

Incidence, Outcomes, and Cost of Foot Ulcers in Patients with Diabetes

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OBJECTIVE— To determine the incidence of foot ulcers in a large cohort of patients with diabetes, the risk of developing serious complications after diagnosis, and the attributable cost of care compared with that in patients without foot ulcers.

RESEARCH DESIGN AND METHODS— Retrospective cohort study of patients with diabetes in a large staff-model health maintenance organization from 1993 to 1995. Patients with diabetes were identified by algorithm using administrative, laboratory, and pharmacy records. The data were used to calculate incidence of foot ulcers, risk of osteomyelitis, amputation, and death after diagnosis of foot ulcer, and attributable costs in foot ulcer patients compared with patients without foot ulcers.

RESULTS— Among 8,905 patients identified with type 1 or type 2 diabetes, 514 developed a foot ulcer over 3 years of observation (cumulative incidence 5.8%). On or after the time of diagnosis, 77 (15%) patients developed osteomyelitis and 80 (15.6%) required amputation. Survival at 3 years was 72% for the foot ulcer patients versus 87% for a group of age- and sex-matched diabetic patients without foot ulcers ($P < 0.001$). The attributable cost for a 40- to 65-year-old male with a new foot ulcer was \$27,987 for the 2 years after diagnosis.

CONCLUSIONS— The incidence of foot ulcers in this cohort of patients with diabetes was nearly 2.0% per year. For those who developed ulcers, morbidity, mortality, and excess care costs were substantial compared with those for patients without foot ulcers. The results appear to support the value of foot-ulcer prevention programs for patients with diabetes.

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Foot ulcers and their sequelae are a major source of morbidity and resource use for patients with diabetes (1–4). The presence of peripheral neuropathy, peripheral vascular disease, and poor glycemic control in conjunction with minor foot trauma increases the likelihood that patients with diabetes will develop foot ulcers. Ulcers, in turn, often progress to infections of the surrounding tissue,

osteomyelitis, and amputation (5). Recognizing the potential for severe morbidity related to foot ulcers, many experts now call for widespread establishment of preventive foot care programs for patients with diabetes (6–9). Clinicians and health plan executives are considering whether to invest in such programs, and if so, what type of foot care programs should be provided. Nevertheless, relatively little is known about

the incidence and cost of caring for foot ulcers or the frequency of associated complications in patients with diabetes.

To address these issues, we identified a cohort of patients with diabetes at Group Health Cooperative of Puget Sound (GHC), a large staff-model health maintenance organization (HMO) in Washington State, and tracked their rate of acquisition of foot ulcers, foot ulcer-related health outcomes, utilization of medical services, and costs over time.

RESEARCH DESIGN AND METHODS

Patient identification

Patients aged ≥ 18 years with type 1 or type 2 diabetes were identified from the GHC administrative data files using methods developed for the Patient Outcomes Research Team (PORT) for Diabetes sponsored by the Agency for Health Care Policy and Research (10). Compared with chart records, the administrative algorithm has been shown to be 96% sensitive and 99% specific for identifying individuals at GHC with diabetes. The database was composed of patients with diabetes who were continuously enrolled at GHC from 1 January 1992 until death or the end of the observation period (31 December 1995). Continuous enrollment was necessary to ensure that all health care utilization was captured over the period of observation.

An algorithm using inpatient and outpatient administrative records was developed to identify new foot ulcers among individuals in the cohort with diabetes (Table 1). An individual was defined as having a new ulcer if the algorithm did not detect a foot ulcer diagnosis for at least 12 months before the initial date of diagnosis. Patients with a diagnosis of osteomyelitis or a lower-extremity amputation at any time prior to the date of foot ulcer diagnosis were excluded from the analysis.

We then compared the results of case-finding using administrative data with the information in the medical record for 471 patients in an effort to estimate its sensitivity, specificity, and predictive value. The medical record was searched for confirmatory diagnosis of foot ulcer over the period of observation.

