Costs of Lower-Extremity Ulcers Among Patients With Diabetes

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OBJECTIVE — The objective of this study was to characterize health care costs associated with diabetic lower-extremity ulcers.

RESEARCH DESIGN AND METHODS — Adult patients with diabetes who had a lower-extremity ulcer episode during 2000 and 2001 were identified using claims data. Ulcer-related direct health care costs were computed for each episode. Episodes were stratified according to severity level based on the Wagner classification.

RESULTS — A total of 2,253 patients were identified. The mean age was 68.9 years, and 59% of the patients were male. The average episode duration was 87.3 ± 82.8 days. Total ulcer-related costs averaged $13,179 per episode and increased with severity level, ranging from $1,892 (level 1) to $27,721 (level 4/5). Inpatient hospital charges accounted for 77% ($10,188) of the overall cost, indicating that hospitalization was a major cost driver. Total ulcer-related costs were significantly higher for patients <65 years of age compared with those of older patients ($16,390 vs. $11,925, $P = 0.02$) and for patients with inadequate vascular status compared with patients with adequate vascular status ($23,372 vs. $5,218, $P < 0.0001$). Patients who progressed to a higher severity level also had significantly higher ulcer-related costs compared with patients who did not progress ($20,136 vs. $3,063, $P < 0.0001$).

CONCLUSIONS — The high costs of treating diabetic lower-extremity ulcers emphasize the value of intensive outpatient interventions designed to prevent ulcer progression.

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Lower-extremity ulcers present a significant burden to patients with diabetes and to the health care system. Of persons with diabetes, 2–3% develop a foot ulcer annually, while the lifetime incidence rate is 15% (1,2). Approximately 3% of hospitalizations among patients with diabetes are attributed to lower-extremity ulcers (2). In patients with diabetes, the length of hospitalization among patients with a lower-extremity ulcer can be >50% longer than that of patients who do not have an ulcer (1).

Diabetic lower-extremity ulcers are responsible for 92,000 amputations annually (3). The 10-year cumulative incidence of lower-extremity amputation is ~5% in younger-onset diabetes (diagnosis before 30 years of age) and 7% in older-onset diabetes (diagnosis at age 30 or older) (4). Within 5 years after their first amputation, 28–51% of patients with diabetes require a second leg amputation (1). Survival after amputation is bleak. The 5-year survival rate after amputation is only 27%, translating to a fourfold increase compared with an age- and sex-matched population (5).

In addition, lower-extremity ulcers are costly to manage. In 1991 and 1992, costs of diabetic lower-extremity ulcers averaged $2,687 per patient per year among a population of patients <65 years of age with private employer–sponsored insurance (6). In an analysis of the 1995 Medicare population, the average cost of treatment for a Medicare patient with a diabetic lower-extremity ulcer was approximately $3,600 per year (7). A cost analysis conducted using 1993–1995 data from a staff-model health maintenance organization estimated that the cost attributed to diabetic lower-extremity ulcer was $27,987 for the 2 years after diagnosis for a male 40–65 years of age (8).

While studies have measured the costs associated with lower-extremity ulcers in select populations, current data evaluating these costs within a diversified population are limited. Although ulcer severity may influence costs, most studies have not examined costs among ulcers of different severity levels. The objective of this study was to examine the current (year 2000 and 2001) economic impact of diabetic lower-extremity ulcers within a managed care organization (MCO) and to evaluate cost variations according to severity level, age, vascular status, and ulcer progression.

RESEARCH DESIGN AND METHODS

— This was a retrospective analysis of medical and pharmacy claims from a large MCO and Prescription Solutions, a pharmacy and medical management company. Longitudinal claims data were used from members residing in California, Oregon, Oklahoma, Texas, and Washington—approximately 2.7 million lives.

The study observation period was from 1 January 2000 through 31 December 2001. Patients aged 18 years or older were included if they had at least one medical claim with a diagnosis of diabetes (online appendix section 1 [available at http://care.diabetesjournals.org]) and at least one ulcer-related medical claim during the observation period. An ulcer-

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Abbreviations: MCO, managed care organization.

