Reduction of amputation rates among Alaska Natives with diabetes following the development of a high-risk foot program

Cynthia Dodgen Schraer, Daniel Weaver, Julien Louise Naylor, Ellen Provost, Ann Marie Mayer

Alaska Native Tribal Health Consortium, Diabetes Program, Anchorage, USA

ABSTRACT

Objective. The prevalence of diabetes is increasing rapidly among Alaska’s Indian, Eskimo and Aleut populations. Approximately half the Native people with diabetes have no road access to hospitals or physicians, presenting a challenge in the attempt to prevent lower extremity amputation as a complication. In late 1998 funding became available for diabetes prevention and treatment among Native Americans. The tribal health corporations in Alaska decided to use a portion of this funding to implement a high-risk foot program to decrease the amputation rate. Program Design. The program initially involved a surgical podiatrist who provided training to local staff and performed preventive and reconstructive surgery on several patients with impending amputations. The program then provided training for a physical therapist to become a certified pedorthist. This individual established the long-term maintenance phase of the program by conducting diabetic foot clinics routinely at the Alaska Native Medical Center, a referral center in Anchorage. He also travels to other regions of the state to provide training for village and hospital-based health care providers and to conduct field clinics. A system was established in a common database management program to track the patients’ foot conditions. Patient education is emphasized. Results. The overall amputation incidence among all Alaska Native patients with diabetes decreased from 7.6/1,000 in the pre-program period (1996 to 1998) to 2.7/1,000 in the post-program period (1999-2001)(p<.001). The rate among Aleuts, who previously had the highest amputation incidence, decreased from 17.4/1,000 to 3.1/1,000 over the same time periods (p<.001). Among people who had had diabetes at least 10 years, the overall amputation incidence decreased from 16.4/1,000 to 6.8/1,000 (p=.021); among Aleuts the rate fell from 24.5/1,000 to 2.6/1,000 (p=.01). Conclusions. Though longer follow-up is needed, these data suggest that even in populations living in isolated regions, diabetic amputations can be prevented by a coordinated system to identify high-risk feet and provide preventive treatment and education in the context of a comprehensive diabetes management program in an integrated health system

Key words: diabetes, amputations, Alaska Natives, foot care

INTRODUCTION

Diabetes appears to have been a rare condition among Alaska Native people prior to the latter part of the 20th century. However, due to the impression among clinicians that this condition was becoming increasingly common, a diabetes registry was established in 1985. The methods of registry maintenance and complication case ascertainment have been previously described (1-3). Briefly, the registry serves as a clinical database for all patients using the Alaska Native Health Care System to assure that patients with diabetes are not lost to follow-up, and that nationally and internationally accepted standards of care are available to these patients, approximately half of whom do not have road access to physicians or hospitals.
The prevalence of diabetes increased by 80% from 1985 to 1998 (15.7/1,000 to 28.3/1,000, age-adjusted to the U.S. 1980 population) (3). Complications, including lower extremity amputation (LEA) occurred in all major ethnic groups, with Aleuts experiencing a disproportionately high incidence of amputation (2). As the numbers of patients increased, it became apparent that foot services needed to be systematized, and that health care providers statewide needed additional training in the prevention, early identification, and management of diabetic foot complications.

At the end of 1998, as part of a national effort to address the growing problem of diabetes in the U.S., funding was made available to the Alaska Native health care system specifically for prevention and treatment of diabetes. A consensus was reached among the tribally managed health care programs that a portion of the funding should be used for the improvement of foot care services.

Program description
At the inception of the foot care program, a surgical podiatrist with long-standing experience among Native Americans with diabetes was contracted to provide surgical services for some individuals with impending amputations, and to assist with the design of a long-term preventive program. Two general components of the program were developed—specialty foot services at the Alaska Native Medical Center (ANMC), the referral center in Anchorage, and a "field" component. At ANMC a physical therapist with a particular interest in diabetic foot problems was identified. The program provided funding for him to become a Certified Pedorthist (C-Ped). This certification requires up to 120 hours of pedorthic education, study of selected references followed by self-examination of knowledge, and passage of a certifying exam. This training qualifies the C-Ped to examine feet and to design and construct specially fitted shoes and orthotics for patients with various forms of foot problems.

