Diabetes- and Nondiabetes-Related Lower Extremity Amputation Incidence Before and After the Introduction of Better Organized Diabetes Foot Care

Continuous longitudinal monitoring using a standard method

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OBJECTIVE — There is a lack of continuous longitudinal population-based data on lower extremity amputation (LEA) in the U.K. We present here accurate data on trends in diabetes-related (DR) LEAs and non-DRLEAs in the South Tees area over a continuous 5-year period.

RESEARCH DESIGN AND METHODS — All cases of LEA from 1 July 1995 to 30 June 2000 within the area were identified. Estimated ascertainment using capture-recapture analysis approached 100% for LEAs in the area. Data were collected longitudinally using the standard method of the Global Lower Extremity Amputation Study protocol.

RESULTS — Over 5 years there were 454 LEAs (66.3% men) in the South Tees area, of which 223 were diabetes related (49.1%). Among individuals with diabetes, LEA rates went from 564.3 in the first year to 176.0 of 100,000 persons with diabetes in the fifth year. Over the same period, non-DRLEAs increased from 12.3 to 22.8 of 100,000 persons without diabetes. The relative risk of a person with diabetes undergoing an LEA went from being 46 times that of a person without diabetes to 7.7 at the end of the 5 years. The biggest improvement in LEA incidence was seen in the reduction of repeat major DRLEAs.

CONCLUSIONS — Our data show that in the South Tees area at a time when major non-DRLEA rates increased, major DRLEA rates have fallen. These diverging trends mark a significant improvement in care for patients with diabetic foot disease as a result of better organized diabetes care.

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Diabetic foot disease is a common complication of diabetes with major worldwide implications (1). Lower extremity amputation (LEA) remains an all too common outcome of this complication (2–5). A major LEA in a person with diabetes profoundly affects his or her independence and future health (6,7). Financially, major LEAs are expensive because of the need for multiple and extended hospitalizations (8).

Authors have reported regularly on LEA rates (5,9–15), but consistent methodology was rarely used (16). Interesting data from different studies are thus available, but direct comparison is difficult.

To allow for more ready comparison of LEA rates between centers, the Global Lower Extremity Amputation Study (GLEAS) group through collaboration developed a standard protocol for LEA data collection (3). The GLEAS protocol describes a standard methodology that centers can use to arrive at population-based diabetes-related (DR) LEA and non-DRLEA rates for their own particular areas. An important point about the GLEAS protocol is that it allows for an estimation of ascertainment of all LEAs to be made so that the completeness of data collected can be assessed.

The South Tees area in the U.K. was part of the original 10-center comparative study using the GLEAS protocol (17). Of the 4 U.K. centers that took part in the original GLEAS study, the South Tees area was found to have by far the highest rate of major DRLEAs (18). In response to these findings, the team in the South Tees area reviewed and significantly altered its provision of diabetes foot care. An initiative called "Feet First" identified gaps in knowledge and practice of foot care in people with diabetes in the South Tees area. The team was restructured, with diabetic foot care overseen by a diabetologist (W.F.K.) who developed the multidisciplinary team, including an important community diabetic chiropody element, along with establishment of care pathways and protocols for managing diabetic foot problems. After completion of the GLEAS study and the implementation of these changes, data were collected for 3 more years in the South Tees area.

Here, we present data on trends in DRLEAs and non-DRLEAs in the South Tees area over a continuous 5-year period. There is a lack of continuous population-based LEA data in the U.K., and this study, to our knowledge, is the longest and most thorough LEA longitudinal incidence study to date for the U.K. The data are a real reflection of trends in LEAs in this community because of the thoroughness of the data collection, the use of valid local diabetes prevalence figures, and the high levels of ascertainment. Data are readily applicable, as they have been collected using a standard methodology and include a nondiabetes comparator.

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Abbreviations: DR, diabetes related; GLEAS, Global Lower Extremity Amputation Study; HES, hospital event statistics; LEA, lower extremity amputation.

