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Disease management for the diabetic foot: Effectiveness of a diabetic foot prevention program to reduce amputations and hospitalizations☆

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Abstract

Objective: To demonstrate the effectiveness of a diabetic foot disease management program in a managed care organization.
Methods: We implemented a lower extremity disease management program consisting of screening and treatment protocols for diabetic members in a managed care organization. Screening consisted of evaluation of neuropathy, peripheral vascular disease, deformities, foot pressures, and history of lower extremity pathology. We stratified patients into low and high-risk groups, and implemented preventive or acute care protocols. Utilization was tracked for 28 months and compared to 12 months of historic data prior to implementation of the disease management program.
Results: After we implemented the disease management program, the incidence of amputations decreased 47.4% from 12.89 per 1000 diabetics per year to 6.18 ($p < 0.05$). The number of foot-related hospital admissions decreased 37.8% from 22.86 per 1000 members per year to 14.23 (37.8%). The average inpatient length-of-stay (LOS) was reduced 21.7% from 4.75 to 3.72 days ($p < 0.05$). In addition, there was a 69.8% reduction in the number of skilled nursing facility (SNF) admissions per 1000 members per year (Table 1) and a 38.2% reduction in the average SNF LOS from 8.72 to 6.52 days ($p < 0.05$).
Conclusion: A population-based screening and treatment program for the diabetic foot can dramatically reduce hospitalizations and clinical outcomes.

Keywords: Diabetes; Foot; Ulcer; Infection; Amputation; Prevention

1. Introduction

Despite many recent advances in medical therapies, the prevalence of diabetes and diabetes related complications continues to increase. There is estimated to be more than 17 million people with diabetes

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in the United States. Half of these patients have been diagnosed, and half do not yet know that they have the disease [1,2]. There has been a steady increase in the prevalence of diabetes over the past 35 years with higher prevalence and complication rates in Mexican Americans, African Americans and Native Americans [3]. For instance, the average prevalence of diagnosed diabetes was three times higher in 1991–1993 compared to 1960. Projections of the impact of diabetes for 2010 and 2020 suggest that this trend is expected to increase at an accelerated rate [3]. Trends in diabetes related complications such as retinopathy, kidney disease and heart disease have also increased significantly. Likewise, the incidence of amputations appears to be steadily increasing. Among persons with diabetes, the number of lower extremity amputations was about 30% higher in 1990 compared to 1980 [4,5].

Several clinical and financial models have indicated that there is the potential for significant reduction in morbid events [6–13] and costs [14–16] when prevention programs are implemented. Multispecialty clinical programs have reported a decrease in amputation, re-amputation, ulceration, hospitalization, length of stay, and missed work days. Much of the existing literature focuses on relatively small groups of high-risk patients. The objective of this study was to evaluate the impact of a disease management program in a large cohort of persons with diabetes in a health maintenance organization (HMO). The goal of the program was to prevent diabetes related lower extremity complications and was based on the implementation of systematic protocols for foot screening, prevention, and treatment of complications. We hypothesized that early identification of risk factors for foot ulcers and amputations, aggressive prevention practices, and standardized wound care protocols would decrease the incidence of foot complications and thereby reduce hospitalizations and lower extremity amputations among persons with diabetes.

2. Materials and methods

We implemented a lower extremity screening and treatment program in San Antonio, Texas. At the beginning of the disease management program 1708 persons with diabetes mellitus were identified. Members with diabetes were identified from inpatient and outpatient administrative databases to identify patients with any 250 ICD-9-CM code [17]. As part of the program a database was established to track clinic events, hospitalizations, procedures and referrals. In addition, these events were verified from claims data for the entire population. XLHealth's Disease Management Program was the sole contracted source for lower extremity care, medical and surgical referral, and case management for the HMO. Over the course of the 28 month evaluation period the number of covered persons with diabetes in the plan increased to 2738 persons with diabetes. Participation in the plan is indicated by the member months of enrollment for the baseline period and Disease Management evaluation period (Table 1).

