

Incidence of amputation is a poor measure of the quality of ulcer care

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ARTICLE POINTS

1 Assessment of the literature on changes in the incidence of amputation is difficult.

2 The incidence of amputation cannot be used as a measure of the quality of ulcer care, unless qualified by markers of disease severity as well.

3 The incidence of amputation is largely beyond the influence of the specialist medical team.

4 Amputation data has potential in documenting aspects of foot disease in the wider population.

5 Expression of incidence of amputation in terms of the at-risk population (those with diabetes) may give an indication of regional or national trends, whereas expression in terms of the total population has limited value beyond being a marker of disease burden.

KEY WORDS

- Amputation
- Amputee
- Quality of care
- Data interpretation

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Introduction

The aim of the St Vincent Declaration (WHO and IDF, 1990) was to formulate targets for improving different aspects of diabetes care, and it was a highly successful initiative in many ways. In the case of foot care, however, the target of achieving a 50% reduction in the incidence of amputation in 5 years was never achievable. The main reason for this was that the baseline incidence was to a large extent unknown. Although discharge/death statistics may be sufficiently accurate in countries such as the US, it is difficult for researchers or healthcare planners to extract reliable information from equivalent databases in many other countries. Although advances are being made, the situation for most remains essentially unchanged – even after 15 years. This article summarises some of the problems encountered in assessing incidences of amputation in the published literature.

The assessment of published work is made difficult by the failure of many authors to distinguish between major and minor amputation. Even when they do, there is no consensus on the definitions used. While most regard a major amputation as one performed above the ankle, some also include operations on the hindfoot and midfoot.

The distinction between minor and major operations is crucial because the two are undertaken for different reasons (either to save the foot or to remove it), in different people (with a foot which is, or is not, salvageable) and with different results (they can or cannot walk). It is also obvious that vigorous attempts to reduce major amputations may be reflected in a rise in minor ones (Holstein et al, 2000). The aggregate figure may give some measure of healthcare costs, but means little in terms of quality of care.

Amputations or amputees?

If the objective is to derive a measure of the quality of care, then it is more logical to count amputees – the number of people who lose part or all of a lower limb – rather than amputations. While it is accepted that some patients undergo repeated operations in an attempt to save the limb, and the total number of procedures per patient (or per limb) is an

additional measure of suffering, the principal indicator is the outcome for the patient: the level of the latest (highest) amputation and, by implication, their residual disability. It is less valuable to count operations than to know how many people with diabetes are no longer able to walk.

Severity of disease or quality of care?

The incidence of amputation (and of amputees) is dependent both on the severity of prevalent disease, and the way in which it is managed. It follows that the incidence of amputation cannot be used as a marker of the quality of ulcer care unless qualified by markers of disease severity as well. If comparisons between centres are to be clinically meaningful, it is essential to characterise both the people managed (including race, gender, glycaemic control, peripheral arterial disease and neuropathy), and the types of foot ulcer they have (including site, area, depth and infection). This information is not generally available unless recorded as part of a prospective study.

Population types

The incidence of amputation is expressed as the number of new events documented in an identified population in a given time (usually per year). It is therefore important to define

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1 Published data on the incidence of amputation are of two broad types: those derived from communities and those from specialist clinics.

2 Data published from a community-wide study may be expressed in terms of the total or the at-risk population, and may be standardised in a variety of ways.

3 Commonly, specialist clinic data are expressed simply in terms of amputations per year, but this is relatively meaningless unless accompanied by a measure of overall clinical activity.

4 Some racial groups appear to be at much higher risk of undergoing amputation, but it is difficult to dissect the precise cause, whether biological or cultural.

5 The structure of health care services will also have a major effect on the care delivered, especially to ethnic minorities and to the more deprived.

not just the numerator (the number of new events), but also the denominator (the population). Published estimates of incidence are of two broad types: those derived from a community and those from a specialist clinic.

