Reducing Lower-Extremity Amputations Due to Diabetes

Application of the Staged Diabetes Management Approach in a Primary Care Setting

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BACKGROUND. While lower-extremity amputation (LEA) is a frequent complication of diabetes, effective strategies for the prevention of LEA in primary care settings have not been extensively studied.

METHODS. This prospective study of American Indians with diabetes in a rural primary care clinic was divided into three periods: the standard care period (1986 to 1989), during which patients received foot care at the discretion of the primary care provider; the public health period (1990 to 1993), during which patients were screened for foot problems and high-risk individuals received foot care education and protective footwear; and the Staged Diabetes Management (SDM) period (1994 to 1996), during which comprehensive guidelines for diabetic foot management were adapted by the primary care clinicians to their practices and were systematically implemented.

RESULTS. A total of 639 individuals contributed 4322 diabetic person-years during the three periods of observation. Patient sex distribution, mean age, and mean duration of diabetes were similar in the three periods. The average annual LEA incidence was 29/1000 diabetic person-years for the standard care period (n= 42), 21/1000 for the public health period (n=33), and 15/1000 for the SDM period (n=20), an overall 48% reduction ($P = .016$). Overall, the incidence of a first amputation declined from 21/1000 to 6/1000 ($P < .001$).

CONCLUSIONS. The customization and systematic implementation of practice guidelines by local primary care providers was associated with improved diabetic foot care outcomes. SDM has relevance to primary care organizations seeking to improve outcomes for patients with diabetes.

KEY WORDS. Diabetes; lower extremity; amputation; primary care; Indians, North American. *(J Fam Pract 1998; 47:127-132)*

Diabetes is a growing problem worldwide,[1] and lower-extremity amputations (LEA) are a frequent complication of the disease.[2,3] Although it has been shown that amputation rates can be reduced through patient participation in selected specialty-based diabetic foot clinics,[4-6] studies of hospital discharge data show that the rate of LEA within the United States has remained relatively stable or has worsened.[3] Despite this finding, effective strategies for the prevention of LEA in primary care settings, where more than 95% of people with diabetes receive their care, have not been ubiquitously implemented. The need for effective foot care programs is especially important to American Indian communities, who not only have an extremely high prevalence of type 2 diabetes but also suffer disproportionately higher rates of LEA.[7]

In a primary care clinic in northern Minnesota, the Indian Health Service (IHS) and a regional tribal health program have studied public health strategies that identify and target high-risk individuals for intensive intervention.[8] Through this process, it was discovered that LEA continues to be among the most prevalent complications of diabetes. This finding led the providers in the clinic to collaborate with the International Diabetes Center to implement a systematic data-based approach to practice changes that promote adherence to locally customized foot care guidelines and protocols, using a process called Staged Diabetes Management (SDM).[9-11]* The purpose of this study was to determine whether SDM, when compared with earlier interventions, affected the rate of LEA among American Indians in a primary care setting without specialty-based care.

