Chapter 18

Lower Extremity Foot Ulcers and Amputations in Diabetes

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SUMMARY

Lower extremity ulcers and amputations are an increasing problem among individuals with diabetes. Data from the 1983-90 National Hospital Discharge Surveys (NHDS) indicate that 6% of hospitalizations listing diabetes on the discharge record also listed a lower extremity ulcer condition. Chronic ulcers were present in 2.7% of all hospitalizations that listed diabetes. The average length of stay (LOS) for diabetes discharges with ulcer conditions was 59% longer than for diabetes discharges without them. Clinical epidemiologic studies suggest that foot ulcers precede ~85% of nontraumatic lower extremity amputations (LEAs) in individuals with diabetes.

More than half of lower limb amputations in the United States occur in people with diagnosed diabetes, who represent only 3% of the U.S. population. NHDS data indicate that there were ~54,000 diabetic individuals who underwent ≥1 nontraumatic LEAs in 1990. Lower-level amputations (toe, foot, and ankle) were more common in individuals with diabetes than without diabetes, while the more disabling above-knee amputations were performed with greater frequency in nondiabetic individuals. Amputation rates are greater with increasing age, in males compared with females, and among members of racial and ethnic minorities compared with whites.

Data from several states indicated that 9%-20% of diabetic individuals experienced a new (ipsilateral) or second leg (contralateral) amputation during a separate hospitalization within 12 months after an amputation. Five years following an initial amputation, 28%-51% of diabetic amputees had undergone a second leg amputation. Perioperative mortality among diabetic amputees averaged 5.8% in 1989-92, according to NHDS data. Five-year mortality following amputation was 39%-68% in various studies.

Several analytic or experimental studies have demonstrated the beneficial effect of patient education on reducing LEAs. A randomized trial showed that patient self-care contracting and health provider and system interventions were effective in preventing serious foot lesions. Several amputation prevention programs have reported striking pre- and post-intervention differences in amputation frequency after instituting comprehensive, multidisciplinary foot care programs.

There are important differences between private insurers and Medicare in hospital reimbursement for foot ulcers and amputations by Diagnosis Related Group (DRG). Hospital reimbursement by Medicare is frequently <50% of the amount reimbursed by private insurers. Data from Colorado indicate that only 13% of individuals undergoing amputation at age ≥75 years were discharged to home or self-care, while the remainder of the survivors required skilled and intermediate care facilities or other institutions for inpatient care.

In summary, nontraumatic lower extremity diabetic ulcers and amputations are an important and costly problem. Systematic approaches to reducing the burden from this complication are needed.

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INTRODUCTION

Many of the estimated 14 million individuals in the United States with diagnosed and undiagnosed diabetes will experience pathologic changes of their lower extremities that when combined with minor trauma and infection may lead to serious foot problems. In the United States, the full extent of the diabetic foot problem is unknown, since this heterogeneous pathology is not uniformly defined, classified, or reported. This chapter presents incidence, prevalence, and risk factor data describing diabetic individuals who have experienced two major adverse foot outcomes, lower extremity ulcers and amputations (see definitions in Appendix 18.1[1]). Also presented is information on subsequent ipsilateral and contralateral amputation and ensuing mortality. Foot ulcer and amputation preventive interventions are addressed, and the chapter concludes with related economic considerations.

DATA SOURCES

Data for this chapter are taken primarily from selected population-based analytic and experimental studies. Much of the population-based information is from the NHDS, which samples ~1% of discharges from U.S. short-stay hospitals[2]. This survey has certain drawbacks (see Chapter 27 for a detailed discussion). The individuals hospitalized are not followed longitudinally because of the sampling strategies employed. It is estimated that, of all hospitalizations of people with diabetes, ~40% do not have diabetes listed on the hospital discharge record[3]. It is not known which hospitalizations of diabetic patients are omitted, but it is likely that amputations are well ascertained. Also, a substantial proportion of discharges are missing racial classification; in 1990, race was unknown for 20% of all NHDS discharges[4]. Because NHDS samples hospital discharges and not individual persons, NHDS hospital discharge rates for diabetes-related diseases and procedures may not necessarily reflect rates per person, that is, persons who are hospitalized more than once for the same condition may be counted more than once. Data from NHDS may thus overcount diagnoses when one person has multiple admissions in a given year for the same problem. Of probable greater importance, however, is the undercounting in NHDS of hospitalizations of people with diabetes[3]. Diabetes status may be misclassified based on discharge summary information, and differential hospitalization rates by diabetes status may occur for conditions of interest. Finally, not included in the NHDS are data from 171 Department of Veterans Affairs (VA) hospitals and from military, private charitable, and several Indian Health Service hospitals.

A second data source is the National Health Interview Survey (NHIS), an annual household survey of a probability sample of the U.S. population. In the 1989 NHIS, a special diabetes supplement was administered to everyone who indicated they had physician-diagnosed diabetes. The supplement asked about diabetes self-care, physician care, and complications[5,6].

FOOT ULCERS

Diabetic foot ulcers are common and are estimated to affect ~15% of all diabetic individuals during their lifetimes[7]. The majority of foot ulcers are treated in outpatient settings, where surveillance is limited. NHDS data from 1983-90 indicated that 6% of all hospitalizations that listed diabetes (~162,500 hospitalizations per year) also listed one of the lower extremity ulcer conditions in Table 18.1[8]. Chronic ulcers, the most frequently observed condition, were present in 2.7% of all hospitalizations that listed diabetes, and in 46% of all hospitalizations that listed any ulcer condition[8].

In the NHDS data, ulcer rates increased ~50% between 1983 and 1990 (Figure 18.1). The highest rates were observed in individuals age 45-64 years. A consis-

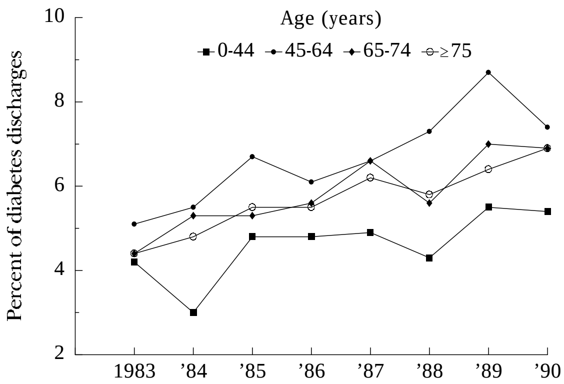
Table 18.1
Hospital Discharge Abstracts Listing Diabetes and Conditions Related to Foot Ulcer, U.S., 1983-90

Lower extremity condition	ICD9-CM codes	Hospital discharges listing diabetes (%)	Distribution of discharges listing both diabetes and an ulcer condition (%)
Lower extremity abcess	682.6-682.7	2.3	38.0
Chronic ulcer	707.xx	2.7	46.1
Charcot foot	94.0	<0.1	0.8
Osteomyelitis	730.xx	1.0	17.3
Paronychia	681.1	0.4	7.5
Septic arthritis	711.06-.09	<0.1	0.8
Varicose ulcer	454.x	0.5	8.3
Any of the above conditions		5.9	100.0

ICD9-CM, *International Classification of Diseases, Clinical Modification*. Average annual number of hospitalizations listing diabetes, 2,744,100; average annual number of hospitalizations listing ulcers, 162,500.

