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A systematic review of foot ulcer in patients with Type 2 diabetes mellitus. I: prevention

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Abstract

Aim To evaluate the role of preventative strategies in reducing foot ulcers in patients with Type 2 diabetes mellitus, both in the general population and those identified to be at a raised risk.

Method A systematic review of interventions to prevent diabetic foot ulcers.

Results Available studies are generally unsatisfactory in their ability to answer the important questions relating to prevention. However, where people with diabetes receive well-organized and regular care with rapid referral to appropriate specialist multidisciplinary teams when problems (or their precursors) occur, ulcer morbidity can be substantially reduced.

Conclusion Foot ulcers are common in people with diabetes and are costly in terms of both patient morbidity and the use of healthcare resources. Although it is nearly a decade since the St Vincent Declaration called for a marked reduction in morbidity to be achieved through better patient management, available evidence suggests that the process of care in Britain is still very variable in quality. Foot care for people with diabetes must be organized to provide monitoring, education and referral in a manner acceptable to patients and realistic for local healthcare providers.

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Keywords diabetes mellitus, diabetic foot, prevention, systematic review

Abbreviations CI, confidence interval; DPN, diabetic polyneuropathy; LI, likelihood ratio; TCD, tactile circumferential discriminator

Introduction

The at-risk or damaged foot in diabetes has been defined as a group of syndromes in which neuropathy, ischaemia and infection lead to tissue breakdown, resulting in morbidity and possible amputation [1].

A local population study of 1077 people with diabetes found that 7.4% of patients had past or present foot ulceration of which 39.4% were neuropathic, 24.2% vascular and 36.4% of mixed aetiology [2]. Several studies, using different populations and methods, suggest 20–40% of people with Type 2 diabetes mellitus have neuropathy and about 5–7% have a foot ulcer [2–4].

Assessment of the economic burden of foot ulcers is hampered by the lack of recent, representative studies [5–7]. This may be a result of the disparate way in which people with diabetes use health services. Analysis of the Health Resource Group code for diabetic episodes with lower limb complication (K17) in 1995–1996 indicates that about 4500 inpatient episodes were spread over 14 different clinical specialities. A local study found that patients with diabetes made up 5.5% of admissions, 6.4% of outpatient attendances and 9.4% of bed-days [8] but the proportion of these visits for the treatment of foot complications is uncertain. This may be set against an

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approximate prevalence of diabetes of 2% in England and Wales [9,10].

Variable quality of care

The St Vincent Declaration called for a 50% reduction in amputations resultant from diabetic gangrene, reflecting the belief that much morbidity is preventable by better patient management [11]. Nevertheless, surveys indicate sub-optimal supervision of elderly patients in hospital, residential care and general practice [4,12–14]. An audit of care for people with diabetes discharged into primary care (where most practices have registers and recall systems) suggested an erratic and generally poor standard of supervision [15]. Other studies have questioned the care received by patients in the community [16,17]. A retrospective survey of a diabetic population found that of the patients receiving hospital care, undergoing non-traumatic amputation, only half had undergone complete foot evaluations in the year preceding initial ulceration or gangrene [18]. Another retrospective study investigating amputations explored causal pathways to amputation in a series of 80 people with diabetes. A sequence of minor trauma, cutaneous ulceration and wound-healing failure applied to 72% of amputations [19]. Thus, whilst current care may often be sub-optimal, the sequence of events leading to ulceration and amputation may be all too predictable.

A systematic review was undertaken to identify effective interventions for the management of the diabetic foot as part of an evidence-based guideline process led by the Royal College of General Practitioners together with other Royal Colleges and professional associations. The findings of the systematic review of effective preventative care are presented here. The treatment of diabetic foot ulcers is addressed in a subsequent article.

Methods

Using an optimally sensitive search strategy of subject headings and text words, the following bibliographic databases were searched: Cochrane Trials Register; MEDLINE; Embase; Cinahl; HealthStar; Psyclit; Science Citation Index; and Social Science Citation Index. All databases were searched from 1983 onwards. Trial registers were searched for ongoing and unpublished trials, and conference proceedings were examined using the Index to Scientific and Technical Conference Proceedings (ISI). Attempts to access 'grey literature' were made using the HMIC database (which included the catalogues of the King's Fund, Nuffield Institute and Department of Health libraries) and SIGLE. Assessment of papers retrieved and abstraction of data were conducted independently by two of the authors (J.M., C.O.) and disagreements were resolved by discussion. For the purposes of this review unpublished manuscripts not awaiting publication are excluded.

Studies were considered if they addressed some aspect of screening, management, prevention or education relating to the foot care of people with diabetes. In each area considered, the best evidence available was used [20]. Where randomized, controlled trials were available, studies of lesser design were excluded unless they added a further dimension to the understanding.

Studies which addressed Type 1 as well as Type 2 diabetes mellitus were included, since there is not known to be any difference in their aetiological role in diabetic foot disease. The intention was to summarize areas of care using meta-analytic techniques if appropriate. Where this was not possible on methodological grounds, reasons are given and a qualitative overview is provided.

