Diabetes and Lower-Limb Amputations in the Community

A retrospective cohort study

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OBJECTIVE — There are few U.K. data on the incidence rates of amputation in diabetic subjects compared with the nondiabetic population.

RESEARCH DESIGN AND METHODS — We performed a historical cohort study of first lower-extremity amputations based in Tayside, Scotland (population 364,880) from 1 January 1993 to 31 December 1994. The Diabetes Audit and Research in Tayside Scotland (DARTS) database was used to identify a prevalence cohort of 7,079 diabetic patients on 1 January 1993. We estimated age-specific and standardized incidence rates of lower-limb amputations in the diabetic and nondiabetic cohorts. Results were compared with a previous study that evaluated lower-extremity amputations in diabetic patients in Tayside in 1980–1982.

RESULTS — There were 221 subjects who underwent a total of 258 nontraumatic amputations. Of the 221 subjects, 60 (27%) patients were diabetic (93% NIDDM), and 63% were first amputations. The median duration of diabetes was 6 years (range: newly diagnosed to 41 years). Nonhealing ulceration (31%) and gangrene (29%) were the two main indications for amputation in the diabetic subjects. Of the 161 nondiabetic subjects, 140 (80%) underwent first amputations. The adjusted incidences in the diabetic and nondiabetic groups were 248 and 20 per 100,000 person-years, respectively. Tayside patients with diabetes thus had a 12.3-fold risk of an amputation compared with nondiabetic residents (95% CI 8.6–17.5). The estimated proportion of diabetic patients in the population rose from 0.81% in 1980–1982 to 1.94% in 1993–1994, whereas the absolute rate of amputation in diabetic subjects was unchanged from that in 1980–1982.

CONCLUSIONS — These population-based U.K. amputation data are similar to amputation rates in the U.S. Amputation rates appear to have decreased significantly since 1980–1982. The impact of diabetes education and prevention programs that target the processes leading to amputation can now be evaluated.

Lower-extremity amputation (LEA) in patients with diabetes is associated with high postoperative mortality (1), a high rate of secondary amputation (2,3), and considerable health care costs (4). Despite the significant health burden of LEA in diabetic patients, there are few studies on its incidence in the community setting. Available data show marked variation among different areas and ethnic groups (4–6) and are difficult to compare because of the lack of population estimates of diabetes prevalence and the lack of a standardized approach to data presentation (7). In Europe, a reduction in amputations related to diabetes of at least one-half within 5 years was a declared aim of the St. Vincent Declaration (8), and the U.S. Government has set a target of a reduction of 40% by the year 2000 (9). Clearly, standardized, population-based data on LEA associated with diabetes are urgently required if these targets are to be realized.

The aim of this study was to use the Diabetes Audit and Research in Tayside Scotland (DARTS) database (10) to perform a retrospective cohort study to achieve the following: *1*) determine the incidence of LEA in people with diabetes by clinical type in 1993–1994, *2*) to calculate the increased risk (rate ratio) of LEA associated with diabetes compared with that in Tayside residents without diabetes, and *3*) to evaluate changes in amputation rates by comparing these data with a previous study that evaluated the epidemiology of diabetes-associated LEA in Tayside in 1980–1983 (4).

RESEARCH DESIGN AND METHODS — The study population comprised a prevalence cohort of 364,880 residents of Tayside, Scotland who were registered with a Tayside general practitioner in January 1993 and who were either still alive in December 1994 or had died in Tayside during this period. Tayside is a geographically compact region in which health care is administered by 278 general practitioners in 78 practices and four Health Care Trusts.

Patient identification

Every patient who is registered with a general practitioner in Scotland is allocated a unique identifying number known as the Community Health Number (CHNo). This is a 10-digit integer, the first 6 digits being the patient's date of birth. Every resident of Tayside who is registered with a general practitioner appears in the centrally held, continually updated computerized record, the Community Health Master Patient Index. This file contains data on address,

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Abbreviations: AR%, attributable risk percent; CHNo, Community Health Number; DARTS, Diabetes Audit and Research in Tayside Scotland; LEA, lower-extremity amputation; MEMO, Medicines Monitoring Unit; PAR%, population attributable risk percent; SMR1, Scottish Morbidity Record 1.