Source: Reference 8, 1983-90 National Hospital Discharge Surveys

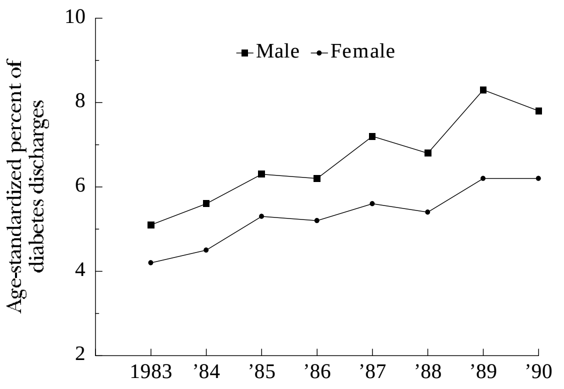
Figure 18.1
Proportion of Hospital Discharges Listing Diabetes that List Lower Extremity Ulcers, by Age, U.S., 1983-90



Source: Reference 8, National Hospital Discharge Survey

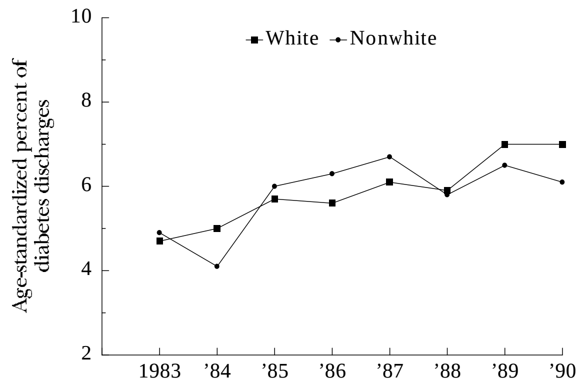
tently higher ulcer rate was found in males than in females (Figure 18.2), but hospitalization rates for the ulcer conditions were not widely divergent for white versus nonwhite patients (Figure 18.3). Figure 18.4 presents average LOS information for hospital discharges that listed diabetes, with and without a listing of a foot ulcer condition. The average LOS for diabetes discharges with these conditions was 59% longer than for diabetes discharges without them. Rates of hospital discharges listing diabetes and lower extremity ulcers are shown by U.S. region in Figure 18.5. Slightly higher rates were found in the Northeast and slightly lower rates in the West[8].

Figure 18.2
Age-Standardized Proportion of Hospital Discharges Listing Diabetes that List Lower Extremity Ulcers, by Sex, U.S., 1983-90



Source: Reference 8, National Hospital Discharge Survey

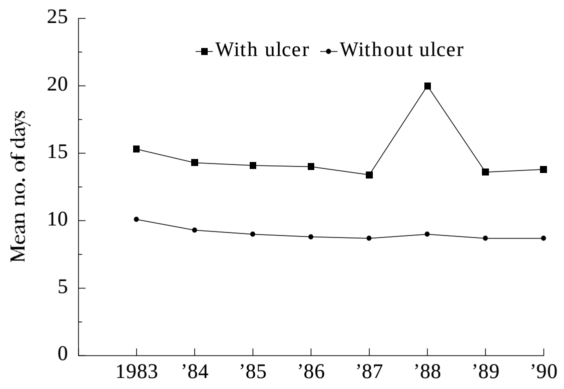
Figure 18.3
Age-Standardized Proportion of Hospital Discharges Listing Diabetes that List Lower Extremity Ulcers, by Race, U.S., 1983-90



Source: Reference 8, National Hospital Discharge Survey

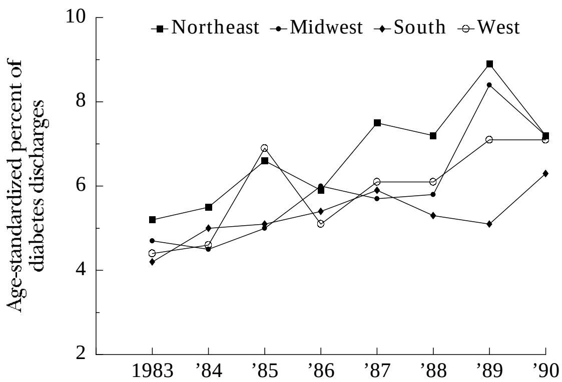
In studies of diabetic outpatients, 6%-43% (depending on ulcer severity) of patients with diabetic foot ulcers ultimately have the most severe diabetic foot outcome, amputation[9-12]. Of NHDS discharges listing diabetes and an amputation, 40% also listed a foot ulcer condition. This is less than half the frequency reported in two clinical epidemiologic studies that systematically assessed neuropathy, ulceration, ischemia, and other factors before amputation. These two studies found that foot ulcers preceded 84% and 85% of amputations, respectively[13-15]. In all likelihood, there is underreporting of foot ulcer conditions in the NHDS.

Figure 18.4
Average Length of Stay for Hospital Discharges Listing Diabetes and Lower Extremity Ulcers, U.S., 1983-90



Source: Reference 8, National Hospital Discharge Survey

Figure 18.5
Age-Standardized Proportion of Hospital Discharges Listing Diabetes that List Lower Extremity Ulcers, by Region, U.S., 1983-90



Source: Reference 8, National Hospital Discharge Survey

Population-based studies investigating the incidence and prevalence of lower extremity diabetic foot ulcers are summarized in Table 18.2[16-20]. In the population-based Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR), the annual incidence of foot ulcers was 2.4% in insulin-taking younger-onset diabetic patients (diagnosed at age <30 years, primarily insulin-dependent diabetes mellitus, IDDM) and 2.6% in older-onset diabetic patients (diagnosed at age ≥30 years, primarily non-insulin-dependent diabetes mellitus, NIDDM)[16].

In a population-based study of diabetic individuals age 15-50 years in Umea, Sweden, annual incidence of foot ulcers was 3% in patients with IDDM. In this study, foot ulcer prevalence for IDDM, NIDDM, and nondiabetic patients was 10%, 9%, and 0%, respectively. In addition, higher frequencies of nonulcerative pathology (hammertoes, callosities, fissures, and dry feet) were observed in diabetic than in nondiabetic patients[17]. In a population-based study in Stockholm, Sweden, foot ulcer prevalence in diabetic subjects was 4.4%[18]. In British studies, diabetic foot ulcer incidence was reported to be 1% and prevalence ranged from 5.3%-7.4%[19,20].

In a prospective study of 754 diabetic individuals followed at the Seattle VA General Internal Medicine Clinic, an annual foot ulcer incidence of 5.6% was found in a 3-year follow-up study[21]. In this clinic population, 28% of patients reported a history of sores on their feet and legs and 7% reported a prior LEA[22].

RISK FACTORS FOR FOOT ULCERS FROM SELECTED ANALYTIC AND EXPERIMENTAL STUDIES

Pathophysiologic, behavioral, and education risk factors have all been associated with development of foot ulcers. A case-control study of risk factors for foot ulcers from the Seattle VA clinic identified absence of Achilles tendon reflexes, foot insensitivity to the 5.07 monofilament, and levels of transcutaneous oxygen tension (TcP02) <30 mmHg as independent predictors of foot ulcers; absent vibratory sensation and low ankle-arm blood pressure index were not associated with this outcome[23]. A positive association between lower extremity neuropathy and history of diabetic foot lesions was reported in a Florida clinic-based study of 314 NIDDM subjects when those with past history of foot ulcers were compared with diabetic controls[24] (Table 18.3). A small study of 35 diabetic ulcer patients and 35 diabetic controls found a higher

Table 18.2
Foot Ulcer Incidence and Prevalence in Selected Population-Based Studies of Diabetic Patients

Ref.	Population studied	Clinical assessment	Annual incidence (%)	Prevalence (%)
16	Cohort of 1,210 IDDM and 1,780 NIDDM patients in southern Wisconsin	Partial	IDDM: 2.4 NIDDM: 2.6	IDDM: 9.5 NIDDM: 10.5
17	298 IDDM and 77 NIDDM patients from Umea County, Sweden, age 15-50 years	Yes	IDDM: 3	IDDM: 10 NIDDM: 9
18	617 patients with unstated type of diabetes from Stockholm County, Sweden	No		4.4
19	811 NIDDM patients from three cities in the U.K.	Yes		5.3
20	212 IDDM and 865 NIDDM patients in 10 U.K. general medicine practices	Yes		7.4

In Reference 16, IDDM are those with diabetes onset at age <30 years and taking insulin; NIDDM are those with diabetes onset at age ≥30 years.

Source: References are listed within the table

Table 18.3
Risk Factors for Foot Ulcers in Diabetic Patients in Selected Analytic and Experimental Studies

Ref.	Patient population	Long duration of diabetes	Neuropathy (vibration or pressure)	Low ankle/arm index	Smoking history	High HbA1c
23	368 clinic patients with IDDM and NIDDM	0	+	0		
24	314 clinic patients with NIDDM	+	+			0
20	212 IDDM and 865 NIDDM patients in 10 U.K. general medicine practices	+	0		0	0
25	35 ulcer patients with unspecified type of diabetes and 35 controls		+		0	0
16	Cohort of 1,210 IDDM and 1,780 NIDDM patients in Wisconsin	+ (NIDDM)			+ (IDDM)	+
28	358 Chippewa Indians with NIDDM	+	+	+		
29	396 clinic patients with NIDDM		+		+	≈
30, 31	135 clinic/emergency room patients with IDDM and NIDDM	+	+	0		

+, statistically significant association; 0, no statistically significant association; ≈, borderline statistically significant association. In Reference 16, IDDM are those with diabetes onset at age <30 years and taking insulin; NIDDM are those with diabetes onset at age ≥30 years.