Data from communities

Community-wide data may be from a district, town, region or country. They are expressed either in terms of the total population (both those with and those without diabetes) or the at-risk population (those with diabetes). When the incidence of amputation is expressed in terms of the total population, it is inevitably influenced by the prevalence of known diabetes: it will be high in communities where diabetes is common, and low where it is not. It follows that its main value is as a marker of disease burden. To make the situation even more complex, the results reported in published studies may be adjusted or standardised in a variety of ways.

Data from specialist clinics

When a specialist clinic is the only one which serves the community, the incidence of recorded amputation can obviously be extrapolated to the whole population. In general, however, disorders of the diabetic foot are managed by so many different groups of clinicians that the data derived from specialist clinics are subject to inevitable selection. Such data can only be made meaningful by defining either the process of selection, or the details of the selected population. The incidence of major amputation is likely to be higher if a certain clinic sees more people with peripheral vascular disease, and lower if their predominant population has neuropathy with good supply.

Data from specialist clinics can also use a variety of denominators – in terms of new referrals (e.g. numbers of ulcers or patients), or new episodes (i.e. considering patients already under review). Most commonly, however, clinic data are expressed simply in terms of amputations per year, but this is relatively meaningless unless accompanied by a measure of overall clinical activity. A good clinic may expect to attract an ever increasing number of referrals and should therefore manage an ever increasing number of amputations, despite the overall quality of

disease management being better.

It follows that a specialist clinic will never be able to use incidence of amputation as a measure of care unless activity is expressed in terms of the number of problems (ulcers, referrals or episodes) managed. The type and severity of these problems must also be documented, since the referral of an increased number of more trivial lesions will also influence the calculation – giving the impression of improvements in management when there may be none.

Factors influencing the actual incidence of amputation

Indigenous population

Some racial groups appear to be at much higher risk of undergoing amputation, but it is difficult to dissect the precise cause – whether biological or cultural. If cultural, it may relate to the education, behaviour or beliefs of the patient, but it is also critically dependent on their standard of living and on the availability and quality of available healthcare. This is especially true when a particular racial group exists as an ethnic minority within a mixed population, since they may be more likely to be exposed to economic hardship and social deprivation.

Structure of healthcare services

The structure of healthcare services will also have a major effect on the care delivered, especially to ethnic minorities and to the more deprived. Such an effect is likely to be minimised if the quality of care is uniform and freely available to all (Leggetter et al, 2002), but exaggerated if health services are heavily dependent of insurance-based remuneration and private practice. When hospitals and professionals are reimbursed per item of service, the details of the system of reimbursement will influence the treatment given.

Professional attitude

Nevertheless, wide variation in incidence of amputation may also be observed in countries such as the UK, with a disease care service which is more uniformly accessible, and even when racial and socio-economic factors have been eliminated. Up to four-fold variation in incidence of amputation was observed

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1 Variation in the incidence of amputations can also be attributed to the differing attitudes of the surgeons involved.

2 The wishes of the patient are also clearly involved in the decision to operate. Their attitude will be coloured by their culture, their other problems (medical and social) and their personality.

3 Since the occurrence of new ulcers has relatively little to do with the actions of the expert medical team, it follows that they may have relatively little influence on the incidence of amputation in the population as a whole.

4 A fall in incidence may only ever be achieved by changes in the behaviour of professionals who may never have heard of the St Vincent Declaration target for foot care.

5 The factors most likely to result in a fall in ulcer incidence will be improved overall quality of lifetime blood sugar control, and a reduction in peripheral vascular disease.

between four centres in the Midlands and Northern England, and it was later shown that much of this could be attributed to variation in the attitude of the surgeons involved (Connelly et al, 2001). Each professional wishes to do the best they can for their patient, but the decisions they make are influenced by their training, experience, available resources and the prevalent medical orthodoxy.