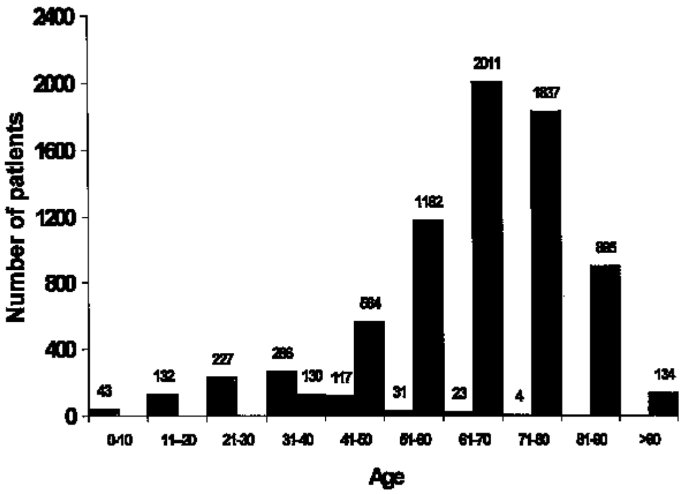

Figure 1—*Distribution of diabetes in Tayside.* ▒, *patients with IDDM;* ■, *patients with NIDDM.*

postcode, practitioner, deceased persons, and date of death. Thus, the demographic breakdown of the Tayside population, deaths, and patient migration can be easily analyzed using these data. The CHNo is used as the patient identifier in all health care activities in Tayside, whether primary or hospital inpatient care.

Data sources for diabetes ascertainment

Diabetic patients were identified by the DARTS/Medicines Monitoring Unit (MEMO) Collaboration. DARTS has been described in detail elsewhere (10). In brief, electronic capture-recapture record linkage of eight diabetes-related data sources has created a diabetes information system for Tayside. Data sources include all hospital diabetes clinics, all cashed prescriptions for diabetes medication and monitoring equipment as ascertained by MEMO (11), hospital discharge data, the community-based mobile diabetic eye screening facility (12), and all HbA_{1c} and plasma glucose results from the regional biochemistry database. Every one of these data sources identifies patients by the CHNo. Validation of our methodology shows DARTS to be 97% sensitive, with a positive predictive value of 97% for the diagnosis of diabetes (10). The World Health Organization criteria for the diagnosis of diabetes were used as the gold standard of comparison.

For the purpose of this study, individuals were classified as having IDDM if aged 0–35 years at diagnosis and treated with insulin and as having NIDDM if treated by diet or oral hypoglycaemic agents or if aged >35 years at diagnosis, irrespective of treatment.

Case definition

An LEA was defined as the complete loss in the transverse anatomical plane of any part of the lower limb. Two possible sources of subjects were used to maximize ascertainment. The primary data source was the Scottish Morbidity Record 1 (SMR1) database. When patients are discharged from a hospital in Tayside, codes for their diagnoses (*International Classification of Diseases, Ninth Revision*) are entered on the Tayside section of the SMR1 database, with the CHNo as an identifier. Details of all admissions since 1980 are held within MEMO. The CHNo allows for the temporal linking of diabetes-specific data with admissions. A case was defined to be any patient within the study population who had any LEA (*Operating and Coding Procedures, Version 4* [OPCS4] codes X09, X093–095, X10, X101, X11, X111, X112, X118–119) in a Tayside hospital during the 2-year study period. The secondary source was an independent computerized database of all patients attending the Dundee Limb Fitting Centre, which provides a rehabilitation service for the whole of Tayside (13).

An experienced research field worker reviewed the original hospital case records in all Tayside hospitals to validate the site and indication for LEA and to record information on clinical and demographic characteristics, including diabetes treatment type, duration of diabetes, comorbidity, and social status.

Amputation classification

Side, level, and date of LEA were recorded for each procedure. LEA level was defined as one of the following: partial toe(s), whole toe(s), partial foot, ankle disarticulation, transtibial, knee disarticulation, or transfemoral. A minor amputation was defined as any LEA distal to the ankle joint; a major amputation was any LEA through or proximal to the ankle joint. Underlying diseases and primary indications for LEA were ascertained. Patients who had LEA as a result of trauma or tumor were excluded.

