjects were instructed to contact the research nurse and decrease their activity until temperatures normalized.

Infrared dermal thermometer

The thermometer is equipped with a "touch sensor" tip that detects contact with skin. Thus, to operate the device, the user places the tip of the device on the skin, which then automatically triggers a temperature measurement and displays it on a liquid crystal display screen. The thermometer has a gooseneck design, which allows the user to reach any point on the bottom or sides of the foot.

Inclusion and exclusion criteria

To be included in the study, subjects were required to be 18–80 years of and to have a history of foot ulceration, a diagnosis of diabetes, the ability to provide informed consent, and ankle-brachial indexes ≥0.70. Subjects were excluded if they had open ulcers or open amputation sites, active osteoarthropathy, severe peripheral vascular disease, foot infection, dementia, or other conditions that would preclude active participation based on the investigator's judgment.

Outcomes and clinical assessment

The primary outcome was foot ulceration, which was defined using previously established criteria (22,23). A questionnaire was administered at the conclusion of the study to evaluate self-reported daily use of prescribed shoes and insoles. An ordinal scale was used to determine whether patients wore therapeutic shoes <4 h, 4–8 h, >8–12 h, or >12 h each day. The neurological assessment consisted of vibratory perception threshold and 10-g monofilament testing using previously described methods (24–26). When assessing monofilament results, we recorded the number of sites missed of 10 sites tested on each foot. The vascular assessment consisted of palpation of foot pulses, noninvasive Doppler, and ankle-brachial indexes.

Sample size justification

Sample size was calculated on the basis of the proportion of study patients we expected to develop ulcers during the 15-month treatment period. These reulceration estimates are based on a previous randomized trial (20) and reports of reulceration in high-risk patients (3–5). We expected that 9% of subjects in the enhanced treatment group would develop ulcers during the evaluation period ($P_o = 0.09$) and that 30% of subjects who received standard therapy would develop foot ulcers. A power of 0.8 was chosen to yield a sample size of 55. We expected a 10% dropout rate. Therefore, we planned to enroll 60 subjects in each group to have 55 subjects complete the study in each treatment arm.

Analysis plan

To make between-group comparisons on continuous-type variables, we used ANOVA for independent samples. For all exposures, an odds ratio (OR) with a 95% CI was identified. For all analyses, we used $\alpha = 0.05$. We evaluated the data using a last observed carried forward intent-to-treat approach (27).

We used a Kaplan-Meier survival analysis to compare the time to develop a foot ulcer by treatment group. We used three statistical tests to examine whether the three treatments were different. First, an overall test was done. Then we used a pairwise comparison, and finally a test for trend was performed. We used the log-rank test, provided in SPSS 10 in the analysis. We used the Pearson χ^2 statistic based on the cell counts of ulcer status versus treatment (standard therapy, structured foot examination, and enhanced therapy) to evaluate the effect of the interventions on incident foot ulceration.

RESULTS — All of the study participants had a history of a foot wound and sensory neuropathy with loss of protective sensation. There were no significant differences in age, duration of diabetes, history of partial foot amputation, severity of sensory neuropathy, or activity level among the three treatment groups. Descriptive characteristics of this population are detailed in Table 1. Data are reported as means ± SD.

A Kaplan-Meier survival analysis was performed to evaluate the time to ulcerate by treatment group (Fig. 2). Subjects were censored when an ulcer developed or if they left the study for other reasons. There was a statistically significant overall difference between the times to develop ulcers by treatment groups using the log-rank test ($P = 0.011$). Simultaneous pairwise comparisons using the log-rank test showed no difference between standard therapy and structured foot examination ($P = 0.910$). However, enhanced therapy was significantly different from both standard therapy ($P = 0.0059$) and structured foot examination ($P = 0.0055$). From the test for trend, there was a statistically significant trend of survival with the enhanced therapy being superior over the standard therapy or structured foot examination ($P = 0.0107$).

The incidence of foot ulceration during the 15-month evaluation period was essentially identical in the standard therapy (29.3%) and structured foot examination (30.4%) treatment arms. There was a >4-fold decrease in the risk of developing foot ulceration in subjects in the enhanced therapy group (8.5%) compared with the standard therapy group (OR 4.48[95% CI 1.53–13.14], $P = 0.008$) and structured foot examination group (4.71 [1.60–13.85], $P = 0.0061$).