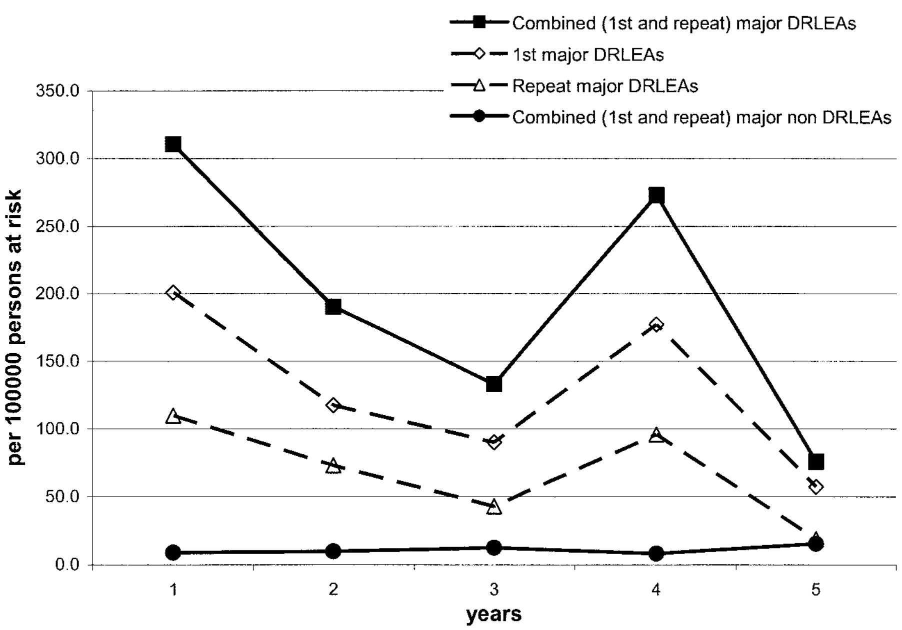

Figure 1—*Year on year change in major LEA rates for individuals with diabetes (first and repeat major DRLEAs are shown separately and combined) and without diabetes (first and repeat major non-DRLEAs are shown as combined only).*

RESEARCH DESIGN AND METHODS

— The South Tees area is an industrialized area in the North of England, bordered by the North Sea, the river Tees, and the North Yorkshire Moors. Middlesbrough is its main urban center. At the 2001 census, the South Tees area had a population of 273,987, which was predominantly white Caucasian (96.4%). It is an area of high long-term unemployment. Of the population, 7.0% are aged >75 years, below the average for England and Wales of 7.6% (19).

Case definition

Materials and methods as per the GLEAS protocol have been published previously (17). LEA was defined as complete loss of any part of the lower limb for any reason, in the following anatomical planes: in the transverse anatomical plane proximal to and including the subtalar joint and in the frontal anatomical plane distal to the subtalar joint. A major LEA was defined as through or proximal to the tarsometatarsal joint and a minor LEA as distal to this joint. First LEA refers to the first event in any patient, as it is felt that this is the main event any service is trying most to prevent. The first major LEA in a patient is defined as that which occurs after an earlier minor LEA. Subsequent events after a first major LEA are repeat events when a new level was attained at a later date including an LEA on the contralateral limb. The GLEAS protocol records previous LEAs even if they occurred before the study period. Repeat events were LEAs for a person who had a previous LEA at any time that was separate from the original event in time and the level at which it occurred. Patients undergoing amputation as a result of trauma alone were excluded.

Data collection

All LEAs from 1 July 1995 to 30 June 2000 within the South Tees area were identified. Four independent data sources (operating theater records, limb fitting center records, hospital discharge data, and community diabetes register) were used to identify patients. LEAs were categorized as first and repeat, major and minor, diabetes related, and nondiabetes related.