Following training, the physical therapist/C-Ped (PT/C-Ped) established a foot specialty clinic located in the Physical Therapy Department at ANMC. A risk category system has been found useful in planning follow-up for diabetic patients’ foot care; four categories of risk have been described (4). Factors determining risk category include the presence or absence of protective sensation, deformities, callus, corns, weakness, history of ulceration, and evidence of vascular disease. A computerized tracking system was established, in which each patient’s risk category is documented, along with a specific diagnosis, follow-up plan, and progress notes. Foot lesions are documented with a digital camera and pictures are compared over time to facilitate assessment of progress.

Examples of common services provided by the PT/C-Ped are routine foot examinations including assessment of sensation by monofilament, toenail and callus trimming, evaluation and fitting for custom shoes, and orthotics. The PT/C-Ped works in consultation with Orthopedics, Vascular Surgery, and the Diabetes Clinic to provide conventional wound care management and off-loading by means of cam boots, healing sandals, total contact casts, and crutches as indicated. Initially, foot clinics were held two half-days each week, but the frequency was increased to five half-days per week to meet demand.

The field component of the program consists of itinerant services by the PT/C-Ped to rural hospitals and clinics. The Diabetes Program holds specialty clinics at many of the regional Native health care facilities, and the PT/C-Ped participates in these clinics periodically. He offers the same services as at ANMC and in addition holds training sessions for local health care providers. The training emphasizes the recognition of factors such as anatomic variations (bunions, hammer toes, Charcot deformities etc.) that place patients at increased risk for pressure-related skin breakdown and ulcer development. He also provides training in neurologic assessment, including the use of monofilaments, and recommendations for early treatment of wounds. Field providers are also trained to assign risk category, evaluate shoes for proper fit, and to assess the need for accommodative shoes for individual problems. In all aspects of the program, patient
education in self-care and early recognition of problems is emphasized.

The Diabetes Program also provides training for village health aides, community-based para-professionals, through the Community Health Aide Program. Diabetic foot care is emphasized in these training sessions. In addition, the Diabetes Program presents a yearly three-day diabetes conference in Anchorage that provides continuing medical education for health care providers. The conference, which is attended by over 200 health care providers from all regions of Alaska, offers a hands-on workshop on diabetes foot care taught by the PT/C-Ped and a diabetes program primary care provider.

METHODS
The numbers of people with diabetes and the number of diabetes-related lower extremity amputations were derived from the patient registry. Registry cases in turn are ascertained from the computerized databases at each regional tribal health facility, including ANMC, and by active and passive case reporting from the diabetes case managers at each facility. All episodes of LEA that occurred on the same leg during the same admission or within one month of discharge were counted as one amputation. Since the number of Alaska Native people with diabetes is rapidly increasing, and since many of the patients may have had this condition for only a brief time, and may therefore be at low risk for amputation, we calculated the incidence of amputation in two ways.

First, we calculated an overall LEA incidence, counting all people with diabetes in the denominator and all diabetes-related amputations, regardless of duration of diabetes. Second, we calculated the incidence of LEA only among those patients who had had diabetes documented for at least 10 years. Our registry was started at the end of 1985, and most patients entered into the registry at that time had unknown dates of diagnosis. Therefore the earliest year in which we were confident that we could identify patients who had had diabetes for at least 10 years was 1996.

We compared data from a pre-program period, 1996-1998, to those from a post-program period, 1999-2001. The differences between pre- and post-program periods were evaluated for significance by Chi-square test using Yates correction, or Fisher’s exact test where appropriate.

RESULTS
The foot care clinic at ANMC has provided services to approximately 300 patients since its inception in 1999. Over 91% of the patient visits are for preventive care, while approximately 8% are for new complications.