The influence of medical orthodoxy is perhaps most obvious in the field of osteomyelitis, especially when localised to the forefoot. In many countries the early removal of infected bone is regarded as good practice, whereas there is evidence that the effective cure rate after minor surgery is quite low (Murdoch et al, 1997; Nehler et al, 1999), and the success of non-operative management may be just as good (Jeffcoate and Lipsky, 2004). Variation in professional attitudes to optimal care is one reason for the wide variation in the incidence of minor amputation between centres.

Patient attitude

The wishes of the patient are also clearly involved in the decision to operate. Their attitude will be coloured by their culture, their other problems (medical and social) and their personality. When faced with the likelihood of losing a leg, some will wish to defer it as long as possible, while others will proceed in the hope of bringing their illness and incapacity to an end. Patient attitudes are, however, inevitably dependent on the advice they are given: the opinion of an independent professional is rarely requested.

The pathway from ulceration to amputation

The incidence of ulceration

When the incidence of amputation is used as a measure of the quality of care, it is assumed that the care being assessed is that of the expert team who manage established ulcers. However, the main factor which puts the leg at risk is the occurrence of an ulcer in the first place, and since the occurrence of new ulcers has relatively little to do with the actions of members of the expert team (Reiber et al, 1999), it follows that they may have relatively little influence on the incidence of amputation

in the population as a whole.

It follows that a fall in incidence in a population may only ever be achieved by changes in the behaviour of professionals who may never have heard of the St Vincent Declaration and its target for foot care. All other things being equal, the factors most likely to result in a fall in ulcer incidence will be improvement in the overall quality of lifetime blood sugar control, and a reduction in peripheral vascular disease from (a) smoking cessation, and (b) increased use of effective lipid-lowering therapy. The role of preventive education has yet to be established (Valk et al, 2001). Having said that, most hospital-based expert teams have additional roles in general diabetes management, with responsibilities for continued training of generalists.

Ulcer management and referral pathways

Specialists also need to establish care pathways which will ensure that ulcers requiring expert assessment are referred as quickly as possible, and that investigation and treatment is initiated with appropriate urgency. Current management falls woefully short of the ideal in many centres, if not most, with delays and poor communication between healthcare professionals being the rule rather than the exception. If these were addressed, the quality of ulcer care should improve and the incidence of amputation might well fall.

Is amputation incidence falling?

For many of the reasons stated above, assessment and interpretation of the literature on changes in incidence of amputation is difficult. A reported fall in incidence may indeed be the result of the establishment of an integrated specialist service, or improved standards of management, but the data require careful analysis.

If they derive from a specialist centre, the reported incidence will be influenced by a change in referral pattern. A clinic led by a physician-diabetologist may see progressively fewer ischaemic limbs if the local vascular unit has had a significant increase in consultant number (as has happened in UK, because of the need to provide comprehensive emergency rotas). With fewer

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1 If the prevalence of known diabetes is increasing, the expression of results as a proportion of the total population (people with and without diabetes) may mask any improvements which are taking place.

2 The incidence of amputation (in patients with and without diabetes alike) is not falling in the US, although there are more encouraging reports from mainland Europe.

3 However, when a unit has reported a fall in incidence of amputation, it has occasionally been from a baseline which was unusually high.

4 The real target should be not just to achieve a fall in amputation incidence, but an incidence that is low.

5 Although amputation is not a very useful measure of the quality of individual patient care in isolation, it has potential in documenting aspects of foot disease in the wider population.

cases of ischaemia referred to the unit, the percentage of patients who end up with an amputation may be expected to fall.

On the other hand, data derived from an unselected population (district, town, region, country) will be dependent on changes in the prevalence of known diabetes. If the prevalence of known diabetes is increasing, the expression of results as a proportion of the total population (those with and without diabetes) may mask improvements which are actually taking place. For these purposes, population-based data are best expressed in terms of the at-risk (those with diabetes) population (van Houtum et al, 2004).