Statistical analysis

Age- and sex-specific episode incidence rates for all LEAs and for all first major and all first minor LEAs were calculated for the Tayside general population and the cohort of

Table 1—*Age and sex breakdown of all diabetic and nondiabetic amputees*

	Male	Female	Total (male + female)	Diabetic			Nondiabetic		
				Male	Female	Total	Male	Female	Total
Age (years)									
<40	8	3	11	1	0	1	7	3	10
40–59	19	9	28	8	1	9	11	8	19
60–79	87	53	140	27	11	38	60	42	102
80+	16	26	42	6	6	12	10	20	30
Median age (range)	68 (14–93)	74 (15–95)	71 (14–95)	68 (34–88)	74 (52–87)	70 (34–88)	68 (14–93)	74 (15–95)	71 (14–95)
Total amputees	130	91	221	42	18	60	88	73	161

Table 2—*Frequency by amputation type of first and all lower-limb amputations in both diabetic and nondiabetic patients*

	Frequency			
	First amputations		All amputations	
	Diabetic	Nondiabetic	Diabetic	Nondiabetic
Amputation				
Major				
Transfemoral	4 (7.7)	15 (10.7)	5 (6)	20 (11.4)
Knee disarticulation	0 (0)	4 (2.9)	1 (1.2)	6 (3.4)
Transtibial	24 (46.2)	55 (39.3)	45 (54.2)	70 (40)
Ankle disarticulation	1 (1.9)	2 (1.4)	3 (3.6)	2 (1.1)
Total	29 (55.8)	76 (54.3)	54 (65)	98 (55.9)
Minor				
Partial foot	1 (1.9)	1 (0.7)	1 (1.2)	1 (0.6)
Whole toe(s)	21 (40.4)	62 (44.3)	27 (32.5)	74 (42.3)
Partial toe(s)	1 (1.9)	1 (0.7)	1 (1.2)	2 (1.1)
Total	23 (44.2)	64 (46.7)	29 (34.9)	77 (44)
Total amputations	52 (100)	140 (100)	83 (100)	175 (100)

Data are *n* (%).

patients with diabetes by means of person-years analysis (14), and 95% CIs were determined assuming the incidence of LEAs followed a Poisson distribution. Incidence rates were directly age- and sex-adjusted to the 1994 population of Scotland. The rate ratio was calculated as the ratio of the LEA rate in the diabetic cohort to the rate of the LEA in the Tayside general population without diabetes. To calculate the percentage of LEAs attributable to diabetes in diabetic patients, the attributable risk percent (AR%) was calculated. This estimates the proportion (expressed as a percent) of the LEAs in diabetic patients that would be eliminated by eliminating diabetes as a disease. The percentage of LEAs in the study population that are attributable to diabetes was expressed as a population attributable risk percent (PAR%). This expresses that proportion of LEA in the study population (both diabetic and nondiabetic) that is attributable to diabetes and thus would be eliminated if diabetes was eliminated (15). The results were compared with a previous record-linkage study that examined the incidence of LEA in Tayside in 1980–1983 (4).

RESULTS — From the study population of 364,880 Tayside residents, DARTS identified 7,079 eligible patients with diabetes. The distribution of patients with NIDDM and IDDM is shown in Fig. 1. The prevalences of IDDM and NIDDM were 0.21 and 1.73%, respectively.

We identified 229 subjects who had undergone LEA during the study period of 1 January 1993 to 31 December 1994, of which 225 were ascertained by the SMR1 record. The remaining four subjects with LEA were identified by the limb-fitting center records only. By using both manual and electronic data-gathering techniques, information on all 229 patients was recorded. Of these, eight were excluded: four because LEA could not be confirmed in the primary medical records, and four because the etiology was trauma or tumor. There were, therefore, 221 valid patients who underwent a total of 258 amputations. Of the 221 subjects, 176 case records were easily retrieved and manually validated. Analysis of these records confirmed record-linkage databases to be 97% accurate for the diagnosis, site, and etiology of LEA. We thus used all 221 cases in the analyses. Of the 221 subjects, 60 (27%) patients were diabetic, of whom 4 (6.7%) had IDDM and 56 (93.3%) NIDDM. Median duration of diabetes was 6 years (range: newly diagnosed to 41 years). There were 161 (73%) subjects who were not diabetic. Table 1 shows the age and sex breakdown of amputees in the Tayside population for 1993–1994.