Not surprisingly, adherence to prevention practices was a pivotal factor in ulcer prevention. In the enhanced therapy group, patients who were compliant with recording foot temperatures at least 50% of the time were significantly less likely to develop a foot ulcer (OR 50.0, $P < 0.001$). Of patients in the enhanced therapy group who developed foot ulcers, 80% did not comply with temperature assessment. However, of patients who did not develop an ulcer in the enhanced therapy group, 92% recorded their foot temperatures at least half the time. Among patients in the structured foot examination group, there was no difference in compliance with recording daily foot inspections in patients who developed ulcers (47.1%) and those who did not (43.6%; $P = 0.81$).

In addition, self-reported adherence with wearing therapeutic shoes and insoles was high in all three treatment arms (Table 1). There was no significant difference in subjects who wore therapeutic shoes and insoles at least 8 h/day among treatment groups (standard therapy 89.5%, enhanced therapy 83.0%, and structured foot examination 73.2%; $P > 0.071$) (Table 1)

Enhanced therapy patients used the temperature monitoring device as a trigger to contact the study nurse, and they identified "areas of concern" more frequently than patients in other treatments arms who relied on visual signs. Significantly more patients in the enhanced therapy group contacted the study nurse for concerns of foot problems than patients in the standard therapy ($P = 0.030$) or structured foot examination groups ($P = 0.026$) (Table 2). Thirty-one subjects in the enhanced therapy group contacted the study nurse. In addition, 7 more patients did not contact the study

Table 1—*Patient characteristics*

Subject population	Standard therapy	Enhanced therapy	Structured foot examination
n	58	59	56
Age (years)	65.0 ± 9.6 (41–80)	65.4 ± 9.3 (42–80)	64.2 ± 8.6 (40–80)
Sex (% male)	53.4	55.9	51.7
Race			
Non-Hispanic white	31 (53.4)	32 (54.2)	31 (55)
Mexican American	24 (41.4)	22 (37.3)	25 (45)
African American	3 (5.2)	3 (5.1)	2 (4)
Type 2 diabetes	56 (97)	55 (93)	53 (95)
Duration of diabetes (years)	13.7 ± 10.3 (2–22)	12.7 ± 9.7 (4–25)	13.8 ± 11.5 (5–31)
Diabetes medication			
Oral	31 (53.4)	32 (54.2)	30 (53.6)
Insulin	13 (22.4)	15 (25.4)	10 (17.9)
Combination	10 (17.2)	11 (18.6)	12 (21.4)
Diet	4 (6.9)	1 (1.7)	4 (7.1)
Ulcer history and locations			
Hallux	7 (12.1)	4 (6.8)	8 (14.3)
Toes	29 (50.0)	35 (59.4)	30 (53.5)
Submetatarsal	21 (36.2)	17 (28.8)	21 (37.5)
Midfoot to heel	3 (5.1)	7 (11.9)	5 (8.9)
Patients with a history of previous amputation	18 (31.0)	13 (22.0)	14 (25.0)
Amputation sites			
Toe	12 (20.7)	11 (18.6)	12 (21.4)
Toe and metatarsal	8 (13.8)	4 (6.8)	4 (7.1)
Midfoot	0	2 (3.4)	2 (3.6)
History of vascular surgery			
Lower extremity bypass	3 (5.2)	0	0
Lower extremity angioplasty	0	0	1 (1.8)
Coronary artery bypass surgery	2 (3.4)	1 (1.7)	0
Cardiac angioplasty	0	0	2 (3.6)
Lower extremity examination			
Neuropathy evaluation			
Semmes-Weinstein 10-g monofilament right	5.2 ± 4.8	5.3 ± 4.7	5.2 ± 4.7
Semmes-Weinstein 10-g monofilament left	4.7 ± 4.3	4.7 ± 4.3	4.7 ± 4.3
Vibration perception threshold right	41.8 ± 9.8 (14–50)	40.6 ± 9.6 (12–50)	40.6 ± 8.6 (14–50)
Vibration perception threshold left	39.3 ± 8.6 (12–50)	38.6 ± 8.1 (11–50)	39.0 ± 8.0 (12–50)
Foot deformity			
Hallux rigidus	50 (86.2)	51 (86.4)	46 (82.1)
Hallux valgus	23 (39.0)	33 (55.0)	12 (21.0)
Claw toe/hammer toe	33 (56.0)	41 (69.0)	41 (73.0)
Vascular examination			
Ankle-brachial index right	1.1 ± 0.4 (0.7–1.5)	1.1 ± 0.4 (0.7–1.5)	1.1 ± 0.6 (0.8–2.0)
Ankle-brachial index left	1.2 ± 0.5 (0.7–1.7)	1.1 ± 0.6 (0.7–1.9)	1.2 ± 0.6 (0.7–1.9)
Activity (steps per day)	3,817 ± 3,364	3,489 ± 2,706	3,963 ± 2,363
Footwear compliance			
Time prescribed shoes were worn (h)			
<4	1 (1.7)	2 (3.4)	0
4–8	5 (8.6)	8 (13.6)	15 (26.8)
>8–12	33 (56.9)	31 (52.5)	19 (33.9)
>12	19 (32.6)	18 (30.5)	22 (39.3)

