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ARTICLE

Reduction of Lower Extremity Clinical Abnormalities in Patients with Non-Insulin-Dependent Diabetes Mellitus

A Randomized, Controlled Trial

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Objective: To evaluate the effect of a patient, healthcare provider, and systems intervention on the prevalence of risk factors for lower extremity amputation in patients with non-insulin-dependent diabetes.

Design: Blinded, randomized, controlled trial.

Setting: Academic general medicine practice.

Participants: Of the 395 patients with non-insulin-dependent diabetes who underwent the initial patient assessment, 352 completed the study.

Intervention: The 12-month intervention was multifaceted. Patients received foot-care education and entered into a behavioral contract for desired self-foot care, which was reinforced through telephone and postcard reminders. Health care providers were given practice guidelines and informational flow sheets on foot-related risk factors for amputation in diabetic patients. In addition, the folders for intervention patients had special identifiers that prompted health care providers to 1) ask that patients remove their footwear, 2) perform foot examinations, and 3) provide foot-care education.

Results: Patients receiving the intervention were less likely than control patients to have serious foot lesions (baseline prevalence, 2.9%; odds ratio, 0.41 [95% CI, 0.16 to 1.00]; $P = 0.05$) and other dermatologic abnormalities. Also, they were more likely to report appropriate self-foot-care behaviors, to have foot examinations during office visits (68% compared with 28%; $P < 0.001$), and to receive foot-care education from health care providers (42% compared with 18%; $P < 0.001$). Physicians assigned to intervention patients were more likely than physicians assigned to control patients to examine patients' feet for ulcers, pulses, and abnormal dermatologic conditions and to refer patients to the podiatry clinic (10.6% compared with 5.0%; $P = 0.04$).

Conclusions: An intervention designed to reduce risk factors for lower extremity amputations positively affected patient self-foot-care behavior as well as the foot care given by health care providers and reduced the prevalence of lower extremity clinical disease in patients with diabetes.

Given that 14 million Americans have diabetes [1], the common complications of this disorder, such as foot ulcers and lower extremity amputations, are of major concern to the medical community. Approximately 20% of all diabetic patients hospitalized in the United States are admitted because of foot complications [2, 3]. Furthermore, about 50% of all nontraumatic amputations in the United States are done in patients with diabetes [1, 4]. This proportion equates to about 55 000 amputations a year [1] or 59.7 amputations for every 10 000 persons with diabetes [5]. Patients who undergo an amputation are at greater risk for a second similar procedure on either the same or the other leg [6, 7]. Yet, it has been estimated that about one half of the amputations in patients with diabetes, or about one fourth of the total amputations done in the United States, are preventable [1, 4].

Recently, the focus has been on preventive strategies that minimize foot damage in diabetic patients and thereby reduce the rates of ulcers and amputations. These preventive strategies are based on two observations: first, that simple efforts on the part of the health care provider or patient can reduce the likelihood of subsequent amputation due to diabetes-associated foot disease [8]; and second, that many of these simple procedures are not being systematically applied by health care providers or patients [9]. For example, studies indicate that physicians infrequently examine the feet of patients with diabetes [9, 10]. Also, most patients with diabetes do not engage in simple foot-care assessments to identify lesions requiring early treatment [11].

Preventive strategies are not systematically applied for several reasons: First, patients may not be aware of foot-care procedures or how to do them, or they may not believe that such procedures can make a difference; second, podiatry and orthopedics services that could assist in foot salvage in diabetic patients may not be available; and, finally, the health care system may make it difficult for patients or health care providers to examine the feet of patients with diabetes [10]. Several uncontrolled studies found that implementation of improved foot-care programs can significantly reduce lower extremity complications in patients with diabetes; these studies showed a 44% to 85% reduction in the rate of lower extremity amputations [4, 12-14]. A recent case–control study also supports the implementation of preventive strategies, such as foot care, use of protective footwear, and aggressive treatment of foot infection by patients or health care providers, to decrease the risk for lower extremity amputation [15].

The intervention in our study was designed to reduce the prevalence of risk factors for lower extremity amputations in patients with non-insulin-dependent diabetes and involved the three major elements of a prevention program: the patient, health care providers, and the health care system. Specifically, we did a randomized, controlled trial to determine whether a comprehensive foot-care intervention could improve patients' knowledge and performance of appropriate foot care; increase the number of referrals to specialty clinics such as the podiatry clinic; increase the frequency of foot examinations by health care providers and the documentation of risk factors in the medical record; and improve short-term patient outcomes such as skin and nail conditions known to be risk factors for ulcers and amputations.

