


Research: Care Delivery

Diabetic foot ulcer incidence and survival with improved diabetic foot services: an 18-year study

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Abstract

Aims To ascertain the effects of improvements in diabetic foot services over 18 years on incidence of diabetic foot ulceration. We also compared survival time from first ulcer development with presence of neuropathy, peripheral vascular disease, age and healing.

Methods Persons with new ulceration and those at high risk of ulcer development were referred to community podiatry from 1998. Their details were recorded, with verbal consent, on a central database. The effects of neuropathy, peripheral vascular disease, healing and age on survival were analysed by Cox proportional hazards ratios.

Results The incidence of first ulcer presentation decreased from 11.1 to 6.1 per 1000 persons between 2003 to 2017 ($P < 0.0001$). Recurrent ulceration incidence remained stable. Prevalence of chronic and new foot ulceration combined increased from 20.7 to 33.1 per 1000 persons ($P < 0.0001$). Ten-year survival was 85% for persons presenting with first ulcer and aged < 65 years, 50% for those aged 65–74 years and 25% for those aged 75–81 years ($P < 0.0001$). In those with peripheral vascular disease 5-year survival was 35% ($P < 0.001$).

Conclusions Integrated care for the diabetic foot in one National Health Service (NHS) health service area over 18 years was associated with a reduction in first presentations of diabetic foot ulceration, but failed to reduce recurrent ulceration. Cumulative prevalence of all ulcers continues to increase. Monitoring ulceration incidence can inform audit and planning of diabetic foot care services. Survival is better than reported previously in persons < 65 years and in the absence of peripheral vascular disease.

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Introduction

Five-year survival in persons who present with diabetic foot ulceration has previously been shown to be as low as 50% [1–7] and to be worse in those with vascular disease [6]. A recent large study of persons living with diabetes at high risk of foot ulceration in Scotland has shown associations between conventional cardiovascular risk factors, ulceration and 2-year survival. Analysis in this large study of high risk, previously ulcerated and currently ulcerated persons did not focus on first presentation of diabetic foot ulceration [8]. Persons living with diabetes and loss of protective foot sensation, foot deformity and or peripheral vascular disease are at high risk of diabetic foot ulceration, and those with previous ulceration are at even greater risk [9]. Regular

community podiatry review for persons at high risk of diabetic foot ulceration has been recommended by the National Institute for Health and Care Excellence (NICE) since 2004. However, attempts to reduce new and recurrent ulceration in high-risk persons have required intensive intervention and follow-up [1,2,10–12]. The development of diabetic foot ulceration is associated with loss of protective sensation [13]. This has been confirmed in the South Devon population [14]. Incidence of amputation resulting from diabetic foot ulceration is also influenced strongly by ethnicity [15,16]. In South Devon, we have shown that integration of diabetes foot care including general practice, community podiatry and secondary care has resulted in a reduction in major amputation incidence from 2005 to 2017 in a high-risk, predominantly white British population [17]. In this geographical area, diabetes foot care has been rationalized since 1998 with a standardized operating procedure for foot examination in general practice and community podiatry. Community and hospital podiatry services were enhanced from 2007, and a NICE compliant multidisciplinary foot

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What's new?

- Prevention of diabetic foot ulceration has been difficult to achieve
- Survival after diabetic foot ulceration has historically been poor
- This study has shown reduction in first diabetes related foot ulceration with improved foot care services
- Participant survival after development of first diabetic foot ulceration was longer than in recent reports especially for those under 65 years of age, where ulcers healed, and in those without peripheral vascular disease
- Adequate commissioning of diabetic foot care services is necessary to prevent first foot ulceration
- Counselling for younger patients with diabetic foot ulceration can be more positive

team (MDFT) was developed by 2010. Further increases in community podiatry staff numbers were introduced in 2012. These improvements enhanced promptness of access to treatment of diabetic foot ulcers in community podiatry and rotation of podiatrists into the MDFT. During this time, the indications for referral from general practice of those at high risk of foot ulceration and all with foot ulcers have remained unchanged. The incidence of first diabetes-related foot ulcers, recurrent ulceration, 5- and 10-year survival after first ulcer presentation have been analysed over the period of improvements in diabetic foot care service provision.