This review does not address specific treatments for neuropathy, peripheral vascular disease or Charcot foot.

Care of the foot without complications

Monitoring

It is argued that primary foot care for people with diabetes involves adequate monitoring and the opportunity to reinforce messages of self-care [21]. Many patients are unable to perform self-monitoring because of poor eyesight and reduced mobility, making it difficult for them to inspect their feet [22,23]. Thus regular contact between professionals and patients is important [24].

Common neurological examinations include tests for vibration by a biothesiometer, tuning fork, or cutaneous pressure sensation, using a 10-g monofilament (5.07). The ability to identify feet at risk of ulceration has been demonstrated prospectively in three studies: two using a biothesiometer and one using a 10-g monofilament.

Rith-Najarian *et al.* [25] prospectively studied a Native American Indian population, dividing patients into four risk categories. These were: **1** sensate with no history of disease; **2** insensate; **3** insensate with visual deformity; and **4** with a history of disease (ulceration or amputation). Patients were followed for 32 months, until first ulcer or amputation. Combining categories **2–4** provides a test sensitivity of 90% and specificity of 86% for predicting ulceration, with likelihood ratios (LRs) (positive test) of 5.2 (95% confidence interval (CI) 4.0–6.7) and LR (negative test) of 0.12 (95% CI 0.05–0.27). An ulcer was about five times as likely to occur in a patient with a history of disease or lack of sensation than in a patient without these factors.

Young *et al.* [26] prospectively categorized patients without previous ulceration or significant ischaemia according to their vibration perception threshold (VPT). Patients were followed for up to 4 years until their first ulcer. Using a threshold of > 25 V, results indicate a test sensitivity of 83%, and a specificity of 62%, with an LR (positive test) of 2.2 (95% CI 1.8–2.5) and an LR (negative test) of 0.27 (95% CI 0.14–0.48).

Abbott *et al.* [27] prospectively investigated the incidence of foot ulcer, for 1 year, in 1033 patients with

Table 1 Randomized trials of organization of care (selected endpoints)

Author	Interventions	Trial detail	Results
Porter, 1982 [39]	**HOS:** Continuing hospital diabetic clinic **GP:** General practitioner care Regular meetings were held between hospital staff and general practice doctors and other professionals before and during the study. A special record form was provided for use by GPs. An administrative system for recalling patients was provided for practices that did not have one.	Blinding level: none Concealment of allocation: not reported Baseline comparability: not reported Numbers randomized: HOS + GP, 197 Loss to follow-up: not recorded	No significant differences between groups in symptoms, limb function, fundi, blood pressure, weight, blood sugar and urine analysis (data not presented). Mortality (count): GP: 17; HOS 8
Hayes *et al.* 1984 [40]	**HOS:** Continuing hospital diabetic clinic **GP:** General practitioner care GP patients were given information leaflets, special record cards, and were advised to be seen every 6 months. GPs had open access to hospital laboratory, dietetic and chiropody services, and freedom to refer back to the clinic	Blinding level: none Concealment of allocation: yes Baseline comparability: yes, except HOS: more abnormal ECGs. Numbers randomized: HOS: 97; GP: 103 Loss to follow-up: HOS: 3; GP: 9	Seen at least once a year: GP: 14 (13.6%); HOS 97 (100%); $P < 0.0001$ Hospitalization (medical): GP: 25 (24%); HOS 17 (18%); $P = 0.24$ Mortality: GP: 18 (17%); HOS: 6 (6%); $P = 0.014$. HbA (mean(SD)): GP 10.4(1.73)%; HOS 9.5(1.77)%; $P < 0.02$
Hoskins *et al.* 1992 [41]	**HOS:** Hospital diabetic clinic **GP:** General practitioner care **SC:** Shared care between GP and clinic All patients received a multidisciplinary assessment at baseline and received an individualized treatment plan. GP/SC clinicians were sent patient management plans, asked to complete 4-monthly reviews and refer patients to clinic for annual assessment. SC group patients were sent their own copy of the management plan. A research nurse liaison reminded patients and GPs of content of the reviews and prompted GPs for the return of test results.	Blinding level: none Concealment of allocation: yes Baseline comparability: yes, except GP: greater proportion of females Numbers randomized: HOS: 65; GP: 72; SC: 69 Loss to follow-up: At 1 years clinic assessment: HOS: 12; GP: 15; SC: 8	Attendance rate at 4-monthly reviews: Visit 1: HOS: 80%; GP: 32%; SC: 82%; Visit 2: HOS: 59%; GP: 28%; SC: 75% Visit 3: HOS: 53%; GP: 35%; SC: 72% Attendance at 1 years complication assessment: HOS: 53%; GP: 57%; SC: 61%. HbA (mean(SD)): HOS 7.3(1.6)%; GP 6.9(1.3)%; SC 6.6(1.6)%; $P = \text{NS}$
Hurwitz *et al.* 1993 [43]	**HOS:** Continuing hospital diabetic clinic **GP:** Prompted general practitioner care GP patients: a computer database sent requests every 6 months to patients for blood and urine samples to be taken in a local health centre or in hospital. Results were sent to patients who were requested to visit their GP within 10 days for review. Annual eye review at a local optometrist was also prompted. Review could occur at hospital as well as with the GP. The database compiled results and provides patient details for referral visits.	Blinding level: none Concealment of allocation: not clear Baseline comparability: yes, except HOS: greater mean systolic blood pressure GP: more patients with leg ischaemia Numbers randomized: HOS: 92; GP: 89 Loss to follow-up: HOS: 14; GP: 3	Seen at least once: GP: 86/89 (96.6%); HOS 78/92 (84.8%); $P = 0.013$ Number of reviews/patient/year; mean (SD): GP 3.0(3.8); HOS 2.4(1.3); $P = \text{NS}$ Hospitalization (diabetes related): GP: 8/89 (9%); HOS 17/92 (18%); $P = \text{NS}$ Referral to dietician: GP: 29/86 (34%); HOS 32/78 (41%); $P = \text{NS}$ Referral to chiropodist: GP: 7/86 (8%); HOS 10/78 (13%); $P = \text{NS}$ Mortality: GP: 7/89 (8%); HOS: 7/92 (8%); $P = \text{NS}$ HbA; mean(SD): GP 10.3(2.3)%; HOS 10.6(2.5)%; $P = \text{NS}$
DICE, 1994 [42]	**HOS:** Continuing hospital diabetic clinic **GP:** Integrated general practitioner care A computer-based record system was used GP: Patients were sent reminders to visit their GP every 3–4 months and annually at the clinic. Clinicians were given written guidelines for care, were prompted when a visit was due and sent a record card for return on completion. HOS: Patients were sent routine clinical appointments.	Blinding level: none Concealment of allocation: not clear Baseline comparability: yes Numbers randomized: HOS: 135; GP: 139, Loss to follow-up: HOS: 32; GP: 22	Reviews/patient in 2 years; mean (SD): GP 5.3(1.4); HOS 4.8(1.7); $P < 0.05$ Foot assessments/patient in 2 years; mean (SD): GP 1.4(1.0); HOS 0.5(0.6); $P < 0.05$. Seen by dietician: GP 32/124 (26%); HOS 44/111 (40%); $P < 0.05$ Seen by chiropodist: GP 72/124 (58%); HOS 29/111 (26%); $P < 0.05$ Mortality: GP: 11/124 (7.5%); HOS: 10/111 (7.9%); $P = \text{NS}$ HbA; mean (SD): GP 5.3(1.7)%; HOS 5.3(1.7)%; $P = \text{NS}$