Prior to implementing the clinical program, we provided a series of education seminars for primary care physicians, physician assistants, and lead nurses in the group to familiarize them with the scope of the problem and the rationale for treatment and prevention practices. We mailed a series of letters to members of

Table 1
Amputations and hospitalizations

	Baseline	Disease management program
Identified persons with diabetes	1708	2738
Diabetic member months	20467	64052
Admissions per 1000	22.86	14.23
Average hospital length of stay (days)	4.75 ± 3.6	3.72 ± 3.4
Admissions per 1000	10.55	3.19
Average skilled nursing facility Length of stay (days)	8.72 ± 5.8	6.52 ± 2.2
Amputation incidence per 1000	12.89	6.18
Toe	31.8	33.3
Midfoot (%)	22.7	27.3
Below knee (%)	31.8	27.3
Above knee (%)	13.6	12.1

the HMO who had an established identifier for diabetes mellitus and invited them to participate in the lower extremity-screening program. The first part of the disease management program involved screening person with diabetes for known risk factors for lower extremity complications [18–20]. A staff podiatrist and nurse conducted the lower extremity screening. They reviewed the patient's past medical history and gave each patient a comprehensive lower extremity physical examination. They screened patients to identify risk factors, such as history of lower extremity pathology (previous foot ulceration, amputation, Charcot arthropathy, lower extremity arterial bypass, or lower extremity angioplasty), peripheral sensory neuropathy, peripheral vascular disease, foot deformities, or abnormal foot pressures.

We assessed lower extremity vascular status by palpating the dorsalis pedis and posterior tibial pulses. If any foot pulse was not palpable, arterial Doppler studies were performed. A diagnosis of peripheral vascular disease was defined as a non-palpable foot pulse and an ankle brachial index <0.80 [21–23]. We identified sensory neuropathy from evaluation with a 10 gm Semmes-Weinstein monofilament (Touch-Test Sensory Evaluator, North Coast Medical Inc., Morgan Hill, CA) and Biothesiometer-VPT Meter (Xilas Medical, San Antonio, TX). Neuropathy was diagnosis based on VPT $>$ 25 V or inability of the patient to feel the Semmes–Weinstein monofilament [24–26]. The musculoskeletal examination focused on identifying structural foot deformities such as hallux abductovalgus, hammer toes or claw toes, tailor's bunions and limited mobility of the first metatarsophalangeal joint (dorsiflexion $<50^{\circ}$) and ankle equinus (dorsiflexion $<10^{\circ}$). Peak foot pressures were measured with the Novel force plate.

We screened and stratified patients based on their risk of diabetic foot complications [18,27,28]. A summary of the criteria used to define both high-risk and low-risk patients is presented in Table 2. After stratifying patients based on their risk for lower extremity pathology, either preventative or acute care was provided based on specific risk-based protocols. Low-risk patients were re-screened annually. The staff podiatrists scheduled high-risk group for group diabetes education, evaluation by a pedorthist, and regular foot care. High-risk patients were scheduled for regular podiatry evaluation at least once a quarter. In addition, a certified pedorthist evaluated patients for therapeutic shoes and insoles at the conclusion of their initial evaluation by the podiatrist. Insoles were replaced three times a year or as deemed necessary by the pedorthist, and therapeutic shoes were replaced at least once a year. Protocols for wound care employed standard wound care practices including off-loading with total contact casts, customized removable cast walkers, and healing sandals, wound debridement, infection control, and lower extremity revascularization.

2.1. Statistical analysis

Hospital utilization and amputation incidence were tracked from 9/1/1998 through 12/31/2000 and compared to 12 months of historic data for this population prior to implementation of the disease management program. We used a chi square test to compare the incidence of amputations, and we used a one-way ANOVA to compare the incidence of hospitalization and length of hospital stay pre and post implementation of the disease management program. For all analyses we used an alpha of 0.05.

3. Results

The average age of subjects screened in the disease management program was 67.2 ± 8.5 years with a range of 23–90. The population reflected the racial and ethnic demographics of the San Antonio metropolitan area; 42.8% of participants were Mexican–American, 53.2% were non-hispanic white and 4.0% were African American. The average duration of diabetes was 11.2 ± 9.5 years with a range of 0–32 years.