A standardized data extraction form was completed from patients' medical records including age, sex, postcode, ethnicity, smoking habit, first or subsequent LEA, diabetes status, side of LEA, duration of diabetes, insulin treatment, and level of LEA. LEA rates were calculated for sex; 20-year age bands; and first, repeat, major, and minor events for individuals with and without diabetes. Completeness of the dataset was estimated using capture-recapture methodologies (20). Estimated ascertainment approached 100% for LEAs in the South Tees area. This estimate of ascertainment is based on identified cases matching the number of estimated cases along with narrow 95% CI for estimated cases.

Population

The denominator populations for non-DRLEAs were 1996 midyear estimates based on 1991 U.K. census data less the population with diabetes. The South Tees area has a high-quality community-based diabetes register as described previously (21). It has been in operation since 1994 and identifies the local population known to have diabetes. Diabetes prevalence for each year was derived from the community diabetes register and was used to calculate DRLEA rates. An age-standardized diabetes prevalence of 1.74% in 1994 for the South Tees area is in keeping with other comparable determinations of diabetes prevalence at the time (22,23). The European standard population as defined by the World Health Organization in 1993 was used for direct age standardization (24).

Statistics

As the measured incidences are for a whole geographical population and not a sample of that population, CIs have not been calculated for incidence. Where shown, 95% CIs were calculated using the confidence interval analysis program (25). A two-sided $P < 0.05$ was considered statistically significant.

RESULTS

— Over 5 years, there were 454 LEAs (66.3% men) in the South Tees area, of which 223 were diabetes related (49.1%). Most LEAs occur in elderly individuals, with 73.6% in individuals aged ≥60 years (70.4% DRLEA and 76.6% non-DRLEA, $P > 0.05$). There was an excess of LEAs in men. Among individuals with diabetes, the male-to-female ratio was 2.91 (95% CI 2.49–3.39), whereas among individuals without diabetes it was half this with a male-to-female ratio of 1.41 (1.18–1.66)). There was an excess of minor LEAs among individuals with diabetes with the minor-to-major ratio being twice that of individuals without diabetes (minor-to-major ratio DRLEAs 1.05 [95% CI 0.86–1.26] vs. non-DRLEAs 0.51 [0.4–0.64]).

All LEAs (i.e., major, minor, first, and repeat)

Among individuals with diabetes, LEA rates went from 564.3 of 100,000 persons with diabetes in the first year to 176.0 of 100,000 persons with diabetes in the fifth

Table 1—*Annual incidence of major LEA for persons with and without diabetes*

Year	DRLEA: major			Non-DRLEA: major		
	First	Repeat	Combined	First	Repeat	Combined
1995–96	200.8	109.7	310.5	7.3	1.4	8.7
1996–97	117.2	72.9	190.2	7.1	2.5	9.6
1997–98	90.1	42.9	132.9	9.6	2.8	12.4
1998–99	177.1	95.8	272.8	4.9	3.1	8.1
1999–00	57.2	18.7	75.8	11.0	4.3	15.3

Data are incidence of 100,000 persons at risk.

year. For non-DRLEAs there was an increase from 12.3 to 22.8 of 100,000 persons without diabetes. The relative risk of a person with diabetes undergoing any LEA went from being 46 times that of a person without diabetes at the start of the study to being only 7.7 times that of a person without diabetes at the end of the 5 years.

DRLEAs

Looking at LEAs among person with diabetes, major DRLEAs make up the main component of the improvement seen. First major and repeat major DRLEA rates fell in parallel (Fig. 1). The downward trend was not consistent throughout the 5 years, and in year 4 there was a rise in first and repeat major DRLEAs. Minor DRLEA rates did not significantly change over the 5 years. Although going from 253.8 of 100,000 persons with diabetes in year 1 to 100.5 in year 5, this difference was offset by a peak in year 4 at 362.9.

Non-DRLEAs

There was a rise in major non-DRLEA rates over the 5 years. First major non-DRLEAs and repeat major non-DRLEA rates combined are shown (Fig. 1). The rise in repeat major non-DRLEA rates is more significant than that for first major non-DRLEAs (Table 1).