Table 2 Randomized trials of patient education (selected endpoints)

Author	Interventions	Trial detail	Results
Rettig *et al.* 1986 [45]	**INT:** Home education (general diabetic care and foot care) provided by nurse **CON:** Not receiving home education INT: Patients received a nurse home visit and completed a needs assessment survey at baseline. Information obtained led to a tailored program of instruction. The number of educational home visits varied, with a maximum of 12. Education areas were diet, urine testing, medication and foot care.	Blinding level: none effective Concealment of allocation: not clear Baseline comparability: yes Numbers randomized: INT: 228; CON: 243 Loss to follow-up: INT: 50; CON:48	*Assessed by nurse at 6 months* Foot care knowledge score; mean (SE): INT: 60.2(1.3); CON: 51.6(1.4); $P = 0.001$ Foot care skill score; mean (SE): INT: 71.8(2.0); CON: 68.9(1.8); $P =$ NS Foot appearance score; mean (SE): INT: 70.2(0.7); CON: 68.8(0.7); $P =$ NS *Assessed by telephone survey at 12 months:* Preventable diabetes-related hospitalization rates; per 1000 subjects/year (SE): INT: 94.4(35.8); CON: 41.5(16.1); $P =$ NS Preventable diabetes related inpatient length of stay; mean (SE): INT: 6.88(1.54); CON: 6.13(1.17); $P =$ NS
Bloomgarden *et al.* 1987 [46]	**INT:** Nine education sessions (general diabetic care and foot care) in addition to usual care **CON:** Usual care INT: Patients attending at least seven sessions were considered 'graduates'. Patients were attending a diabetic clinic. Approximately 90% of those enrolled were black or Hispanic. The program lasted 1.6 ± 0.3 years in the education group, with 1.5 ± 0.3 years of care in the control group.	Blinding level: none apparent Concealment of allocation: not clear Baseline comparability: yes, except: CON: foot lesions more common; INT: higher fasting blood glucose, higher number of hospitalizations in previous year. Numbers randomized: INT: 165; CON: 180 Loss to follow-up (%) INT: 20; CON: 23	*Assessed by interviewer at 18 months* Knowledge score; mean (SD): INT: 5.8(1.6); CON: 5.3(1.7); $P = 0.0073$ Behaviour score; mean (SD): INT: 4.3(1.6); CON: 4.1(1.6); $P = 0.01044$ HbA1c; mean (SD): INT: 6.1(2.0); CON: 6.3(2.0); $P = 0.1995$ Foot lesions (minor and severe), at final evaluation: INT: 51%; CON: 65%; $P =$ NS (56% of the intervention group were considered graduates: this subgroup scored consistently better than non-graduates in knowledge and behaviour scores)
Barth *et al.* 1991 [48]	**INT:** Four special foot care sessions in addition to a normal education programme **CON:** Normal education programme Recruitment by radio and newspaper campaign, general practice referral and diabetic clinic referral. Patients received either conventional or intensive education in groups of 8–10. CON: 14 h over 3 consecutive days (foot care 1 h session). INT: Additional four weekly sessions of 1.5–2.5 h (total 9 h) on foot care using motivational techniques. A podiatrist took 3 sessions and psychologist one.	Blinding level: none apparent Concealment of allocation: not clear Baseline comparability: yes, except: INT: greater peripheral vascular disease Numbers randomized: INT: 32; CON: 38 Loss to follow up (%): INT: 5; CON: 3	*Assessed by a podiatrist at baseline, 1, 3, and 6 months (analyses using repeated measures with baseline covariates).* The intensive care group showed significantly greater improvement in foot care knowledge ($P < 0.001$)and compliance with foot care routine ($P = 0.012$). However, both groups showed significant improvement over time and differences in absolute scores were small at 6 months, approx 2/12 for knowledge and 1/12 for compliance. The intensive care group showed significantly greater compliance with advice to consult a podiatrist ($P = 0.008$) and a greater reduction in foot problems ($P < 0.006$) at 1 month but neither of these effects were significant at 6 months