Type and indication for amputation

The 60 subjects with diabetes underwent a total of 83 LEAs, 52 (63%) of which were first LEAs. In the nondiabetic population, 161 subjects underwent 175 LEAs, 140 (80%) of which were first LEAs. Diabetic patients were, therefore, more likely to undergo surgical revision, amputations of more of the leg or of another leg: 37% of diabetic patients underwent further surgery compared with 20% of the nondiabetic

Table 3—*Frequency of etiologies preceding first and all amputations in both diabetic and nondiabetic groups*

	Frequency			
	First amputation		All amputations	
	Diabetic	Nondiabetic	Diabetic	Nondiabetic
Etiology				
Vascular				
Claudication	1 (1.9)	12 (8.6)	1 (1.2)	12 (6.9)
DVT	0 (0)	1 (0.7)	0 (0)	1 (0.6)
Ischemia	6 (11.5)	16 (11.4)	14 (16.9)	23 (13.1)
Necrosis	0 (0)	1 (0.7)	0 (0)	1 (0.6)
PVD	9 (17.3)	25 (17.9)	13 (15.7)	38 (21.7)
Ulceration	16 (30.8)	25 (17.9)	26 (31.3)	29 (16.6)
Infective				
Cellulitis	2 (3.8)	0 (0)	2 (2.4)	0 (0)
Gangrene	15 (28.8)	27 (19.3)	23 (27.7)	32 (18.3)
Infection	1 (1.9)	1 (0.7)	2 (2.4)	2 (1.2)
Osteopathology				
Bone deformity	1 (1.9)	24 (17.1)	1 (1.2)	27 (15.4)
Osteoarthritis	0 (0)	2 (1.4)	0 (0)	2 (1.2)
Rheumatoid arthritis	0 (0)	1 (0.7)	0 (0)	1 (0.6)
Neurological				
Pain	1 (1.9)	5 (3.6)	1 (1.2)	7 (4)
Total	52 (100)	140 (100)	83 (100)	175 (100)

Data are *n* (%). DBT, deep venous thrombosis; PVD, peripheral vascular disease.

Table 4—*Diabetic and nondiabetic first amputations rates in Tayside between January 1993 and December 1994*

		Amputations		Incidence density (per 10^5 person-years)			Attributable risk	
	Total	Nondiabetic	Diabetic	Nondiabetic (IDn)	Diabetic (IDd)	Rate ratio (RRd)	AR%	PAR%
Age (years)								
Males								
>40	7	6	1	3.19	106.38	33.35 (4.03–276.69)	97.00	13.86
40–59	16	9	7	9.65	342.13	35.45 (13.23–95.05)	97.18	42.52
60–79	76	53	23	90.11	618.96	6.87 (4.22–11.18)	85.44	25.86
80+	16	10	6	108.98	890.21	8.17 (2.99–22.34)	87.76	32.91
Total	115	78	37	22.32	501.63	22.47 (15.22–33.20)	95.55	30.74
Males adjusted by age	—	—	—	23.07	280.80	12.17 (8.74–16.95)	92.11	—
Females								
>40	3	3	0	1.70	0.00	—	—	—
40–59	6	5	1	5.36	69.54	12.97 (1.52–110.83)	92.28	15.38
60–79	44	35	9	46.75	266.90	5.71 (2.75–11.86)	82.49	16.87
80+	24	19	5	86.68	405.84	4.68 (1.75–12.50)	78.63	16.38
Total	77	62	15	16.94	221.17	13.06 (7.44–22.93)	92.34	17.99
Females adjusted by age	—	—	—	17.36	188.02	10.83 (7.32–16.03)	91.49	—
Total population	192	140	52	19.56	367.28	18.78 (13.67–25.79)	94.67	25.64
Total population adjusted by age and sex	—	—	—	20.10	247.91	12.33 (8.64–17.52)	92.00	—

Data are *n* or *n* (95% CI). IDn, incidence density of all nondiabetic lower-limb amputations per 10^5 person-years; IDd, incidence density of all diabetic lower-limb amputations per 10^5 person-years; RRd, relative risk of diabetic versus nondiabetic population (IDd/IDn).

population. There were seven sites of LEA identified. Table 2 shows the frequency by site, including major and minor criteria, of first and all LEAs recorded in the two groups. The 13 different indications for LEA are shown in Table 3. The two main indications for first LEA in the diabetic subjects were nonhealing vascular ulceration (31%) and gangrene (29%).

Incidence and relative risk of LEA and comparison with LEA in 1980–1982

The age- and sex-standardized incidence densities of LEA, relative risk, and attributable risk of diabetes for first LEA are shown in Table 4. More than 28% of all LEAs in the population were attributable to diabetes. In people with diabetes, 92% of the amputations are directly attributable to diabetes. The age- and sex-standardized incidence densities and relative risks of major and minor LEA are shown in Table 5. The crude episode rate of first LEA for diabetic subjects was 367 per 100,000 person-years, compared with 20 per 100,000 patient-years in nondiabetic subjects. Table 6 shows the diabetes-related and unrelated LEAs performed in Tayside in 1980–1982 (4) and 1993–1994.

