DM

The North-West Diabetes Foot Care Study: incidence of, and risk factors for, new diabetic foot ulceration in a community-based patient cohort

C. A. Abbott, A. L. Carrington, H. Ashe, S. Bath, L. C. Every, J. Griffiths, A. W. Hann*, A. Hussein, N. Jackson, K. E. Johnson, C. H. Ryder, R. Torkington, E. R. E. Van Ross, A. M. Whalley, P. Widdows, S. Williamson and A. J. M. Boulton†

Diabetes Foot Clinic, Disablement Services Centre, Withington Hospital, *Medical Statistics Research Support Unit, University of Manchester, and †University Department of Medicine, Manchester Royal Infirmary, Manchester, UK

Accepted 4 November 2001

Abstract

Aims To determine the incidence of, and clinically relevant risk factors for, new foot ulceration in a large cohort of diabetic patients in the community healthcare setting.

Methods Diabetic patients (n = 9710) underwent foot screening in six districts of North-west England in various healthcare settings. All were assessed at baseline for demographic information, medical and social history, neuropathy symptom score, neuropathy disability score, cutaneous pressure perception (insensitivity to the 10 g monofilament), foot deformities, and peripheral pulses. Two years later, patients were followed up via postal questionnaire to determine the incidence of new foot ulcers. Cox's proportional hazards regression analysis was used to determine the independent, relative risk of baseline variables for new foot ulceration.

Results New foot ulcers occurred in 291/6613 patients who completed and returned their 2-year follow-up questionnaire (2.2% average annual incidence). The following factors were independently related to new foot ulcer risk: ulcer present at baseline (relative risk (95% confidence interval)) 5.32 (3.71–7.64), past history of ulcer 3.05 (2.16–4.31), abnormal neuropathy disability score (≥ 6/10) 2.32 (1.61–3.35), any previous podiatry attendance 2.19 (1.50–3.20), insensitivity to the 10 g monofilament 1.80 (1.36–2.39), reduced pulses 1.80 (1.40–2.32), foot deformities 1.57 (1.22–2.02), abnormal ankle reflexes 1.55 (1.01–2.36) and age 0.99 (0.98–1.00).

Conclusions More than 2% of community-based diabetic patients develop new foot ulcers each year. The neuropathy disability score, 10 g monofilament and palpation of foot pulses are recommended as screening tools in general practice.

Diabet. Med. 19, 377–384 (2002)

Keywords foot ulcer, incidence, screen, risk factor, neuropathy disability score, population

Abbreviations NSS, neuropathy symptom score; NDS, neuropathy disability score; FDS, foot deformity score; PVD, peripheral vascular disease; NWDFCS, The North-West Diabetes Foot Care Study; GP, general practitioner

Introduction

Clinical studies have consistently identified measures of peripheral neuropathy as predicting diabetic foot ulceration [1–3], with some evidence for other associations such as peripheral

Correspondence to: Caroline Ann Abbott PhD, Diabetes Foot Clinic, Disablement Services Centre, Withington Hospital, Manchester M20 8LB, UK. E-mail: ca.abbott@btinternet.com

vascular disease (PVD), limited joint mobility, foot deformities and duration of diabetes [3–5]. However, despite an increasing wealth of such evidence for clinical risk factors for diabetic foot ulceration, most research focuses on specific groups of diabetic patients. Indeed, such studies are invariably case-controlled in design [4,6,7], or, if prospective analyses, assess relatively small, clinic-based groups of patients subject to selection-bias [1,3,8].

Clinically relevant risk factors for foot ulceration in diabetic patients receiving care in the community healthcare setting have not yet been determined, even though these are the diabetic patients who are, or should be, screened by practice nurses, podiatrists and general practitioners (GPs).

In the North-West Diabetes Foot Care Study (NWDFCS), a prospective analysis of a very large cohort of diabetic patients receiving community healthcare in the North-west Region of England, we aimed to determine: (i) the incidence of foot ulceration in such patients; (ii) which of the simple clinical foot screening methods widely used in clinical practice are most effective for predicting the risk of diabetic foot ulceration in the community.

Patients and methods

All adults diagnosed with Type 1 or Type 2 diabetes, according to WHO criteria, were targeted in six health care districts of North-west England: Central Manchester, South Manchester, Bolton, Rochdale, Oldham and Wigan. GP teams and hospital-based diabetes teams in each district were invited to become involved in this project that provided a foot screening service for all diabetic patients on their lists. One full-time research podiatrist or research nurse was appointed to screen diabetic patients in the GP practices, diabetes centres and hospital out-patient clinics for each district. Screening commenced in April 1994 and continued for 2 years. At GP practices, the vast majority of patients were screened whilst attending for their annual review; others were screened whilst attending podiatry clinics. Remaining patients were invited to attend a special clinic at the practice, or the patient was visited residentially.