Source: References are listed within the table

prevalence of absent ankle jerks, decreased light touch sensation, and absent peripheral pulses in diabetic foot ulcer subjects compared with an equal number of controls[25]. These findings were confirmed in a study of subjects with current or former diabetic foot ulcers. Also identified as risk factors were longer diabetes duration and presence of retinopathy[20] (Table 18.3).

The role of autonomic neuropathy in diabetic foot ulcer etiology was explored in a small study in which 19 diabetic foot ulcer subjects had decreased heart rate variation with deep breathing, compared with diabetic controls without foot ulcers[26]. Similarly diminished cardiovascular reflexes (indicating autonomic neuropathy) were reported in diabetic foot ulcer cases compared with diabetic controls[27]. These cross-sectional data suggest that peripheral neuropathy, arterial insufficiency, and foot deformity may all contribute to the development of diabetic foot ulcer. Since these studies did not collect data prospectively, they cannot establish whether these phenomena temporally preceded foot ulcer occurrence. Prospective research is usually required to ascertain this association.

Several prospective studies of risk factors for diabetic foot ulcers have been completed. The WESDR cohort study protocol did not include lower extremity measurements but did find that high glycosylated hemoglobin levels were associated with an increased risk of foot ulcer in all diabetic subjects[16] (Table 18.3). Smoking, presence of retinopathy, older age, longer diabetes duration, presence of proteinuria, and low diastolic blood pressure were associated with increased risk of foot ulcer in the WESDR, depending on whether onset of diabetes occurred before or after age 30 years[16]. These results do not suggest any measures to prevent specific lower extremity foot ulcers; however, they do suggest that better glycemic control and, in younger populations, smoking cessation might decrease foot ulcer incidence.

In a prospective study of Chippewa Indians, the role of clinically defined foot deformity and absence of protective sensation based on monofilament testing was assessed[28]. An increased risk of ulceration was associated with both deformity and diminished sensation (Table 18.3). A prospective study of inner-city patients with NIDDM found that neuropathy and smoking history were significant risk factors for ulcers but that high levels of glycated hemoglobin were of borderline significance[29]. Another prospective study found high foot pressure to be positively associated with diabetic foot ulcer occurrence[30] (Table 18.3). Foot pressure was measured using an expensive and clinically impractical device, the Optical Pedobarograph[30,31]. The authors suggested that a simple and inexpensive Harris Mat imprint could be substituted and yield the same information, but they did not present supporting evidence. Risk factor information regarding associations between ulcers and low ankle/arm index and smoking has been inconsistent[16,20,23,25,28,32,33].

Table 18.4
Average Annual Number and Percent Distribution of Hospital Discharges Listing Lower Extremity Amputations, by Amputation Level and Presence of Diabetes on the Discharge Record, U.S., 1989-92

Amputation level	No diabetes No.	No diabetes %	Diabetes No.	Diabetes %	Total No.	Total %
Toe	12,427	24.1	21,671	40.3	34,098	32.3
Foot/ankle	2,967	5.8	7,773	14.5	10,740	10.2
Below knee	11,048	21.4	13,484	25.1	24,527	23.3
Knee disarticulation	778	1.5	704	1.3	1,482	1.4
Above knee	20,028	38.8	8,612	16.0	28,640	27.2
Hip/pelvis	386	0.7	87	0.2	473	0.5
Not specified	3,971	7.7	1,378	2.6	5,349	5.1
Total	51,605	100.0	53,709	100.0	105,309	100.0

Source: Reference 34, 1989-92 National Hospital Discharge Surveys

LOWER EXTREMITY AMPUTATIONS

Amputations are surgical procedures performed for multiple indications including gangrene, peripheral arterial occlusion, nonhealing ulcers, severe soft tissue infections, osteomyelitis, trauma, tumors, and deformities. Based on NHDS data, there was an annual average of ~110,000 discharges from U.S. short-stay hospitals that listed an amputation in 1989-92[34]. Almost all (96%) of these amputations involved a lower extremity. Of all discharges listing LEAs, ~51% listed diabetes, even though persons with diabetes represent only ~3% of the total U.S. population.

The average annual number of LEAs by level of amputation and whether diabetes was listed on the discharge record, based on the 1989-92 NHDS, is shown in Table 18.4. These data indicate that lower-level amputations (toe, foot, and ankle) were more common in amputation discharges listing diabetes than in amputation discharges without diabetes (54.8% versus 29.9%). Above-the-knee amputations, which are more disabling than lower-level amputations, were less frequent in amputation discharges that listed diabetes than in amputation discharges not listing diabetes (16.0% versus 38.8%)[34].

Selected hospital discharge data[35-42] are shown in Table 18.5. In statewide data, the age-adjusted amputation rate calculated per estimated diabetic or total population is ~15-40 times higher for diabetic than for nondiabetic individuals. The proportion of hospital discharges listing an amputation that also listed diabetes ranged from 45%-63% (Table 18.5). The highest amputation rate was found in the Pima Indian cohort, in which 95% of all amputations were in diabetic subjects[43]. Table 18.5 also shows information on amputation level and average duration of hospitalization for these studies.

In the 1989 NHIS, people with and without known diabetes were asked whether they had ever had an amputation. Despite the higher mortality of diabetic amputees, there was a 10-fold higher amputation prevalence for diabetic versus nondiabetic individuals age ≥18 years (Table 18.6).

Table 18.5
Nontraumatic LEA Findings from Selected Hospital Discharge and Cohort Studies

			Age-adjusted number of LEAs per 10,000 persons per year		Diabetes-specific findings		
Ref.	LEA	State or group studied	No diabetes	Diabetes	Diabetes among LEA cases (%)	Below-knee and above-knee of total LEA (%)	Mean duration of hospital stay (days)
Hospital Discharge Studies							
35	Any	Colorado		37	55	45.5	15.4
36	Any	Rhode Island	2.5	88	53	57	33
37	Any	New Jersey		77	63	56	40
38	Any	U.S., six states	2.0	58	45	65	30
39	Any	U.S., NHDS		81	51	43	20.6
40	Any	Washington	1.0	52	50		
41	Any	California	1.2	47	55	62	21
42	Any	Veterans Administration			50	55	
Cohort Studies							
43	First	Pima Indians	1.3	137	95	16	

LEA, lower extremity amputation; NHDS, National Hospital Discharge Survey.

Source: References are listed within the table

Table 18.6
Amputation Prevalence Reported by Individuals Age ≥18 Years, U.S., 1989

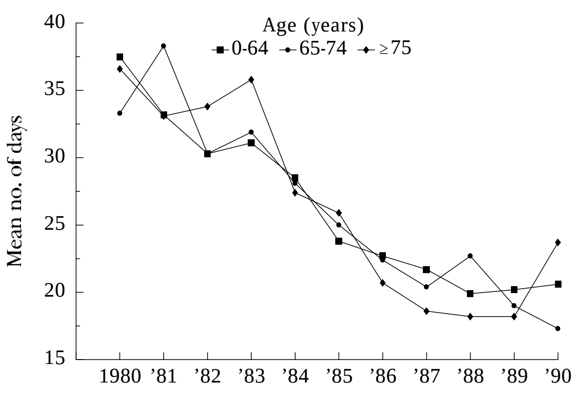
Age (years)	No diabetes (%)	Diabetes (%)
18-44	0.17	1.6
45-64	0.36	2.4
≥65	0.61	3.6
Total	0.29	2.8

Sample sizes: no diabetes, n=20,062; diabetes, n=2,390.