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

Table 1—*Patient and episode characteristics by presenting severity level*

	Presenting severity level					
	Level 1	Level 2	Level 3	Level 4/5	All	*P**
n	1,065 (47.3)	486 (21.6)	143 (6.4)	559 (24.8)	2,253 (100)	—
Patient characteristics						
Age (years)	69.2 ± 11.6	68.4 ± 11.7	66.0 ± 14.1	69.5 ± 11.7	68.9 ± 11.8	0.008
Male	603 (56.6)	267 (54.9)	97 (67.8)	359 (64.2)	1,326 (58.9)	0.0008
Medicare + Choice health plan	861 (80.9)	381 (78.4)	104 (72.7)	471 (84.3)	1,817 (80.6)	0.007
Chronic disease score	4.9 ± 3.5	4.7 ± 3.3	4.7 ± 3.4	4.9 ± 3.5	4.8 ± 3.4	0.63
Inadequate vascular status	352 (33.1)	184 (37.9)	60 (42.0)	392 (70.1)	988 (43.9)	<0.0001
Malignant neoplasm of lymphatic and hematopoietic tissue	15 (1.4)	4 (0.8)	0 (0)	5 (0.9)	24 (1.1)	0.37
Episode characteristics						
Episode duration (days)						
Mean ± SD	88.8 ± 82.2	71.9 ± 69.2	90.0 ± 81.7	97.0 ± 93.0	87.3 ± 82.8	<0.0001
Median	63	49	67	66	62	
Amputation during episode	116 (10.9)	70 (14.4)	33 (23.1)	463 (82.8)	682 (30.3)	<0.0001
Ulcer-related inpatient hospitalization during episode	113 (10.6)	114 (23.5)	39 (27.3)	273 (48.8)	539 (23.9)	<0.0001
Outcome severity level						
Level 1	753 (70.7)	—	—	—	753 (33.4)	—
Level 2	81 (7.6)	341 (70.2)	—	—	422 (18.7)	—
Level 3	73 (6.9)	48 (9.9)	102 (71.3)	—	223 (9.9)	—
Level 4/5	158 (14.8)	97 (20.0)	41 (28.7)	559 (100)	855 (38.0)	—

Data are *n* (%) or means ± SD, unless otherwise indicated. *Level of significance for the comparison across the different presenting severity levels.

related medical claim was defined as a claim with a diagnostic or procedure code representing a lower-extremity ulcer (online appendix section 2); specific codes were selected from those described in previous publications (6,7).

Identification of episodes of care

Episodes of care were identified for each patient and consisted of three periods: pretherapy, therapy, and post-therapy. The therapy period began on the day of the first ulcer-related medical claim and continued until the end of service date of the last ulcer-related claim before the post-therapy period. The pretherapy period was defined as the 90-day period before the therapy period during which no ulcer-related medical claims occurred. The post-therapy period was the 90-day period following the therapy period during which no ulcer-related medical claims occurred. Episodes were excluded from the analysis if any of the following situations occurred: *1*) the patient was not continuously enrolled for the entire episode (including the pretherapy, therapy, and post-therapy periods); *2*) the 90-day pretherapy or post-therapy periods fell outside of the study observation period; *3*) the ulcer was still in progress at the end of the study observation period; or *4*) the duration of the therapy period was ≤7 days (because shorter episodes would likely represent a minor skin condition, not a lower-extremity ulcer). For patients with more than one episode, only the first episode was included in the analysis.

Severity stratification

To stratify each episode according to severity, a severity grading system (based on the system used by Holzer et al. [6], which was adapted from the Wagner classification [9]) was used. Level 1 was defined as a superficial ulcer, level 2 as a deeper ulcer (i.e., cellulitis) without bone involvement, level 3 as a deep ulcer with bone involvement (i.e., osteomyelitis, periostitis), and level 4/5 as gangrene or amputation. Levels 4 and 5 were merged because they were difficult to distinguish on the basis of medical claims.

Episodes were grouped into mutually exclusive cohorts based on the presenting severity level, which was defined as the severity stratification code at the index date. If there was more than one severity code at index, the highest level of severity was chosen. In addition, episodes were stratified according to their outcome severity level, which was defined as the highest level of severity during the therapy period. Episodes that could not be classified according to presenting or outcome severity level were excluded.