Participants and methods

Participants

All persons with high risk of diabetes related foot ulceration, and those with new foot ulcers were referred by general practice to community podiatry from 1998. This was reinforced by the introduction of a standard operating procedure (SOP) for foot annual review as part of regular meetings with the secondary care team. All practices were advised to refer persons living with diabetes who developed foot ulceration to community podiatry. A domiciliary podiatry service to access housebound persons living with diabetes was commenced in 2000. Verbal consent was obtained from all persons living with diabetic foot ulceration for their clinical details to be recorded on a database maintained by the community podiatry department from 2001. A diabetes-related foot ulcer was defined as any break in the skin below the ankle in a person living with diabetes. We analysed the community podiatry database from 2001 to 2017 for trends in age, incidence and prevalence of diabetic foot ulceration, neuropathy and peripheral vascular disease and survival following first foot ulcer. It has also been

possible to assess the Torbay Hospital MDFT database to ascertain the number of persons living with diabetes presenting with foot ulceration who were not previously known to community podiatry.

First diabetic foot ulcer was diagnosed from participant history, examination and confirmed by previous records over the preceding 5 years. Ulcer healing within first 2 years of follow-up was recorded. Recurrent ulceration included presentations with breakdown of initial foot ulcer or any new ulcer on either foot. Reasons for discharge and death were recorded. To ensure completeness of follow-up the South Devon community podiatry database was linked with the NHS digital Spine database [18]. The Torbay Hospital MDFT database was interrogated to identify persons living with diabetes who were referred directly to the hospital for foot ulceration without community podiatry involvement. Status, alive or deceased was ascertained in all of the 1640 persons recorded as developing a first foot ulcer over the 18 years.

Clinical examination

Protective foot sensation was assessed with 10-g monofilaments perception. Diabetic neuropathy was diagnosed as failure to perceive two or more 10-g monofilament stimuli in both feet, with and without neuropathic symptoms. High risk for foot ulceration was confirmed if there was loss of perception of only one or two 10-g monofilament stimuli. Extensive callus, foot deformity, vascular disease or previous ulceration were also taken to confirm high risk. Peripheral vascular disease was identified by delay of > 5 s in great toe capillary refill time, absence of one or more foot pulses to palpation or monophasic or absent foot pulses with Doppler.

Statistical analysis

Numbers of diabetic foot ulcers per year and per 5-year period were expressed as incidence and prevalence per 1000 persons living with diabetes recorded on the Quality Outcome Framework (QOF) register. The total number of persons per year with diabetes and foot ulcer disease, new, old and recurrent was measured to calculate cumulative prevalence of foot ulceration. The total number per year of persons with first ever diabetic foot ulceration, as described above, was taken as incidence of first ulceration. All are expressed per 1000 on the diabetes QOF register. Kaplan–Meier estimator and Cox proportional hazard ratios were generated for the effects of age, ulcer healing, gender, presence or absence of neuropathy and peripheral vascular disease on survival of persons with diabetes from the date of first development of foot ulceration. All statistical analysis was conducted in 'R'.

Ethical considerations

Persons living with diabetes who presented to community podiatry services in South Devon gave verbal consent for

Table 1 Demographic details of persons with diabetic foot ulcers, first ever, recurrent and chronic in Torbay and South Devon Health Care Trust 2003 to 2017

	Years			P-value*
	2003–2007	2008–2012	2013–2017	
All ulcers, first, recurrent and chronic average /1000 year	20.7 (1.3)	24.9 (3.0)	33.1 (6.2)	0.007
Mean age, years	73.1 (12.2)	74.0 (12.0)	76.2 (12.2)	NS
% Female	44.5	39.9	37.1	NS
Home care per 1000 DM	1.9 (0.3)	2.6 (0.3)	5.5 (1.9)	0.0005
% Neuropathy	54.4	54.5	56.9	NS
% Peripheral vascular disease	19.8	14.2	14.7	0.0022

*Significance levels shown are unpaired *t*-tests 2003 to 2007 vs. 2013 to 2017 (± SD). DM, diabetes mellitus; NS, not significant.

inclusion of their details on a centralised data base. The South Devon Healthcare ethics committee was consulted regarding retrospective audit of the data. As this was an audit of anonymised data it was not considered necessary to formally seek ethics committee approval.

Results

Hospital clinic only referrals

Some 83 persons with a diabetic foot ulcer who were unknown to community podiatry during the course of this study were identified through searches of the Torbay Hospital diabetic foot database. Thirty-one had severe ischaemia and proceeded to vascular intervention. Twenty-seven had chronic foot ulcers which were reviewed by the hospital podiatry team. Twenty-five presented with first foot ulcer, of which nine healed within 2 years of follow-up. They have not been included in this analysis.

Loss to follow-up

Some 21 participants with healed ulcers and seven with unhealed ulcers were excluded from the analysis of healing and recurrent ulceration as they had less than 1 year of podiatry follow-up.