The level of GP involvement in the study was calculated for three randomly selected districts (Bolton, Oldham and Central Manchester). In these districts, 84%, 75%, and 45% of all GP practices, respectively, became involved in the NWDFCS, giving a mean GP response rate of 68%. In Central Manchester, the district with the lowest proportion of participating GPs, the large majority of all practices in the district (90% of participating and 75% of non-participating practices) ran their own diabetes mini-clinics, i.e. diabetes care provision in GP practices involved in this study was comparable to that of the district as a whole. In the three districts, 80%, 58%, and 42%, respectively, of all listed diabetic patients for involved GPs were screened. Thus, on average, 60% of involved GPs' diabetic patients were screened, representing a large sample selection from the general diabetic population attending community healthcare clinics.

Prior to screening, all podiatrists attended a series of training sessions at the NWDFCS headquarters in order to standardize screening techniques.

Screening measurements

At baseline, the following variables were recorded for all patients: gender, age, ethnic origin (based upon patients' appearance and grandparental origin), socioeconomic classification (based upon the Registrar General's classification [9]), and whether or not the patient lived alone. A medical history was taken, including duration and treatment of diabetes, and patients' social history included details of smoking history and evidence of regular alcohol consumption (> 7 units/week). Medical records were examined to determine if patients were registered blind/partially sighted, or had impaired vision so that they were unable to see their own feet clearly. Patients were also questioned as to whether they had previously attended a podiatrist for a routine visit, treatment and/or foot care advice. Repeated evidence of protein in urine, ongoing haemodialysis or continuous ambulatory peritoneal dialysis, or previous kidney transplant indicated nephropathy. Details of past or present foot ulcers were documented via examination and accessing the podiatry/medical notes. A foot ulcer was defined as a full thickness skin break at least to Wagner Stage 1, occurring distal to the malleoli. Patients were assigned a footwear risk category, dependent on which type of shoe was worn most often: low risk = trainers, lace-ups, boots (low heel), extra depth/surgical shoes; moderate risk = 'slip-ons'/casual shoes, bar or buckle fastened shoes, slippers; high risk = open-toe sandals, high-heeled shoes, flip-flops.

Peripheral neuropathy was assessed by a variety of techniques: a modified neuropathy symptom score (NSS) was used to determine the severity of neuropathic symptoms [10]. Signs of neuropathy were determined using a modified neuropathy disability score (NDS) [10] derived from abnormalities of pain sensation using a Neurotip™, vibration sensation using a 128-Hz tuning fork, dorsal temperature sensation using warm and cool rods, and Achilles reflex using a tendon hammer. For one foot, each sensory test scored 0 for normal sensation or 1 for abnormal sensation; ankle reflex scored 0 if present, 1 if present with reinforcement or 2 if absent. The maximum score was 10 for both feet, with a score ≥ 6 indicating moderate to severe neuropathy [10]. For patients with trans-femoral or trans-tibial unilateral amputation, NDS was assessed on the remaining foot, and the score was then doubled for the statistical analysis. Cutaneous pressure perception was assessed using 1 g, 10 g and 75 g Semmes Weinstein monofilaments (Gillis W. Long Hansens's Disease Center, Carville, LA, USA) at three validated plantar sites (1st and 5th metatarsal heads and the heel [11]) on each foot. With eyes closed, the patients were required to elicit a 'yes/no' response to monofilament pressure and correctly identify the site of contact. Each filament was placed against the plantar surface of the foot in a perpendicular fashion so that it bent with a constant force, commencing with the 1 g filament. If the 1 g filament was not felt at any one site the 10 g filament was then tested at that position. Furthermore, if the 10 g was not felt, the 75 g monofilament was similarly applied. For statistical analysis, insensitivity to at least the 10 g monofilament at any one site on either foot indicated abnormal sensation [6,11]. A novel, six-point foot deformity score (FDS) was devised using the following dichotomous variables: small muscle wasting (interossei wasting sufficient to cause 'troughing' between

tendons), hammer or claw toes, bony prominences, prominent metatarsal heads, Charcot arthropathy and limited joint mobility (lack of contact between any of the metacarpal-phalangeal joints during prayer sign). Each deformity scored 1 when present or 0 when absent, on either foot. A combined score of ≥ 3 was arbitrarily defined as indicative of significant foot deformities.

Peripheral vascular status was assessed by palpation of the dorsalis pedis and posterior tibial pulses on both feet. Presence of two or less of the four pedal pulses, either with or without the presence of oedema, indicated PVD. For patients with major unilateral lower limb amputation, the number of foot pulses was doubled for the statistical analysis. In addition, patients were questioned about any previous peripheral angioplasty or peripheral bypass surgery they had undergone to determine peripheral vascular history.