Repeat LEAs

Among individuals with diabetes, the biggest improvement in LEA rates was seen in the repeat major events (Fig. 1). Repeat minor DRLEA rates over the 5 years remained stable. The repeat major non-DRLEA rate more than tripled when the first year of the study is compared with the fifth year (Table 1). Repeat minor non-DRLEA rates over the 5 years also increased significantly.

DRLEA rates were high in the South Tees area at the start of the 5-year study period. In the South Tees area the relative risk for a person with diabetes undergoing a major LEA (either a first or repeat event combined) was 35.5 times that of a person without diabetes at the start of the study and, by the end of the 5 years, the relative risk had fallen to 5.0.

CONCLUSIONS

— Ultimately, a person with diabetes should have an LEA risk approaching that of a person without diabetes. At the start of the 5-year study period the chance of a person with diabetes undergoing an LEA was 46.0 (95% CI 25.7–90.6) times that of a person without diabetes. The chance of a person with diabetes undergoing a major LEA was still 35.5 (18.9–76.8) that of a person without diabetes. By the end, the risk of a person with diabetes undergoing any LEA or a major LEA was down to 7.7 (4.99–12.9) and 5.0 (2.82–9.43) times that of a person without diabetes.

The fall in DRLEAs overall has been achieved through a far greater reduction in major DRLEAs compared with minor DRLEAs. The significance of the fall in major DRLEAs is increased by the rise in major non-DRLEA events particularly because of the rise in repeat major non-DRLEAs.

The variation in annual LEA rates in the later years of the study is interesting. It reflects the results seen in other studies that have shown a falling trend or stable trend with time but associated with large year-to-year variation in LEA incidence (15,26). To smooth out year-to-year variation, we calculated 3-year rolling averages. For combined (first and repeat) major DRLEAs, the first 3-year average was 211.2 of 100,000 persons with diabetes and the third 3-year average was 160.5 of 100,000 persons with diabetes. For combined (first and repeat) major non-DRLEAs, the change from the first to the third 3-year average was from 10.2 to 11.9 of 100,000 persons without diabetes.

We were concerned to know whether the very low DRLEA rates achieved in the fifth year of the study were maintained beyond the end of the study but to date have not been able to collect data in the same detail according to the GLEAS protocol. However, hospital event statistics (HES) for the South Tees area show that whereas the low DRLEA rates for the fifth year of our study are the best achieved to date, the HES data for the following years (available up to 2003) are the next lowest DRLEA rates. HES for non-DRLEAs show that for the years after the end of our study rates continue to rise.

Likely explanations of results

The principal change to diabetic foot care over the period studied was the establishment of a dedicated diabetic foot care team with a community-based chiropody service. This included establishment of care pathways and protocols for managing diabetic foot problems with input from a vascular and orthopedic surgeon, orthotist, diabetic chiropodists, and a single diabetologist. Educational events to raise awareness of diabetes foot complications were organized.

Angioplasty practice changed over this period. More angioplasties per angiogram were done. The increased rate of angioplasties per angiogram was seen both in individuals with and without diabetes, but the rate of increase was greater among individuals with diabetes. HES for the South Tees area show that for individuals with diabetes the ratio of femoral angioplasty to angiogram was 0.20 in 1997 and 0.42 in 2001. For patients without diabetes, the ratio increased but not to the same extent, going from 0.23 to 0.29 over the same period.

Another change in care for the population with diabetes immediately preceding and continuing through this period is the increased prescribing of medication with the aim of modifying cardiovascular risk. This is seen in the increased prescribing of lipid-lowering, antihypertensive, and antiplatelet medication. The diabetes register between 1995 and 2001 shows that the percentage of individuals recorded to be taking a statin, aspirin, or an ACE inhibitor increased from 5.2 to 20.0% ($P < 0.001$), from 21.7 to 32.6% ($P < 0.001$), and from 14.5 to 37.5% ($P < 0.001$), respectively (27).

Smoking in patients attending the hospital diabetes clinic over the same period has remained high. In 1995, 20% of men and 19.3% of women were recorded as being smokers, whereas in 2001 18.1% of men ($P > 0.05$) and 19.8% of women ($P > 0.05$) were smokers (27). Smoking habits in the general population of northeast England has changed little over the same period.