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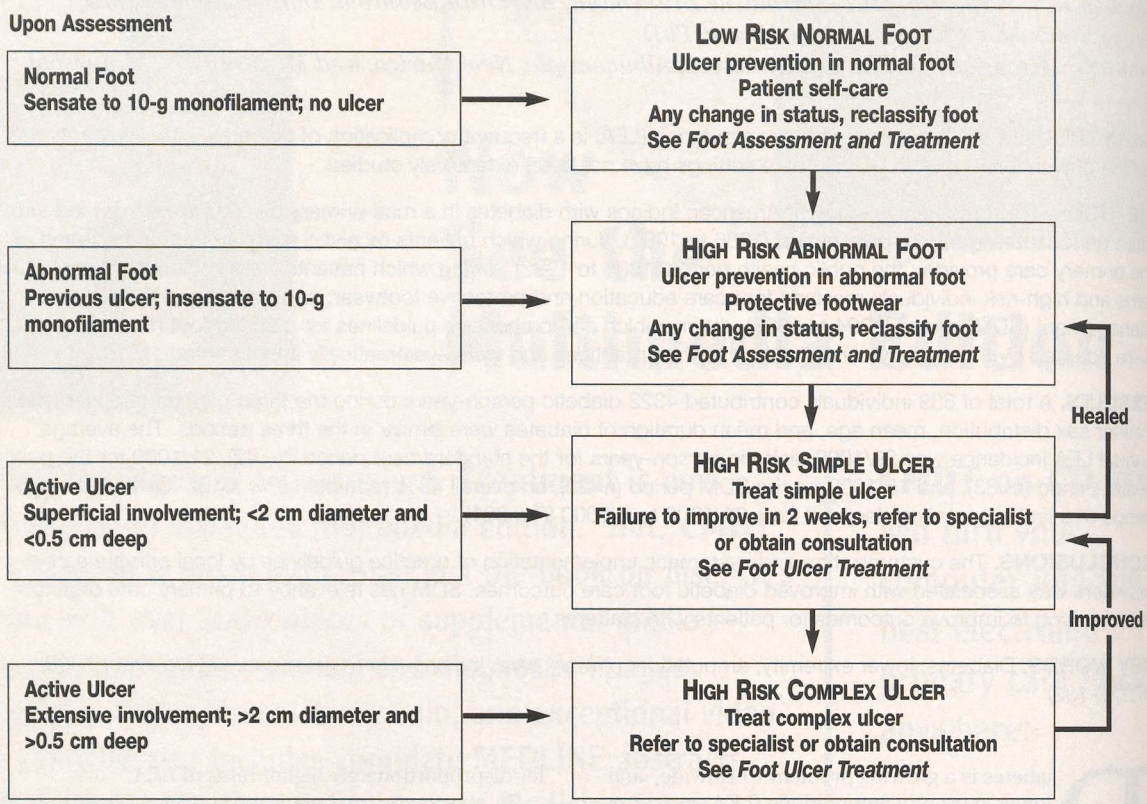
* Staged Diabetes Management (SDM) is a comprehensive diabetes quality-improvement program that utilizes locally customized practice guidelines in conjuction with systematic changes to promote adherence to prescribed care. SDM is not a commercial product and is not for purchase. It has been implemented in a wide range of health care settings with the support of grants. For information on the implementation of SDM, contact Roger Mazze, MD, International Diabetes Center, 3800 Park Nicollet Boulevard, Minneapolis, MN 55416; (218) 993-3393. E-mail: http://www.methodisthospital.com/SDM-MAIN.htm

FIGURE

Practice Guidelines: Diabetic Foot Management



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METHODS

Our study reviewed observations gathered prospectively from 1986 to 1996 by an IHS facility serving approximately 5000 Chippewa Indians in northern Minnesota. During the 11-year study period, 639 people with diabetes were identified in the community through active and passive surveillance systems described elsewhere.[12] All persons identified through surveillance were entered into a diabetes registry and followed thereafter. Baseline registry information indicated that LEA was the most common major complication experienced in the community by persons with diabetes. Amputation rates were noted for three intervention periods: the first when diabetes patients in the community received standard care, the second when they received public health care, and the third when SDM was implemented.

During the standard care period (1986 to 1989), patients were screened for foot problems and received care at the discretion of the primary care provider. Patient records revealed no evidence of a consistent or systematic approach to foot disease management. During the public health period (1990 to 1993), simple preventive services were organized and targeted for those individuals with high-risk findings on examination. Patients who presented to a diabetes clinic were referred to the physical therapy department for an annual foot examination. The criteria for a high-risk examination included insensitivity to the 10-g monofilament, a foot deformity, or a history of foot ulcer or amputation.[13,14] Preventive services were provided at the discretion of staff physical therapists and pedorthists and included self-care education, routine palliative foot care, and the provision of protective footwear. There were no detailed guidelines or flow sheets for these specific services. Patients with active ulcers received conventional management from local primary care providers and the regional community hospital. As in the standard care period, the approach to ulcer assessment and treatment was neither systematic nor consistent.