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Abbreviations: CPT-4, Current Procedural Terminology Version 4 DSS, Decision Support System; GHC, Group Health Cooperative of Puget Sound; HMO, health maintenance organization; ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification

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

Table 1—Administrative algorithm for identifying foot ulcers and their sequelae

Condition	Administrative identifier	Description
Foot ulcer	ICD-9-CM 707.1	Ulcer of lower leg
	ICD-9-CM 707.1 and 041, 681.1, 682.6, 682.7, or 682.9	Ulcer of lower leg with infection or cellulitis
Osteomyelitis	ICD-9-CM 730	Osteomyelitis, periostitis, other infections involving bone
Amputation	ICD-9-CM 84.10-84.15	Amputation below knee
	CPT-4 28810, 28820 ICD-9-CM 84.17	Amputation above knee

Matched control group

Each foot ulcer patient with diabetes was matched with four control patients with diabetes who had no recorded history of foot ulcer, osteomyelitis, or amputation during the 4-year period of observation. Control subjects with diabetes but without a diagnosis of foot ulcer were randomly selected (without replacement) from the database by assigning each potential control subject a random number and then choosing subjects sequentially, matched to ulcer cases by age (± 2.5 years) and sex.

Database

The source of the clinical data and cost estimates was the Decision Support System (DSS), implemented at GHC in 1989 to provide standardized automated step-down cost accounting for health care provided to members (11). The DSS links clinical and financial data through a cost accounting management system. Departments captured in the database include medical staff, nursing, pharmacy, laboratory, radiology, hospital inpatient, and community health services. Units of service are weighted as relative value units for ancillary departments, such as physical therapy, technical relative value units for radiology, College of Anatomical Pathology units for laboratory, and time-weighted outpatient visits for medical staff. The cost per unit that results from this cost-accounting system reflects the actual costs of medical personnel and supplies needed to provide the service, as well as overhead costs, such as administration, charting, and automated information systems. Independent audits of DSS records are conducted periodically.

Tracking outcomes and health care utilization over time

Records for the foot ulcer group were searched forward from the date of diagno-

sis for ICD-9-CM (*International Classification of Diseases, Ninth Revision, Clinical Modification*) procedure and CPT-4 (*Current Procedural Terminology Version 4*) codes for osteomyelitis and amputations above and below the knee (Table 1). Hospital days, emergency room visits, and outpatient (nonemergent) clinic visits were tracked for both groups over the duration of the observation period.

Survival rates were computed for the ulcer and control groups. The life table method was used to estimate survival at monthly intervals from the time of diagnosis until the end of the period of observation (31 December 1995).

Because the foot ulcer diagnosis was often recorded as the primary reason for the office visit multiple times during the weeks to months after the initial record, it was not possible to identify patients who incurred a second ulcer after the first foot ulcer was recorded. Additionally, it was not possible to determine from the coding data whether osteomyelitis or amputation occurred on the same limb as the foot ulcer.

Method of cost analysis

The goal for the cost analysis was to produce an incidence-based estimate of the excess cost of care for diabetic patients who develop a foot ulcer over the costs of care for diabetic patients without foot ulcers. The cost analysis was limited to patients who developed a foot ulcer in 1993 and diabetic control patients matched by age and sex to the foot ulcer patient for the month in which the foot ulcer was diagnosed. Total medical care costs for both groups were determined for the year before diagnosis and for the 1st and 2nd years after diagnosis, starting from the month of diagnosis. Before performing the cost analysis, all costs were adjusted to constant 1995 dollars using the medical care component of the consumer price index. A 5%

discount rate was applied to costs in the 2nd postdiagnosis year.