Table 2 Continued

Author	Interventions	Trial detail	Results
Kruger *et al.* 1992 [49]	**INT:** Participatory education (foot care) in addition to usual care **CON:** Usual care Patients entering the hospital diabetes programme enrolled. CON: Videotape and supplementary explanation from an instructor on foot care. Patients were encouraged to examine their feet daily and given a daily checklist. INT: Participatory hands-on teaching/learning sessions (actual foot washing, inspection, care of corns and calluses, cutting toe-nails, evaluating problems and suitable footwear). Patients received an education kit with materials (buff pads and an inspection mirror).	Blinding level: none apparent Concealment of allocation: not clear; randomization by odd/even week of enrolment Baseline comparability: not reported Numbers randomized: INT:23; CON: 27 Loss to follow-up: INT: 8; CON: 12	*Assessed by trialists* Knowledge score: INT: 19/23 (83%); CON: 22/27 (82%); p = NS *Self reported measures* Daily foot inspection: INT: 10/15 (66.7%); CON: 10/15 (66.7%); *P* = NS Daily foot washing: INT: 13/15 (86.7%); CON:11/15 (73.3%); *P* = NS Use of pumice stones for corns: INT: 4/15 (26.7%); CON: 4/15 (26.7%); *P* = NS Trimming toenails regularly: INT: 12/15 (80.0%); CON: 10/15 (66.7%); *P* = NS Improvement in keeping toenails shorter: INT: 12/15 (80.0%); CON: 13/15 (86.7%); *P* = NS No significant differences were found in assessment skills, neurometer readings, or assessment of photographs of feet by podiatrists.
Litzelman *et al.* 1993 [50]	**INT:** Participatory education (foot care) in addition to usual care **CON:** Usual care Patients in a general medicine practice received a risk assessment and interview concerning foot behaviour and care at baseline. INT: Patients received foot-care education (in groups of 1–4) conducted by nurse clinicians and entered into personalized behavioural contracts, reinforced by telephone and postcard reminders at 1 and 3 months. Health care providers were given practice guidelines, informational flow sheets and prompts to perform visual examination and provide education.	Blinding level: none apparent Concealment of allocation: not clear; randomization by primary care team Baseline comparability: INT: HbA_{1c} greater. Numbers randomized: INT:191; CON: 205 Loss to follow-up: INT + CON: 43	Serious foot lesions at 1 year: odds ratio (INT vs. CON) = 0.41; 95% CI 0.16–1.00; *P* = 0.05 Any foot lesions at 1 year: odds ratio (INT vs. CON) = 0.65; 95% CI 0.36–1.17; *P* = 0.15 Self-reported care, average score; mean (SD) (12 questions: 1 = almost always, 5 almost never): INT: 1.90 (0.42); CON: 2.12 (0.49); *P* = 0.0001 Foot examination during office visits: INT: 68%; CON: 28%; *P* < 0.001 Receiving foot-care education from healthcare providers: INT: 42%; CON: 18%; *P* < 0.001 Referral to podiatrist: INT: 10.6%; CON: 5.0%; *P* = 0.04 Amputations: INT: 0.5%; CON: 2.0%; *P* = 0.20

established neuropathy (VPT ⩾ 25 V on at least one foot and VPT ⩽ 30 V on both feet). For each 1-unit increase in VPT at study baseline, the risk of a first ulcer increased by 5.6%. For each unit increase in the muscle and reflex components of the Michigan diabetic polyneuropathy (DPN) score, the risk of a first ulcer increased by 5.0%.