Methods

Setting

Our study, the design of which is summarized in Figure 1, was done from April 1989 to March 1991 in the academic general medicine practice of the Regenstrief Health Center in Indianapolis, Indiana [16]. The practice is subdivided into four primary care teams (labeled A, B, C, and D), each with its own nursing and clerical staff. Each team sees patients for eight half-day sessions per week, with each session staffed by one or two faculty internists and two to four housestaff. Teams A and C were randomly assigned to the intervention group; teams B and D were assigned to the control group. Previous studies in which this method of randomization was used have shown no baseline interteam differences in patient characteristics and physician practice behavior and no effect of the team on the study outcome [16-19].

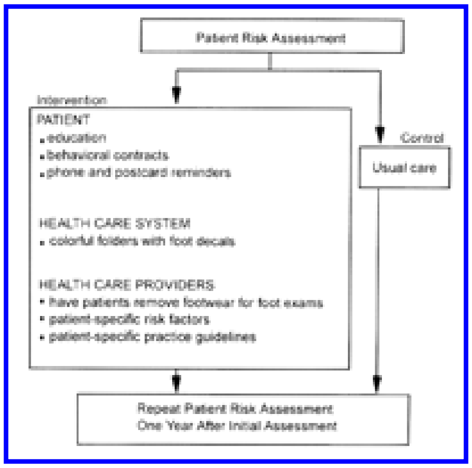

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Figure 1. **Summary of the study design.**

Patient Identification and Recruitment

The computerized Regenstrief Medical Record System [20] was used to identify approximately 3000 patients with non-insulin-dependent diabetes, as well as the date and time of their next appointment. Only patients with non-insulin-dependent diabetes who were seen at least two times in the preceding year by the same provider were included in the study. Additional criteria for inclusion were as follows: an age greater than 40 years; a diagnosis of diabetes after 30 years of age; a diagnosis of diabetes based on National Diabetes Data Group criteria [21] or the presence of disease requiring medication for the control of hyperglycemia; an intention to obtain care at the general medicine practice for the next 2 years; and a body weight that was either ideal or heavier than ideal. Exclusion criteria included pregnancy; major psychiatric illness, including dementia; terminal illness likely to cause death within 1 year; renal failure (serum creatinine > 440 µmol/L); previous bilateral amputations above or below the knee; or an inability to provide any self-care. Patients of investigators involved in the protocol were also excluded from the study.

Of the 728 eligible patients, 244 refused to participate, 89 enrolled in the study but failed to keep their appointments for assessment, and 395 were assessed by trained nurse-clinicians. Of the 395 patients assessed, 352 (89%) completed the study; 43 patients (11%) did not complete the study for the following reasons: death (11 patients); change of residence (15 patients); illness (6 patients); transportation problems (3 patients); and miscellaneous reasons (8 patients).

Patient Assessment

Samples for determining fasting plasma glucose, cholesterol, triglyceride, high-density lipoprotein, hemoglobin A_{1C}, and C-peptide levels were obtained from enrolled patients and immediately transported to a certified laboratory for analysis. Patients gave a history and had a physical examination at study entry and approximately 1 year later (mean, 11.8 ± 1.5 months). These examinations focused on risk factors for amputation and were administered by two trained nurse-clinicians who were blinded to the patients' experimental conditions. Foot-related data derived from the history and physical examination included the patient's self-reported foot-care behaviors; the quality of the patient's examination of his or her feet; the severity of any foot lesions; and the presence of musculoskeletal abnormalities, dermatologic conditions, peripheral vascular disease, and peripheral neuropathy (the neuropathy assessment included quantitative measures of pressure and temperature sensation).