Outcome measures

The primary outcomes were ulcer-related pharmacy, medical, and total costs measured over each episode's therapy period. Ulcer-related pharmacy costs were defined as the outpatient prescription costs for ulcer-related oral antibiotics (i.e., prescriptions filled within 7 days before or after an ulcer-related medical claim or a previous ulcer-related antibiotic prescription) plus the costs for topical recombinant human platelet-derived growth factor. Ulcer-related medical costs were defined as the medical charges with an ulcer-related diagnosis or procedure code listed as the primary diagnosis. Medical costs were further stratified into charges associated with acute inpatient hospitalization (i.e., at least 1 day length of stay), other inpatient hospitalization (i.e., <1 day length of stay), inpatient skilled nursing facility, emergency department, outpatient hospital, outpatient office, and home therapy. While skilled nursing and home therapy charges were analyzed, these data may not be complete. Total ul-

cer-related costs were calculated as the sum of the ulcer-related pharmacy and medical costs.

Other variables included Chronic Disease Score (10) (a measure of comorbidity calculated during the pretherapy period), vascular status (inadequate vs. adequate), presence of a diagnosis of a malignant neoplasm of the lymphatic and hematopoietic tissue (online appendix A, section 3) during the pretherapy or therapy period, and presence of a diagnosis of amputation (online appendix A, section 4) during the therapy period. Patients were considered to have inadequate vascular status if they had a diagnosis code listed in online appendix A, section 4, during the pretherapy or therapy period.

Statistical methods

Statistical analyses were performed using SAS, version 8.2. Patient characteristics and costs were analyzed using descriptive statistics and χ^2, t, or F tests. Cost data were also analyzed using nonparametric tests. Because the results remained consistent, only the parametric test results are reported. All statistical tests were two sided with an α of 0.05.

RESULTS

Patient and episode characteristics

A total of 2,332 patients were identified. After excluding 79 patients whose episode could not be classified according to severity level, the final study population consisted of 2,253 patients.

Patient and episode characteristics are displayed in Table 1. The mean age was 68.9 years, and 59% were male. Approximately 44% of patients had inadequate vascular status, and this proportion increased with severity level, ranging from 33% for level 1 to 70% for level 4/5.

The average episode duration was 87.3 ± 82.8 days (median 62 days; range 8–542 days). Amputations occurred in 682 (30.3%) patients. Approximately 24% experienced an ulcer-related acute inpatient hospitalization, with the lowest proportion among patients with severity level 1 (11%) and the highest among severity level 4/5 (49%) ($P < 0.0001$). Of 1,694 episodes presenting as level 1, 2, or 3, 498 patients (29.4%) progressed to a higher outcome severity level.

Ulcer-related costs

Table 2 displays the ulcer-related phar-

Table 2—*Ulcer-related health care costs per episode*

Cost source	Outcome severity level: Level 1	Level 2	Level 3	Level 4/5	All	P*
n	753	422	223	855	2,253	—
Total ulcer-related pharmacy costs	$59 ± 181 (0)	$97 ± 216 (10)	$262 ± 535 (75)	$132 ± 305 (6)	$114 ± 294 (5)	<0.0001
Acute inpatient hospitalization charges	$918 ± 8,606 (0)	$2,937 ± 10,511 (0)	$8,638 ± 23,760 (0)	$22,336 ± 47,788 (0)	$10,188 ± 32,587 (0)	<0.0001
Other inpatient hospitalization charges	$14 ± 295 (0)	$13 ± 190 (0)	$20 ± 281 (0)	$78 ± 584 (0)	$39 ± 417 (0)	0.006
Skilled nursing facility charges	$63 ± 792 (0)	$409 ± 3,199 (0)	$596 ± 4,766 (0)	$1,335 ± 5,065 (0)	$663 ± 3,794 (0)	<0.0001
Emergency department charges	$17 ± 265 (0)	$51 ± 230 (0)	$121 ± 799 (0)	$97 ± 464 (0)	$64 ± 424 (0)	0.0003
Outpatient hospitalization charges	$296 ± 1,367 (0)	$255 ± 1,476 (0)	$837 ± 2,079 (0)	$1,382 ± 3,887 (0)	$754 ± 2,730 (0)	<0.0001
Outpatient office visit charges	$324 ± 561 (140)	$313 ± 584 (128)	$756 ± 1,620 (250)	$675 ± 1,709 (83)	$498 ± 1,253 (127)	<0.0001
Home therapy charges	$200 ± 1,450 (0)	$271 ± 1,120 (0)	$1,025 ± 3,120 (0)	$1,686 ± 4,684 (0)	$859 ± 3,269 (0)	<0.0001
Total ulcer-related medical charges	$1,833 ± 8,969 (285)	$4,248 ± 12,108 (383)	$11,993 ± 25,655 (2,395)	$27,589 ± 49,615 (10,304)	$13,065 ± 34,491 (828)	<0.0001
Total ulcer-related costs (pharmacy + medical)	$1,892 ± 8,972 (324)	$4,345 ± 12,133 (490)	$12,255 ± 25,683 (2,899)	$27,721 ± 49,627 (10,419)	$13,179 ± 34,511 (930)	<0.0001

Data are means ± SD (median). *Level of significance for the comparison of mean costs across outcome severity levels.

