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

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Authors' objectives
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 raised risk.

Searching
The following databases were searched: Cochrane Controlled Trials Register, MEDLINE, EMBASE, CINAHL, HealthSTAR, PsycLIT, Science Citation Index and Social Sciences Citation Index. All databases were searched from 1983 onwards. The search strategy used was reported as having been optimally sensitive using both subject headings and textwords. Trial registers were searched for ongoing and unpublished trials, and conference proceedings were examined using the Index to Scientific and Technical Conference Proceedings (ISTP). Attempts to access 'grey literature' was made using the HIMC database (which includes the catalogues of the King's Fund, Nuffield Institute and Department of Health libraries) and SIGLE.

Study selection
Study designs of evaluations included in the review
In each area, the best evidence available was reported to have been used (see Other Publications of Related Interest no.1). Where randomised controlled trials (RCTs) were available, studies of lesser design were excluded unless they added a further dimension to the understanding. Unpublished manuscripts not awaiting publication were excluded.

Specific interventions included in the review
Studies were considered if they addressed some aspect of screening, management, prevention or education relating to the foot care of individuals with diabetes. The review did not address specific treatments for neuropathy, peripheral vascular disease or Charcot foot. Specific interventions reported by studies included: continuing hospital diabetic clinic, general practitioner (GP) care, shared care between GP and clinic or integrated GP care; home education or education sessions (general diabetic care and foot care) versus usual care or nurse home visits; special foot care sessions in addition to normal education programme versus normal education programme; participatory education (foot care) in addition to usual care versus usual care; identification and protection of patients at a substantial raised risk of ulceration versus usual care; treatment with a custom made rigid orthotic device versus conventional podiatric care; wearing therapeutic shoes with custom moulded insoles versus patients wearing own shoes.

Reference standard test against which the new test was compared
The review did not include any diagnostic accuracy studies that compared the performance of the index test with a reference standard of diagnosis.

Participants included in the review
Individuals with Type 2 diabetes. Studies that addressed Type 1 as well as Type 2 diabetes were included. Studies that only included participants with Type 1 diabetes were excluded.

Outcomes assessed in the review
The a-priori outcome measures considered for the review were not reported. Specific outcome measures reported by included studies were as follows: symptoms, limb function, fundi, blood pressure, weight, blood sugar and urine analysis, mortality, patient seen at least once a year, hospitalisation, HbA or HbA1c (unit of measurement for glycohaemoglobin assay), attendance rate at 4-monthly reviews, attendance at 1 year complication assessment, number of reviews per patient per year or 2 years, referral to dietician, referral to chiropodist, foot assessment per patient in 2 years, seen by dietician, seen by chiropodist, foot care knowledge, foot care skill, foot appearance, preventable diabetes-related hospitalisations or inpatient stay, behaviour score, foot lesions (serious or any), self reported foot care, amputations (major or minor), ulceration, use of protective footwear.
How were decisions on the relevance of primary studies made?
Assessment of papers retrieved was conducted independently by two of the authors and disagreements were resolved by discussion.

Assessment of study quality
The validity criteria used to assess studies included, level of blinding, concealment of allocation, baseline comparability, numbers randomised and loss to follow-up. The validity assessment was deemed to have been undertaken at the same time as the data extraction, which was conducted independently by two of the authors, and any disagreements were resolved by discussion.

Data extraction
Data extraction was conducted independently by two of the authors and disagreements were resolved by discussion. The categories of data extraction used included: reference details, intervention, trial detail (validity assessment), and results.

Methods of synthesis
How were the studies combined?
The authors noted that it had been the intention to summarise areas of care using meta-analytic techniques if appropriate. However, this was not possible on methodological grounds and studies were combined in a narrative summary.

How were differences between studies investigated?
Heterogeneity between some included studies was discussed in a narrative.

Results of the review
The review included 13 RCTs and 3 prospective studies). For the care of the foot without complications, three prospective studies looked at neurological examination to identify feet at risk of ulceration (n= minimum of 1033), five RCTs evaluated the organisation of care (n=1,058) and five RCTs evaluated patient education (n=1,332). For the foot at raised risk of complications, one RCT evaluated screening and an intervention for patients with feet at raised risk of ulceration (n=2,001) and two RCTs evaluated the use of orthotics or therapeutic shoes (n=89).

Organisation of care of the foot without complications (5 RCTs, n=1,058):
No formal comparative evidence was found to indicate that any optimal arrangement of health care professionals exists for diabetic foot care.

Patient education, with regards to the foot without complications (5 RCTs, n=1,332):
Intensive, prompted education, requiring action from both patients and clinicians, may reduce foot complications over relatively short periods of time, although the evidence is inconclusive concerning the best method. Available trials featured inadequate follow-up to assess the potential for primary care prevention of 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 organisational strategy prompting foot care, may be unproductive.

Screening and intervention for patients with feet at raised risk of ulceration (1 RCT, n=2001 (patients in the intervention group (n=1001) were screened and patients at raised risk (n=259) were recalled)):
The trial demonstrated the potential for screening and protection of patients at greatest risk of ulceration. The authors gave a note of caution in interpreting the trial due to the lack of any demonstration of comparability of treatment groups at baseline coupled with an unspecified process of randomisation.

Footwear of patients with feet at risk of ulceration (2RCTs, n=89): Without consideration of 'optimized' normal shoes
as an alternative and confirmatory studies on larger patients numbers, the relative effectiveness and cost-effectiveness of providing therapeutic shoes remains uncertain.

**Cost information**
The possible cost-saving by some of the interventions is discussed briefly, but no analysis is presented. One study reported that filaments were easy to use, light and cheap (12/set) when compared to a biothesiometer weighing 2.5 kg, requiring a power source and costing £400. It was also reported that on available evidence, it is likely that monofilaments provide a cost-effective alternative to first-line monitoring for neuropathy.

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

**CRD commentary**
This was a fairly well conducted review although the inclusions criteria were not always specified a priori. The aims were clearly stated and a comprehensive literature search was undertaken which included a search of the ‘grey literature’. Unpublished manuscripts not awaiting publication were excluded, the extent of which was not reported, and it is therefore not known if important information was left out. A systematic procedure involving one or more reviewers was used to assess the relevancy of retrieved articles and to perform data extraction. The authors also assessed the validity of included trials. Relevant details of included RCTs were clearly presented in tables and described in the text, although the information on included participants was limited. The narrative summary relating to monitoring the diabetic foot without complications included data from non-RCTS which were not presented in tabular format and were not described in detail. Differences between included studies were briefly discussed and a narrative synthesis of the results was appropriate. The overall findings for each section were not always clearly presented. However, the authors’ conclusions follow from the results, which took into consideration the poor quality of the included studies.

**Implications of the review for practice and research**
Practice: The authors note that the trial data provided two important messages. First, vigilant and trained health care professionals can identify the emerging risk factors for ulceration at relative little cost. Second, highly structured and high effort interventions are required to modify the behaviour of those at most risk from ulceration. These interventions may be expensive to implement but, nonetheless, cost-effective in narrow health care 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 economic grounds.

Research: The authors note that the most informative trial, which randomised participants to screening (where those identified as being at risk were entered into a foot protection programme) or usual care, urgently needs to be repeated in a less selective group of patients, possibly using neurological and vascular assessments as the basis of inclusion. They also note that the comparison of ‘optimised’ normal shoes with special therapeutic footwear remains a research issue.

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Other publications of related interest

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.