Source: 1989 National Health Interview Survey

The number of hospital discharges listing an amputation and diabetes in the NHDS increased 29%, from 36,000 in 1980 to 54,000 in 1990[39]. Although the annual rates fluctuated between 5.1 and 8.1 per 1,000 diabetic population (estimated from the NHIS), there was a 29% overall increase between 1980 and 1990[39]. During this period, the length of hospital stay for discharges listing both diabetes and an amputation decreased dramatically, from an average of 35.8 days to 20.6 days (Figure 18.6). This is likely related to the advent of the DRG system. Another source of relevant hospital discharge data comes from the U.S. Department of Veterans Affairs. During fiscal years 1986-90, VA hospitals reported the average annual number of hospital discharges in which both nontraumatic LEA procedures and diabetes were listed was 8,997; the number without diabetes listed was 8,223[42]. Both groups averaged 1,300 amputation revisions annually[42]. These data are limited in that they reflect hospital discharges rather than individuals; however, they do suggest the importance of the amputation problem in VA hospitals.

Figure 18.6
Average Length of Stay for Hospital Discharges Listing Diabetes and Lower Extremity Amputation, U.S., 1980-90



Source: Reference 39, National Hospital Discharge Survey

RISK FACTORS FOR AMPUTATIONS

AGE

The number of discharges listing diabetes and an amputation per 1,000 estimated diabetic population, based on the NHDS and the NHIS, increases with advancing age (Figure 18.7). In 1990, the estimated amputation rate was 1.4 and 2.4 times higher for individuals age 65-74 years and age ≥75 years, respectively, compared with those age 0-64 years[39].

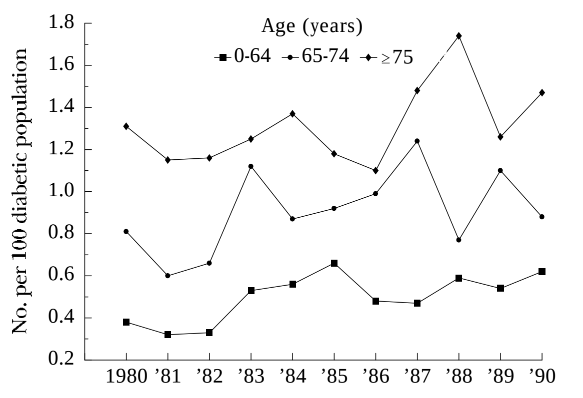
SEX

Figure 18.8, based on the NHDS and NHIS, indicates that the estimated amputation rate in diabetic subjects is higher for males than for females. This is a uniform finding in most U.S. hospital discharge studies, with 1.4-2.7 times excess risk for males compared with females[38,39]. In 1990, the age-adjusted amputation rate for diabetes, computed from NHDS and NHIS data, was 61% higher in males than females (10.3 per 1,000 versus 6.4 per 1,000)[39]. This amputation risk was more pronounced in younger males.

RACE/ETHNIC BACKGROUND

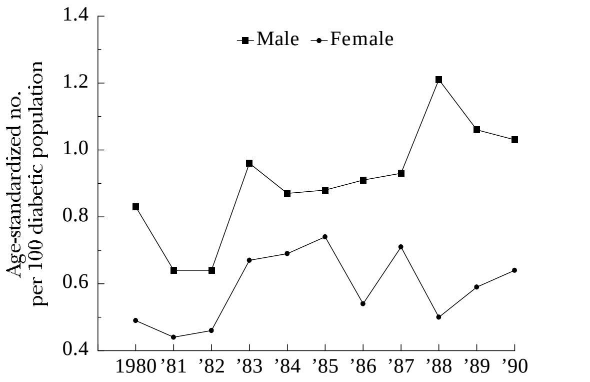
Amputation rates based on hospital discharges were generally higher for blacks than for whites after adjusting for age, as shown in the 1980-90 NHDS data presented in Figure 18.9. For Native Americans living on the Gila River Indian Reservation, the incidence of

Figure 18.7
Number of Hospital Discharges Listing Diabetes and Lower Extremity Amputation per 100 Diabetic Population, by Age, U.S., 1980-90



Source: Reference 39, National Hospital Discharge Survey

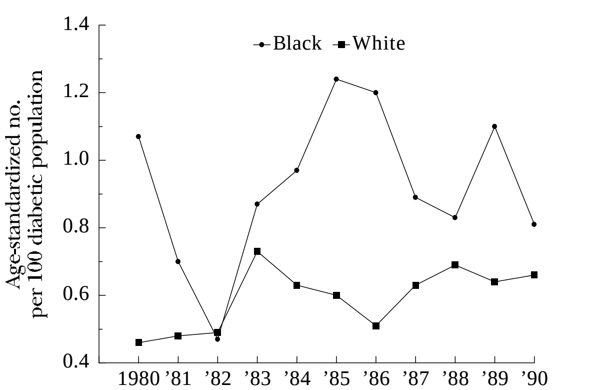
Figure 18.8
Age-Standardized Number of Hospital Discharges Listing Diabetes and Lower Extremity Amputation per 100 Diabetic Population, by Sex, U.S., 1980-90



Source: Reference 39, National Hospital Discharge Survey

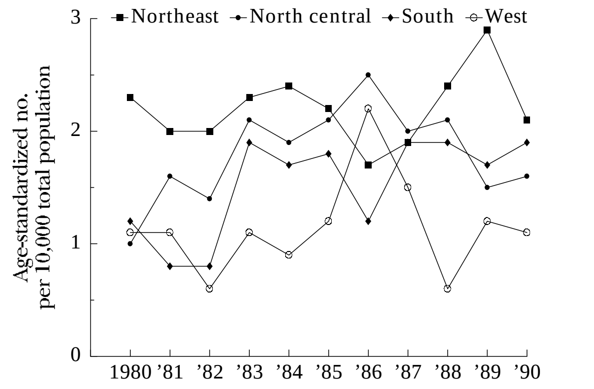
amputations was 24.1 per 1,000 person-years compared with 6.5 per 1,000 person-years for the general U.S. diabetic population[43]. A statewide California hospital discharge database was analyzed to determine the incidence of LEAs and amputation revisions (ICD9-CM codes 84.1 and 84.3) in diabetic individuals in California in 1991. The estimates of age-adjusted diabetic amputation rates for all amputation levels were 44.4 per 10,000 in Hispanics, 56.0 per 10,000 in non-Hispanic whites, and 95.3 per 10,000 in African Americans[44]. Higher-level amputations (e.g., above the ankle) were also reported to be performed more frequently in African Americans than in Hispanics or non-Hispanic whites. In San Antonio,

Figure 18.9
Age-Standardized Number of Hospital Discharges Listing Diabetes and Lower Extremity Amputation per 100 Diabetic Population, by Race, U.S., 1980-90



Source: Reference 39, National Hospital Discharge Survey

Figure 18.10
Age/Race-Standardized Number of Hospital Discharges Listing Diabetes and Lower Extremity Amputation per 10,000 Total U.S. Population, by Region, 1980-90



Source: Reference 39, National Hospital Discharge Survey

TX, amputation rates were 66.5 per 10,000 for whites, 120.1 per 10,000 for Mexican Americans, and 181.2 per 10,000 for African Americans. When compared with LEA rates in nondiabetic subjects of similar ethnic status, the relative risks were 26.9, 29.1, and 25.3 for whites, Mexican Americans, and African Americans, respectively[45]. Population-based data used to determine amputation rates by racial/ethnic group seldom have information that allows investigators to control for the potentially confounding effects of socioeconomic status and health care factors.

GEOGRAPHIC REGION

Age-adjusted amputation rates by U.S. region are shown in Figure 18.10. Despite year-to-year variation, the Northeast tends to have higher rates than the West[39].

PERIPHERAL NEUROPATHY

Several analytic studies have provided evidence for an association between neuropathy and LEA. Impaired vibratory perception was a statistically significant risk factor for amputation after controlling for age, sex, and diabetes duration in the cohort study of Pima Indians[43] and in the Seattle VA case-control study[14] (Table 18.7). In the latter, the significance of this predisposing condition in terms of population-attributable risk percent was high because of the higher prevalence of hypoesthesia among cases (78%) than among controls (18%).