Prospective follow-up

Two years after their original screening date (± 6 weeks) all patients were re-contacted via postal questionnaire, to assess the incidence of any new foot ulcers occurring since baseline. The first new foot ulcer event that occurred within the follow-up period was recorded as the final outcome for each patient. All returned questionnaires reporting a positive new ulcer event were rigorously cross-checked, i.e. patients were re-interviewed over the telephone by the podiatrist and source podiatry and GP notes were also examined. Thus, reported new ulcer events were confirmed and reported false-positive events were eliminated. In addition, a random sample of 300 returned questionnaires reporting no new ulcer event were similarly cross-checked.

Ethical approval was obtained from the research ethics committees for this study.

Statistical analysis

For comparison of baseline variables between groups, χ^2 tests were performed for categorical data, and Student's *t*-tests were carried out for continuous data where means or geometric means are presented (the latter for data that required a $\log_e$ transformation to produce a satisfactory approximation to a normal distribution). In addition, some variables were stratified into normal and abnormal categories, then χ^2 tests were performed.

To assess the relationship between the baseline variables and incidence of new foot ulceration, Cox's proportional hazards regression analysis was carried out for each variable separately. This method was used with the constraint of constant follow-up time as it enables the estimation of relative risk. For these cross-sectional data, the use of logistic regression, from which odds ratios are obtained, is inappropriate. It is now conventional to analyse cross-sectional studies (using methods other than logistic regression) to obtain estimates of relative risks rather than odds ratios [12]. Forward and backward stepwise methods with Cox's proportional hazards regression were carried out to identify the best subset of independent predictors.

SPSS 9.0 for Windows statistical package was used for all statistical analyses.

Results

Screened cohort

A total of 9710 diabetic patients were screened in the six districts over 2 years; 6527 (67.2%) were screened in the primary care setting (GP practices), 3147 (32.4%) in the secondary care setting (hospital out-patients, podiatry clinics), while 36 (0.4%) were screened at home. Baseline characteristics are given in Table 1. The prevalence of active foot ulceration in this cohort of patients, identified at screening, was 1.7% (n = 165). The median duration of the ulcers was 8 weeks (I.Q. range 2–16 weeks) with median Wagner grade classification being 1 (1–2). The main cause of ulceration was pressure from footwear (55%), whereas trauma (15%), fissure (7%), self-treatment/injury (6%) and unknown or other causes accounted for the rest (17%). The overall prevalence of past ulceration was 3.1% (n = 295) throughout all districts. The prevalence of lower limb amputation at any level was found to be 1.3% (n = 122). No amputation site was specified for 12 of the amputation subjects. For the rest, the various sites of amputation were as follows: 18.2% (n = 20) above knee; 28.2% (n = 31) below knee; 0.9% (n = 1) through metatarsal bones; 11.8% (n = 13) great toe +/– other toes; 38.2% (n = 42) other toe(s) or ray(s) (not including great toe); 2.7% (n = 3) toes unspecified. Directly following baseline screening, 1231 (12.7%) patients were referred appropriately for podiatry and 62 (0.6%) patients were referred to the vascular surgeon.

At 2 years follow-up, each screened patient (n = 9710) received a postal questionnaire. In total, 7410 questionnaires were returned to NWDFCS headquarters, with no reply ever received from 2300 patients. Of the 7410 replies, 6668 were from patients who had completed their questionnaires, 126 from patients only partially completing their questionnaires (response rate of 70.0%), while the remainder of the returns informed of patients who had died (n = 405) or moved to a different address (n = 211) during the follow-up period. Of the 6668 patients who returned completed forms, 6613 patients were either confirmed to have developed or not developed new foot ulcers during the follow-up period. The remaining 55 questionnaires reporting various foot problems were unable to be confirmed as new ulcers, and thus were excluded from the analyses. We present data therefore for 6613 patients who were screened at baseline, completed their 2-year follow-up questionnaire and whose new ulcer events were confirmed. In total, 291/6613 patients developed new foot ulcers during follow-up, giving an overall ulceration incidence of 4.4%, i.e. average annual ulceration incidence of 2.2%. In the random sample of returned questionnaires in which patients reported no new ulcer events (n = 300), rigorous cross-checking revealed that no new ulcer event had been missed by this follow-up method.