During the years 1996-2001, a total of 34 Alaska Native individuals with diabetes (7 Eskimos, 13 Indians, 14 Aleuts) experienced 48 amputations. Among all Alaska Native people with diabetes, the incidence of LEA decreased from 7.6/1,000 in the three years preceding the foot care program (1996-1998) to 2.7/1,000 in the three years after initiation of the program (1999-2001) (p<.001). The Aleuts, who have had the highest LEA incidence, experienced the greatest decrease, from 17.4/1,000 to 3.1/1,000 (p<.0001) The Indian and Eskimo diabetic populations also experienced decreases; however, among Indians the change was not significant.

(Results table)

Table 1. Amputations Among All Alaska Natives with Diabetes 1996-2001.

| Ethnic Group | Pre-program (1996-1998) | Post-program (1999-2001) | Reduction | P |
|--------------|-------------------------|--------------------------|-----------|---|
|              | diabetic person-years    | amputations incidence /1000 | diabetic person-years    | amputations incidence /1000 | % |
| Eskimo       | 1355                    | 9                        | 1979.5     | 4 | 70 % | 0.047 |
| Indian       | 1950                    | 7                        | 2655.5     | 8 | 16 % | 0.94 |
| Aleut        | 921.5                   | 16                       | 1273       | 4 | 82 % | <.001 |
| All Native   | 4226.5                  | 32                       | 5908       | 16 | 64 % | <.001 |
Of the 48 amputations, 15 occurred when diabetes had been documented for less than 10 years. These 15 amputations occurred in 11 individual people.

Among people with diabetes documented for 10 years or more, the all-Native LEA incidence decreased from 16.4/1,000 to 6.8/1,000 (p=.021); among Aleuts the decrease was from 24.5/1,000 to 2.6/1,000 (p=.01). Though the rates decreased among Eskimos and Indians, the decreases were not statistically significant. (Table II)

DISCUSSION

Several studies and reviews have documented that many underlying components contribute to the development of LEA among people with diabetes. These include neuropathy, peripheral artery (macrovascular) disease, deformity, altered biomechanics, callus, nail pathology, poorly controlled hyperglycemia and hypertension, smoking, and duration of diabetes of 10 years or more. (5,6)

Studies and reviews have also documented that several aspects of care can reduce the incidence of foot ulcers and subsequent amputation. Management of underlying metabolic and physiologic problems, most notably by achieving good glucose and blood pressure control, as well as cessation of smoking, is recommended. (6,7) Measures directly affecting the feet such as appropriate foot exams, evaluating neurologic status, use of orthotics and protective footwear, and management of calluses and toenail deformities also decrease amputation rates. (5,6,8) The roles of a multidisciplinary team approach, including reconstructive surgery when necessary, patient education, health care provider education, and registration of amputations have also been described in amputation prevention. (5,6,8,9)

Many of these effective strategies do not require high degrees of technology, but they do require specific clinical acumen and skills. To make these strategies available to patient populations living far from major medical centers has been our challenge.

Several factors in the Alaska program may have contributed to a reduced amputation incidence. The Alaska Native Diabetes Program has been in existence for over 15 years, and through the use of a patient registry, few patients have been lost to follow-up. Yearly audits at each major health facility have focused attention on aspects of care that may influence the progression of macrovascular disease and neuropathy. Assessments of blood pressure and glycemic control, lipid levels, and smoking status are included in these audits. Provision of patient education and complete foot exams are also assessed. Results of these audits have demonstrated that Alaska has consistently shown lower glycosylated hemoglobin levels than other regions in the Indian Health Service monitoring program. In Alaska, over 60% of patients have received education each year and 70% or more have received complete foot exams (Indian Health Service program data). The Alaska Native health care system has made available newer medications that have shown promise in the reduction of complication rates in general and improvement of glycemic and blood pressure control. These include angiotensin converting enzyme inhibitors, angiotensin receptor

| Ethnic Group | Pre-program (1996-1998) | Post-program (1999-2001) | Reduction | P |
|--------------|------------------------|--------------------------|-----------|---|
|              | diabetic amputations incidence per person-years /1000 | diabetic amputations incidence per person-years /1000 | %         |   |
| Eskimo       | 405.5 7 17.3           | 501.5 4 8.0              | 54 %      | 0.235 |
| Indian       | 610.5 7 11.5           | 742 6 8.1               | 29 %      | 0.722 |
| Aleut        | 326 8 24.5            | 384.5 1 2.6              | 89 %      | 0.01 |
| All Native   | 1342 22 16.4         | 1628 11 6.8            | 59 %      | 0.021 |

Table II. Amputations Among Alaska Natives with Diabetes ≥ 10 years Duration 1996-2001.
blockers, metformin, thiazolidinediones and lipid control agents. The degree to which these may have contributed to a reduction in the risk factors for LEA among Alaska Native people with diabetes is not known.