A number of other techniques are available for assessing neuropathic deficit: the tactile circumferential discriminator (TCD) [28]; the graduated tuning fork [29,30]; thermal discrimination devices; and others [31] but these have not been evaluated prospectively.

Several studies have compared biothesiometers and monofilaments with no conclusive evidence that either is more sensitive or specific [28,32]. A recent study addressing the reproducibility of monofilament, biothesiometer and pedal pulse assessments reported that only the monofilament gave adequately reproducible results (over 85%) for measurements repeated after 2 weeks [33]. Kumar *et al.* [32] reported that filaments were easy to use, light (150 g) and cheap (£12/set) when compared to a biothesiometer weighing 2.5 kg, requiring a power source and costing £400. On the available evidence, it is likely that monofilaments provide a cost-effective alternative in first-line monitoring for neuropathy.

Neuropathic assessment is only one aspect of consensus-based guidelines for monitoring patients with diabetes

[21]. Regular visual inspection and vascular and musculoskeletal evaluations have also been recommended. No direct evidence concerning the optimal content or frequency of visual inspections in the general population of patients with diabetes was found. However, clear benefits of monitoring people with diabetes are evident from the reduced morbidity achieved by aggressive intervention where risk factors are identified (see below: *Screening and intervention in feet at risk of ulceration*). No studies in patients with diabetes were found addressing screening for lower-limb ischaemia and subsequent risk of ulceration. Studies evaluating the sensitivity of a number of methods for detecting ischaemia in various patient groups have recently been reviewed [34].

Adequate glycaemic and blood pressure control have been demonstrated to reduce the incidence and progression of diabetic morbidity, although no direct impact upon foot ulceration has been found [35–37].

Organization of care

Shared care has been defined as 'the joint participation of hospital consultants and general practitioners (GPs) in the planned delivery of care for patients with a chronic condition, informed by enhanced information exchange over and above routine discharge and referral notices' [38]. There are several models, e.g. devolving care of certain patients to primary care until a problem occurs, or retaining annual visits to a hospital clinic with interim care in general practice. Five trials were identified involving Type 2 or both Type 1 and Type 2 diabetic patients [39–43]. Selected details of these studies are shown in Table 1.

Two early British studies [39,40] differ from the others in that no automated system of recall was provided to prompt either patients or general practitioners to initiate a consultation. The study by Porter [39] was published as a letter and provides insufficient detail. In the second study, by Hayes *et al.* [40], nearly all local general practices agreed to participate and there was a relatively long period of follow-up (5 years) compared to other studies. This study suggests poorer follow-up and overall mortality for patients receiving general practice rather than hospital care.

Hoskins *et al.* [41] in an Australian study, demonstrated that similar levels of follow-up could be achieved either with properly structured shared care or hospital care, but loss to follow-up in both groups was considerable, limiting the usefulness of the endpoint comparisons.

Two recent British studies reported by the Diabetes Integrated Care Evaluation (DICE) team [42] and Hurwitz *et al.* [43] featured regular prompting of patients and/or doctors and patient reviews with specified components. These studies reported overall mortality and glycaemic control that were at least as good in general practice as with hospital outpatient care, while losses to follow-up were significantly lower. One of these studies found that primary care patients were more likely to be referred to a chiropodist than hospital attenders [43], while the other found no significant difference [42]. The consequent benefit in reduced foot complications is not known.

Interpreting the results of these trials presents a number of problems. The two recent British studies enrolled self-selecting local practices. The patients randomized were self-selecting, stabilized, had no major medical complications and were already attending hospital. The follow-up in these two trials was 2 years. The relative success of shared care in the later trials may be a result of the implementation of structured recall and review, but could also reflect the use of (enthusiastic) volunteer practices and patients, or the relatively short follow-up periods and the trial context.

In each of the trials, the unit of randomization and analysis is the patient. However, some general practitioners will have provided care for more than one patient randomized to the same intervention, introducing a form of clustering, potentially reducing degrees of freedom and leading to spurious accuracy. Additionally, general practitioners may have seen patients from both the shared care and hospital care arms, thereby introducing contamination. Given these concerns, statistical pooling of data by meta-analysis at the level of the patient is not appropriate.

None of the trials reported components of foot surveillance or foot complications in any detail. The optimal period for routine surveillance of emergent foot problems is unclear, but the later trials used periods of 3–6 months. Neither do the trials provide guidance on the relative merits of diabetes mini-clinics in general practice as opposed to care provided in routine general practitioner consultations. One trial featured two mini-clinics and one routine care practice in the shared care group, but did not present stratified findings [43].

A recent review [44] suggested that, at discharge to general practice, the exchange of information between specialists and both general practitioners and patients may be unhelpfully delayed and inadequate in content. In time, centralized computer databases of patient records could provide a solution, but structured communication appears an important facet of collaborative shared care.