Details of baseline characteristics for the 'responding' (n = 6613) and 'non-responding' (n = 2300) diabetic screened population are also in Table 1. These populations were similar

Table 1 Baseline characteristics of all screened patients, patients returning their questionnaires, and non-responding patients

Variable	All patients (n = 9710)	Responders (n = 6613)	Non-responders (n = 2300)
Age in years	61.3 [± 14.1]	61.7 [± 13.3]	58.2 [± 15.6][a]
Duration diabetes in years	8.9 [± 11.1]	8.6 [± 10.4]	8.7 [± 15.8]
Male	53.8%	53.2%	54.6%
	(n = 8965)	(n = 6133)	(n = 2128)
Socio-economic class:			
1 (professional)	145 (1.6%)	98 (1.6%)	35 (1.6%)
2 (intermediate)	1086 (12.1%)	778 (12.7%)	245 (11.5%)
3 (skilled)	4588 (51.2%)	3193 (52.1%)	1030 (48.4%)
4 (partly skilled)	1334 (14.9%)	873 (14.2%)	346 (16.3%)
5 (unskilled)	1812 (20.2%)	1191 (19.4%)	472 (22.2%)
Ethnicity:			
White Caucasian	8508 (87.6%)	5940 (89.8%)	1829 (79.5%)[a]
African-Caribbean	260 (2.7%)	159 (2.4%)	83 (3.6%)
South Asian	920 (9.5%)	501 (7.6%)	381 (16.6%)
Other	22 (0.2%)	13 (0.2%)	7 (0.3%)
Live alone	2137/9361 (22.8%)	1436/6564 (21.9%)	481/2300 (20.9%)
Blind/impaired vision	1324/9619 (13.8%)	859/6556 (13.1%)	287/2300 (12.5%)
Nephropathy	254/9541 (2.7%)	157/6507 (2.4%)	66/2300 (2.9%)
Foot ulcers:			
Present	165/9638 (1.7%)	98/6568 (1.5%)	40/2279 (1.8%)
Past	295/9638 (3.1%)	186/6568 (2.8%)	62/2279 (2.7%)
Smoking history:			
Present	2078/9682 (21.5%)	1341/6600 (20.3%)	565/2294 (26.4%)
Past	3512/9682 (36.3%)	2518/6600 (38.2%)	691/2294 (30.1%)
Regular alcohol (> 7 units/week)	4332/9631 (45.0%)	3096/6574 (47.1%)	898/2277 (39.4%)
Neuropathy disability score ≥ 6	2171/9688 (22.4%)	1402/6460 (21.7%)	496/2291 (21.6%)
10 g monofilament insensitivity	1978/9476 (20.9%)	1278/6487 (19.7%)	454/2237 (20.3%)
≤ 2 pedal pulses	2043/9699 (21.1%)	1306/6610 (19.8%)	443/2292 (19.3%)

Values are either number (percentage prevalence) or mean [SD]. 'Responders' were patients who were screened at baseline, returned their 2-year follow-up questionnaire, and whose new ulcer status was confirmed. This group does not include patients who returned incomplete forms (n = 126), or patients whose reported ulcers were unable to be confirmed (n = 55). 'Non-responders' were patients who were screened at baseline and who did not reply to their 2-year follow-up questionnaire. This group does not include patients who were since discovered to have died (n = 405) or moved away (n = 211) after screening.

[a]Significantly different to the 'responders', $P < 0.0001$ (χ^2 test for categorical data, Student's t-test for continuous data).

for all baseline variables measured, apart from a different distribution of ethnicity in the 'responders' compared with the 'non-responders' (South Asians 7.6% vs. 16.6%, respectively, $P < 0.0001$), and a lower age for the 'non-responders' (61.7 vs. 58.2 years, respectively, $P < 0.0001$). Baseline prevalences of foot ulcers were very similar for both 'responders' (4.3%) and 'non-responders' (4.5%). Furthermore, neuropathy (NDS ≥ 6) was present in 21.7% and 21.6% of 'responders' and 'non-responders', respectively, whereas PVD was prevalent in both groups at 19.8% and 19.3%, respectively.

Risk of new ulcers—univariate analysis

Univariate Cox's proportional hazards regression analysis provided a statistically significant increased relative risk of new foot ulcers for the following baseline variables: increasing diabetes duration, unilateral lower limb amputation, history of foot ulcers (past and present), impaired vision, abnormal NSS, abnormal NDS, impaired pain, vibration and temperature sensation, insensitivity to the 10 g monofilament (also increasing monofilament insensitivity: 1 g, 10 g, 75 g; data not shown), abnormal ankle reflexes, foot deformities, reduced foot pulses, any previous podiatry attendance or foot care advice, vascular history, nephropathy, increasing age, being male, living alone, 'low risk' footwear (Table 2).

There was no significantly increased relative risk of new foot ulcers for socioeconomic status, smoking history, alcohol consumption, all group ethnicity and site of amputation (data not shown).