Chronic ulceration, age and co-morbidity

There was an increase in annual prevalence of all diabetic foot ulcers (first, recurrent and chronic combined) during the course of the study. The number of diabetes-related foot ulcer participants in residential care or confined to home increased significantly from 17 in 2001 to 139 in 2017. The increase in chronic ulceration numbers per annum from 2012 onwards is linked to increased frequency of follow-up facilitated by increase in community podiatry staffing. Percentages with neuropathy remained constant, whereas peripheral vascular disease decreased Table 1.

New and recurrent ulceration

There was a statistically significant fall in new diabetic foot ulcer incidence when analysed as an annual trend and in 5-year periods. The incidence of recurrent foot ulceration remained stable over the same periods (Table 2). Annual numbers of new, recurrent, domiciliary and chronic diabetic foot ulcer participants from 2003 to 2017 are shown in the Table 3. One-tenth of the total diabetic foot ulcers from 2003 to 2012 occurred in domiciliary care participants. This increased to one-fifth from 2013 to 2017 (28.6% by 2017). There has been a sharp increase in annual chronic ulceration recorded from 2012; this is likely to have resulted from increased community podiatry staff numbers which has allowed more frequent review of participants with chronic ulceration. The percentage of participants with first ever diabetic foot ulceration who were alive and healed 12 weeks after presentation has not varied significantly between 2011 and 2017 (31.1, 30.1, 28.9, 32.4, 37.2 and 30.7%, respectively).

Survival trends

Survival was not influenced by gender, but older persons and those with peripheral vascular disease were found to have

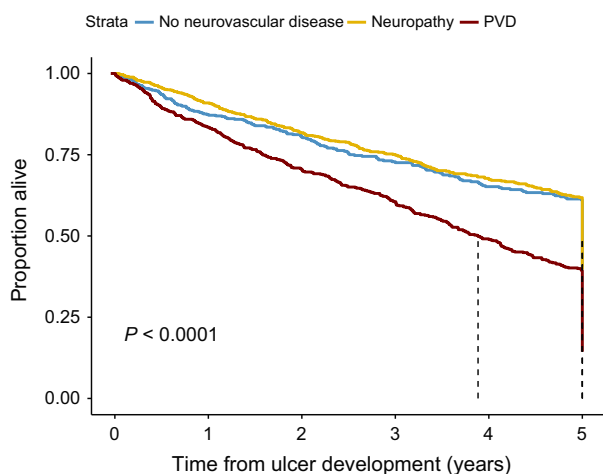
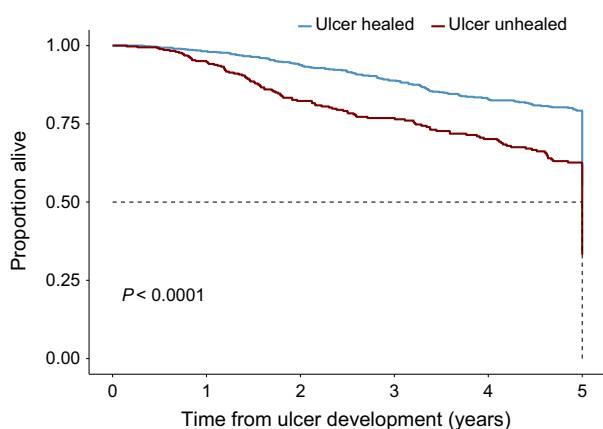
Table 2 Five-year incidences of first ever and recurrent diabetes related foot ulcers expressed as annual incidence/1000 persons living with diabetes

	Years			P-value*
	2003–2007	2008–2012	2013–2017	
QOF diabetes numbers mean/year for each 5 year period	10664	13940	16051	0.001
First ever ulcers all in a 5-year period	543	604	493	
Incidence of first ulcer mean/year over 5 years	11.1 (1.1)	12.5 (1.4)	6.1 (1.5)	0.0006
Recurrent ulcers all in a 5-year period	382	570	614	
Incidence of recurrent ulcers average/year over 5 years	7.3 (1.2)	8.4 (1.7)	7.7 (2.4)	0.35

*Significance levels shown are unpaired *t*-tests 2003 to 2007 vs. 2013 to 2017. Ulcer incidence expressed as mean (SD).