Diabetes prevalence changed significantly in the South Tees area as it has elsewhere over this period. We calculated DRLEA rates using a fixed denominator of the general population for major DRLEAs, and for years 1 to 5 the rates were, respectively, 8.9, 10.6, 7.2, 10.5, and 3.8 of 100,000 general population. Whereas the trend is less marked using this method, the overall change is maintained, with the trend for major DRLEAs still downward and the major non-DRLEAs still increasing significantly. However, we feel that use of a flat denominator would be incorrect, as it does not reflect the real change in patients with diabetes in the population (in year 1 there were 4,607 individuals with diabetes and in year 5 there were 6,254 individuals with diabetes in the South Tees area).

Weak points of the study

Our data in common with all LEA studies can only suggest the most likely reasons for the improvement seen across the whole South Tees population. It is not clear evidence for cause and effect. Also, the extent or importance of each of the contributing factors can only be listed as most likely, and the direction and amount contributed by different factors has not been quantified.

It is not clear why there should be an increase in LEA rates among individuals without diabetes. Although all major non-DRLEA rates increased, the main increase was seen in repeat major non-DRLEA events. At the start of the period, repeats accounted for one in five major non-DRLEAs, and at the end of the 5 years repeats accounted for two in five major non-DRLEAs episodes. It is known that variation in clinical decision making exists among surgeons considering LEA in borderline cases (28). The main change to the surgical structure over the period was the establishment of a regional vascular unit based at the South Tees area where previously the unit had been local. However, improvements in surgeon volume does not benefit lower extremity arterial surgery in terms of outcomes in the same way as other vascular procedures, such as carotid endarterectomy and abdominal aortic aneurysm repair, and may actually lead to an increase in procedure rates (29). We have not classified the etiology of the LEA in terms of ischemic, neuroischemic, or neuropathic.

Strong points of the study

We have used a number of methods to enhance the completeness and accuracy of our data. Our study is population based; therefore, results are widely applicable. We used multiple data sources and allowed for the use of capture-recapture methods so that an estimate of ascertainment could be achieved. Collection of data in a standard way and presentation of standardized rates mean that our data are potentially comparable to a wide range of centers. The presentation of DRLEA rates alongside non-DRLEA rates emphasizes the improvement in major DRLEA rates and points to the importance of having non-DRLEA data included. By using direct diabetes prevalence data, the accuracy of our data for this population is increased.

In this study, the estimate of ascertainment for LEAs approaches 100%. The high level of ascertainment does not reflect a guarantee that all cases were identified, as no method can do that, but the search using this method was as thorough as possible and at worst we only missed an occasional case.

We believe this study is important in a number of other ways. It is an accurate reflection of changes in LEA rates across a population rather than in a clinic itself. This study reaffirms the positive effect that a multidisciplinary foot team approach has on reducing LEAs seen in a clinic setting (30). Our study shows the improvement is not just to the clinic population but also to the diabetic population served by the clinic. The improvement in nondiabetes LEA data is further enhanced in the context of rising non-DRLEA rates. Without the comparison with non-DRLEA data, the relative improvement in DRLEA incidence would have been lessened. This study is a natural extension of the GLEAS incidence study, following LEA rates over 5 years in one of the centers that took part in the original study. The robustness and standardization of the data allow for comparison with other studies. The completeness of the study is based on it being a whole population study, estimation of ascertainment by capture-recapture methodologies, use of local valid diabetes population prevalence figures, and comparison with the nondiabetes rate, using multiple data sources presented in a standardized way.

In summary, our data show that in the South Tees area at a time when major non-DRLEA rates increased major DRLEA rates have fallen. These diverging trends mark a significant improvement in care for patients with diabetic foot disease as a result of better organized diabetes care. Our study shows the importance of including a non-DRLEA comparison. A case-control study would be an efficient approach to further explore the specific changes seen in our study.

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