The evidence, however, is that the incidence of both major and minor amputation (in patients with and without diabetes alike) is not falling in the US, although there are more encouraging reports from mainland Europe (for a review, see Jeffcoate and van Houtum, 2004). It should be noted, however, that when a unit has reported a fall in incidence of amputation, it has occasionally been from a baseline which was unusually high. The real target should be not just to achieve a fall, but an incidence that is low.

Limitation of amputation as an endpoint in isolation

Ultimately, an amputation is merely an operation, undertaken for whatever reason in a particular person. As such, it is an incomplete reflection of how well that person has been managed. Since peri-operative mortality is high, and long-term survival is poor, incidence of amputation should be properly complemented by a record of survival. Moreover, some amputation wounds heal quickly while others do not, and the patient is even more incapacitated after the procedure than before. New ulcers may occur – either on the same foot after minor surgery, or on the other.

It follows that any realistic attempt to measure the quality of ulcer care must take into consideration late sequelae and measures of mood and function or incapacity.

Conclusion

Many factors underlie the decision to perform an amputation. Moreover, assessments of the incidence of amputation are subject to many different factors, and interpretation of the

published literature is difficult. While much could be achieved if agreement was reached on the definitions and methods used in such assessments, incidence is largely beyond the influence of the specialist team. The specialist management of established ulcers should incorporate markers of survival and patient well-being. Although amputation is not a very useful measure of the quality of individual patient care when taken in isolation, it has potential in documenting aspects of foot disease in the wider population. Expression of incidence of amputations (or, preferably, amputees) in terms of the at-risk population may give an indication of regional or national trends, while the expression in terms of the total population has limited value beyond being a marker of disease burden and healthcare costs. ■

Connelly J, Airey M, Chell S (2001) Variation in clinical decision making is a partial explanation for geographical variation in lower extremity amputation rates. *British Journal of Surgery* **88**: 529-35

Holstein P, Ellitsgaard N, Olsen BB et al (2000) Decreasing incidence of major amputations in people with diabetes. *Diabetologia* **43**: 844-47

Jeffcoate WJ, Lipsky BA (2004) Controversies in diagnosing and managing osteomyelitis of the foot in diabetes. *Clin Inf Dis* (in press)

Jeffcoate WJ, van Houtum WH (2004) Amputation as a marker of the quality of foot care in diabetes. *Diabetologia* (in press)

Leggetter S, Chaturvedi N, Fuller JH, Edmonds ME (2002) Ethnicity and risk of diabetes-related lower extremity amputation: a population-based, case-control study of African Caribbeans and Europeans in the United Kingdom. *Archives of Internal Medicine* **162**: 73-78

Murdoch DP, Armstrong DG, Dacus JB, Laughlin TJ, Morgan CB, Lavery LA (1997) The natural history of great toe amputations. *Journal of Foot and Ankle Surgery* **36**: 204-08

Nehler MR, Whitehill TA, Bowers SP et al (1999) Intermediate-term outcome of primary digit amputations in patients with diabetes mellitus who have forefoot sepsis requiring hospitalisation and presumed adequate circulatory status. *Journal of Vascular Surgery* **30**: 509-17

Reiber GE, Vileikyte L, Boyko EJ et al (1999). Causal pathways for incident lower-extremity ulcers in patients with diabetes from two settings. *Diabetes Care* **22**: 157-62

Valk GD, Kriegsman DMW, Assendelft WJ (2001) Patient education for preventing diabetic foot ulceration: a systematic review. *Endocrinology and Metabolism Clinics of North America* **31**: 633-58

van Houtum WH, Rauwerda JA, Ruwaard D, Schaper NC and Bakker K (2004) Reduction in diabetes related lower extremity amputations in the Netherlands: 1991–2000. *Diabetes Care* (in press)

World Health Organisation (Europe) and International Diabetes Federation (Europe) (1990) Diabetes care and research in Europe: the Saint Vincent Declaration. *Diabet Medicine* **7**: 360