Does contact with a podiatrist prevent the occurrence of a lower extremity amputation in people with diabetes? A systematic review and meta-analysis

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ABSTRACT
Objective: To determine the effect of contact with a podiatrist on the occurrence of Lower Extremity Amputation (LEA) in people with diabetes.

Design and data sources: We conducted a systematic review of available literature on the effect of contact with a podiatrist on the risk of LEA in people with diabetes. Eligible studies, published in English, were identified through searches of PubMed, CINAHL, EMBASE and Cochrane databases. The key terms, ‘podiatry’, ‘amputation’ and ‘diabetes’, were searched as Medical Subject Heading terms. Reference lists of selected papers were hand-searched for additional articles. No date restrictions were imposed.

Study selection: Published randomised and analytical observational studies of the effect of contact with a podiatrist on the risk of LEA in people with diabetes were included. Cross-sectional studies, review articles, chart reviews and case series were excluded. Two reviewers independently assessed titles, abstracts and full articles to identify eligible studies and extracted data related to the study design, characteristics of participants, interventions, outcomes, control for confounding factors and risk estimates.

Analysis: Meta-analysis was performed separately for randomised and non-randomised studies. Relative risks (RRs) with 95% CIs were estimated with fixed and random effects models as appropriate.

Results: Six studies met the inclusion criteria and five provided data included in meta-analysis. The identified studies were heterogeneous in design and included people with diabetes at both low and high risk of amputation. Contact with a podiatrist did not significantly affect the RR of LEA in a meta-analysis of available data from randomised controlled trials (RCTs); (1.41, 95% CI 0.20 to 9.78, 2 RCTs) or from cohort studies; (0.73, 95% CI 0.39 to 1.33, 3 Cohort studies with four substudies in one cohort).

Conclusions: There are very limited data available on the effect of contact with a podiatrist on the risk of LEA in people with diabetes.

INTRODUCTION
A worldwide diabetes epidemic is unfolding.1 Diabetes is associated with a significantly increased risk of Lower Extremity Amputation (LEA). LEA rates vary between populations with estimates ranging from 46 to 9600/105 people with diabetes.2 A number of factors influence the occurrence of an LEA in people with diabetes; including

ARTICLE SUMMARY

Article focus
People with diabetes are at increased risk of Lower Extremity Amputation (LEA). As the prevalence of diabetes escalates worldwide, it is anticipated that there will be an increase in the number of LEAs.

It is assumed that contact with a podiatrist prevents the occurrence of an LEA.

This systematic review aims to determine from available literature the documented effect of contact with a podiatrist on the occurrence of an LEA in people with diabetes.

Key messages
Very limited data are available and the authors conclude that there is insufficient evidence to determine whether contact with a podiatrist has an effect on the risk of LEA in people with diabetes.

Some existing studies suggest that contact with a podiatrist has a positive effect on shorter-term outcomes including patient knowledge of foot care and ulcer recurrence.

Further research on the long-term outcome of LEA is warranted.

Strengths and limitations of this study
This is the first systematic review which investigates if contact with a podiatrist prevents the occurrence of an LEA in people with diabetes.

Failure to demonstrate an effect on this long-term outcome is most likely due to limitations of available studies.

Limitations include that studies in this systematic review looked at different sample populations ranging from patients with low baseline risk to patients with active disease. Also, included randomised controlled trials were underpowered to detect a significant difference for the outcome of LEA.
hypertension, obesity and hyperglycaemia. In the foot, previous ulceration, infection and ischaemia are proven risk factors. Nearly 85% of amputations begin as foot ulcers among persons with diabetes. Protective factors include control of clinical parameters and screening to identify those people at high risk and many LEAs are preventable. The effects of clinical and sociodemographic risk factors on the occurrence of an LEA have been well documented in people with diabetes.