In 1994, screening, diagnostic, and treatment guidelines were implemented in the SDM period.[9-11] Practice guidelines were developed to address the specific criteria for

diagnosis, risk-factor assessment, treatment options, therapeutic targets, monitoring, and follow-up (available on request from S.R-N and on the *Journal* website at www.jfp.denver.co.us). An algorithm was developed (Figure) to identify four risk categories: low-risk normal foot, high-risk abnormal foot, high-risk simple ulcer, and high-risk complex ulcer. Specific decision pathways were created to guide the foot examination in terms of sensitivity to a 10-g monofilament, specification of foot abnormality, application of an ischemic index, and diameter and depth of ulcers. Additional algorithms include treatment options and follow-up schedules.

The adoption of SDM led to changes in both the structure and process of care. A foot-care team was formed consisting of a family physician, two clinic nurses (one of whom was the designated coordinator), a home care nurse, a nutritionist, and a registrar. This team met monthly to develop coordinated strategies for improving access to and utilization of appropriate foot care services. Flow sheets based on SDM algorithms were produced, and a copy was placed in each patient's chart. Standing orders and standardized ulcer assessment and management protocols for each risk category were implemented.

Throughout the three study periods, amputation was defined as the loss of any part of a lower limb. Cases were identified through review of medical records of patients known by clinic and community health staff to have had an amputation. Additional cases were ascertained from the IHS hospitalization discharge diagnosis database (ICD-9-CM procedure codes 84.10-84.17). This database included patients hospitalized at IHS facilities as well as patients at non-IHS facilities if the IHS contracted for part or all of the care. The diabetes registrar recorded all known amputation cases. Multiple amputations on the same limb during a single hospitalization or repeat amputation on the same limb within 1 month of a previous amputation were considered a single amputation at the highest level. Amputations occurring among individuals who sought all their care outside the IHS system (<5%) were excluded. A major amputation was defined as either a "below the knee amputation" or an "above the knee amputation." Average annual LEA incidence rates for the standard care, public health, and SDM periods were calculated by dividing the number of LEA cases for each period by the sum of the diabetes cases at risk for amputation on the registries on December 31 for each year of the respective periods. Patients were considered at risk for a first amputation if both lower limbs were intact. Subjects with at least one partially intact limb below the knee were considered at risk for any amputation or major amputation. Statistical significance was determined by the chi-square method, using Epi-Info version 6.04b software.[15]

TABLE 1

Mean Age, Sex Distribution, and Mean Duration of Diabetes Among Active Registrants for Each Intervention Period (N=639)

	Intervention Period		
	Standard Care (1990 to 1993)	Public Health (1990 to 1993)	SDM (1994 to 1996)
No. of patients	428	449	475
Person years	1464	1543	1313
Mean age, y (SD)	53.9 (±12.9)	53.6 (±13.1)	54.2 (±13.0)
Sex, % female	54.4	56.8	56.8
Diabetes duration, y (SD)	8.3 (±6.5)	8.5 (± 6.4)	9.7 (± 7.2)

SDM denotes Staged Diabetes Management; SD, standard deviation.

TABLE 2

Clinical Characteristics of Selected Diabetes Registrants During the Public Health and SDM Intervention Periods

Intervention Period	No. Charts Audited*	Percent Hb A_{1c}, mean (SD)	Mean Arterial Pressure (mm Hg), mean (SD)	Serum Creatinine (μmol-L), mean (SD)	Total Serum Cholesterol (μmol-L), mean (SD)	Percent Past or Current Tobacco Use	Percent Proteinuria (>Trace)
Public Health	129	9.4 (±2.2) (1990 to 1993)	132 (±16)	106 ± 106 (1.2 ± 1.2 mg/dL)	5.33 ± 1.24 (206 ± 48 mg/dL)	78	48
SDM (1994 to 1996)	142	9.6 (± 2.1)	136 (± 13)	115 ± 106 (1.3 ± 1.2 mg/dL)	5.43 ± 1.09 (210 ± 42 mg/dL)	84†	39†

SDM denotes Staged Diabetes Management; SD, standard deviation.
* Standard annual diabetes medical record review conducted 1992 to 1996.[16]
†No statistical difference ($P > .10$) compared with public health period.