Patients were questioned about their regular foot-care routine and were asked to show how they examined their feet. During this self-examination, nurse-clinicians observed whether patients' scrutinized the toenails, the soles of the feet, and the area between toes. Musculoskeletal and dermatologic abnormalities were assessed using standard definitions of findings such as callus, hammer toe, and Charcot foot [3, 22]. The nurse-clinicians palpated the dorsalis pedis, posterior tibial, and femoral pulses bilaterally in their assessment for peripheral vascular disease. If a pulse was absent at any one of the six sites palpated, the assessment was considered abnormal. Foot lesions were rated for severity using the Seattle Wound Classification System [23], which ranges from a grade of 1.1 (absence of lesions) to a grade of 10 (entire foot or leg is gangrenous). In our study, a foot lesion was defined as any wound, with or without functional interruption of the protective cutaneous barrier, ranging from a superficial scratch to an ulcer involving the epidermis. A serious foot lesion was defined by a severity grade of at least 1.3, which indicates a minor, nonulcerated lesion with clinical evidence of healing sufficient to close previous interruption of the cutaneous barrier [23] or a blister. Pressure and temperature sensations were measured using the 5.07-log (0.1 mg)-force Semmes-Weinstein monofilament and the thermal sensitivity testing apparatus, according to standard techniques [24-26]. Thermal sensitivity was considered abnormal if the patient had a value greater than 2 standard deviations from the mean value for a group of healthy persons without diabetes (warm > 2.04 °C; cool > 1.58 °C).

Practice Patterns of Health Care Providers

Immediately after each scheduled visit, study patients had a structured interview [10] with a research assistant, who asked about foot self-examination and foot-care education given by health care providers (the primary care physician or nursing personnel). In addition, a chart audit was conducted by a nurse-clinician who was blinded to the patients' experimental condition. Information abstracted from the medical record included the physician's documentation of the findings from the history and physical examination; any referral to podiatry, orthopedics, or vascular surgery clinics; and diagnostic-test ordering related to the evaluation and treatment of diabetes-associated foot problems.

Intervention

The intervention cohort was exposed to several risk-reduction strategies. The nurse-clinicians conducted the patient education session with one to four patients, covering appropriate foot-care behaviors and footwear, using a commercially available slide and audiotape presentation [27] and pamphlets [28]. Behavioral contracts regarding desired foot-care behaviors were negotiated with each patient. Follow-up was done by telephone 2 weeks after the education sessions to remind patients about the "contracted behavior." Additionally, postcard reminders, detailing the agreed-on behaviors, were sent at 1 and 3 months to patients in the intervention group.

The systems intervention, designed to direct health care providers' attention to the prevention of patient-specific risk factors, consisted of colorful folders with foot decals to identify intervention patients. The folders prompted health care providers to ask patients to remove their footwear, to perform foot examinations, and to provide foot-care education at each visit. Physicians received an informational flow sheet providing patient-specific risk factors and foot-care practice guidelines for assessment, diagnostic work-up, treatment, and referral recommendations. This flow sheet was clipped to the front of the intervention patient's chart during each visit.

Folders and flow sheets were removed from the charts after each visit to avoid exposing members of the control teams to intervention materials. One year after the initial assessment, all study patients underwent a repeated history and physical examination, again performed by nurse-clinicians blinded to patients' experimental conditions.

Statistical Analysis

Analyses of variables measured during the reassessment period are adjusted for baseline measurements. Specifically, to test for the effect of the intervention, we modeled the response of interest at reassessment as a function of its baseline value and randomization status using standard analysis of covariance and logistic regression (for binary and ordinal categorical) techniques. Where no baseline measure was collected, standard analyses for row times column tables were computed (using chi-square and Fisher exact tests). For outcomes that were foot specific (such as severity ratings based on the Seattle Wound Classification), the methods developed by Zeger and Liang [29] were used. These methods model the outcome of interest as a function of foot-dependent (fungal infections, corns) and foot-independent (age, foot-care behaviors) covariates. Because we were only able to estimate point prevalence and not true incidence, odds ratios were calculated.

Our controlled trial was designed to test whether this intervention would decrease lower extremity clinical abnormalities and increase appropriate behaviors. Targeted outcomes included foot lesions and dermatologic abnormalities. Thus, for primary hypotheses, we indicate the results of both the one-sided and two-sided tests of significance.

Although an exit interview and a chart audit were conducted after each visit, only data collected after the first visit were used in the analyses of health care providers' practice patterns because history, physical findings, and resultant diagnostic work-up and treatment could affect the need to re-examine the feet, record the history and physical findings, and document diagnostic and treatment plans on subsequent visits.