A multidisciplinary group was set up under the aegis of the British Diabetic Association to report on the implementation of the St Vincent Declaration guidelines with respect to diabetic feet [24]. Among its recommendations was specific consideration of the role of co-ordinated multidisciplinary teams in providing care. No formal comparative evidence was found to indicate that any optimal arrangement of healthcare professionals exists for diabetic foot care.

Patient education

Surveys suggest that people with diabetes may not have sufficient skills or knowledge to manage their condition

Table 3 Randomized controlled trial of screening and intervention for patients with feet at raised risk of ulceration

Author	Interventions	Trial detail	Results
McCabe *et al.* 1998 [57]	**INT:** Identification and protection of patients at a substantially raised risk of ulceration **CON:** Usual care Patients were recruited from diabetic outpatient clinics and randomly assigned to screening or usual care. INT: All patients were screened. Patients with foot deformities, history of foot ulceration, or an ankle–brachial index ≤ 0.75, were are asked to re-attend and were reassessed. Measurement by monofilaments, biothesiometer, and palpitation of pedal pulses was included but the use of the findings of these techniques is unclear. Gross peripheral vascular or neuropathic disease appears to have been used to identify patients. Patients confirmed at risk were entered into a foot protection programme (FPP – weekly clinics provided chiropody and hygiene maintenance, hosiery, protective shoes as well as education on daily hygiene, clothing and footwear).	Blinding level: none apparent Concealment of allocation: not reported Baseline comparability: not reported Numbers randomized: INT: 1001; CON: 1000 Loss to follow-up (%): Not attending follow-up examination: INT: 323/1001 (32%) (however, 159 (16%) had attended, but not at a special appointment) CON: 531/1001 (53%)	Ulceration (incidence) at 2 years: INT: 24/1001 (2.4%); CON: 35/1000 (3.5%); $P > 0.14$ Proportion of ulcers proceeding to amputation: INT: 7/24 (29%); CON: 23/35 (66%); $P = 0.006$ Amputations (major or minor): INT: 7/1001 (0.7%%); CON: 23/1001 (2.3%); $P < 0.04$ Amputations (major): INT: 1/1001 (0.1%%); CON: 6/1001 (0.6%); $P < 0.01$ Chiropody, regular attendance: INT: 47%; CON: 36% Use of protective footwear: FPP: Of 127 patients, 87 (68.5%) responded to a questionnaire about usage. 36% claimed to use provided footwear at all times, 27% never wore the footwear

properly [22,23]. The common elements of patient education are foot hygiene, treatment of callus, awareness of fungal infections and actions required for cutaneous injuries.

Six randomized trials of educational interventions were identified, with varying levels of message reinforcement [45–50]. Selected details of these studies are found in Table 2. A further study [51] was excluded since it related only to people with Type 1 diabetes mellitus. One study [47] enrolled only patients with infection, ulceration or prior amputation and this is discussed in the subsequent review.

Educational interventions varied in form, setting, length of follow-up (range 6–18 months) and numbers enrolled (between 50 and 471 patients randomized). Studies consistently reported relative improvements in knowledge about foot care and behaviour in intervention groups, although the value of these findings is unclear. No other consistent patterns are present in the study methods or findings and it is necessary to interpret the findings of studies individually.

Rettig *et al.* [45] evaluated a home education programme (covering general areas of diabetic care as well as foot care) in 471 patients. A nurse individually tailored the education programme during home visits to intervention patients. The findings 6 months after enrolment showed no difference in foot appearance scores or hospitalization between groups (based upon a checklist of 16 abnormal conditions observed during foot inspection).

Bloomgarden *et al.* [46] evaluated a diabetes clinic educational programme in 202 patients. Nine sessions covered general diabetic care and foot care using various media: films, a card game, slides, and role-playing. At 18 months, no statistically significant differences in the occurrence of foot lesions were found between groups.

Barth *et al.* [48] evaluated an intensive foot care education intervention, recruiting 70 patients by radio and newspaper campaigns as well as from general practice and diabetes centres. The intervention group received 9 h of education over a 4-week period, in addition to usual care. These sessions used a motivational technique and were staffed by a podiatrist and a psychologist. The intensive care group showed significantly greater compliance with advice to consult a podiatrist ($P = 0.008$) and a greater reduction in foot problems ($P < 0.006$) at 1 month but neither of these effects were significant at six months.

Kruger *et al.* [49] evaluated a foot care education programme in 50 patients beginning hospital diabetes care. In addition to usual care, the intervention group received participatory hands-on teaching and learning sessions. These included foot washing, inspection, care of corns and calluses, toe-nail cutting, problem evaluation and suitable footwear. An education kit with materials was provided. At 6-months, no changes in knowledge or behaviour were observed.

Litzelman *et al.* [50] evaluated a foot-care education programme conducted (in groups of one to four) by nurse clinicians in a general practice setting with 396 patients.