Data are means ± SD (range) or *n* (%).

nurse when they observed elevated foot temperatures but decreased their activity based on pedometer activity data. When we compared the number of steps per day for the 3 days before and 3 days after an elevated temperature was identified, on average, there was a 51.2% decrease in activity, representing an average reduction of 1,725 ± 1,784 steps/day.

Based on inspection of their feet, subjects in the structured foot examination group contacted the study nurse 18 times, and subjects in the standard therapy group contacted the study nurse 17 times. However, by the time patients in the stan-

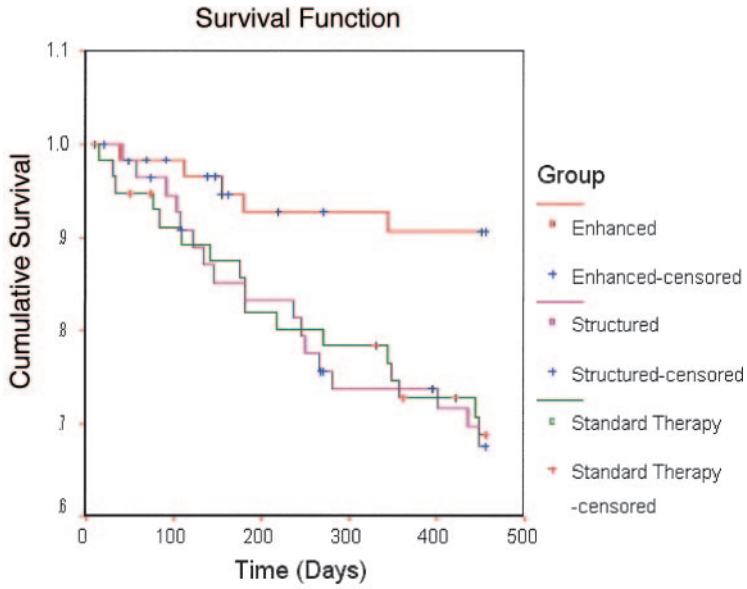

Figure 2—*Kaplan-Meier survival analysis of time to ulceration by treatment group. Kaplan-Meier survival analysis demonstrated a significantly longer time to ulcerate in the enhanced therapy group compared with the structured foot examination and standard therapy groups. The mean time to ulcerate was 429.5 ± 11.9 in the enhanced therapy group, 377.3 ± 18.4 in the structured foot examination group, and 378.5 ± 18.6 in the standard therapy group.*

dard therapy and structured foot examination groups contacted the study nurse, usually a foot ulceration had already developed (structured therapy group 94.4%; structured foot examination group 100%).