Risk of new ulcers—multivariate analysis

The Cox's proportional hazards regression analysis model that best fits the data confirmed the strongest associations identified

Table 2 Predictive variables for new foot ulcers using separate Cox's proportional hazards regression models

Characteristic		Number of participants	Relative risk	95% confidence intervals	*P*-value
Gender:	Females	3094	1.00		0.0047
	Males	3518	1.41	(1.11, 1.78)	
Age:	62 years (16, 100)	6593	1.01	(1.00, 1.02)	0.0039
Lives alone:	No	5128	1.00		0.006
	Yes	1436	1.43	(1.11, 1.85)	
Blind/impaired vision:	No	5697	1.00		< 0.0001
	Yes	859	2.55	(1.97, 3.30)	
Nephropathy:	No	6350	1.00		0.0025
	Yes	157	2.23	(1.33, 3.75)	
Diabetes duration	5.0 years (0.6, 60)	6580	1.53	(1.36, 1.72)	< 0.0001
Amputation:	No amputation	6526	1.00		< 0.0001
	Amputation (any level)	70	9.57	(6.44, 14.22)	
History of foot ulcers:	None	6284	1.00		< 0.0001
	Present at baseline	98	15.13	(10.97, 20.86)	
	Past	186	8.49	(6.21, 11.61)	
Footwear:	Low risk	3144	1.00		0.034
	Medium risk	1922	0.69	(0.52, 0.91)	
	High risk	679	0.90	(0.61, 1.32)	
Neuropathy symptom score:	(0–4)	4351	1.00		< 0.0001
	(5–9)	2251	1.94	(1.54, 2.43)	
Neuropathy disability score:	(0–5)	5058	1.00		< 0.0001
	(6–10)	1402	6.28	(4.93, 7.99)	
Pain sensation:	Normal (0)	4578	1.00		< 0.0001
	Abnormal 1 side (1)	779	2.03	(1.40, 2.95)	
	Abnormal both sides (2)	1245	5.05	(3.94, 6.48)	
Vibration sensation:	Normal (0)	4351	1.00		< 0.0001
	Abnormal 1 side (1)	856	2.41	(1.69, 3.43)	
	Abnormal both sides (2)	1398	4.95	(3.83, 6.39)	
Temperature sensation:	Normal (0)	5196	1.00		< 0.0001
	Abnormal 1 side (1)	717	2.66	(1.97, 3.59)	
	Abnormal both sides (2)	626	3.94	(2.99, 5.19)	
Ankle reflex scores:	Both present (0)	3131	1.00		< 0.0001
	Present with reinforcement 1 side (1)	255	0.48	(0.12, 1.98)	
	Present with reinforcement both sides (2)	790	2.88	(1.88, 4.39)	
	Absent 1 side/present with reinforcement 1 side (3)	202	4.86	(2.77, 8.53)	
	Absent both sides (4)	2148	5.12	(3.75, 6.98)	
Foot deformity score:	(0–2)	4640	1.00		< 0.0001
	(3–6)	1954	2.56	(2.04, 3.22)	
Monofilament	Sensitive to 10 g	5209	1.00		< 0.0001
	Insensitive to 10 g	1278	4.82	(3.82, 6.07)	
Foot pulses (number):	(4)	4663	1.00		< 0.0001
	(3)	641	1.52	(1.02, 2.26)	
	(2)	868	2.51	(1.87, 3.37)	
	(1)	175	4.03	(2.54, 6.37)	
	(0)	263	4.72	(3.28, 6.78)	
Peripheral vascular history:	No	6209	1.00		0.0003
	Yes	207	2.31	(1.46, 3.64)	
Ever had podiatry or footcare advice	No	1992	1.00		< 0.0001
	Yes	4424	3.23	(2.27, 4.60)	

Age and diabetes duration in years are expressed as mean (range) and geometric mean (range), respectively. The numbers of participants with missing data for each characteristic are not shown.
Of the 6613 subjects who were analysed, 291 subjects developed new foot ulcers. Cox's proportional hazards regression with constant follow-up time was used to calculate relative risk estimates for each of the potential predictors of foot ulceration.

Table 3 Independent predictors of new diabetic foot ulceration, using Cox's proportional hazards multiple regression analysis

	Relative risk	95% CI	*P*-value
History of ulcers:			
(Baseline = none)	1.00		< 0.0001
Present	5.32	3.71–7.64	
Past	3.05	2.16–4.31	
Neuropathy disability score:			
Normal (0–5)	1.00		< 0.0001
Abnormal (6–10)	2.32	1.61–3.35	
Any previous podiatry:			
No	1.00		< 0.0001
Yes	2.19	1.50–3.20	
10 g monofilament:			
Sensitive	1.00		< 0.0001
Insensitive	1.80	1.36–2.39	
Foot pulses:			
Normal (3,4)	1.00		< 0.0001
Abnormal (0–2)	1.80	1.40, 2.32	
Foot deformity score:			
Normal (0–2)	1.00		0.0004
Abnormal (3–6)	1.57	1.22–2.02	
Ankle reflex score:			
(baseline = 0)	1.00		0.005
1	0.40	0.10–1.65	
2	1.99	1.26–3.12	
3	2.25	1.24–4.10	
4	1.55	1.01–2.36	
Age	0.99	0.98–1.00	0.011