Table 3—Total ulcer-related costs per episode, stratified by vascular status and age

Outcome severity level	Vascular status: Adequate	Vascular status: Inadequate	P*	Age: <65 years	Age: 65 years and older	P†	All patients
n	1,265	988	—	633	1,620	—	2,253
Level 1	$1,716 ± 8,634 (288)	$2,433 ± 9,944 (490)	0.38	$2,772 ± 12,201 (416)	$1,597 ± 7,581 (289)	0.21	$1,892 ± 8,972 (324)
Level 2	$3,269 ± 10,646 (359)	$6,762 ± 14,706 (1,143)	0.02	$5,776 ± 14,698 (590)	$3,756 ± 10,878 (463)	0.17	$4,345 ± 12,133 (490)
Level 3	$11,258 ± 24,881 (2,527)	$14,003 ± 27,103 (3,116)	0.44	$14,518 ± 32,906 (3,291)	$10,861 ± 19,997 (2,749)	0.36	$12,255 ± 25,683 (2,899)
Level 4/5	$11,686 ± 23,014 (2,740)	$34,845 ± 56,203 (17,408)	<0.0001	$33,502 ± 64,013 (11,873)	$25,518 ± 42,750 (9,808)	0.08	$27,721 ± 49,627 (10,419)
All	$5,218 ± 16,049 (462)	$23,372 ± 46,929 (5,233)	<0.0001	$16,390 ± 44,054 (1,408)	$11,925 ± 29,891 (834)	0.02	$13,179 ± 34,511 (930)

Data are means ± SD (median). *Comparison of the mean costs for episodes among patients with adequate vascular status versus patients with inadequate vascular status. †Comparison of the mean costs for episodes among patients <65 years of age versus patients ≥65 years.

macy, medical, and total costs. Total ulcer-related costs averaged $13,179 per episode and increased according to outcome severity, ranging from $1,892 (level 1) to $27,721 (level 4/5). Inpatient acute hospitalization costs represented the majority of costs, averaging $10,188 per episode.

Total ulcer-related costs were higher among patients with inadequate vascular status than among patients with adequate vascular status ($23,372 vs. $5,218, respectively, $P < 0.0001$). Total ulcer-related costs were also higher for patients <65 years of age than for patients 65 years and older ($16,390 vs. $11,925, $P = 0.02$) (Table 3).

Total ulcer-related costs were analyzed for patients who presented with severity level 1, 2, or 3 and then progressed to a higher outcome severity level, as compared with patients who did not progress (Table 4). Patients who progressed to a higher severity level had higher ulcer-related costs compared with patients who did not progress ($20,136 vs. $3,063, $P < 0.0001$).

CONCLUSIONS— In this population of patients with diabetes and lower-extremity ulcers, total ulcer-related costs averaged $13,179 per episode. Consistent with other studies (6,7), acute inpatient hospital charges accounted for 77% of the overall charges, indicating that hospitalization was a major cost driver.

Episode costs increased with severity level, and these increases appear to be ulcer-driven since comorbidity scores were similar across ulcer severity levels. Higher costs were observed among younger patients, patients with inadequate vascular status, and patients whose ulcer progressed to a higher severity level. Costs averaged $4,465 higher for patients <65 years compared with older patients. On average, costs were $18,154 higher for patients with inadequate vascular status compared with patients with adequate vascular status. This cost difference is consistent with other studies (6) and is not surprising, given that ischemia and compromised circulation owing to inadequate vascular status can prolong ulcer healing and increase the risk of amputation (1,11). Patients presenting with severity level 1, 2, or 3 and whose ulcer progressed to a higher severity experienced more than $17,000 higher costs on