There was a significant reduction in the incidence of amputations, diabetic foot related admissions, and average length of stay for acute bed days and skilled nursing facility bed days after the implementation of the XLHealth Disease Management Program. After the disease management model was implemented, the incidence of amputations decreased 47.4% from 12.89 per 1000 diabetics per year to 6.18 ($p < 0.05$). The number of foot-related hospital admissions decreased 37.8% from 22.86 per 1000 members per year to 14.23 (37.8%). The average inpatient length-of-stay (LOS) was reduced 21.7% from 4.75 to 3.72 ($p < 0.05$). In addition, there was a 69.8% reduction in the number of

Table 2
Diabetic foot risk classification, screening criteria, interventions

Risk category	Risk criteria	Testing criteria	Prevention
Low-risk			
0	No neuropathy	Feels 10 g Semmes–Weinstein at 10 locations. Vibration perception threshold <25 V	Yearly evaluation
	No PVD	Dorsalis Pedis and posterior tibial foot pulses are palpable, ABI >0.80	
	No deformity	Hallux valgus, claw toes, equines	
	No history of foot pathology	No history of ulceration	
		No history of amputation	
		No history of lower extremity bypass	
		No history of intermittent claudication or rest pain	
High-risk			
1	Neuroapthy No deformity No PVD No history of ulcer, amputation charcot, or bypass	Misses >1 site with 10 g Semmes–Weinstein Vibration perception threshold ≥25 V	Patient education as needed Therapeutic shoe vs. athletic shoes Over-the-counter supportive insoles Podiatry 12–16 weeks
2	Neuropathy and deformity or PVD	Dorsalis pedis and posterior Tibial foot pulses are not palpable and ABI <0.80	Patient and family education
	No history of ulcer, amputation, charcot or bypass		Arterial Doppler studies to verify PVD
			Medical management of PAOD Over-the-counter vs. custom accommodative insoles Podiatry 10–12 weeks
3	History of foot pathology	History of previous pathology:	Prioritize patient and family education
		Foot ulceration Foot or leg amputation Charcot arthropathy Lower extremity bypass	Custom insoles and therapeutic shoes Custom shoes for Charcot patients Podiatry 8–12 weeks
4	Active lower extremity disease	Active disease:	Arterial Doppler studies to rule out PVD
		Ulceration	Vascular consultation as needed: revascularization via bypass or angioplasty
		Infection	Wound debridement and off-loading in total contact cast or other devices as needed
		Charcot	Charcot: bisphophonates, immobilization, bone stimulator, surgical reconstruction
		Peripheral vascular disease	Infectious diseases consultation: emperic antibiotic therapy, cultures from deep tissue or bone to direct oral and IV therapy

skilled nursing facility (SNF) admissions per 1000 members per year (Table 3) and a 38.2% reduction in the average SNF LOS from 8.72 to 6.52 days ($p < 0.05$).

4. Conclusion

4.1. Effectiveness of prevention programs

Several studies in Europe and the U.S. have reported reduction in lower extremity complications when prevention and treatment programs were instituted [6–13]. The results of the XLHealth disease management model are similar to several of these studies that have reported reduction of amputations of 48–78% [6–13], reduction of re-ulceration of 48% [6] and reduction in hospitalizations of 47–49%. [10,12] The baseline amputation rate in this study (12.9 per 1000) were significantly higher than in other reports, but similar to amputation epidemiology previously reported for South Texas [36]. Amputations in Colorado, Rhode Island, New Jersey, Washington and California ranged from 3.7 to 8.8 per 1000 persons with diabetes per year [4]. However, several of these reports are more than a decade old and may not reflect the increasing prevalence of diabetes or lower extremity amputations.

There may be no better example of preventable complications that continue to be neglected than the milieu of pathologic processes that lead to limb amputation. Despite an increasing body of evidence that preventive care significantly reduces morbid events, comprehensive services to prevent lower extremity complications are not often available. There is a need in most communities for a diabetic foot disease management program to screen patients and initiate prevention practices, educate physicians and patients, and identify morbidity and risk factors early, when prevention practices can be effective. The current medical model in the U.S. is driven by urgent or emergent medical care with very little attention, organization or effort directed at disease prevention. Even in health care systems that carry the financial burden of complications, such as the Veterans Administration or large managed care organizations, there often is not a cogent, organized systematic approach for preventive care [29–31].