CONCLUSIONS

— There are few data from population studies of amputation in diabetes. This study provides information on incidence densities of LEAs, as well as the relative and attributable risks of LEA associated with diabetes, in the Tayside region of Scotland. To the best of our knowledge, these are the first longitudinal data on the incidence of amputation in a defined population achieved by comparing our results with a previous record-linkage study of LEA performed in Tayside in 1980–1982.

We believe that our results are a true reflection of LEA rates in the community for three reasons. First, we have previously shown that the DARTS capture-recapture methodology maximizes case ascertainment of diabetes in the community with 97% sensitivity and a positive predictive value of 97% for the diagnosis of diabetes (10). We therefore believe the denominator of diabetes prevalence is a true reflection of known diabetes. However, given the often subclinical nature of NIDDM, it is possible that some individuals with this condition have not been identified. Second, because all health care activities in Tayside are identified by the CHNo and are documented in the medical records, we believe that LEA case ascertainment was not biased in this study. The accuracy of hospital discharge coding was confirmed by the hospital case record validation. The completeness of ascertainment was confirmed by independent validation of cases with the records of the local limb-fitting center. Although some amputations at the transphalangeal level, especially if associated with other surgical interventions, may not have been coded adequately, it is likely that any major amputation would have been registered and coded and would therefore be noted in the medical record. Third, the residents of Tayside live in a well-defined geographical area of both rural and inner-city communities with a low rate of migration.

Our study does have some limitations. The most important consideration is that the population studied is a prevalence cohort of patients who survived to 1 January 1993. We could not determine how many patients with diabetes died before the study was conducted, and therefore the cohort was selected for those surviving with diabetes.

Our data confirm the findings of previous studies that gangrene and nonhealing ulceration are major factors in the final causal pathway leading to amputation (16–18), that the median age of diabetic

Table 5—*Data on both diabetic and nondiabetic first major and first minor amputations in Tayside between January 1993 and December 1994*

		Amputations				Incidence density (per 10^5 person-years)				Rate ratio (95%CI)	
		Major		Minor		Major		Minor			
	Total	Nondiabetic (n^+)	Diabetic (d^+)	Nondiabetic (n^-)	Diabetic (d^-)	Nondiabetic (IDn^+)	Diabetic (IDd^+)	Nondiabetic (IDn^-)	Diabetic (IDd^-)	Major (RRd^+)	Minor (RRd^-)
Age (years)											
Males											
<40	7	2	1	4	0	1.06	106.38	2.13	0.00	100.36 (9.09–1102.34)	—
40–59	16	5	5	4	2	5.36	244.38	4.29	97.75	45.59 (13.22–157.27)	22.79 (4.18–124.34)
60–79	76	31	15	22	8	52.70	403.66	37.40	215.29	7.66 (4.14–14.16)	5.76 (2.57–12.91)
80+	16	7	2	3	4	76.29	296.74	32.69	593.47	3.89 (0.81–18.65)	18.15 (4.08–80.78)
Total	115	45	23	33	14	12.87	311.82	9.44	189.80	24.23 (14.67–39.98)	20.11 (10.77–37.53)
Males adjusted by age	—	—	—	—	—	13.33	200.59	9.73	170.69	15.05 (9.94–22.79)	17.54 (10.98–28.03)
Females											
<40	3	0	0	3	0	0.00	0.00	1.70	0.00	—	—
40–59	6	1	0	4	1	1.07	0.00	4.29	69.54	—	16.21 (1.81–144.81)
60–79	44	18	4	17	5	24.04	118.62	22.70	148.28	4.93 (1.67–14.56)	6.53 (2.41–17.68)
80+	24	12	2	7	3	54.74	162.34	31.93	243.51	2.97 (0.67–13.22)	7.63 (1.98–29.42)
Total	77	31	6	31	9	8.47	88.47	8.47	132.70	10.45 (4.36–25.02)	15.67 (7.47–32.89)
Females adjusted by age	—	—	—	—	—	16.58	128.60	8.64	121.51	7.76 (5.04–11.95)	14.06 (8.33–23.74)
Total population	192	76	29	64	23	10.62	204.83	8.94	162.45	19.29 (12.58–29.56)	18.17 (11.29–29.24)
Total population adjusted by age and sex	—	—	—	—	—	14.48	184.66	9.17	144.18	12.75 (8.43–19.29)	15.72 (9.58–25.80)