TABLE 3

Average Annual Incidence of Lower-Extremity Amputation (LEA) Among Patients, by Intervention Period

Period	Person-Years at Risk	No. of Cases of LEA	LEA/1000 Diabetic Person-Years	% Change	*P* Value*
Standard Care					
Any LEA	1464	42	29	—	—
First LEA	1414	30	21	—	—
Major LEA	1464	16	11	—	—
Public Health					
Any LEA	1543	33	21	-28	.20
First LEA	1467	18	12	-43	.06
Major LEA	1543	12	8	-27	.37
SDM					
Any LEA	1313	20	15	-48	.016
First LEA	1246	7	6	-71	.0006
Major LEA	1313	11	8	-27	.49

SDM denotes Staged Diabetes Management.
* Chi-square compared with standard care period.

Mean age, sex distribution, and mean duration of diabetes were calculated using demographic data listed in the diabetes registry for the cohorts of each period. Clinical characteristics, such as metabolic control (Hb A_{1c}), blood pressure, serum cholesterol, serum creatinine, urinary protein, and history of tobacco use, were ascertained from a sample of medical records collected as part of the IHS annual quality assurance review during the public health and SDM periods.[16] These data were not consistently collected before these periods.

TABLE 4

Incidence Rates of Lower-Extremity Amputation, by Intervention Period and Selected Risk Groups

Risk Group	Intervention Period: Standard Care	Public Health	SDM
Sex			
Male	34	36	20
Female	25	11	12
Age, y			
<55	17	11	13
≥55†	41	33	18
Diabetes duration, y			
<10†	9	3	1
≥10†	59	47	32

Note: Rates per 1000 person-years.
SDM denotes Staged Diabetes Management.
† $P < .05$ when the SDM period rate was compared with the baseline rate.

RESULTS

A total of 639 individuals contributed 4322 diabetic person-years during the 11 years of observation. Sex distribution, mean age, and mean duration of diabetes did not vary significantly among those who participated in the standard care, public health, and SDM periods (Table 1). In addition, clinical characteristics directly and indirectly associated with the risk of amputation, such as Hb A_{1c}, mean arterial blood pressure, serum creatinine, serum cholesterol, current or past tobacco use, and urinary protein, were similar in a sample of individuals in the public health and SDM periods (Table 2). While these data were unavailable for the standard care period, other data sources for these clinical variables did not suggest any difference between this period and the later periods.

Of the 639 individuals in the study, 59 experienced 95 lower-extremity amputations in 4324 diabetic person-years at risk for amputation, for an average annual incidence rate of 22/1000 during the 11 years of the study. The average annual amputation incidence for the standard care period was 29/1000, declining to 21/1000 in the public health period. A further reduction in LEA rate to 15/1000 was observed in the SDM period. A 48% reduction overall ($P = .016$) was found when the standard care and SDM periods were compared. Among persons with intact limbs, the rate of first amputation was reduced by 71% (21/1000 in the standard care period to 6/1000 in the SDM period, $P < .001$). In addition, there was a trend toward fewer major amputations, but the reduction in rate

(27%) was not statistically significant (Table 3).

LEA incidence rates were higher among men, subjects older than 55, and those who have had diabetes for 10 or more years. When the SDM period was compared with the standard care period, a trend for reduction in amputation incidence was seen in all sex, age, and duration of diabetes risk groups (Table 4). Among women and subjects younger than 55, amputation incidence increased slightly between the public health and SDM periods, but the difference is not statistically significant.