Table 18.7
Risk Factors for Nontraumatic Lower Extremity Amputation in Diabetic Individuals in Analytic and Experimental Studies

		Pathophysiologic factors				Self care		History	
Ref.	Study group	Neuro-pathy	PVD and/or cutaneous circulation	High blood pressure	Total cholesterol	High HbA1c or glucose	History of smoking	Foot ulcer	Retino-pathy
60	Cohort of 875 Oklahoma Indians with NIDDM			+(SBP, men) +(DBP, women)	+(women)	+(men)	0	+	+
16	Cohort of 1,210 IDDM and 2,990 NIDDM patients in Wisconsin			+(DBP, IDDM)		+	+	+	+
43	Cohort of 4,399 Pima Indians with NIDDM	+		0	0	+	0		+
14	Case-control study of 38 IDDM and 278 NIDDM in Seattle VA hospital	+	+	0	0	+	0	+	+

PVD, peripheral vascular disease; SBP, systolic blood pressure; DBP, diastolic blood pressure; +, statistically significant association; 0, no statistically significant association. In Reference 16, IDDM are those with diabetes onset at age <30 years and taking insulin, NIDDM are those with diabetes onset at age ≥30 years.

Source: References are listed within the table

LOWER EXTREMITY ARTERIAL DISEASE

Lower extremity arterial disease has been considered to be among the most important reasons for amputation in individuals with and without diabetes. Until recently, clinicians made little distinction between the relative adequacy of cutaneous circulation and its relationship with major arterial circulation. The literature regarding healing of surgical amputation sites strongly suggests that parameters that reflect principally arterial perfusion provide different clinical information regarding cutaneous circulation than more direct techniques for assessing this compartment[7,46-48]. Furthermore, there is evidence that adequate cutaneous perfusion depends not only on the underlying arterial circulation but may be critically influenced by other factors, including skin integrity, mechanical effects of repetitive pressure, and presence of tissue edema[49].

Cutaneous circulation (measured using transcutaneous oxygen tension, TcPO2), reflects oxygen diffusion across the skin barrier resulting from tissue equilibration after capillary delivery and tissue utilization at the dermis[50]. TcPO2 values associated with below-knee amputation healing potential suggest that values <20 mmHg are associated with poor healing, values of 20-40 mmHg are associated with intermediate healing potential, and values >40 mmHg are associated with high likelihood of healing[51]. The Seattle VA study showed that average below-knee and dorsal foot TcPO2 values <20 mmHg, when compared with the >40 mmHg reference group, yielded an odds ratio of 161 (95% confidence interval (CI) 55-469); for patients with values of 20-40 mmHg, the odds ratio was 7.5 (95% CI 4.0-14.1)[14]. This association persisted after controlling for the potentially confounding effects of age, race, duration, diabetes type, socioeconomic status, and diabetes severity.

The presence of intermittent claudication, used to define atherosclerosis obliterans in the Framingham Study in Massachusetts, was 3.8 and 6.5 times more common in diabetic than in nondiabetic males and females, respectively[52]. Rochester, MN data indicated that arteriosclerosis obliterans, defined as peripheral pulse deficits, was present in 8% of subjects at diabetes diagnosis, in 15% after 10 years diabetes duration, and in 45% after 20 years of clinical diabetes[7]. In subjects in the University Group Diabetes Program (UGDP), intermittent claudication seldom led to amputation, although the predicted 13-year cumulative risk for intermittent claudication was 38% for males and 24% for females[53]. The Seattle VA study compared individuals with Doppler ankle/arm index values <0.45 with those with values >0.70 (normal range ≥0.90) and found the unadjusted amputation odds to be 55.8 (95% CI 15-209)[14].

The major alterable risk factors implicated in atherosclerosis development in nondiabetic subjects are cigarette smoking, lipoprotein abnormalities, and high blood pressure. These have all been assumed to be similarly atherogenic in diabetic populations[52,54,55]. The prevalence of smoking in the United States is well described[56,57]. Smoking prevalence for individuals with diabetes is shown in Chapter 7. No consistent relationship, either positive or negative, has been reported between smoking and diabetes itself [55]. Although many studies, including the Framingham Study, show a relationship between smoking and coronary heart disease, intermittent claudication, and arteriosclerosis obliterans, direct evidence is more limited for the effect of smoking on lower leg lesions and amputation in diabetes[52,58]. Smoking was a statistically significant risk factor for amputation in an Indianapolis, IN study[29], was of borderline significance in the WESDR study[16], and was not a risk factor in two other studies[14,43] (Table 18.7).

Lipoprotein abnormalities, which include elevated levels of plasma triglyceride, very low-density lipoprotein (VLDL) cholesterol, and low-density lipoprotein (LDL) cholesterol and decreased levels of high-density lipoprotein (HDL) cholesterol, may be more prevalent in diabetic than in nondiabetic individuals. Lipoprotein abnormalities have been associated with peripheral vascular disease in diabetic patients[59], but there are few data evaluating direct effects on risk for amputation. Two analytic studies examined the possible effect of serum cholesterol level on amputation risk and reported no statistically significant association between increasing levels of total cholesterol and amputation[14,43] (Table 18.7). Total cholesterol was a significant risk factor for amputation in women in one study[60], and low levels of HDL subfraction 3 were reported to be a statistically significant risk factor for amputation in the Seattle, WA study[14].

DIABETES TYPE

Diabetes is a heterogeneous disorder, with differing etiologies, requirements for treatment, and manifestations in individuals with IDDM and NIDDM[61]. For clinical and research purposes, characterizing diabetes by type is important, although precise classification may be problematic because of the lack of an unequivocal marker. Four-year amputation incidence was 2.2% for both insulin-taking individuals with diabetes onset at age <30 years (predominantly IDDM) and individuals with diabetes onset at age ≥30 years (predominantly NIDDM) in the WESDR cohort study in southern Wisconsin[16]. In the population-based Rochester, MN study, amputation risk was lower for individuals with IDDM than NIDDM (28.3 per 10,000 versus 35.6 per 10,000)[62]. The Seattle VA study found the odds ratio comparing individuals with IDDM to NIDDM was 1.7; however the confidence interval included unity[14]. Other analytic and experimental studies with information on diabetes type included exclusively NIDDM subjects[29,43,53].

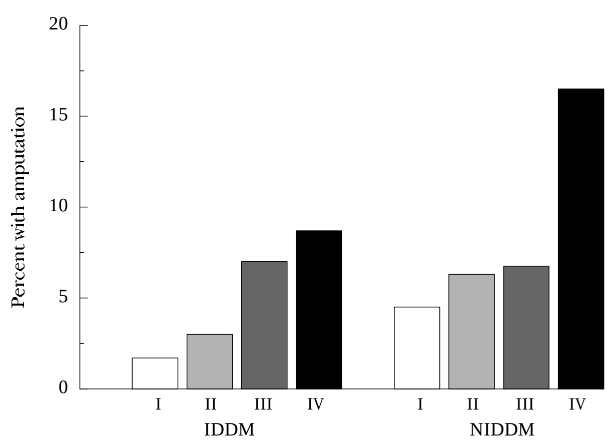
GLYCEMIC CONTROL

In the Diabetes Control and Complications Trial (DCCT), IDDM patients treated with intensive metabolic control had HbA1c values that were substantially lower than the conventional treatment group yet were not in the nondiabetic range. This lowering was associated with a reduction in the subsequent development of several complications, including clinical neuropathy[63]. Although the study was unable to address LEA as a major outcome, fewer peripheral vascular events occurred among members of the intensively treated group[63].

The relationship between glycemic control and amputation was addressed by West, who found a twofold increased risk of leg lesions, including gangrene, among diabetic individuals with higher blood glucose levels compared with those with lower blood glucose levels[64]. Analytic studies demonstrated statistically significant increased amputation risk with elevated fasting plasma glucose, 2-hour postload glucose, or glycosylated hemoglobin[14,16,43,60]. In the prospective WESDR study in southern Wisconsin, there was a significant and substantial increase in the 10-year incidence of amputation with increasing glycosylated hemoglobin quartile measured at baseline (Figure 18.11). The availability of health care should be evaluated as a potential confounding factor when assessing the relationship between glycemic control and amputation.

Figure 18.11

Ten-Year Incidence of Lower Extremity Amputation by Glycosylated Hemoglobin Quartile in IDDM and NIDDM



Data are from the Wisconsin Epidemiologic Study of Diabetic Retinopathy; glycosylated hemoglobin was measured at baseline, and the cohort was followed for 10 years with ascertainment of amputation.