Multiple regression analysis using a one-part generalized linear model was used to determine excess medical expenditures for the foot ulcer patients (12). The generalized linear model is useful for observations for which the distribution of costs is highly skewed to the right with nonconstant variance. It allows for a reparameterization of the model rather than transformation of the dependent variable. This way, the original dollar scale is retained (D.B., S.D.R., unpublished observations). Two-part models are often used because sizable proportions of patients typically incur zero costs over the period of observation. The analysis was limited to patients with diabetes, however, and <2% of these patients had zero costs over the period of observation. To allow reparameterization using the generalized linear model, the two-part model was converted to a one-part model by adding \$1 to those who had zero expenditures.

Patients were first stratified into three age-groups: 18–39, 40–64, and ≥ 65 years. Inputs were added to the regression model to control for sex and comorbidities other than the comorbidities of interest (diabetes and foot ulcer). A modified version of the chronic disease score was used to perform this comorbidity adjustment (14). The chronic disease score is a case-mix adjustment methodology that uses physician ratings of disease severity based on prescription drugs taken during a 1-year period. It explains variations in health care utilization, costs, hospitalization, and mortality in the managed care organization that was the source for this study (14,15). The chronic disease score was modified so that it would not case-mix adjust for diabetes.

Costs are reported as the ratio of total health care costs for foot ulcer patients over those for control subjects. This analysis was performed because the relative cost of caring for foot ulcer patients may be less variable among the wide variety of health care systems in the U.S. (e.g., HMOs, network health plans) than the absolute cost of care. In addition, relative costs may be more meaningful than absolute costs to leaders and decision-makers in those systems. Second, the regression model was used to determine absolute difference in the total cost of care for a representative foot ulcer patient compared with control subjects. This result demonstrates the expected level of attributable costs the HMO incurs when one of its patients with diabetes develops a foot ulcer.

Table 2—Demographic characteristics of patients with new-onset ulcers among the diabetic cohort

Characteristic	Diabetes with foot ulcer	All diabetes
n	514	8,905
Sex (% M)	52	52
Average age	66.3 ± 12.8	65.8 ± 12.5
Percent with coexisting complication at time of diagnosis		
Hypertension	56.4	30.1
Eye disease	23.0	44.2
Peripheral vascular disease	23.1	13.0
End-stage renal disease	2.6	1.4
Prior myocardial infarction	7.0	9.3
Prior stroke	13.0	8.7

Data are % or means ± SD.

RESULTS

Incidence of foot ulcers

A total of 8,905 patients with type 1 or type 2 diabetes who were continuously enrolled from 1 January 1992 through 31 December 1995 or until their death were identified in the GHC database. Among this group, 514 new foot ulcer cases were recorded between 1 January 1993 and 31 December 1995 (cumulative incidence 5.8% over 3 years). The chart audit revealed that the administrative algorithm had a sensitivity of 74% and a specificity of 94% for detecting foot ulcers over the period of observation.

Table 2 lists the average age, sex, and diabetes-related comorbidities at the time of onset. The prevalence of several diabetes-related comorbidities and complications was higher for foot ulcer patients than for the overall cohort with diabetes. The lack of difference in myocardial infarction rates between ulcer patients and all members of the cohort with diabetes may highlight the distinction between the pathogenesis of myocardial infarction versus other microvascular complications, and is consistent with observations of amputation itself (16).

Clinical outcomes

A substantial proportion of foot ulcer patients developed osteomyelitis or went on to amputation. There were 12 ulcer patients (2.3%) diagnosed with osteomyelitis at the time the foot ulcer was diagnosed; 67 (13%) individuals were diagnosed with osteomyelitis subsequent to their diagnosis of foot ulcer. Among all foot ulcer patients, 80 (11.2%) had a lower-extremity amputation during the follow-up period. Of those also diagnosed with osteomyelitis, 36% had a lower-

extremity amputation during the follow-up period.

Foot ulcer patients suffered a higher mortality than their counterparts without foot ulcers. Survival from the time of diagnosis was significantly reduced for the foot ulcer group compared with the control group (Fig. 1); however, survival was not significantly different for foot ulcer patients who required amputation versus those who did not require amputation. Cumulative survival at 36 months was 87% for the diabetic control group and 72% for all foot ulcer patients (log-rank test, $P < 0.0001$).