CONCLUSIONS — Specialty diabetic foot clinics have been shown to reduce the incidence of ulceration and amputation in high-risk patients (2,28,29). Often these foot clinics provide protective shoes and insoles, foot-specific education, and advanced clinical care. These clinics usually deliver services that are well above the local community standard. However, even in specialty foot clinics, recurrence of diabetic foot ulcers is often very high, generally ranging from 25 to 80% per annum (30–33). In ideal circumstances, high-risk patients can only be evaluated in specialty clinics four to six times a year. Patients and their families must bridge the gap between examinations. Therefore, self-monitoring to identify areas on the foot that are injured is critical to prevent ulceration and lower extremity amputation.

Self-care may be the single most important factor in preventing complications in individuals with a high risk for diabetic foot ulceration (34–36). Patients and their families must be able to monitor the lower extremities to identify signs of disease and precursors to injury. The medical community has, to date, failed to provide any practical, efficacious tool to help in this process. At most, clinicians encourage self-inspection and occasionally suggest that patients use a mirror to evaluate the bottom of the foot. Unfortunately, many diabetic patients with a high risk for ulceration cannot see their feet because of obesity, limited joint mobility, or visual impairment (37). As demonstrated in this study, most of the time, self-inspection skills are not effective in identifying the subtle precursors to ulceration. By the time patients in this study were able to visualize areas of concern, it was too late, and an ulceration had already developed. The results of this study surprisingly suggested that structured self-inspection with the aid of a mirror provided no overt risk reduction compared with general diabetic foot education. The incidence of foot ulceration in the standard therapy and structured foot examination groups was similar to that in studies using "standard" prevention practices as described in this project (2,31,33).

The intervention in this study, namely home temperature monitoring, proved to be an effective approach to provide objective feedback, so patients could modify their activity and protect their foot before ulceration developed. The majority of study subjects were able to use the device as an early warning system and reduce their activity until temperatures normalized. Enhanced therapy patients used the temperature device to identify abnormalities more often than the other groups (standard therapy and structured foot examination patients) could by visual inspection or palpation alone. Overall, 88% of patients in the enhanced therapy group recorded their temperatures >50% of the time during the 15-month study period. Patients who developed ulcers did not comply with measuring their foot temperatures; four of five (80%) subjects who were assigned to use the temperature device and developed ulcerations did not

Table 2—*Clinical outcomes, adverse events, and voluntary withdrawals*

Outcomes	Standard therapy	Enhanced therapy	Structured foot examination
n	58	59	56
Patients who contacted study nurse after self-examination	18 (31.0)	31 (52.5)	17 (30.4)
Foot ulceration	17 (29.3)	5 (8.5)	17 (30.4)
Withdrawal from study because of adverse events			
Foot trauma	1 (1.7)	1 (1.7)	0
Fracture	0	1 (1.7)	2 (3.6)
Death	2 (3.4)	1 (1.7)	0
Osteomyelitis: no ulcer	0	0	1 (1.8)
Motor vehicle accident	0	0	1 (1.8)
Myocardial infarction	0	1 (1.7)	0
Voluntary withdrawal from study			
Too much to do	2 (3.4)	6 (10.2)	2 (3.6)
Moved out of town	1 (1.7)	0	0

Data are *n* (%).

adhere to their prescribed assessment regimen.

This study was successful in amalgamating observations from previous studies and putting them in the hands of high-risk subjects in the form of a simple, easy to use device. The vast majority of participants were able to comply with instructions and subsequently prevent foot ulcerations. The rates of compliance with this program seemed to be much higher than those for home blood glucose monitoring, for which the prevalence of noncompliance can be as high as two-thirds (38,39). Thus, the results of this study suggest that equipping individuals with diabetes at highest risk for foot ulceration with simple skin temperature devices may significantly reduce the risk for foot ulcers. In fact, just as with comprehensive general programs aimed to facilitate good glucose control (40), a regimen incorporating home temperature monitoring may allow individuals to monitor their "dose" of activity by checking their skin temperatures just as they might monitor their dose of insulin by checking their glucose. It seems likely that the cost benefit of home temperature monitoring might be much better than that for using glucose strips for home monitoring. In addition, a tool to adjust activity could help with the dilemma of exercising for better health versus the need to rest and protect the foot to avoid foot ulcers.

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