Table 4 Randomized controlled trials of footwear in patients at raised risk of ulceration

Author	Interventions	Trial detail	Results
Colagiuri *et al.* 1995 [58]	**INT:** Treatment with a custom made rigid orthotic device **CON:** Conventional podiatric care Patients were assessed by a podiatrist at enrolment INT: Plaster casts of callused feet were taken. From the cast, a rigid orthotic device was made of a thermal pliable plastic and was balanced for position and contact. The device was light, extending from the heel to behind the metatarsal heads and could be used in sports shoes. Subjects were asked to wear the device at least 7 h a day and to be reviewed 1–3 weeks after commencement for appropriate fitting. Patients in this group did not have callus debrided. CON: Patients attended the podiatrist at 3 monthly intervals	Blinding level: none apparent Concealment of allocation: not reported Baseline comparability: yes Numbers randomized: INT:9; CON: 11 Loss to follow-up (%): none	Mean callus grade at baseline: INT: 1.9; CON:1.6 Mean callus grade at 12 months: INT: 1.2; CON:1.7 Number of calluses (at 12 months): improved: INT: 16; CON: 2 same: INT: 6; CON: 23 worse: INT: 0; CON: 7 (reported Fischer's exact test $P < 0.02$) This statistic is questionable since calluses are not independent but clustered by foot and patient
Uccioli *et al.* 1995 [59]	**INT:** Patients wearing therapeutic shoes with custom moulded insoles **CON:** Patients wearing own shoes Patients were enrolled at one of two teaching hospitals. All patients received guidance on foot care and footwear. Neuropathy was evaluated by vibratory perception threshold and peripheral vascular disease by ankle/brachial index. INT: Therapeutic shoes were provided at the beginning and 6 months into the study. Shoes were of soft thermoformable leather with semirocker soles and were super-depth to fit customized insoles and toe deformities. Insoles were made of a special dual material to relieve local pressure and absorb high pressure points. CON: Patients attended the podiatrist at 3 monthly intervals.	Blinding level: none apparent Concealment of allocation: not reported Baseline comparability: not adequately quantified Numbers randomized: INT:33; CON: 36 Loss to follow-up (%): none reported	Relapse rate (at 1 years): INT: 9/33 (27.7%); CON: 21/36 (58.3%); $P = 0.009$

Intervention patients agreed to personalized behavioural contracts, reinforced by telephone and postcard reminders at 1 and 3 months. Additionally, healthcare providers were given practice guidelines, informational flow sheets and prompts to perform visual examination and provide education. At 1 year, there was a significant reduction in serious lesions for patients receiving the educational intervention (odds ratio 0.41, $P = 0.05$), from a baseline prevalence in both groups of nearly 3%. Four amputations were reported in the control group and one in the intervention group ($P = 0.2$). Considerably improved rates of visual examination and provision of education during clinician contact were reported in the intervention group.

The unit of analysis (the patient) differs from the unit of randomization (primary care team) raising questions about the validity of statistical estimates presented, although the authors claim no 'team effect' upon study outcome.

The available studies provide inconsistent messages about the value of education. Small sample sizes, different endpoints and lack of a common approach weaken their interpretation. Only two of the larger studies reported serious lesions as endpoints. Litzelman *et al.* [50] indicated that where patients agree to behavioural contracts and receive periodic reminders, then foot ulcers could be prevented. The study by Bloomgarden *et al.* [46] featuring nine educational sessions using a range of teaching media, found no significant change. A further factor complicating interpretation is that patients enrolled in studies may be at certain phases in the disease process, making their clinical values atypical. Consequently, both treatment and control groups may show considerable improvement over the period of follow-up.

Intensive, prompted education, requiring action from both patients and clinicians, may reduce foot complica-

tions over relatively short periods of time, although the evidence is inconclusive concerning the best method. Available trials feature inadequate follow-up to assess the potential for primary care prevention of foot complications. The value of education interventions in the longer term is unknown and the likelihood is that important messages and habits will need reinforcing periodically in patients and health professionals. It is possible that education activities conducted in isolation, without integration into a broader organizational strategy promoting foot care, may be unproductive.

The foot at raised risk of complications

Identifying the foot at risk of complications

Epidemiological and clinical risk factors for ulceration have been extensively researched. With the exception of neuropathy, visual deformity and previous ulceration, for which prospective studies are available, research findings are inconclusive. Other reported risk markers are old age, duration of diabetes, peripheral vascular disease, renal disease, plantar callus, poor vision, poor footwear, cigarette smoking, social deprivation and social isolation [2,3,19,27,52–56]. Studies using different methods, (different) patient data and including (different) selections of risk factors come to different conclusions about their relative importance in predicting complications. Deciding at what level and in which combinations these manifestations become clinically important is hampered by the lack of availability of good intervention studies exploring a range of thresholds.

Screening and intervention for patients with feet at raised risk of ulceration

McCabe *et al.* [57] reported a screening and protection programme conducted in an English diabetic outpatient clinic setting that randomized 2001 patients (see Table 3). Patients in the intervention group ($n = 1001$) were screened and patients at raised risk ($n = 259$) were recalled. Following a second assessment, 192 (19.2%) patients were entered into a foot protection programme. These patients had gross neuropathy, indicated by foot deformities, vascular disease, indicated by an ankle–brachial index $\leqslant 0.75$, or a history of ulceration. Although tests with monofilaments, biothesiometer and palpation of pedal pulses were conducted, it is unclear what role these played in patient identification. Patients in the foot protection programme were eligible for weekly clinics providing chiropody and hygiene maintenance, hosiery and protective shoes as well as education on daily hygiene, clothing and footwear.