Economic end points

Health service utilization. Foot ulcer patients used significantly more inpatient and outpatient resources than the age- and sex-matched control subjects, averaging 0.24 more emergency department visits, 22 more outpatient visits, and 4.6 more inpatient hospital days in the 1st year after diagnosis

(Table 3). In the 2nd year after diagnosis, nonemergency outpatient visits and hospital days declined for the foot ulcer group but remained stable for the control group.

Costs of care. Figure 2 shows the unadjusted average monthly expenditures for foot ulcer patients before and after the point of diagnosis. Costs rose from baseline in the month before the date of diagnosis, reflecting both the cost of the evaluation preceding diagnosis and the lag time between diagnosis and recording of the diagnosis in the administrative database. Costs appear to return to baseline over the following 12–14 months.

The relative level of expenditures for foot ulcer patients compared with that for patients without foot ulcers computed from the multivariate cost analyses are listed in Table 4. In the year before diagnosis, the cost of care for the ulcer patients was 1.5–2.4 times greater than the cost of care for the population without foot ulcers. In the year after diagnosis, the relative cost of care for foot ulcer patients was up to 5.4 times greater than the control group. The relative cost of care returned to near prediagnosis levels for the foot ulcer patients, but remained up to 2.8 times greater than costs for the control patients in the 2nd year. Table 5 lists excess costs (amount that costs of care for foot ulcer patients exceeded costs for non-ulcer patients) and attributable costs (excess cost of care for the foot ulcer group that are likely attributed to the foot ulcer over the time period of interest) for a representative patient.

CONCLUSIONS— We sought to determine the incidence, outcomes, and costs of treatment for foot ulcers in a retro-

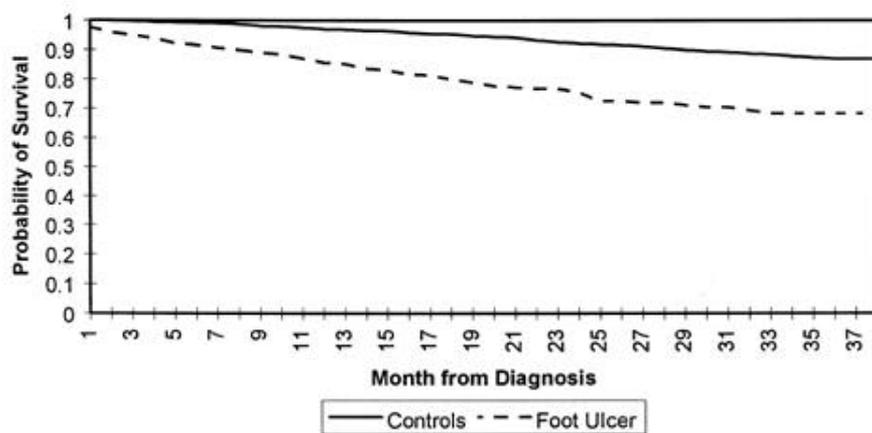


Figure 1—Actuarial survival from the time of diagnosis for foot ulcer patients and matched control patients from the cohort of patients with diabetes.

Table 3—Average mortality-adjusted utilization of health services per patient for foot ulcer patients and control subjects during the defined period of observation

Average visits per year*	Control patients		Foot ulcer patients	
	Year 1	Year 2	Year 1	Year 2
Emergency department	0.18 ± 0.03	0.21 ± 0.05	0.42 ± 0.11	0.49 ± 0.23
Outpatient, not emergency department	13.05 ± 0.47	13.35 ± 0.52	35.08 ± 9.18	27.92 ± 2.40
Inpatient days	1.46 ± 0.23	1.60 ± 0.60	6.03 ± 2.32	4.06 ± 2.61

Data are means ± SD. *Differences between control and foot ulcer patients were all significant to at least $P < 0.001$ by paired approximate *t* testing, assuming unequal variances.