Source: Reference 91

CLINICAL DURATION OF DIABETES

Diabetes diagnosis usually marks the onset of "clinical disease"; however, disease processes could have been ongoing prior to diagnosis, especially for NIDDM. After adjusting for age and sex, clinical duration of diabetes remained a statistically significant risk factor for amputation in several analytic studies[16,43]. Population-based amputation data from Rochester, MN indicated that the risk of LEA following diabetes diagnosis was 6% at 20 years and 11% at 30 years[62].

HEALTH CARE FACTORS AND HEALTH HISTORY

Visit frequency, provider practices, co-morbidity, and other discrete measures reflecting parameters of health care and health history have been found to be significant protective or risk factors in experimental and analytic amputation studies[65,66]. Prior history of lower extremity ulcers was reported in several studies[14,16,60]. A positive history of retinopathy was significantly associated with increased amputation risk in four studies[14,16,43,60](Table 18.7).

NEW AMPUTATION AND SECOND LEG AMPUTATION

Statewide hospital discharge data for California, Colorado, and New Jersey indicated that 9%-20% of individuals experienced subsequent amputation(s) on separate hospitalizations within a year[35,37,41]. At 12 months post-operation, new (ipsilateral) or second leg (contralateral) amputations occurred in 9% and 13% of amputees in New Jersey and California, respectively[37,41]. Table 18.8 reviews reports on new amputations in amputees at 1-60 months following their initial amputation. Although in the United States it is difficult to monitor information on ulcer and amputation over time, other countries have registries to facilitate this tracking. Information from the Danish Amputation Register, which excludes toe amputations, indicated that 19% of all patients undergoing major amputation for arteriosclerosis and gangrene had a new amputation within 6 months. At 48 months following amputation, this had increased only to 23%[67,68].

Descriptive studies have reported that ~6%-30% of amputees will undergo second leg amputations within 1-3 years of their initial amputation[68-73]. Table 18.9 reports the frequency of second leg amputations among initial amputation survivors. The Danish registry reported that at 4 years, 38% of nondiabetic and 52.6% of diabetic amputees had undergone a second leg amputation. The frequency of second leg amputations increased from 12% at 1 year to 28%-51% at 5 years[68-73]. There has been little improvement during the last two decades in preventing this morbidity. Even in individuals who have undergone an initial

Table 18.8

Reports from Selected Studies of New Amputation (Ipsilateral) Among Individuals Surviving an Initial Amputation

Ref.	Time interval (months)	Population	New (ipsilateral) amputation (%)	Study population with diabetes (%)
68	1	Denmark	10*	27
74	6	Malmohus Co., Sweden	15	100
68	6	Denmark	19*	27
37	12	New Jersey	9	100
41	12	California	13	100
15	12	Lund, Sweden	14	100
69	36	Newcastle, U.K.	13	100
15	36	Lund, Sweden	30	100
67, 68	48	Denmark	23*	27
15	60	Lund, Sweden	49	100

*Danish Amputation Register data, excludes toe amputations.

Source: References are listed within the table

Table 18.9

Reports from Selected Studies of Second Leg (Contralateral) Amputation Among Individuals Surviving an Initial Amputation

Ref.	Time interval (months)	Population	Second leg (contralateral) amputation (%)	Study population with diabetes (%)
68	12	Denmark	11.9*	27
72	12	Birmingham, U.K.	12.2	100
72	24	Birmingham, U.K.	15.5	100
68	24	Denmark	17.8*	27
70	24	Los Angeles, CA	28.0	100
69	36	Newcastle, U.K.	6.0	100
72	36	Birmingham, U.K.	22.7	100
68	36	Denmark	27.2*	27
73	36	New York	30.0	100
72	48	Birmingham, U.K.	27.3	100
68	48	Denmark	52.6*	100
72	60	Birmingham, U.K.	28.2	100
70	60	Los Angeles, CA	46.0	100
73	60	New York	51.0	100

*Danish Amputation Register data, excludes toe amputations.

Source: References are listed within the table

amputation, the obvious increased risk for subsequent amputation does not appear to be uniformly translated into preventive patient and provider care actions.

MORTALITY FOLLOWING AMPUTATION

Peri-operative diabetic amputation mortality, defined as death within 30 days following surgery, averaged 5.8% in the United States in 1989-92, according to NHDS data[8]. In-hospital mortality has declined in case-series reports from as high as 50% in the mid-1930s to 1.5% in the mid-1980s. Mortality in amputees is not uniform across populations. The 1991 statewide California hospital discharge data indicated an age-adjusted amputation mortality rate of 5.67% in blacks, compared with 1.64% in Hispanics and 2.71% in non-Hispanic whites[44].

Table 18.10
Reports from Selected Studies on Mortality Following Lower Extremity Amputation

Ref.	Time interval	Population	Mortality following amputation (%)	Study population with diabetes (%)
71	Perioperative	Scotland	5.0	26
8	"	NHDS, 1989-92	5.8	100
74	"	Malmohus Co., Sweden	9.0	40
37	"	New Jersey, statewide	10.0	100
69	"	Newcastle, U.K.	10.0	100
72	"	Birmingham, U.K.	15.1	100
76	12 months	Detroit, MI	10.5	100
75	"	Lund, Sweden	15.0	100
72	"	Birmingham, U.K.	16.3	100
68	"	Denmark	18.4*	27
69	"	Newcastle, U.K.	40.0	100
74	"	Malmohus Co., Sweden	41.0	40
68	24 months	Denmark	19.2*	27
72	"	Birmingham, U.K.	29.1	100
69	"	Newcastle, U.K.	50.0	100
74	"	Malmohus Co., Sweden	51.0	40
68	36 months	Denmark	20.3*	27
72	"	Birmingham, U.K.	34.5	100
73	"	New York	35.0	100
75	"	Lund, Sweden	38.0	100
60	"	Oklahoma Indians	40.2	100
76	"	Detroit, MI	50.0	100
68	48 months	Denmark	22.5*	27
71	"	Scotland	50.0	26
74	"	Malmohus Co., Sweden	72.0	40
43	60 months	Pima Indians	39.0	100
73	"	New York	59.0	100
60	"	Oklahoma Indians	59.6	100
76	"	Detroit, MI	63.7	100
75	"	Lund, Sweden	68.0	100

*Danish Amputation Register data, excludes toe amputations. NHDS, National Hospital Discharge Survey.

Source: References are listed within the table

Table 18.10 outlines the interval between LEA and mortality in several populations[8,37,43,60,68-76]. The range for 1-year mortality was 11%-41%, 3-year mortality was 20%-50%, and 5-year mortality was 39%-68%. Serious co-morbid conditions are common in this population, and mortality in amputees is often attributed to cardiac or renal complications[60]. Higher overall mortality rates have also been reported in diabetic amputees relative to nondiabetic or other diabetic individuals in studies of Pima Indians in Arizona and Native Americans in Oklahoma[43,60].

FOOT ULCER AND AMPUTATION PREVENTION STRATEGIES

Self-reported preventive practices have been linked with decreased risk of lower extremity complications. Among diabetic individuals identified in the 1989 NHIS, 22% of all patients stated that they never checked their feet, but 52% checked their feet at least daily (Table 18.11). Foot self-exams were reported more frequently by subjects with IDDM and insulin-treated NIDDM than by NIDDM subjects not treated with insulin (Table 18.11). However, there was little variation by age in the proportion who checked their feet at least once per day (Table 18.12). The 1989 NHIS also provided information on the frequency of foot examinations made by health professionals. Table

Table 18.11
Frequency of Foot Checks in the Past Week Performed by Individuals with Diabetes, Age ≥18 Years, U.S., 1989

No. of times feet checked per week	All subjects with diabetes (%)	IDDM (%)	NIDDM, insulin-treated (%)	NIDDM, not insulin-treated (%)
0	22.2	9.2	14.5	28.5
1-2	19.8	18.8	20.1	19.8
3-4	5.2	8.0	5.8	4.5
5-6	0.3	0.0	0.3	0.4
7-8	51.6	62.5	58.3	46.2
≥9	1.0	1.6	1.1	0.7

Sample size, all diabetic subjects, n=2,261.