In 2008, a task force report by the Foot Care Interest Group of the American Diabetes Association, which included podiatrists, stated that all people with diabetes should be assigned to a foot risk category. These categories were designed to direct referral to and subsequent therapy by a speciality clinician or team but did not refer specifically to the role of podiatry. Recent guidelines from Scotland outline a diabetic-risk stratification and triage tool, highlighting which people need podiatry referral. According to these guidelines, all patients classified as moderate risk (ie, at least one risk factor present), severe risk or with active disease require podiatry review. Podiatry is practiced as a specialty in many countries and in many English-speaking countries, the older term of ‘chiroprist’ may still be used. According to the National Health Service in the UK, there is no difference between a chiroprist and a podiatrist. It is assumed that podiatrists prevent LEAs by treating existing disease and educating people with diabetes on proper foot care. However, the effect of patient contact with a podiatrist on the risk of LEA in people with diabetes is unproven.

Two previous Cochrane reviews by Dorresteijn et al have looked first at the effect of an integrated care approach and second, the effect of patient education on the outcome of LEA in people with diabetes. The first of these reviews found no high-quality evidence evaluating an integrated care approach and insufficient evidence of benefit in preventing diabetic foot ulceration. The second review, updated in 2012, concluded that there is insufficient robust evidence that limited patient education alone is effective in achieving clinically relevant reductions in ulcer and LEA incidence. Individual patient contact with a podiatrist was not examined as an intervention in either review. Thus, the objective of the present systematic review of the published literature is to examine the effect of contact with a podiatrist on risk of LEA in people with diabetes.

METHODS
The research question, inclusion and exclusion criteria and proposed methods of analysis were specified in advance and documented in a protocol (attached as a supplementary file).

Search Strategy
PubMed, CINAHL, EMBASE (Excerpta Medica) and Cochrane databases were searched to identify relevant studies published up to and including 25 September 2011. The key terms, ‘podiatry’, ‘amputation’ and ‘diabetes’, were searched as Medical Subject Heading terms. Randomised and observational studies, published in English, which reported the effect of contact with a podiatrist on risk of LEA in people with diabetes (type 1 or 2), were included. No date restrictions were imposed. Cross-sectional studies, review articles, non-systematic reviews, chart reviews and case series were excluded. A manual search for references cited in relevant articles was performed. All potentially eligible studies were independently reviewed by two authors (CMB and PMK).

Data abstraction and quality assessment:
Using a standardised data collection form, two reviewers (CMB and PMK) independently abstracted information on the study design, year of study, characteristics of participants, interventions and outcomes, control for potential confounding factors and risk estimates. A modified version of a checklist developed by Downs and Black for assessing the methodological quality of both randomised and non-randomised studies of healthcare interventions was used to critically appraise the studies in this review. Inconsistencies between reviewers were discussed and resolved through consensus.

Statistical analysis
Review Manager Software V.5 (Revman 5.0; the Cochrane Collaboration, Oxford, England) and STATA V.12IC were used for statistical analysis. The relative risk (RR) with 95% CI was recorded for included studies. One study presented individual results for four various stages of disease so this study was analysed as four sub-studies. Meta-analysis was performed separately for randomised and non-randomised studies, using either the fixed or random effects model as appropriate. Statistical heterogeneity was assessed with Cochran’s Q statistic. Cochran’s Q is computed by summing the squared deviations of each study’s estimate from the overall meta-analytic estimate, weighting each study’s contribution in the same manner as in the meta-analysis. p Values were obtained by comparing the statistic with a χ² distribution with k−1 degrees of freedom (where k is the number of studies). To assess publication bias, a funnel plot of the overall estimate and its SE was derived.

RESULTS
Four hundred and ninety-nine titles were retrieved from searches of electronic databases. Duplicates (138) were removed and 361 titles/abstracts were reviewed. Eighteen papers were considered for review after initial screening of titles and abstracts. Three further studies were identified as potentially eligible from reference checking. After reviewing the full text articles, six studies met the inclusion criteria; two randomised controlled trials (RCTs) and four cohort studies (figure 1).
Studies were excluded because of study design for example, chart review/audit; intervention for example, contact with a multidisciplinary team instead of contact with a podiatrist; or in one case, the study was described in another article already included in this systematic review.