4.2. Barriers to prevention

Even though many of the critical tools and practices to prevent amputations are inexpensive, non-invasive, and easy to use, most diabetic patients will tell you that their primary care physician does not inspect their feet let alone test for neuropathy, vascular disease, or foot deformity. Several authors have reported the relative infrequency of foot evaluation by primary care physicians and surgeons. In the primary care setting only 23–49% of persons with diabetes have their feet evaluated on a yearly basis [32,33]. Even when patients are hospitalized for lower extremity complications their foot evaluation may be inadequate. Armstrong and colleagues reported that only 14% of diabetics hospitalized for a foot infection received a rudimentary lower extremity exam [34].

Unfortunately, even when risk factors are made known to physicians, their behavior often does not change. For instance, Del Aguila et al. [40] found that referral to sub-specialists did not increase when primary care physicians were informed of the presence of peripheral sensory neuropathy or peripheral vascular disease. There are a number of reasons why the diabetic foot is often ignored in general medical practice. The process leading to ulceration and amputation is still not well understood by many health care professionals. Partly, this is because for the average internist with a few hundred patients with diabetes under their care, a foot complication is a rare event. The incidence of amputation is 3.7–12.5 per 1000 diabetics per year [4,35,36] and the incidence of lower extremity wounds is 10–65 per 1000 diabetics [4,35,37–39]. So, in a panel of 150 patients with diabetes, a primary care physician would not be confronted with these problems often. In addition, the syndrome of diabetic foot pathology is often complex and involves changes of integument, nerve function, perfusion and bony structures in the foot, and there are still many misconceptions among many health care providers and administrators about what contributes to the development of ulcers and amputations and even less understanding of how or if complications can be prevented.

For many physician groups, a local referral resource to screen, risk stratify persons with diabetes, and provide treatment for high-risk patients would be a valuable adjunct to other diabetes prevention services and screening practices. Screening results

can then be incorporated into a diabetic foot risk classification system such as those previously described by Rith-Najarian and Lavery [11,18] in order to prioritize the health care needs of high-risk patients. In the XLHealth Disease Management Program, we screened patients in approximately 20 min with assessment of previous foot complications, peripheral pulses, peripheral sensation with the Semmes-Weinstein monofilament and Biothesiometer-VPT Meter and peak foot pressures on the sole of the foot with a force plate as well as evaluation for foot deformities and joint range of motion.

Screening and prevention was the first step in this program towards disease management. However, a large part of the effectiveness of the Diabetex Program included wound care protocols that were implemented by staff podiatrists and a network of peripheral vascular surgeons, infectious diseases specialists, home health care nurses, and other health care professionals. Aggressive off-loading, debridement, infection control, vascular testing and revascularization were key elements of the program. This element of the program is more difficult to describe or provide a recipe for success. There were several elements that seem to have enhanced care plans such as providing open access for patients by eliminating referral barriers often encountered in ''gate-keeper driven'' programs. Many of our durable medical equipment needs could be taken care of on-site, and the program had the flexibility of providing transportation when this was a barrier for care. A staff pedorthist and lab were available on-site to fabricate shoes and insoles and to provide a streamlined, one-stop treatment service. The pedorthist was available to assess shoes and insoles at the same time high-risk patients had their lower extremities assessed. In addition, having a staff and network of health care providers with expertise and focus on diabetes related complications improved decision-making and enhanced outcomes.

4.3. Limitations

One of the limitations of the study was the reliance on historic data for baseline results. However, because the primary end points are well documented in claims data and both hospital admissions and procedures are routinely captured, we were confident that these outcomes were accurate. We used claims data as well to verify hospitalizations and amputations we recorded in our disease management database and found the two data sets to provide the same outcomes.

In summary, the disease management model to screen, risk stratify and provide prevention service for high-risk patients was effective in reducing lower extremity amputations, hospitalizations and the length of hospitalization in a HMO study population. The barriers to this type of program are more organizational than because of expensive equipment or the lack of subspecialty training in the medical community.

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