It is encouraging to note that although Aleuts have experienced a higher amputation incidence than other Alaska Native groups, the magnitude of reduction has also been greater. The initially higher rate may indicate an increased susceptibility to consequences of the insulin resistance syndrome, and is consistent with the observation that this group has had a higher rate of myocardial infarction and a higher prevalence of diabetes (1,2). However, the reduction in the amputation rate gives hope that efforts by both patients and health care providers may reduce the risk of adverse outcomes.

Over 32% (11 of 34) of the LEA patients had an amputation when diabetes had been documented for less than 10 years. This may indicate that diabetes exists for a significant time prior to diagnosis. It may also indicate that the course of events leading to amputation, most notably peripheral macrovascular disease, begins prior to the onset of diabetes. This would be consistent with observations that there is an association between cardiovascular disease and higher glucose levels even below those diagnostic of diabetes (10-12). These observations may imply that diabetes programs should address the needs for risk factor reduction among those who have pre-diabetes (impaired fasting glucose and impaired glucose tolerance).

Our observation period among people with documented duration of diabetes over 10 years has been relatively short, and raises the question as to whether it is reasonable to attribute decreased LEA rates to our interventions. A study among African Americans with diabetes demonstrated that after one year of enrollment in an amputation prevention program, amputation incidence decreased by 79% (13). A study among Native Americans in Minnesota demonstrated a reduction in LEA incidence from 29/1,000 to 21/1,000 within three years of instituting a systematized foot care program, and a further reduction to 15/1,000 within three years of beginning a process called Staged Diabetes Management (14).

It is difficult to compare LEA rates in different populations because of differences in case ascertainment, case definitions, population characteristics and other factors. However, data suggest that Alaska Native people with diabetes may be faring as well as or better than other U.S. diabetic populations. Our previously published overall incidence of LEA among all Alaska Natives with diabetes in the years 1986 through 1998 of 6.1/1,000 (3) was lower than rates for other Native Americans with diabetes, which have been reported to range from 7.3/1,000 to 29/1,000 (14,15), and within the range reported for the US (3.7/1,000 to 11/1,000 (16,17). These rates do not take into account the length of time patients have had diabetes. One of the national health objectives for 2000 was to reduce the LEA rate from a 1991 baseline of approximately 8/1,000 to a target of 5/1,000 persons with diabetes. (17) It appears that we are succeeding in this goal overall, and are not far from it even among those who have had diabetes at least 10 years.

Whether or not our rates of amputation will continue to improve is not known. However, our program has demonstrated that providing focused training to a non-physician professional (in this case a physical therapist), and then supporting this professional to provide specific training to primary care providers appears to be a feasible approach. This focused specialty foot care occurs within the context of comprehensive diabetes management programs at the village clinic, regional hospital and referral medical center levels. In addition, providing an infrastructure in terms of regularly scheduled foot clinics and a referral mechanism extending from the village clinics to the referral medical center has allowed patients to have maximum access to the expertise of the PT/C-Ped. Future plans of the ANMC Diabetes Program are to include a
podiatrist on the team and to enhance services to villages through the use of telemedicine imaging.

CONCLUSION
In summary, our data suggest that amputation prevention in isolated populations is possible by developing a program to maximize the skill levels of available personnel and to coordinate referral services for patients with high-risk foot conditions.

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Cynthia Schraer
Alaska Native Tribal Health Consortium
Diabetes Program
3925 Tudor Centre Drive
Anchorage Ak 99508
USA

Email: cdschraer@anmc.org