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**The prevalence of all cause major and minor lower limb amputation in the
diabetic and non diabetic population of England 2003-2013.**

Short Title: Prevalence of amputations in English diabetics

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Guarantor: NA had full access to all the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis.

Contributorship: NA generated the hypothesis, set up, analysed and interpreted all data and was lead writer. GNT, PSG and FT helped develop the hypothesis, analyse and interpret the data and critically commented on the manuscript.

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What this study adds:

- Rates of major amputation, although decreasing, continue to be six times higher in diabetics than non diabetics.
- Rates in non diabetics are reducing at a slower rate than diabetics
- The rise in the minor amputation rate is driven by male non diabetics.
- We suggest the diabetic foot model, where access to vigilant foot care services reduce the risk of amputation, be investigated for, non diabetic sufferers of peripheral arterial disease

Word count: 1807**Keywords:** amputation, peripheral arterial disease, revascularisation, endovascular

The prevalence of all cause major and minor lower limb amputation in the diabetic and non diabetic population of England 2003-2013.

Introduction

Major lower limb amputation i.e. above the ankle is a devastating consequence of both diabetic neuropathy and peripheral arterial disease (PAD). PAD affects the lower limbs has the same underlying pathology as coronary heart disease and classically presents as intermittent claudication but can lead to foot ulcers, gangrene, and ultimately amputation.¹⁻³ Whilst diabetes is a major cause of all amputations (major and minor) in England, the vast majority (over 90%) of the 5000 major amputations undertaken in England every year⁴⁻⁵ in people over 50 years are related to PAD.⁵⁻⁶

Our aim was to ascertain the yearly prevalence of lower limb amputation (both major and minor) and revascularisation in England between 2003 and 2013 in those aged 50-84. and investigate the changing prevalence in the diabetic and non diabetic population.

Method

We interrogated the Hospital Episode Statistics (HES) database which captures every hospital patient encounter in England with approximately 52 million in and outpatient episodes added each year.⁷ Information regarding patient demography, risk factors, diagnosis and intervention is collected. A subset of this main database covering in-patient admissions between 1st April 2003 and 31 March 2013 was created.

From HES, we obtained the number lower limb amputations (major and minor) and revascularisation (both endovascular and surgical), as defined by the Office of Population, Census and Surveys (OPCS) classification⁸ performed in patients aged 50-84 years. All 10 operative field codes were searched. Amputations were defined as major, if they were above the ankle (OPCS code X09) and minor if below (X10,11). We additionally collated procedures on amputation stumps (X12), the majority of which were re-amputation to a higher level. However, this code did include additional procedures such as debridements of stumps. Lower limb revascularisation procedures included both endovascular and surgical procedures from the aorta to distal lower limb vessels (OPCS code L26, L51, L52, L54, L59, L60, L63, L66).

We chose the age group, 50-84 as they represent 40% of the entire English population⁹ and the vast majority likely to have amputations attributable to peripheral arterial disease. We omitted 2% of the population aged 85 and over (half of whom are over 90)⁹ as life expectancy in England is 78 for a man and 82 for a woman¹⁰, and it was felt that a higher proportion in this age group could be performed for palliative reasons, regardless of significance of peripheral

arterial disease (for example pain control in bed-ridden patients with mixed ulceration or pressure necrosis).

Prevalence rates, per 100 000, were calculated using HES data as the numerator with the denominator population derived from the Office National Statistics (ONS) mid year population estimates.¹¹ The denominator diabetic population was calculated by applying the age specific prevalence of diabetes to census estimates from the national Health and Lifestyle survey for England 2003-2012¹² This is an annual government run survey since 1991 collecting information on physical health, lifestyle behaviours, social care, physical measures, mental health and well being¹². The age specific non diabetic population was derived by removing the diabetic population from the whole population. The diagnosis of diabetes in amputees was extracted from HES data. The number of major amputees who were diabetic was based on co-morbidities coded in the HES database using the ICD-10 code of diabetes (E10-E14). We applied the same proportions of major amputees with diabetes to those who had minor and amputation stump procedures.

We age standardised the overall rates in England to the 2011 census and additionally standardised the diabetic population to the 2011 European population¹³ to facilitate international comparisons using standard techniques.¹⁴ We did not calculate confidence intervals as we used the whole population to calculate prevalence.

Results

Ten year period prevalence (fig 1)

There were 42 294 major lower limb amputations (22 645 above knee; 19 658 below knee), 52 525 minor amputations and 355 545 revascularisations (endovascular 288 148; surgical 67 397) over the ten year period. Figure 1 (a and b) illustrates the yearly age adjusted prevalence of amputation (major and minor) and revascularisation from 2003 to 2013 respectively. The prevalence, per 100 000, of major amputation has reduced by almost 20% (27.7 to 22.9), whereas minor amputations have increased by 15% (29.9 to 35.2). Revascularisations have also increased by 20% (199.8 to 245.4), although surgical revascularisations have risen at double the rate of endovascular revascularisations (surgery 35% rise, 34.0 to 51.6: endovascular 15% rise; 165.0 to 193.9). The overall ratio of endovascular to surgical revascularisation in England has reduced over the last ten years from 4.7:1 to 3.9:1.

Relationship between diabetes, gender and prevalence of major amputation (tables 1 and 2)

Table 1a describes the proportion of diabetics among major amputees and the general population with table 1b giving the absolute numbers used to derive rates. Age standardised absolute prevalence rates in male and female diabetics in 2003 and 2013 is given in table 2. Although decreasing over time, major amputation rates remain six times higher in diabetics compared with non diabetics. Amputation rates in both groups remain approximately double in men compared with women. Approximately half of major amputees are not diabetic with this group experiencing a rate of decrease that is approximately half that of diabetics.