Source: 1989 National Health Interview Survey

Table 18.12
Percent of Diabetic Individuals Who Report Checking Their Feet at Least Once per Day, Age ≥18 Years, U.S., 1989

Age (years)	All subjects with diabetes (%)	IDDM (%)	NIDDM, insulin-treated (%)	NIDDM, not insulin-treated (%)
18-44	53.8	61.0	52.1	49.0
45-64	56.3	85.1	65.9	48.4
≥65	48.7		54.8	45.3
All ages	52.5	64.1	59.4	46.9

Sample size, all diabetic subjects, n=2,261.

Source: 1989 National Health Interview Survey

Table 18.14
Percent of Diabetic Individuals Who Report Having Seen a Podiatrist in the Past Year, Age ≥18 Years, U.S., 1989

Age (years)	All subjects with diabetes (%)	IDDM (%)	NIDDM, insulin-treated (%)	NIDDM, not insulin-treated (%)
18-44	10.5	6.6	16.1	8.3
45-64	14.7	16.7	18.3	11.8
≥65	21.0		29.0	16.8
All ages	16.9	7.9	22.5	14.0

Sample size, all diabetic subjects, n=2,389.

Source: 1989 National Health Interview Survey

18.13 shows that 53% of diabetic patients reported no foot exam by a health professional within the past 6 months, 27% had one to two exams, 10% had three to four exams, and 10% received more than four foot exams in the previous 6 months. The frequency of having no foot exam was highest in NIDDM patients not using insulin (59%). Table 18.14 provides information on the proportion of diabetic subjects in the 1989 NHIS who reported seeing a podiatrist within the previous year. Overall, only 17% reported that they had seen this specialist.

A randomized 12-month trial evaluated the effectiveness of comprehensive patient, health care provider, and system interventions on risk factors for amputation in 352 patients with NIDDM[65]. Patients were randomized to a foot-care education group that provided education, behavioral contracting for foot care, and telephone and postcard prompts. Physicians assigned to intervention patients received practice guidelines, information on amputation risk factors and footcare practice, and prompts. Selected findings from this study suggest that physicians detected ulcers in the intervention group more frequently when an ulcer was present (Table 18.15). Similarly, foot self-care behaviors were reported more frequently by intervention than by control patients. Physicians of intervention patients were more likely to document lower extremity abnormalities in their patients than were physicians of control patients[65]. The intervention group was significantly more likely to report appropriate foot care behaviors than the control group. In a prospective randomized study, 203 patients at the Tucson VA hospital in Arizona were randomized to an education or no education group[77]. The

Table 18.13
Frequency of Foot Checks in the Past 6 Months Performed by Health Professionals, as Reported by Individuals with Diabetes, Age ≥18 Years, U.S., 1989

No. of times health professional checked feet in past 6 months	All subjects with diabetes (%)	IDDM (%)	NIDDM, insulin-treated (%)	NIDDM, not insulin-treated (%)
0	52.7	51.4	43.5	59.1
1-2	27.3	34.0	29.8	25.0
3-4	10.0	8.9	12.6	8.4
>4	10.0	5.7	14.2	7.5

Sample size, all diabetic subjects, n=2,356.

Source: 1989 National Health Interview Survey

Table 18.15
Selected Findings from a Trial of NIDDM Patients Randomized to 12-Month Multifaceted Foot-Related Interventions

	Odds ratio	95% Confidence interval	
Patient outcomes			
Serious foot lesions	0.41	0.16-1.00	
Dry or cracked skin	0.62	0.39-0.98	
Ingrown nails	0.59	0.39-0.92	
Self-foot care behaviors			
Wash feet	0.51	0.30-0.87	
No soaking of feet	0.67	0.45-0.99	
Inspect feet	0.23	0.12-0.42	
Inspect shoes	0.64	0.40-1.00	
Dry between toes	0.27	0.10-0.75	
	Intervention (%)	**Control (%)**	**p-value**
Physicians' documentation			
Ulcers present	23.8	11.1	<0.01
Pulse examination	9.2	3.0	<0.01
Dry or cracked skin	8.7	2.0	<0.01
Callus or corn	6.5	1.0	<0.01

Source: Reference 65

intervention consisted of a 1-hour class and patient instructions for foot care. Clinical care for both groups was identical. After ~1 year of followup, there was a threefold excess risk for both foot ulcers and amputations in the group receiving no education. In a case-control study, a threefold increased amputation risk was observed in patients who had not received targeted foot or general outpatient diabetes education compared with those who had[14]. Patient education provided at the time of diabetes diagnosis and in hospital settings did not show the same benefit as formal outpatient diabetes education more proximal in time to amputation[14].

Appropriate footwear has the potential to decrease diabetic foot ulcers in individuals with diabetes and foot insensitivity[11,78]. In 1987, Congress mandated a Medicare demonstration project to determine whether provision of a shoe benefit to enrollees with severe diabetic foot disease would be "cost-neutral." This demonstration project enrolled 4,373 Medicare patients who applied for therapeutic shoe coverage and randomized them to extra therapeutic shoe coverage or standard Medicare coverage. In a sample of 3,428 patients followed for 12 months, overall Medicare payments were $451 (3.8%) higher for the treatment than for the control group, and payments specifically for foot care services were $318 (14.6%) higher for the treatment than for the control group, notably exceeding the entire allowable $118 shoe benefit. The study concluded, however, that there was a reasonable chance that the benefit was cost-neutral, and thus therapeutic shoes became a covered Medicare benefit in 1993[79].

Over the past two decades, studies focusing on amputation prevention used pre- and post-program comparisons[80,81]. A multidisciplinary diabetic foot clinic was established at King's College in London, England, and for 3 years the staff provided treatment and footwear to 239 diabetic patients with foot ulcers. Healing was achieved in 86% of neuropathic ulcers and 72% of ischemic ulcers. Ulcer recurrence was reported for 26% of patients with special shoes compared with 83% who wore their own shoes. A 50% reduction in amputation was observed comparing pre- and post-program amputation frequency[11].

In Memphis, TN, 556 individuals with diabetes were discharged from central hospital clinical care to an outpatient clinic close to their residence. After 7 years of followup, the pre- and post-intervention data suggested that total hospitalization was decreased by 47% and amputations by 69%. Costs were considerably lower due to reduced need for hospitalization[82]. A diabetes detection and control center, inpatient ward, outpatient clinics, and professional and patient teaching were implemented at Grady Memorial Hospital in Atlanta, GA. Amputation frequency decreased almost 50% comparing pre- and post-intervention findings over several years[83]. In summary, the preventive and educational interventions described above suggest available strategies to reduce development of diabetic foot ulcers and amputations.

ECONOMIC CONSIDERATIONS

Although the actual cost of diabetic foot problems in the United States is not known, several studies provide helpful information on related utilization and cost. Foot ulcers are an expensive problem, and, in fiscal year 1992 under DRG reimbursement code 271 (skin ulcer), Medicare received 23,352 inpatient claims averaging $10,171 and reimbursed hospitals on average $4,683 per case, or 46% of this amount (Table 18.16). Under DRG 271, private insurance patients were hospitalized nearly 50% longer, and the average reimbursement was $11,655 to hospitals and $434 to providers[84,85]. In one study of the U.S. economic costs of NIDDM, it was estimated that in 1986 "chronic skin ulcers" alone accounted for $150 million of the estimated $11.6 billion direct NIDDM costs[86]. This study did not report costs for peripheral neuropathy, peripheral vascular disease, or amputation.

The discharge status of diabetic individuals who underwent amputation in 1989-91 was monitored in Colorado[35]. The percentage of patients discharged to home or self-care declined from 66% for those age <45 years to 23% for those age ≥75 years. Conversely, as age increased, an increasing proportion required transfers from home or self-care to acute, skilled, and intermediate care facilities and other institutions for inpatient care[35].