spective analysis of patients with diabetes in a large staff model HMO. We relied on automated claims data, verified by chart audits, to derive the estimates. In a cohort of 8,905 patients with diabetes, 514 acquired a new foot ulcer during the 3 years of observation (1.9% per year). There were 77 patients diagnosed with osteomyelitis at or after the time the foot ulcer was recorded, and 80 required partial amputation of a lower limb. Excess mortality was observed for the foot ulcer patients compared with the control group. The attributable cost for foot ulcer care was nearly \$28,000 during the 2 years after diagnosis.

Previous published studies of foot ulcers have reported prevalence rather than incidence rates, thus there are no studies with which we can directly compare our findings. The amputation rate noted in this study

(11.2%) lies within ranges reported from other studies, although reported frequencies vary widely. Observational studies suggest that 6–43% of patients with diabetes and a foot ulcer eventually progress to amputation (2,17–20). Retrospective studies suggest that lower-extremity ulcers precede 71–85% of amputations in this population (2,5,21).

In a study of American veterans with diabetes, Boyko et al. (22) found that the relative risk of death was 2.39 for those with foot ulcer compared with those without foot ulcer.

Few studies have examined the cost of foot ulcers in patients with diabetes. A Swedish group reported a total cost of care over 3 years at \$26,700 (1993 U.S. dollars) for patients with foot ulcers and critical ischemia and at \$16,100 for those without critical ischemia. High short- and long-

term costs of care for those who progress to amputation have also been noted (23–26).

We found that relative costs for the foot ulcer patients were higher than those for diabetic patients without foot ulcers in the year before diagnosis, even after controlling for age, sex, and comorbidity. Some of these prediagnosis costs may be explained if foot ulcer-related diagnostic evaluations (e.g., office visits, x-rays) were incurred prior to the time that the diagnosis was recorded on the administrative database. In addition, although all comorbidities listed in Table 2 and many non-diabetes-related comorbidities are included in the chronic disease score adjustment methodology, some diabetes-related complications are not (e.g., gastroparesis, peripheral neuropathy). Thus, a portion of excess costs in the year prior to diagnosis could be attributed to unadjusted comorbidity in the foot ulcer group.

There are important limitations to consider when using automated databases for research. First is the ability of administrative data to accurately detect the conditions in question. The chart validation results suggest that we have underestimated incidence. Most initial foot ulcer diagnoses were made in the outpatient setting. Clinic physicians check off precoded diagnostic information on administrative forms at the time of the visit. It is likely that the cases we have identified are those with more severe ulcers; that is, those that were the primary diagno-