Relationship between diabetes, gender and prevalence of minor amputations (tables 3 and 4)

The rise in the overall minor amputation rate (figure 1) appears to be driven by the non diabetic male population (table 3). The rate in the diabetic population is stable in men and decreasing in women. The same pattern is seen for stump procedures (table 4) i.e. a rise in the non diabetic population with a fall in the diabetic population. In contrast to major and minor amputations, women experienced a greater rise in stump procedures than their male counterparts.

Discussion

Summary

Our ten year analysis of English hospital data has shown the overall prevalence of major amputation to have decreased by approximately 20% and both minor amputation and revascularisation rates increased by a similar proportion. The rates of major amputation in the diabetic population have reduced by approximately 40% over the last ten years yet remain six times higher than non diabetics. However, half of all major amputations undertaken in England were in non diabetics with this group experiencing a much slower rate of decrease.

Context of study

The reduced rates of major amputation in diabetics despite a rising prevalence of diabetes¹² suggest national campaigns such as Putting Feet First and improvements in the processes of diabetes care delivery via the Quality and Outcomes Framework and annual audits of these processes via the National Diabetes Audit are contributing positively to outcomes.¹⁵⁻¹⁶

However, as prevalence of major amputation in diabetics remains much higher than non diabetics, continued vigilance is required especially as around one fifth of diabetics do not get annual foot checks.¹⁶

Our overall age adjusted rate in England is, however, very different from those studies reporting the prevalence of major amputation in England to be in the region of 5/100 000.^{5,17-18}

Of these studies, only Moxey et al⁵ presented sufficient methodological data to allow comparison. They reported the five year period prevalence (2003-2008) of both major and minor amputation using HES and census data across England and its regions but only included those with an admission diagnosis of 'peripheral vascular disease' regardless of age. They

reported a prevalence rate that was five times lower than the present study. We believe, the dissimilar rates between our studies is because of errors in their article. Firstly, their rates were actually per 10 000 and not per 100 000, secondly, their denominator was the whole of the United Kingdom (including children) whereas their numerator was only England (age groups studied not given). Finally, they did not present either age or gender specific results and did not age standardise their overall result.

What our study adds

The pattern of major amputation in non diabetics particularly the slower rate of decrease was concerning. Further, the increase in the minor amputation rate appears to be driven by male non diabetics. We believe the prevailing pathology in this group is PAD and as this disease also leads to foot ulcers and amputation, we suggest the diabetic foot model, where access to vigilant foot care services reduces the risk of amputation, be investigated for, non diabetic sufferers of PAD.

Limitations of study

There are, however, several limitations to our study. Firstly, our choice of using the 50-84 year age group to capture PAD amputations. Our strategy excluded cases in those aged 85 and over but included those relating to cancer and trauma - this is in contrast to Moxey et al⁵ who used PAD in the diagnosis to exclude non PAD related amputations. We did not employ this strategy because a recent systematic review found primary diagnosis in HES to be only 83% accurate¹⁹, further, many of the 5% of major amputations not related to PAD, mainly trauma⁶ are outside those aged 50-84. Finally, the excluded population over 84 comprise approximately 350 000 people, of whom half are over 90.¹¹ Despite, the different strategies, our numerator over a

comparable period was approximately 13% lower than Moxey et al⁵. We therefore do not believe these limitations affected our conclusions and only minimally affected our age specific rates. The use of the Health and Lifestyle Survey to determine the diabetic population has been employed before¹⁷ although general practitioner returns data,¹⁸ primary care trust quality and outcomes framework (PCT-QoF) data,²⁰ census data removing an appropriate diabetic populations²¹⁻²² and validated diabetic registers used in regional Scottish prevalence studies²³⁻²⁵ can be used instead. Thirdly, we did not look specifically at primary versus conversion amputations i.e. below knee to above knee as the code we used i.e. X12 also included other procedures on stumps e.g. debridements. Our experience is that these procedures are badly coded i.e. conversion to above knee amputation is generally coded as 'above knee amputation' and thus is likely to be an under-estimate. Finally, we did not examine duration of diabetes or other changing characteristics of this population e.g. better management when interpreting time trends as this data is not available from the HES database.

Our data are therefore reliant on accurate hospital coding. The sensitivity of HES co-morbidity coding especially diabetes has not been published; a small scale validation study of our own (in press) has shown sensitivity of diabetes coding to be approximately 76% with specificity of 98%. Whilst this is true for major amputations, we have not looked at diabetes coding accuracy for minor and repeat amputations. Thus, our calculation of age specific prevalence of minor and repeat amputation by diabetic status derived by applying major amputation diabetes proportions maybe, again, be an under-estimate.

The role of studies, like ours, on large databases, ultimately, is to generate hypothesis to test in clinical trials. An incidence study with a similar methodology to Jorgensen et al²⁶ would provide valuable insight into national time trends. However, such a study is not possible in England because linkable national datasets are not currently available.

Conclusion

We have shown the overall major amputation rate in England over the last ten years to have decreased. Over the same period, minor amputation and revascularisation procedures have increased. However, rates of major amputation in diabetics remain six times higher than non diabetics suggesting continued vigilance is essential. However, half of all major amputees are not diabetic with the rise in minor amputations driven by non diabetic men. We suggest services for this group, i.e. non diabetics, particularly access to foot services, be evaluated.

Competing interests: None declared

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