Data are *n* or *n* (95% CI). IDn^+, incidence density of all nondiabetic major lower-limb amputations per 10^5 person-years; IDd^+, incidence density of all diabetic major lower-limb amputations per 10^5 person-years; IDn^-, incidence density of all nondiabetic minor lower-limb amputations per 10^5 person-years; IDd^-, incidence density of all diabetic minor lower-limb amputations per 10^5 person-years; RRd^+, relative risk of major amputation in diabetic versus nondiabetic population (IDn^+/IDd^+); RRd^-, relative risk of minor amputation in diabetic versus nondiabetic population (IDn^-/IDd^-).

LEA is ~70 years (19–21), and that there is a significantly higher incidence of LEA in men than in women (17). Our data also confirm previous reports that >90% of LEA associated with diabetes occurs in people with NIDDM (19). The calculated risks of LEA derived from our study are, therefore, applicable primarily to people with NIDDM, and few conclusions can be made regarding people with IDDM. Our data also suggest that people with diabetes are at increased risk of further surgery (19), with 37% of amputations in diabetic patients being a revision or second LEA, compared with 20% in the nondiabetic population. In our study, we excluded LEA associated with trauma and tumor from the analyses because these were not thought to be diabetes-related. Excluding them could theoretically lead to an underestimation of the incidence of LEA and, thus, an overestimation of the risk associated with diabetes. Because only four cases of LEA were excluded for these reasons, however, we do not think this had a significant impact on our study. Furthermore, the rate of first LEA in our study is similar to that reported in the most comprehensive study of LEA in North America (19). For example, the age- and sex-adjusted incidence of major amputation in diabetic patients in our study and in the Rochester study were 248 and 274 per 100,000 person-years, respectively. Other estimates of the incidence of LEA in diabetes have varied, depending on the methods used and the populations studied. A major problem in previous studies has been lack of data on the diabetic population, resulting in the use of estimates of diabetes prevalence for incidence calculations (20–22) and the use of a single data source for the ascertainment of cases (21).

Table 6—*Rates and relative risks of becoming a major amputee in 1980–1982 compared with 1993–1994*

	Diabetes prevalence (%)	Diabetic amputees *n*	Diabetic amputees Median age	Diabetic amputees % of all amputees	Nondiabetic amputees *n*	Nondiabetic amputees Median age	Rate ratio
1980–1982	0.81	93	70	27	250	73	46
1993–1994	1.94	52	70	27	140	70	19

Rate ratio data are not adjusted for age.

To the best of our knowledge, these are some of the first longitudinal data on first LEA rates in a defined population. A previous study in 1980–1982 (4) used identical record-linkage methods to identify first LEAs in Tayside but estimated the prevalence of known diabetes by sending a questionnaire to a random sample of general practitioners asking for numbers of diabetic patients by age, sex, and treatment type. The estimated proportion of diabetic subjects in the population rose from 0.81% in 1980–1982 to 1.94% in 1993–1994. This increase may be explained partly by a better ascertainment of diabetes in 1993–1994 but most probably indicates that the prevalence of diabetes has risen and that the rate of LEA in people with diabetes has fallen considerably. Thus, the prevalence and number of diabetic patients at risk has more than doubled in the interval, whereas the number of LEAs among diabetic patients has fallen. This may well reflect changes in medical care between 1980–1982 and 1993–1994. Although the methodologies used in the two studies were not identical, we conclude that the LEA rate in diabetic patients has decreased significantly since 1980–1982.

In summary, these data indicate that >90% of all diabetes-related LEAs occur in people with NIDDM. Furthermore, the risk of undergoing an LEA when compared with that in individuals without diabetes, was increased >18-fold, and >25% of all amputations were attributable to diabetes. Initial comparison with amputation rates in 1980–1982 suggest no change in the mean age of amputation but a significant improvement in the underlying amputation rate in diabetes. In an effort to reduce the population burden of diabetes morbidity, the St. Vincent Declaration has set a goal of reducing amputation rates by 50% (8). Clearly, methods are urgently required to allow precise monitoring of outcomes defined by the declaration in defined populations. Our study shows the benefits of record linkage and capture-recapture methodology in defining population-based outcomes of diabetes care.

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