Table 4 —*Total ulcer-related costs per episode by progression of severity

	Outcome severity level				Progressed to higher severity		
Presenting severity level	Level 1	Level 2	Level 3	Level 4/5	No	Yes	*P*†
Level 1							
Mean	$1,892	$6,436	$11,830	$18,898	$1,892	$14,009	
SD	$8,972	$18,721	$22,456	$32,168	$8,972	$27,523	
Median	$324	$604	$3,064	$4,940	$324	$2,813	
n	753	81	73	158	753	312	<0.0001
Level 2							
Mean	—	$3,848	$19,641	$35,695	$3,848	$30,381	
SD	—	$9,926	$39,595	$63,086	$9,926	$56,766	
Median	—	$475	$4,370	$15,945	$475	$10,709	
n	—	341	48	97	341	145	<0.0001
Level 3							
Mean	—	—	$9,083	$30,528	$9,083	$30,528	
SD	—	—	$18,018	$44,699	$18,018	$44,699	
Median	—	—	$1,725	$11,722	$1,725	$11,722	
n			102	41	102	41	0.005
All							
Mean	—	—	—	—	$3,063	$20,136	
SD	—	—	—	—	$10,501	$40,392	
Median	—	—	—	—	$374	$4,471	
n					1,196	498	<0.0001

*Costs for patients who presented with severity level 1, 2, or 3. Total ulcer-related costs for patients presenting as severity level 4/5 averaged $28,626 ± $51,145 (median $10,921). †Comparison of the mean costs for episodes among patients who progressed to a higher severity level versus patients who did not progress.

average than those whose ulcers did not progress.

Of the identified episodes, 22% progressed to a higher severity level, 30% required amputation, and 24% resulted in an inpatient hospitalization. These numbers are high, considering that patients in this study had medical insurance and therefore access to health care. These results emphasize the importance of early detection and aggressive treatment of lower-extremity ulcers, and they suggest the need for effective intervention programs designed to prevent hospitalization and ulcer progression.

Episode cost ($13,179) in this study was higher than in previously published studies. In an analysis of 1991 and 1992 data from patients under the age of 65 years with diabetes and lower-extremity ulcers, average payment per episode was $4,595 (6). Another analysis of 1995 data estimated that ulcer-related Medicare spending averaged $3,609 per year among patients with diabetic lower-extremity ulcers (7). There are several explanations for the differences in these data. Because costs in the present analysis were from 2000 and 2001 data, they would be expected to be higher than costs from earlier years. Costs in this analysis were based on charges, which are higher than actual costs. In contrast, studies using Medicare data may underestimate the costs of treatment because they only include costs for services that qualify for reimbursement. Definition of episode could contribute to differences in episode duration and costs among the different studies. In the present study, episode duration ranged from 8 to 542 days. To evaluate whether costs were inflated by the longer episodes, total ulcer-related costs were recalculated after excluding 25 patients (1% of the study population) with episodes longer than 365 days, which resulted in costs similar to those of the study population ($13,017 ± $34,513 vs. $13,179 ± $34,511).

The medical costs in this analysis were those associated with a primary (i.e., first-listed) ulcer-related diagnosis, which may underestimate the costs of a lower-extremity ulcer episode. In contrast, an analysis using costs associated with any ulcer-related diagnosis may have greater limitations because it likely overestimates the costs by including costs associated with other diagnoses. For this analysis, the costs associated with a primary diagnosis of lower-extremity ulcer were reported because they were less likely to inappropriately include costs associated with other high-cost complications of diabetes, such as cardiovascular and renal diseases.

Because this study was conducted among patients in the western United States who have employer-based insurance or Medicare + Choice, the results may not be representative of all patients with diabetic lower-extremity ulcers. As with other database analyses, these data are subject to errors in diagnosis coding, incomplete claims, and unobservable factors that may have influenced outcomes. Costs associated with outpatient intravenous antibiotics may not have been captured since the database does not always contain claims for outpatient intravenous medications. Classification of episode severity level was attempted using a coding stratification based on the Wagner system (6,9), but this method may not sufficiently characterize patients' level of disease. In addition, this analysis did not assess patients' degree of glucose control, a factor that has been associated with several diabetes complications, including neuropathy (12).

This study provides insight into the current health care costs associated with treating diabetic lower-extremity ulcers.

Treatment of diabetic lower-extremity ulcers is costly, especially among younger patients, patients with inadequate vascular status, and patients whose ulcer progressed to a higher severity. These results emphasize the value of intensive outpatient interventions designed to prevent hospitalization and ulcer progression.

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