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Patients

Characteristics of patients who were enrolled in the study are shown in Table 1. Patients in the intervention group had a higher hemoglobin A_{1C} value at baseline than did controls. No differences were found between the groups regarding other characteristics. Compared with patients who completed the study, patients who did not complete the study had a higher hemoglobin A ($_{1C}$) level (11.7% ± 2.3% compared with 10.1% ± 2.4%; $P < 0.01$); no differences were found in race, sex, age, body mass index, or the proportion of patients taking insulin or oral hypoglycemic agents (data not shown, $P > 0.12$). The 11 patients who died were more likely than patients completing the study to have been taking insulin (82% compared with 50%; $P = 0.06$) and less likely to have been taking oral hypoglycemic agents (18% compared with 44%, $P = 0.05$); no difference was found between these groups in race, sex, age, body mass index, or hemoglobin A_{1C} level (data not shown, $P > 0.12$).

View this table: [in this window] [in a new window]	Table 1. **Patient Characteristics***

No difference was found between the intervention and control groups regarding either average time from study entry to the first visit (3.9 ± 2.6 compared with 4.1 ± 3.0 months; $P = 0.12$) or total number of visits to the practice during the study period (2.2 ± 1.4 compared with 2.3 ± 1.5; $P = 0.68$).

Patient Outcomes

The intervention reduced the prevalence of lower extremity abnormalities at the close-out examination. Intervention patients were approximately 0.41 times as likely as control patients to have serious lesions (based on the Seattle Wound Classification Scale [23]). In addition, they were less likely to have dryness or cracking of the skin, ingrown toenails, and fungal nail infections when compared with control patients (Table 2). There was a trend toward fewer fungal skin infections and instances of interdigit maceration in the experimental group. No difference was found between groups regarding the presence of corns, calluses, and improperly trimmed nails. At the end of the 1-year intervention, four amputations had been done in the control group compared with one in the intervention group.

View this table: [in this window] [in a new window]	Table 2. **Effect of the Intervention on Patient Outcomes**

Patient Behavior

Using a 5-point scale (1 = almost always; 5 = almost never), patients responded to 12 questions about self-foot-care behavior. After adjusting for baseline scores, we found that the intervention group reported lower (more appropriate) mean scores (intervention group, 1.90 ± 0.42; control group, 2.12 ± 0.49; $P = 0.0001$). Controlling for baseline behaviors and randomization status, we found that intervention patients more frequently reported washing their feet, not soaking their feet, inspecting their feet, inspecting the inside of shoes, drying between toes after washing, and filing calluses (Table 3). The effects of the intervention on the remaining foot-care behaviors, with the exception of wearing socks with shoes, were also in the hypothesized direction but were not statistically significant. Intervention patients were more likely than control patients to report that they avoided going barefoot outdoors (baseline prevalence, 89%; odds ratio, 1.92; 95% CI, 0.85 to 4.35; $P = 0.10$). No differences were found between the two groups with regard to going barefoot indoors or using heating pads and hot water bottles on the feet. Intervention patients were approximately twice as likely as controls to examine the plantar surfaces during self-examinations (baseline prevalence, 66%; odds ratio, 1.81; CI, 1.02 to 3.21; $P = 0.04$). No differences were found between the two groups regarding self-examination of toenails and areas between the toes.

View this table: [in this window] [in a new window]	Table 3. **Effect of the Intervention on Self-Foot-Care Behaviors**

Behavior of Health Care Providers

Intervention patients were more likely than control patients to be asked to remove their shoes and socks by nursing personnel while being shown to an examination room (53% compared with 17%; $P < 0.001$) or by the primary care physician when in the examination room (28% compared with 14%; $P < 0.001$). Patients in the intervention group were also more likely than control patients to have their feet examined at office visits (68% compared with 28%; P< 0.001) and to receive foot-care education from a health care provider (42% compared with 18%; $P < 0.001$).

Physicians on intervention teams were more likely than physicians on control teams to record having asked patients about symptoms of neuropathy at the first visit (7.6% compared with 2.5%; $P = 0.02$). The two teams did not differ in recording information derived from the history about the presence or absence of claudication, pain at rest or at night, foot deformities, dry or cracked skin, foot or nail infection, or foot lesions. Intervention physicians were more likely to record having examined the feet for ulcers, peripheral pulses, dry or cracked skin, calluses or corns, and fungal infections (Table 4). No differences were found in the physician teams' recording of ingrown toenails, improperly trimmed nails, cellulitis, foot deformities, or sensory abnormalities.