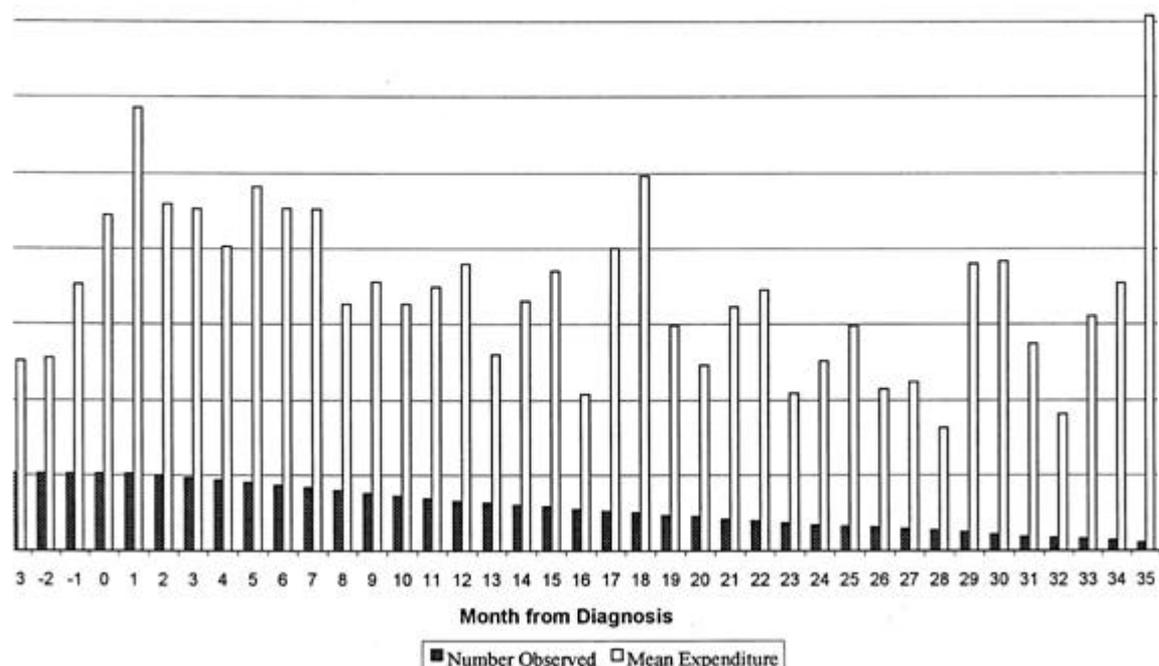


Figure 2—Average monthly expenditure for foot ulcer patients from time of diagnosis.

Table 4—Ratio of mean expenditures for diabetic patients with foot ulcers compared with diabetic patients without foot ulcers over the period of observation

Year of observation from date of diagnosis	Age (years)		
	18–39	40–64	≥65
–1	1.96 (0.40–9.65)	2.42 (1.34–4.38)	1.45 (0.40–5.36)
1	5.40 (1.20–4.33)	4.12 (2.35–7.22)	2.67 (1.65–4.31)
2	2.59 (0.56–2.06)	2.83 (1.57–5.11)	1.56 (0.91–2.67)

Data are ratios of mean expenses (95% CI).

Table 5—Annual expenditures for representative foot ulcer patient and control patient (male, aged 40–64 years, average number of comorbidities by chronic disease score) from time of diagnosis

Year of observation from diagnosis date	Foot ulcer patient expenditure (\$)	Diabetic control patient expenditure (\$)	Excess cost (\$)
–1	15,748	4,927	10,821
1	26,490	5,088	21,402
2	17,245	5,110	12,135
Attributable cost	27,987		

The attributable cost is calculated as the difference between average expenditures in years 1 and 2 and expenditures in the year before diagnosis.

sis for the encounter. A second limitation was that it was not possible to determine, for patients with osteomyelitis or amputation, whether their foot ulcer was the initial factor leading to these events. This study establishes a correlation, but not causality, between these events. Third, it was not possible to determine the duration of diabetes from the database. A final limitation is the representativeness of this HMO patient population compared with foot ulcer patients in general. For example, race data from previous GHC surveys of individuals with diabetes indicate that ~17% of GHC enrollees with diabetes were nonwhite at the time of this study. Extrapolation of the outcome and cost data to nonsimilar populations should thus be made with caution.

These cost estimates only account for direct medical care costs incurred by a managed care organization before patient copays (which are minimal for nearly all services, including medications, at GHC). The costs of continuing intermediate or skilled nursing care for foot ulcer patients are also not included. Other studies suggest they may be substantial (27).

Implications for preventive foot care in patients with diabetes

Studies suggest that the majority of patients with diabetes do not receive regular foot examinations (28–30) or the standards of

foot care recommended by the American Diabetes Association (10,31). Several approaches have been tried to reduce the rate of foot ulcers, including the use of diabetes miniclinics within primary care practices (32,33), encouraging better organization of patient education (34,35), or case management by nurse specialists under the supervision of a diabetologist (36). Although the cost-effectiveness of foot ulcer prevention and care programs remains to be determined, these data suggest that investment in these programs may yield early and substantial benefits.

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