

Are We Underestimating Diabetes-Related Lower-Extremity Amputation Rates?

Results and benefits of the first prospective study

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OBJECTIVE — The objective of this study was to accurately determine the incidence of lower-extremity amputation using prospective data collection and to compare the results with those obtained by retrospective methods.

RESEARCH DESIGN AND METHODS — The study was carried out over a 3-year period in a large district general hospital covering a clearly defined and relatively static population. All diabetic inpatients with foot problems were identified and followed-up until discharge or death. The demographic and admission details, medical history, investigations, procedures, and history and etiology of the foot lesion were collected twice weekly by a specialist nurse and podiatrist from all relevant wards. Thus, all subjects who underwent amputation could be identified. For comparison, retrospective data were collected from the hospital coding activities database, operating theater log books, anesthetic database, and limb-fitting records.

RESULTS — The total population of the region in 2000 was 337,859, of which 9,183 were known to have diabetes. The total number of amputations during the 3-year survey period was 79, of which 45 were major and 34 minor. In our local population, the mean incidence during the survey period (1997–2000) equates to 7.8/100,000 general population and 2.85/1,000 diabetic population for all amputations, 4.5/100,000 general population and 1.62/1,000 diabetic population for major amputations, and 3.3/100,000 general population and 1.23/1,000 diabetic population for minor amputations. The prospective survey detected all lower-extremity amputations identified by the various retrospective methods; however, for the reverse, this was not the case. All of the retrospective methods, including the most commonly used (ICD-9 and OPCS-4 coding), failed to detect all of the cases revealed by the prospective survey (error rate ranging from 4.2 to 90.6%), and between 4.5 and 17.4% of amputations were misclassified.

CONCLUSIONS — This study demonstrates the advantages of prospective data collection as a means of determining the incidence of lower-extremity amputations and highlights the limitations of retrospective data collection methods, which underestimate the incidence. In particular, the operating theater records, which have been the gold standard for many surveys, were found to be unreliable. Moreover, we have shown a 47% reduction in the major amputations during the survey period. Thus, we recommend that a prospective audit be incorporated into the activities of the specialist foot care team as a means of assessing and improving clinical care.

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

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Foot complications, including amputations and ulceration, are a major cause of morbidity and mortality in people with diabetes, as well as a source of considerable cost to health care agencies (1–10). Estimating the total burden of all foot complications is difficult because the associated problems are managed by different elements of the health services and by health professionals from various specialties. For these reasons, amputation rates have been most commonly recommended as the indicator of the quality of foot care (11–13). It is an easily defined end point, and ascertainment of data can be straightforward because it usually involves inpatient care under a defined specialist team. Thus, when the St. Vincent's task force made their declaration in October 1989 to improve diabetes care across Europe (for foot care), they chose the target of a reduction in lower-extremity amputations of 50% within 5 years (13). Although this target is justified, it is only possible to know if this has been achieved if baseline and yearly amputation rates are known in each locality and are reliable.

Over the past decade, there have been numerous studies reporting on the incidence of lower-extremity amputation in diabetic populations (14–18). These have revealed considerable variation both globally and within the same country (1,14,16–20). Such variations have been attributed to differences in ethnicities within the various populations and differences in local medical and surgical practices. However, variations in the definition of amputation and, in particular, the accuracy of data ascertainment are crucial (14,17,19–23). In the majority of these reports, the latter has been noted by the authors to be an area of concern, since all studies to date have been retrospective (15,24–28). Furthermore, in many studies, the denominators, i.e., the general population and the diabetic population, could not be fully defined because the in-

Table 1—All nontraumatic amputations (major and minor) in diabetes and incidence over the 3-year study period

	1997–1998	1998–1999	1999–2000
All amputations	32	23	24
Rate/100,000 general population	9.6	6.8	7.1
Rate/1,000 diabetic population	3.48	2.50	2.61

stitutions covered catchment areas that overlap with other institutions (29).