The total charges and reimbursements for inpatients with LEAs are shown in Table 18.17 for private insurance and Medicare patients. These data indicate that the majority of all amputation claims submitted to Medicare are for DRG 113. The average hospital reimbursement for this DRG by private insurers was $26,940, compared with the Medicare reimbursement of $10,969. The average LOS was ~10% longer for private patients with lower limb amputations (DRG 113) than for Medicare patients, was similar for private and Medicare patients with toe and upper limb amputation (DRG 114), and was 14% shorter for private patients with "lower limb endocrinology amputations" than for Medicare patients[84,85]. The DRG gen-

Table 18.16

Charges and Reimbursements for Inpatients with Lower Extremity Conditions, 1992

DRG code	Code description	Private Insurance, 1992: Average $ physician payment	Private Insurance, 1992: Average LOS (days)	Private Insurance, 1992: Average $ reimbursed hospital	Medicare, FY 1992: No. of bills	Medicare, FY 1992: Average LOS (days)	Medicare, FY 1992: Average $ charged	Medicare, FY 1992: Average $ reimbursed hospital
12	Degenerative nervous system disorders, including Charcot foot	695	23.4	16,473	52,324	12.0	10,373	5,234
130	PVD, with complications, including varicose ulcer	566	7.8	7,406	77,251	7.8	7,781	3,354
131	PVD, without complications, including varicose ulcer	353	5.9	5,023	26,178	6.3	5,040	2,162
238	Osteomyelitis	560	9.3	9,162	7,139	13.2	12,651	5,945
263	Skin graft and/or debridement of ulcer or cellulitis, with complications	1,705	18.1	17,379	30,835	19.3	21,288	10,942
264	Skin graft and/or debridement of ulcer or cellulitis, without complications	1,663	10.2	10,972	3,946	11.1	10,845	4,994
271	Skin ulcers	434	17.8	11,655	23,352	12.0	10,171	4,683
277	Cellulitis, age >17 years, with complications, including septic arthritis	411	6.2	5,677	76,623	8.2	7,612	3,379
278	Cellulitis, age >17 years, without complications, including septic arthritis	271	4.5	3,992	25,514	6.1	4,917	2,143
287	Skin graft, debridement for endocrine disorders	1,290	14.4	14,037	6,939	18.4	19,708	9,501

LOS, length of stay; PVD, peripheral vascular disease; DRG, diagnosis related group. Private insurance excludes patients with Medicare and Medicaid and workers compensation claims.

Source: References 84 and 85

eral rehabilitation code 462 is widely used for all patients, including those with amputations who require subsequent hospitalization for physical therapy, gait training, and assistance to restore activities of daily living. The LOS is longer and reimbursement is greater for private insurance patients than for Medicare patients.

Systematic modifications in care of patients presenting with limb-threatening ischemia in 1984-90 were made at the New England Deaconess Hospital in Boston, MA. Based on the experience of 100 patients in 1984 and 96 patients in 1990, the frequency of diabetic amputation decreased from 44% to 7%, the frequency of popliteal and tibial bypass grafts remained constant, and the frequency of dorsalis pedis bypass grafts increased. The length of hospitalization decreased from 44.1 days for amputees and 34.1 days for bypass grafts recipients in 1984 to 22 days for both groups in 1990. The average bypass graft cost was

Table 18.17

Charges and Reimbursements for Inpatients with Lower Extremity Conditions and Rehabilitation, 1992

DRG code	Code description	Private Insurance, 1992: Average $ physician payment	Private Insurance, 1992: Average LOS (days)	Private Insurance, 1992: Average $ reimbursed hospital	Medicare FY 1992: No. of bills	Medicare FY 1992: Average LOS (days)	Medicare FY 1992: Average $ charged	Medicare FY 1992: Average $ reimbursed hospital
113	Lower limb amputation	2,436	20.3	26,940	39,287	18.4	23,978	10,969
114	Toe and upper limb amputation	1,215	11.9	12,879	8,119	11.6	13,107	6,003
285	Lower limb endocrinology amputation	1,545	16.1	19,911	6,064	18.4	22,444	11,115
462	Rehabilitation	976	23.9	21,536	197,876	16.0	14,413	7,719

LOS, length of stay; DRG, diagnosis related group. Private insurance excludes patients with Medicare and Medicaid and workers compensation claims.

Source: References 84 and 85

$19,808 in 1984 and $15,981 in 1990, while amputation costs were $20,248 in 1984 and $18,341 in 1990. The authors concluded that, despite the fact they were able to improve quality of care, maximize limb salvage, and reduce LOS and overall cost, their Medicare reimbursement was insufficient and resulted in an average loss of $7,480 per admission[87].

A southern California referral hospital computed costs for 94 patients undergoing lower extremity bypass graft procedures (35% with diabetes) and 53 patients undergoing primary below-the-knee amputation (56% with diabetes). The average cost (in 1985 dollars) was $23,500 for each subject having bypass surgery compared with $24,700 for those undergoing primary amputation, while the LOS averaged 17.6 days and 21.0 days, respectively[88].

Costs in 1984 dollars were reported in a follow-up study of 106 patients (diabetes status not specified) treated at a New England medical center for limb-threatening ischemia[89]. The average cumulative cost of care was $40,769 for a lower extremity bypass with a mean followup of 2.2 years, versus $40,563 for an amputation with a mean followup of 1.8 years, although subjects undergoing these procedures differed in severity of lower extremity ischemia. After presenting information on charges and costs, the authors concluded that DRG reimbursement closely approximated current cost (which equals 73.6% times the charge), or $19,932 for reconstruction and $19,241 for amputation[89].

CONCLUSIONS

The results of prospective research on diabetic foot ulcers indicate this outcome is related to poor glycemic control and longer diabetes duration. High foot pressure also appears related to this outcome, although inexpensive clinical means to measure this phenomenon have not been tested. Neuropathy in the lower extremities is also associated with the development of diabetic foot ulcers. The following important potential risk factors for diabetic foot ulcer have not been well studied prospectively: micro- and macrovascular circulation in the lower extremities, presence of autonomic neuropathy, foot anatomy and range of motion, abnormal plantar pressure, skin condition of lower extremities (edema, dry skin), gait abnormalities, x-ray deformities, self-care factors, and visual acuity. Examination of these factors is crucial to enhance understanding of diabetic foot ulcer pathophysiology and to enable the design of effective preventive interventions.

The analytic studies on pathophysiologic risk factors for LEA indicate strong evidence linking this outcome to lower extremity ischemia and peripheral neuropathy. Although relative risks are higher for factors related to ischemia, population-attributable risks may be higher for neuropathy, due to the high frequency of foot insensitivity in at-risk populations. Other documented risk factors include elevated glycated hemoglobin levels, history of foot ulcers, and retinopathy. Associations between diabetic amputation and smoking, hypertension, and total cholesterol are not conclusive. Although these factors may be very important early in the development of atherosclerotic disease, other risk factors more proximal in time to the amputation have higher relative risks.

Important standardization is needed in amputation data collection. Population-based numerator data currently do not indicate whether the left or right extremity was involved or whether an amputation is a first-event amputation, reamputation, new amputation, second leg amputation, or bilateral amputation. Greater precision in data collection would enhance our understanding of the problem in populations and increase our ability to target interventions to persons and groups at highest risk.

Additional prospective research is needed to address factors leading to amputation such as ulcer healing, management, and recurrence. Population-based research would benefit from modifications in NHDS sampling strategies to allow tracking of patients in selected areas over time. In nonrandomized analytic studies, control of co-morbidity and diabetes severity is needed to minimize bias. Population-based studies are needed to address rehabilitation aspects and long-term quality-of-life issues related to LEAs.

Nontraumatic lower extremity diabetic ulcers and amputations are an important and costly problem to patients, health care systems, and the U.S. government. To move toward the U.S. goal of a 40% reduction in amputations by the year 2000, as outlined in *Healthy People, 2000*[90], coordinated agency, interdisciplinary, clinician, and patient efforts are needed to implement strategies shown to be effective in reducing the impact of this problem.

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APPENDIX

Appendix 18.1
Definitions

Ulcer: A cutaneous erosion characterized by a loss of epithelium that can extend to or through the dermis to involve deeper tissues. Although ulcers may result from various etiologic factors, they are characterized by an inability to self-repair in a timely and orderly manner.

Amputation: Removal of the terminal, nonviable portion of an extremity.

First-event amputation: The first primary amputation in an individual irrespective of side and level.

Reamputation: Amputation of an extremity with a prior unhealed amputation that involves limb shortening.

Amputation revision: Modification of an existing amputation not involving important bone shortening, e.g., scar revision or removal of bone spur.

New amputation: Amputation of an extremity with a prior healed amputation (ipsilateral).

Second leg amputation: Amputation in a patient with prior contralateral leg amputation.

Bilateral amputation: Simultaneous amputation of both lower extremities, irrespective of level.

Source: Amputation definitions are adapted from Reference 1.