DISCUSSION

Few studies of amputation prevention programs in primary care settings have been published.[17-18] Our study documents one of the longest periods of observation, and correlates care practices with actual amputation rates. A recent study of primary care clinics in southern Sweden reported a 22% reduction in overall amputations 10 years after an improvement in access to multidisciplinary diabetic foot-care services.[5] The finding in our study of a 48% reduction in amputation rates among individuals with almost 10 years' duration of diabetes is remarkable and is similar only to reductions reported by specialty treatment centers.[6,19] Although this study was not a controlled clinical trial, the demographic and clinical characteristics of the individuals in the three periods of observation were similar, and all were residing in a well-defined geographic community.

Our study occurred during a period when the age-adjusted US hospitalization rate for diabetic amputation increased from 7.0 /1000 in 1986 to 8.2 /1000 in 1994.[3] This suggests that the 48% decline in amputation rates observed in our study is associated with the different care practices described, rather than a national change in diabetes foot care. It is not possible to determine whether a specific element of SDM was responsible for the observed improved outcomes or whether, as is likely, there were several reasons. The intervention strategies that we used were broadly defined, and focused on patient education, provision of protective footwear, and conventional wound care. These services are typically available in rural communities and have been effective in other settings.[4-6, 8, 20, 21] The foot screening process may have increased both patient and provider awareness of the individual's high-risk foot status. Such awareness has been associated with increased provider prescription of preventive foot-care services among patients with diabetes.[22] The clear criteria for recognition of complicated ulcers and prompt referral for specialty wound care were also likely to have been contributing factors to limb salvage.[23] Coordination of care through SDM and similar processes has also been associated with improved foot care and other diabetic outcomes.[4, 6, 9, 19, 24] Moreover, the screening and risk stratification techniques are simple and low-cost, and the system changes to promote their incorporation into clinical practice are practical for primary care settings.

No discussion on diabetic complication prevention would be complete without mention of the importance of improving glycemic control. Improving metabolic control has been associated with reduced risk for diabetic peripheral neuropathy[25] and, in turn, can interrupt the cascade of pathological events that result from an insensate foot.[26] The mean Hb A_{1c} levels in our study (9.4 to 9.6%) were 2% higher than the target levels recently established by the American Diabetes Association.[27] These observations suggest that amputation rates could be reduced further through interventions early in the disease's course that target metabolic control.

While a detailed cost-benefit analysis was beyond the scope of this study, the direct medical cost for a single amputation has been estimated at $46,900.[28] Thus limb salvage represents potential savings that could be directed toward other prevention efforts. The direct cost of implementing SDM in the clinic in this report was approximately $8,300. This figure was based on the salaries of personnel who were taken away from direct patient care to develop the guidelines and system changes, and the cost for provider training on diabetic foot care. The costs for maintaining SDM involved commitment to monthly 1-hour interdisciplinary staff meetings, assignment of an advance practice nurse to perform foot examinations and palliative foot care, and allocation of resources for protective footwear. These costs were balanced by the benefits of easier clinical decision-making, increased patient satisfaction, and improved outcomes. It is also reasonable to assume that preventing first amputations led to an additional medical benefit of improved short-term survival rates. It has been shown that in similar populations, the 5-year mortality rate is 40% following a first amputation.[29]

CONCLUSIONS

At baseline, amputations were a frequent diabetic complication from diabetes in this primary care setting. Reductions in amputation rates (28%) during the public health period were associated with screening individuals for high-risk foot problems and targeting them with simple interventions, including patient education and provision of protective footwear. More substantial reductions in amputation rates (48%) were achieved when a framework for system changes embodied in Staged Diabetes Management was implemented. The formation of a foot-care team, development of consensus guidelines, use of flow sheets and standing orders, a tracking system for patient follow-up, and program evaluation substantially contributed to the beneficial outcome. The magnitude of limb preservation associated with the SDM approach to diabetic foot care suggests that other complications, such as retinal and renal disease, may also benefit from this approach. In summary, the SDM format has rele-

vance for primary care organizations seeking to improve a wide range of outcomes for patients with diabetes.

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