To be accurate and complete, the data should ideally be based on a population within a defined area, rather than from specialist units with referral from an undefined population, and should be prospective so that cases are less likely to be missed. Thus, we designed a prospective study to accurately determine the incidence of lower-extremity amputation in our district general hospital, which serves a clearly defined and relatively static population. For comparison, we also calculated the incidence of lower-extremity amputation for the same population using the retrospective methods commonly used in other studies to estimate any potential inaccuracy arising from the use of retrospective assessment alone.

RESEARCH DESIGN AND METHODS

The survey was carried out in the Ipswich Hospital National Health Service Trust between October 1997 and September 2000. It was approved by and conducted according to the regulations of the hospital's audit department. The Ipswich Hospital is a large district general hospital that serves a predominantly Caucasian population (95%). The total population in 1998, 1999, and 2000 was 334,644, 335,749, and 337,859, respectively. Due to reorganization of the East Suffolk health authority (the catchment area covered by the hospital) into three primary care trusts, complete data based on the returns from all general practices for the diabetic population were available for the year 2000 only. We used these data for the entire 3-year study period. During 2000, the number of people registered to have diabetes was 9,183. The catchment population is well defined and comprises people living in a largely rural geographic area, from which there are few cross-boundary referrals for all medical and surgical specialties.

Definition of amputation

A lower-extremity amputation was defined as the complete loss in the transverse anatomical plane of any part of the lower limb. All amputations were classified as either major or minor. Major amputations were defined as those above the ankle and minor as those below the ankle. Patients undergoing amputation as a result of trauma or tumor were excluded. Revisions of procedures within a 3-month period were considered as one, with the later procedure documented (e.g., revision of a below-knee to an above-knee amputation was recorded as an above-knee amputation).

Prospective inpatient ward-based survey

The survey was carried out by a diabetes nurse and a podiatrist both specializing in diabetic foot problems. The study was conducted on all medical, geriatric surgical, and orthopedic wards. Before starting the study, all senior nursing staff on these wards were informed of the aims, rationale, and importance of the survey. The wards were visited twice weekly to identify all patients with diabetes and to follow-up those with any active foot problems and those who developed new foot problems during their hospital stay. These patients were then followed until discharge or death.

A structured data collection form was used to ensure consistent data collection

by the investigators. This included demographic details, medical history, admission details, investigations and procedures, and the history and etiology (where discernable) of their foot lesion. This article solely reports the amputation data.

Hospital activity coding procedures

The Ipswich hospital National Health Service Trust uses ICD-9 (*International Classification of Diseases, 9th revision*) and OPCS-4 (*Operating and Coding Procedures, version 4*) coding systems. Details of all the patients coded with lower-limb amputations were obtained at yearly intervals from the hospital's coding department. Their hospital notes were reviewed to select those with diabetes and to verify the amputation details.

Operating theater records and anesthetic database

In addition to the hospital activity coding procedures, all amputations should appear in the theater records. The theater logbooks record surgical procedures performed in each operating theater for each day. The information is recorded manually by theater staff and verified by the operating surgeon and anesthetist. One of the investigators trawled the logbooks for each year to identify all entries referring to lower-extremity amputation. Dates, level of amputation, and patient hospital number were recorded.

Independent of the theater record, the anesthetic department also maintains a computerized database of all elective surgical procedures. This was also used to identify amputations.

The data on all amputations identified from these two sources were cross-checked with patient hospital notes to verify the procedure undertaken and to

Table 2—Major nontraumatic amputations in diabetes and incidence rates over the 3-year study period

	1997–1998	1998–1999	1999–2000
Major amputations	21	14	10
Above/below knee	5/16	5/9	3/7
Male/female	11/10	10/4	6/4
Rate/100,000 (total) general population	6.3	4.2	3.0
Male/female	6.7/5.8	6.1/2.3	3.6/2.3
Rate/1,000 diabetic population	2.28	1.52	1.08
Male/female	1.20/1.08	1.08/0.43	0.65/0.43

Table 3—Minor nontraumatic amputations in diabetes and incidence rates over the 3-year study period

	1997–1998	1998–1999	1999–2000
Minor amputations	11	9	14
Male/female	8/3	8/1	10/4
Rate/100,000 (total) general population	3.3	2.7	4.1
Male/female	4.9/1.8	4.9/0.6	6.0/2.3
Rate/1,000 diabetic population	1.20	0.98	1.52
Male/female	0.87/0.32	0.87/0.11	1.10/0.43

ascertain that the patient had a confirmed diagnosis of diabetes.