in the univariate analyses, although the independent effect of many other variables was lost. The only significant factors to predict independently new foot ulceration were: history of foot ulcers (past or present at baseline), abnormal NDS (≥ 6/10), any previous podiatry or foot care advice, insensitivity to the 10 g monofilament, reduced number of pedal pulses, foot deformities, increasing abnormal ankle reflex score. The results of this analysis are in Table 3.

Discussion

In this study a mass foot screening programme was undertaken to examine a large sample of patients (n = 9710) from the general diabetes community. Great efforts were made to minimize selection bias for this cohort by screening the vast majority of patients as they attended diabetes annual review in various healthcare settings. Overall, approximately two-thirds of all patients were screened in the primary care setting, with the remainder seen at secondary care sites. Although only 60% of participating GPs' patients were screened at practices, most remaining patients were screened whilst attending hospital or diabetes centre annual review clinics.

Despite best efforts to screen a representative community cohort of diabetic patients, validating such a sample is difficult. Selection biases are inevitable due to patient non-attendance for annual review and screening appointments. Further, despite nearly all GPs initially agreeing to take part, we screened at only 68% of practices in 2 years due to time constraints. Determination of accurate diabetes population figures was also a problem, due to the general lack of accurate diabetes registers at this time. We did, however, obtain estimates of the total diabetic population (1994–1996) from various sources (Family Health Services Authority, Medical Advisory and Audit Group, existing GP records, podiatry records), and 9710 patients equated to approximately 41% of all diabetic patients in these six districts. From the sheer size of the study this large patient cohort is probably a reasonable representation of the community-based diabetes population in NW England.

The prevalence and average annual incidence of diabetic foot ulceration in the diabetic cohort was 1.7% and 2.2% (for surviving patients), respectively. Ulcer incidence was determined for the screened patients who returned their follow-up questionnaires; however, some non-response bias is inevitable. We were unable to cross-check all 9710 patients' contact details at follow-up, due to lack of resources, therefore a small, unknown proportion of people who moved address would not have received their questionnaire, but despite this we achieved a good postal response rate (70% of original sample). Baseline characteristics were very similar between responders and non-responders, therefore the confirmed ulcer incidence rate for the responders (2.2%) may be extrapolated to the entire patient sample. We did not attempt to determine why 2300 people did not reply to our questionnaire, or access their medical records to identify new ulcers because this data capture method was different from self-reporting and cross-checking.

Prospective estimates of the incidence of diabetic foot ulcers are rare [13]. In a retrospective cohort study of 8905 diabetic patients, Ramsay *et al.* [14] determined the average annual incidence of foot ulceration to be almost 2%, whereas the incidence in a population-based sample of older-onset diabetic patients was 2.6% p.a. [13]. These rates are comparable to that of our prospectively assessed cohort from the diabetic community.

We used univariate analysis to demonstrate the large number of simple relationships that exist between diabetic new foot ulcer and its potential predictors, reflecting that many of these variables are acting as proxies for the real predictors. The multivariate analysis, adjusted for a higher degree of interrelationship between the predictors, eliminated the proxy associations and identified the strongest independent risk factors.

Past history of foot ulcers, and foot ulcers present at baseline, were the strongest variables independently related to the risk of new foot ulcer events, confirming previous observations [5]. Patients with foot ulcers may be predisposed to this outcome due to a combination of different pathological factors such as micro- and macrovascular dysfunction, and peripheral nerve damage, creating a very high risk for the patient. Although history of amputation was strongly associated with future ulcer risk in the univariate analyses, it was not a risk

factor in the final multivariate model. This is undoubtedly because the independent effect of the amputation itself was confounded by concomitant ulcer history (63% of all amputees screened at baseline also carried a history of foot ulcers on their remaining limb).

The best independent measure of peripheral neuropathy for predicting new foot ulcer risk was the NDS. Using NDS ≥ 6 to define clinical neuropathy, neuropathy prevalence in our population was 22%, similar to the rate in a UK hospital clinic population (28%) when using the same diagnostic criteria [10]. Absent/reduced ankle reflex also independently predicted foot ulceration, as elsewhere [2,6]. The lack of clear progression of the increasing ankle reflex score data probably reflects the predominance for reflexes to be either both fully present or absent on testing. All other individual NDS tests—pin-prick, vibration, and temperature sensation—although associated in univariate analyses, were not independently related to the development of foot ulcer. The complete NDS, however, had a much greater predictive power than reflexes alone.