Table 4 Kaplan–Meier analysis of ten year survival after first diabetic foot ulceration according to age at diagnosis

Age group (years)	Time point (years)	No. at risk	Proportion alive	Standard error	Lower 95% CI	Upper 95% CI
< 65	10	167	0.698	0.025	0.652	0.748
65–74	10	117	0.458	0.026	0.411	0.511
75–81	10	38	0.236	0.027	0.188	0.296
> 81	10	8	0.051	0.016	0.028	0.095

**FIGURE 1** Survival over time (years) following recognition of first ulcer in diabetic population stratified by no neurovascular disease (blue), neuropathy (yellow), peripheral vascular disease (red).**FIGURE 2** Comparison of survival over time in years following development of first ulcer stratified by ulcer healed on follow-up (blue), or not (red).

strengthening of the foot protection service and development of a NICE-compliant MDFT. Prevention of foot ulceration in those living with diabetes is critically dependant on their own foot care, annual foot review and access to podiatry. For success, there must be readiness of all healthcare professionals to offer education when the person is receptive, systematic and enthusiastic care in general practice, and fully staffed

community podiatry services. Incidence of new foot ulceration is thus a key performance indicator of efficacy in diabetic foot care services and is likely to influence amputation rates. There is an urgent need to link practice and community nurses with community podiatrists and for this team to be seen as part of the multidisciplinary diabetes foot team.

There has been a reduction in peripheral vascular disease over time in this population which is likely to be related to the fall in smoking prevalence. Smoking rates in South Devon have mirrored those in England (33 and 38% of females and males, respectively in 1980, and 14.8% in sexes in 2017) [21,22]. Advanced age and peripheral vascular disease remain strong markers of reduced survival. These results are consistent with the National Diabetes Foot Audit (<https://www.hqip.org.uk/resource/national-diabetes-foot-care-audit-fourth-annual-report>) [23] which has evaluated factors associated with ulcer free survival at 12 and 24 weeks in England.

Previous diabetic foot ulceration constitutes the highest risk for subsequent foot ulceration in diabetes [1,9,10,12,24]. Effective foot protection to reduce re-ulceration is challenging [25]. Our data indicate that current advice and surveillance for previously ulcerated persons have not succeeded in reducing recurrent ulceration. Research is needed to explore new offloading techniques and early introduction of customized orthoses where early warning of shear stress has been identified such as redness, heat and callus formation. In this study, recurrent ulceration has included all new ulcers whether breakdown of the first presenting foot ulcer or a new ulcer on the same or other foot. This emphasizes the need to assess and treat all vulnerable areas of both feet once a diabetic foot ulcer has developed. Prospective trials of corrective orthopaedic surgery to reduce foot pressures are also needed.

The strengths of this study are that it derives from a stable population over 18 years that is at high risk of diabetic foot ulceration, and that the referral patterns from general practice have remained unchanged during this time. It is also of importance that the ulceration incidence and survival can be set in the context of improvements in the whole foot care pathway in the area, changes which have been associated with a sustained and significant reduction in major amputation incidence [17]. The weaknesses are that it has not been possible to record all of the ulcer severity scores, or causes of death in every person. More intense screening for diabetes may have led to the increase in QOF-registered

persons living with diabetes with the possibility that this would diminish the severity of diabetes in that population. This would be expected to reduce the prevalence of all complications of diabetes related to duration of glucose intolerance. However, within this data set, the prevalence of all diabetic foot ulcer disease has increased in spite of possible inclusion of ‘early’ diabetes in the QOF numbers. A recent study found microvascular and macrovascular complications of Type 2 diabetes to be present in 30% of persons at diagnosis [26]. Complications have also been shown to develop rapidly after diagnosis [27]. Moreover, the constant incidence of recurrent ulceration, the fall in first time ulcers, and the longer survival of those < 65 years and those free from peripheral arterial disease are important to highlight.

The population studied is > 98% white British, in an area with pockets of high deprivation indices and where > 50% of the population living with diabetes is older than 65 years of age. Our findings may not be generalizable to persons from other ethnic groups living with diabetes.

In summary, this analysis shows that the incidence of first diabetic foot ulceration, but not recurrent ulceration is reduced in association with improvements in diabetes footcare. Peripheral vascular disease, failure of ulcer healing and age were associated with reduced survival. More intense follow-up and bespoke orthoses may be necessary to reduce re-ulceration. Careful auditing of diabetic foot ulcer numbers can form the basis for appropriate commissioning of foot protection services by clinical commissioning groups. These results can inform future development of the National Diabetes Foot Care Audit, in particular to analyse first time and recurrent ulceration incidences. Participation in the National Diabetes Foot Care Audit should be mandatory for providers of diabetes foot care in order to comprehensively measure how incidence and outcome are affected by ethnicity, site and severity of foot ulceration and service provision.

Contributors

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Competing interests

None declared.

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Ethical Approval

The study was approved by the Medical Ethics Committee of [INSTITUTION], and informed consent was obtained from all participants. This research study was conducted in accordance with the guidelines of the Declaration of Helsinki.

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