Limb-fitting records

The geographical area within which the survey was conducted is served by three limb-fitting centers, all of which are in adjacent districts. Details of all patients with diabetes who attended these centers for artificial-lower limb prostheses were collected yearly.

Statistical analysis

Incidence rates for all, major, and minor amputations were expressed per 100,000 of the general population and per 1,000 of the diabetic population. The different methods of data collection were compared to identify any discrepancies in the recorded amputations.

RESULTS

Amputation rates

The amputation rates expressed for both the diabetic and total population are shown in Table 1. There is a year-on-year trend for a fall in total and major amputations. The incidence of total amputations for 1997–1998, 1998–1999, and 1999–2000 was 9.6, 6.8, and 7.1 per 100,000 of the general population, respectively, and 3.48, 2.50, and 2.61 per 1,000 people with diabetes, respectively (Table 1). For major amputations, the figures were 6.3, 4.2, and 3.0 per 100,000 of the general population and 2.28, 1.52, and 1.08 per 1,000 people with diabetes, respectively (Table 2). Minor amputations remained relatively unchanged (3.3, 2.7, and 4.1 per 100,000 of the general population and 1.20, 0.98, and 1.52 per 1,000 people with diabetes, respectively) (Table 3).

Missed amputation data

The prospective ward survey method identified all amputations found by the

other methods combined, and all amputation levels were found to be correctly recorded when rechecked with the notes. Thus, the prospective survey was used as the gold standard. Based on this, over the 3-year period, the Hospital Coding method missed between 4.2 and 8.7% of the total amputations (Table 4) and between 13.0 and 16.7% of the amputations were incorrectly classified (Table 5). Examples of the type of misclassification include noting an amputation but failing to record the history of diabetes and referring to an angioplasty as a procedure but failing to record the removal of a digit.

The theater record logbooks were even less accurate; between 12.5 and 22% of the amputations were not recorded and between 4.5 and 9.4% were incorrectly classified. Data for the anesthetic database were only available for the first 2 years of the survey due to an anesthetic database software problem. For these 2 years, ~9% of the amputations were not recorded and between 6.3 and 17.4% were incorrectly classified. The limb-fitting records were found to be highly unreliable, with 29 amputations (90.6%) missed in the first year. Thus, it was decided not to gather any further data after this year.

CONCLUSIONS— Lower-extremity amputations in people with diabetes are a major cause of morbidity and mortality and place a significant economic burden on society (1–10). The importance of cost-effective and comprehensive man-

agement programs for this potentially preventable complication cannot be underestimated. Accordingly, it is essential to have accurate information on the incidence of amputations to assess the impact of such programs. To date, all of the published studies have relied on retrospective data collection methods (11–18). To the best of our knowledge, this is the first study to use a prospective inpatient survey to accurately assess amputation rates.

With any retrospective method, there is the risk of the data not being entered in the first place, incorrect entry, and loss of data. We believe the risks are minimized when the data are collected prospectively, particularly if done by those with an interest in diabetic foot problems and who are also involved in the care of these individuals, as in the present study. Indeed, this appears to be the case because the current prospective survey detected all lower-extremity amputations identified by the various retrospective methods. However, the reverse was not the case. All the retrospective methods, including the most commonly used (ICD-9 and OPCS-4 coding), failed to detect all of the cases revealed by the prospective survey. The data from limb-fitting centers were the least accurate and indeed proved to be very unreliable. This may reflect the fact that many of the patients were elderly and too frail to become ambulant on prostheses and therefore elected to remain wheelchair bound. Also, several patients died before referral for the limb fitting. For these reasons, we abandoned this method after the first year. Theoretically, theater records should be reliable; however, this was not the case. Surprisingly, nearly 20% of amputations were not detected by this method. It is possible that some of the operations may not have been recorded or that the investigator failed to find all of the entries, as trawling through the records is tedious and time consuming. We also know that one theater record went missing. The hospital’s anesthetic database,

Table 4—Missed amputations

	1997–1998	1998–1999	1999–2000
Hospital coding	2 (6.25)	2 (8.7)	1 (4.2)
Theatre logbooks	7 (21.9)	5 (21.7)	3 (12.5)
Anesthetic database	3 (9.4)	2 (8.7)	N/A
Limb-fitting records	29 (90.6)	N/A	N/A

Data are n (%). N/A, not available.