The 10 g monofilament was one of the strongest independent risk factors for foot ulcers, confirming findings of other case-control and prospective studies [6,8,15–17]. Many studies recommend the use of multiple (> 8) plantar sites for monofilament testing. Our finding that insensitivity to the 10 g force at any one of only three plantar sites on either foot can independently predict foot ulceration, provides a more practical application of this screening method. Although there is some evidence that repeated use of the 10 g monofilament may affect reproducibility of applied force [18], the predictive power of the monofilament was retained in the present study.

Reduced foot pulses independently predicted patients at risk of foot ulcer, and so may be a realistic clinical alternative to more sophisticated peripheral vascular assessments [5,6,19]. Although ankle/brachial pressure index has been identified as an independent risk factor in a recent prospective study [5], it has failed to predict ulceration in three separate case-control studies [4,6,7], possibly due to a high prevalence of medial calcification in diabetic subjects. Palpation of diabetic pedal pulses may have relatively low reproducibility [20], yet with standardized training it appears to be an effective screening test for vascular risk.

A combination score for foot deformities is described here for the first time, with ≥ 3 abnormalities independently predicting foot ulcer risk. Charcot deformity and hammer toes previously have been independently associated with foot ulcer risk [5,21], supporting these data. We can thus recommend that the diabetic foot care team increases its emphasis on reducing the effects of foot deformities described here, with increased use of orthopaedic footwear in high-risk patients.

A surprising result was the inclusion of any previous podiatry attendance and/or foot care advice, which the majority of patients had undertaken, as an independent foot ulcer risk in the multivariate model. This was also independent from the effect of any confounding podiatry referrals that may have occurred after screening. Although this seems to suggest that podiatry attendance may have directly caused foot ulcers, this is most unlikely. The result probably reflects that ulcers occur more frequently in patients whom healthcare professionals have identified as being 'at risk' and who have seen the podiatrist at least once since developing diabetes.

Decreasing age independently predicted increased ulcer risk, as elsewhere [2]. The reasons for this are unclear but may reflect the fact that older patients are probably less mobile than younger patients, and thus are less exposed to potentially traumatic situations for the 'at risk' foot.

Potential confounders of this multivariate analysis cannot be ignored. New ulcer occurrence would also be influenced by potential risk factors not measured at baseline, e.g. the extent of healthcare provision, patient behavioural factors, compliance with foot care advice, etc. Where patients receive well-organized and regular care with rapid referral to appropriate specialist multidisciplinary teams before problems occur, ulceration can be prevented and morbidity reduced [22]. We have not been able to report on the provision of primary health care services here, i.e. diabetes miniclinics, diabetes podiatry clinics, for all six health care districts. However, it is common knowledge that the process of healthcare in the UK is very variable in quality, possibly influencing ulcer outcomes. An audit of care for diabetic patients discharged into primary care has suggested an erratic and generally poor standard of supervision [23]. The patients that were screened at baseline received foot care leaflets and useful local telephone numbers and contact addresses so that any future foot problems could be addressed immediately, and were referred when appropriate for podiatry and peripheral vascular tests. Thus, empowering the patient, easing access to appropriate care, improving attitudes and motivation potentially may influence future ulceration rates for these community-based patients.

In conclusion, we have demonstrated, by screening and follow-up, that over 2% of a large cohort of diabetic patients seen in the community setting will develop new foot ulcers each year. Furthermore, we now have important confirmation that the simple measures of peripheral neuropathy and PVD, i.e. NDS and/or 10 g monofilament plus foot pulse palpation, which are currently used in clinical practice can (i) identify the 'high risk' patients, and (ii) predict the onset of new foot ulcer events. Even if these community-based ulcers are more superficial than diabetic ulcers typical of the 'high risk' clinic, we should aim to reduce their occurrence. The simple screening procedures validated in this report are already in place in many clinical practice settings, and their use should enable appropriate patient foot care management via education and referral to podiatrists, orthopaedic surgeons, vascular surgeons, nurse specialists or orthotists, to protect the community-based diabetic foot.

Acknowledgements

We are indebted to Margaret Lyons-Burton for expert database management throughout the study. This study was

supported by a grant from the Department of Health. Research podiatry positions were funded by the local district health authority purchasers.

References

1 Young MJ, Breddy JL, Veves A, Boulton AJ. The prediction of diabetic neuropathic foot ulceration using vibration perception thresholds. A prospective study. *Diabetes Care* 1994; **17**: 557–560.

2 Abbott CA, Vileikyte L, Williamson S, Carrington AL, Boulton AJ. Multicenter study of the incidence of and predictive risk factors for diabetic neuropathic foot ulceration. *Diabetes Care* 1998; **21**: 1071–1075.