When compared to the control group, the intervention group demonstrated nonsignificant trends in reduced ulceration and minor amputations, and statistically significant reductions in overall and major amputation. Of those presenting with ulcers, significantly fewer progressed to amputation in the intervention group, suggesting that ulcers were spotted sooner and treated more effectively.

When the costs of intervention are set against the savings in reduced amputation alone, the authors conclude that the intervention appears cost saving. Thus, it is possible that the entrance criteria to the foot protection programme may have been too stringent and a broader inclusion may prove acceptably cost-effective.

The only note of caution in interpreting the trial is the lack of any demonstration of comparability of treatment groups at baseline coupled with an unspecified process of randomization.

Hospital outpatient attendees enrolled in the study tended to be older people with diabetes. Younger patients were more likely to be seen in general practice in the locality [McCabe, personal communication]. This may explain a relatively high prevalence of gross risk factors. The study demonstrates the potential for screening and protection of patients at greatest risk of ulceration.

Footwear of patients with feet at raised risk of ulceration

Diabetic disease processes, notably neuropathy, may lead to changes in foot posture and abnormal weight bearing. Plantar callus, a risk factor for ulceration, indicates abnormal foot pressures and occurs most frequently under the metastarsal heads. Specially designed footwear has been proposed as a method for reducing abnormal foot pressures and thus foot ulcers. Two randomized, controlled trials evaluating footwear in at-risk patients were identified (see Table 4).

Colagiuri *et al.* [59] randomized 20 patients to conventional podiatric care (3-monthly visits) or to wearing custom-made rigid plastic inserts, formed from castings of the callused feet. Enrolled patients had uncomplicated callus without any history of ulceration. After 1 year, patients with inserts appeared to show improvement of grade of callus, while patients receiving usual care showed little change.

Uccioli *et al.* [59] randomized 69 patients with previous ulceration to therapeutic shoes including custom-made inserts or to normal footwear. At 12 month follow-up, patients with therapeutic shoes had about half as many ulcer relapses or new ulcers as the normal footwear group (58.3% vs. 27.7%; $P = 0.009$). No details of the severity of ulceration were provided.

The latter study, featuring patients at very high risk of ulceration, suggests important health benefits from appro-

priately designed footwear. Protective footwear was a component of the foot protection programme reported by McCabe *et al.* [57], although no details are provided. An analysis of the predictive factors of ulceration suggested that the type of shoe worn may be independently important [56] and raises the possibility that patients provided with normal, well-fitting shoes that distribute abnormal pressures may also reduce their risk of ulceration. This remains a research issue where 'optimized' normal shoes could be usefully compared with special therapeutic footwear. Without consideration of this pragmatic alternative and confirmatory studies on larger patient numbers, the relative effectiveness and cost-effectiveness of providing therapeutic shoes remains uncertain.

Discussion

Care provided to people with diabetes to minimize the risk of foot ulceration is known to be of variable quality and yet there is considerable understanding of the manner in which foot ulcer disease most often arises and progresses. Prospective studies have shown that it is possible to predict those patients in whom ulceration is most likely to occur. Well-designed and conducted studies should demonstrate the ability of organization, education, monitoring and intervention to improve health outcomes and to attain the St Vincent standard of reduced morbidity. However, available trials often suffer from inadequate size, duration of intervention and inappropriate outcomes to address the issues relating to foot ulcer prevention.

The most informative trial, by McCabe *et al.* [57], relates to the identification and aggressive intervention in patients with gross risk factors for ulceration. It demonstrates that careful organization and monitoring will benefit patients if they are referred promptly to a specialist multidisciplinary programme of care. This study urgently needs to be repeated in a less selected group of patients, possibly using neurological and vascular assessments as the basis of inclusion. It is likely that some level of broader inclusion, while remaining organizationally realistic, would identify a more appropriate threshold of intervention for achieving reduced morbidity and acceptable cost-effectiveness.

The agreement of individual management plans between health professionals and patients is a central tenet of consensus statements on care [24]. The study by Litzelman *et al.* [50] provides some evidence to support this view, being the only large educational programme trial involving personalized behavioural contracts and telephone/postcard reminders as well as an organizational intervention for the healthcare providers. This is the only trial of an educational intervention package to show a significant reduction in serious lesions at 1 year.

The rather sparse trial data provide two important messages. First, vigilant and trained health care professionals can identify the emerging risk factors for ulceration at relatively little cost. Second, highly structured and high-effort interventions are required to modify the behaviour of those at most risk of ulceration. These interventions may be expensive to implement but nonetheless cost-effective in narrow healthcare budget terms. The burden of disease is such that protecting these patients is likely to make sense not only in patient health terms but also on broader social and economic grounds.

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