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Table 5—Incorrectly coded amputations

	1997–1998	1998–1999	1999–2000
Hospital coding	5 (15.6)	3 (13)	4 (16.7)
Theatre logbooks	3 (9.4)	2 (8.7)	1 (4.5)
Anesthetic database	2 (6.25)	4 (17.4)	N/A
Limb-fitting records	N/A	N/A	N/A

Data are n (%). N/A, not available.

though used for booking emergency procedures, was primarily designed to book and record elective procedures. Therefore, it is not surprising that it may have missed some emergency amputations. Although the combined ICD-9 and OPCS-4 coding systems detected most of the amputations, 15% of cases were incorrectly classified.

A few recent reports have used the district diabetes database to determine their amputation rates (8). We were unable to comparatively assess this method, as there is no district-wide diabetes database for the population in this study. Nevertheless, we believe that many of the previously described problems also apply to this method, as the data are retrospectively entered. Furthermore, as the inpatient postoperative mortality is between 10 and 20%, the unrecorded numbers are likely to be high (27,30,31). Another potential error occurs as a result of individuals who are newly diagnosed with diabetes during their admission for amputation. They may not be entered into the diabetes district database until some time after their discharge into the community.

For several reasons, we believe that this prospective study provides the most accurate estimation of the incidence of lower-extremity amputation reported thus far. First, as we have demonstrated, this methodology maximizes case ascertainment. Second, the population covered lives in a well-defined geographical area where there is a low rate of migration and little cross-boundary referral, unlike the situation that tends to occur in many inner-city areas. The few such cases have been excluded from the analysis. Thus, we believe that the numerator and denominator used to calculate the incidence for the general population are accurate. In addition, the number of patients with diabetes in this population is well defined. It is based on the returns to the primary care trusts from all general practices within the

hospital's catchment area. Although there is the potential for some inaccuracy in these returns, this is very likely to be more accurate than the method used in many reports (28,32) in which amputation incidence was estimated from an assumed prevalence of diabetes (usually between 2.4 and 4.0%).

Prospective data collection may be seen as labor intensive, since it involves twice-weekly visits to all relevant hospital wards. Nevertheless, there were other significant benefits gained from these visits that we believe justify the time and cost. The diabetes foot team not only assisted with the care of many of these patients but also provided an important education resource for medical and nursing staff on these wards. We believe that this raised the awareness of the problems faced by inpatients with diabetes, including their susceptibility to pressure-induced heel ulcers and foot infection. This was demonstrated by proactive contacts from the wards, with queries and education requests to the diabetic foot team that were rare before the survey. These still continue. It is noticeable that during the 3 years of the study, the amputation rates fell consecutively, which may partly reflect this raised level of awareness and the resulting improved inpatient care. Of course, this is a relatively short period from which one should be careful in drawing such conclusions. Nevertheless, it is noticeable that the amputation rate at the outset was already low, with only few of the published studies describing such low rates (33,34). The beneficial outcomes of this survey have enabled us to recently secure funding to resume the survey.

In conclusion, all of the retrospective methods were found to have limitations and underestimated amputation rates when compared with those obtained by the prospective audit. Although ICD-9 and OPCS-4 coding missed only a small number of cases, this accounted for be-

tween 4 and 9% of the total number of diabetes-related lower-extremity amputations, an error that was compounded by the significant number of misclassifications. Such errors would have considerable resource implications considering the huge expenditure globally. Thus, we would recommend prospective survey as the most accurate means of auditing amputation rates. We would also recommend that this be incorporated into the activities of the specialist foot care team, as this strengthens the quality of data and has the benefits of improved clinical care.

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