View this table: [in this window] [in a new window]	Table 4. **Effect of the Intervention on Physicians' Documentation of the Presence or Absence of Physical Findings**

Physicians exposed to the intervention were more likely than physicians assigned to the control teams to refer patients to the podiatry clinic (10.6% compared with 5.0%; $P = 0.04$). No differences were found between teams in the pattern of patient referral to orthopedics and vascular surgery clinics.

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We did a randomized, controlled trial to determine whether risk-reduction strategies can decrease the frequency of foot complications known to be risk factors for lower extremity amputations in diabetic persons. Previous studies found that changing patients' or health care providers' knowledge may not change behavior [30, 31]. Systems interventions, such as chart reminders, however, can be effective in modifying physicians' practice patterns [17, 19, 32]. Other systems interventions such as postcard reminders have been shown to increase patient compliance with visits to health care providers [33], and patient contracts have been useful in improving patient compliance with recommended strategies, including self-examination of feet [34]. Previous studies have found that physicians infrequently examine patients' feet when patients are placed in the examining room fully clothed [9, 10]. However, the likelihood that physicians would evaluate patients' feet increased three to four times when patients were instructed to remove their footwear before the doctor's arrival in the examination room [10]. In our study, patient and health care-provider education in combination with systems interventions improved patients' knowledge of appropriate foot-care behavior, patients' and health care providers' performance of appropriate foot-care behaviors, and patient outcomes.

Although the intervention was effective in many areas, it did have limitations. The intervention did not improve all foot-care behaviors. Individual behaviors that were specifically noted in the contract ("dry between toes," "file calluses") were more likely to improve than behaviors that were described in more general terms. For example, the instruction "avoid injury to your feet" resulted in improved behavior with regard to going barefoot outdoors but had no beneficial effect on indoor barefoot behavior. The contracts would probably have been more effective if they had been more specific.

Although intervention physicians were more likely than control physicians to refer patients to the podiatry clinic, the low referral rate was disappointing given the importance of podiatric interventions in the prevention of lower extremity abnormalities. The low rate of referral to the orthopedics clinic may have been associated with a belief that surgical correction of foot deformities is not beneficial in preventing diabetes-associated foot complications or that the risks of surgical correction are too great in patients who have multiple chronic diseases. The low rate of referral to vascular surgery is probably attributable to the low prevalence of absent pulses (7%).

Although intervention physicians' documentation of risk factors for foot complications improved, the percentages recorded were low. It is likely that physicians documented only positive or abnormal findings in the medical record. Providing physicians with a checklist of symptoms and signs of diabetes-associated foot complications, to be completed at each visit, would probably have been more effective.

The major limitation of our trial was that neither the sample size nor the length of follow-up was adequate to show that these interventions can reduce the incidence of lower extremity amputations. The multifaceted nature of the intervention also prevented assessment of the relative contributions of the individual components (patient, health care provider, system) to outcomes. Additionally, the study was conducted in an academic practice that provided care predominantly to poorly educated and indigent black women with non-insulin-dependent diabetes, a factor that limits the generalizability of our findings.

The strengths of our trial were its simplicity, low cost, and effectiveness in reducing lower extremity abnormalities. The study materials, including folders, foot decals, postage, printing, and educational materials, cost less than $5000. The major expense of the study was the salary support for the nurse-clinicians who did the assessments and for the research assistant who processed the charts. However, we believe that implementing similar interventions in other practice settings could easily be done by educating and involving existing office personnel. Foot-care programs should be implemented in primary care settings to reduce the incidence of diabetes-associated lower extremity abnormalities and amputations, as well as the personal and economic burden associated with such outcomes.

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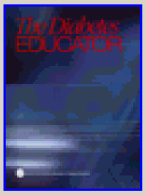

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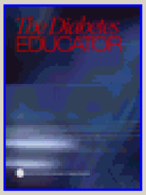

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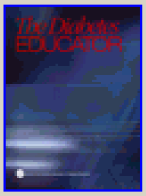

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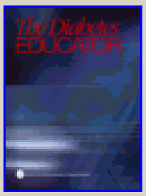

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