3 Pham H, Armstrong DG, Harvey C, Harkless LB, Giurini JM, Veves A. Screening techniques to identify people at high risk for diabetic foot ulceration: a prospective multicenter trial. *Diabetes Care* 2000; **23**: 606–611.

4 Lavery LA, Armstrong DG, Vela SA, Quebedeaux TL, Fleischli JG. Practical criteria for screening patients at high risk for diabetic foot ulceration. *Arch Intern Med* 1998; **158**: 157–162.

5 Boyko EJ, Ahroni JH, Stensel V, Forsberg RC, Davignon DR, Smith DG. A prospective study of risk factors for diabetic foot ulcer. The Seattle diabetic foot study. *Diabetes Care* 1999; **22**: 1036–1042.

6 McNeely MJ, Boyko EJ, Ahroni JH, Stensel VL, Reiber GE, Smith DG *et al.* The independent contributions of diabetic neuropathy and vasculopathy in foot ulceration. How great are the risks? *Diabetes Care* 1995; **18**: 216–219.

7 Sriussadaporn S, Mekanandha P, Vannasaeng S, Nitiyanant W, Komoltri C, Ploybutr S *et al.* Factors associated with diabetic foot ulceration in Thailand: a case-control study. *Diabet Med* 1997; **14**: 50–56.

8 Litzelman DK, Marriott DJ, Vinicor F. Independent physiological predictors of foot lesions in patients with NIDDM. *Diabetes Care* 1997; **20**: 1273–1278.

9 Fox AJ, Adelstein AM. Occupational mortality: work or way of life? *J Epidemiol Community Health* 1978; **32**: 73–78.

10 Young MJ, Boulton AJ, MacLeod AF, Williams DR, Sonksen PH. A multicentre study of the prevalence of diabetic peripheral neuropathy in the United Kingdom hospital clinic population. *Diabetologia* 1993; **36**: 150–154.

11 Mueller MJ, Diamond JE, Delitto A, Sinacore DR. Insensitivity, limited joint mobility, and plantar ulcers in patients with diabetes mellitus. *Phys Ther* 1989; **69**: 453–459; discussion 459–462.

12 Altman DG, Deeks JJ, Sackett DL. Odds ratio should be avoided when events are common. *BMJ* 1998; **317**: 1318.

13 Moss SE, Klein R, Klein BE. The prevalence and incidence of lower extremity amputation in a diabetic population. *Arch Intern Med* 1992; **152**: 610–616.

14 Ramsey SD, Newton K, Blough D, McCulloch DK, Sandhu N, Reiber GE *et al.* Incidence, outcomes, and cost of foot ulcers in patients with diabetes. *Diabetes Care* 1999; **22**: 382–387.

15 Kumar S, Ashe HA, Parnell LN, Fernando DJ, Tsigos C, Young RJ *et al.* The prevalence of foot ulceration and its correlates in type 2 diabetic patients: a population-based study. *Diabet Med* 1994; **11**: 480–484.

16 Sosenko JM, Kato M, Soto R, Bild DE. Comparison of quantitative sensory-threshold measures for their association with foot ulceration in diabetic patients. *Diabetes Care* 1990; **13**: 1057–1061.

17 Kumar S, Fernando DJ, Veves A, Knowles EA, Young MJ, Boulton AJ. Semmes-Weinstein monofilaments: a simple, effective and inexpensive screening device for identifying diabetic patients at risk of foot ulceration. *Diabetes Res Clin Pract* 1991; **13**: 63–67.

18 Yong R, Karas TJ, Smith KD, Petrov O. The durability of the Semmes-Weinstein 5.07 monofilament. *J Foot Ankle Surg* 2000; **39**: 34–38.

19 Kalani M, Brismar K, Fagrell B, Ostergren J, Jörneskog G. Transcutaneous oxygen tension and toe blood pressure as predictors of outcome of diabetic foot ulcers. *Diabetes Care* 1999; **22**: 147–151.

20 Edelman D, Sanders LJ, Pogach L. Reproducibility and accuracy among primary care providers of a screening examination for foot ulcer risk among diabetic patients. *Prev Med* 1998; **27**: 274–278.

21 de Sonnaville JJ, Colly LP, Wijkel D, Heine RJ. The prevalence and determinants of foot ulceration in type II diabetic patients in a primary health care setting. *Diabetes Res Clin Pract* 1997; **35**: 149–156.

22 Mason J, O'Keefe C, McIntosh A, Hutchinson A, Booth A, Young RJ. A systematic review of foot ulcer in patients with Type 2 diabetes mellitus. I: prevention. *Diabet Med* 1999; **16**: 801–812.

23 Dunn NR, Bough P. Standards of care of diabetic patients in a typical English community. *Br J Gen Prac* 1996; **46**: 401–405.