Table 1 describes the included studies according to study design, participants, interventions and outcomes. Quality of included studies was assessed and all studies were deemed of suitable quality for inclusion (tables 2 and 3). Risk of foot disease at baseline was assessed using the Diabetic foot risk stratification and triage system from the Scottish Intercollegiate Guidelines Network (SIGN) guidelines (see online supplementary appendix 1). Results of included studies are presented in table 4.

Results from available studies were pooled together in separate meta-analyses for RCTs and observational studies. Five of these studies provided sufficient data to allow meta-analysis. For RCTs, the fixed effects model was applied (Q=0.328, p=0.567) and for cohort studies, the random effects model is reported as there was evidence of significant heterogeneity between the cohort studies (Q=32.698, p=0.000). Meta-analysis of the two RCTs yielded an insignificant pooled RR of 1.41 (95% CI 0.20 to 9.78) while meta-analysis of the cohort studies also yielded an insignificant pooled RR of 0.73 (95% CI 0.39 to 1.33; figure 2).

Data required for inclusion in the meta-analysis was unavailable for one eligible study. Lavery et al compared people with diabetes on dialysis and people with diabetes with a history of a healed ulcer. During a 30-month evaluation period, only 30% of patients from both groups combined were seen for preventative care prior to ulceration. The amputation incidence density was high in both groups (dialysis group 58.7 and ulcer group 13.1/1000 person-years). However, it was not possible to extract the LEA event rate in those who did or did not have contact with a podiatrist.

Visual inspection of the funnel plot produced for the included studies shows no strong evidence of publication bias (figure 3).

DISCUSSION
In this systematic review, we conclude that there is insufficient evidence to determine whether contact with a podiatrist has an effect on LEA in people with diabetes.

Strengths and limitations of this review
This is the first systematic review that the authors are aware of that investigates if contact with a podiatrist prevents the occurrence of an LEA in patients with diabetes. A thorough literature search examining multiple databases was undertaken and six studies with two different study designs were included. While individual study design meta-analysis was performed in an effort to pool the available data, we acknowledge that heterogeneity exists between studies included in the meta-analysis in terms of baseline diabetic foot risk and type of intervention.

Included studies looked at different sample populations ranging from patients with low baseline risk to patients with active disease. For example, Romnemaa et al recruited patients with diabetes from the national drug reimbursement register in Finland which is representative of the total population with diabetes. However, Plank et al recruited patients with diabetes from a tertiary referral centre which represents a population of patients with diabetes that have developed complications requiring referral to a tertiary centre. In five of the six included studies, the population at risk were patients with diabetes. However, Sowell et al examined a population mix of patients with diabetes, peripheral vascular disease (PVD) and gangrene. It was decided to include this study due to the dearth of research in this area.

This difference in populations studied between the Sowell paper and the other five studies needs to be highlighted as a limitation in this review.

The diabetic foot risk of the participants at baseline (low-active) reflects the different treatment settings at recruitment and highlights heterogeneity amongst the studies (table 1). Cochran’s Q statistic was used to assess heterogeneity. For RCTs, the fixed effects model was appropriate but this meta-analysis is limited as there are only two included studies. For cohort studies, the Q statistic of 32.698 (p=0.000) indicated that strong heterogeneity existed so the random effects model was applied to account for both random variability and the variability in effects among the studies. However, use of the random effects model limits the conclusions that can be drawn from the meta-analysis. ‘A priori’
<table>
<thead>
<tr>
<th>Study (author, country, year)</th>
<th>Type of study</th>
<th>Participants</th>
<th>Interventions</th>
<th>Source of data used in study</th>
<th>Length of follow-up</th>
<th>Baseline risk as per diabetic foot risk stratification</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ronnemaa, Finland, 1997&lt;sup&gt;14&lt;/sup&gt;</td>
<td>RCT</td>
<td>530 patients with diabetes randomised</td>
<td>Intervention: 45 min individual patient education Podiatric care visits as necessary Control: Written information</td>
<td>Clinical report forms</td>
<td>1 and 7 years</td>
<td>Low</td>
<td>Primary: Patient knowledge about foot care Secondary: ulcer incidence Amputation rate Primary: Recurrence rate of ulcers Secondary: Amputation rate Death Number of amputations</td>
</tr>
<tr>
<td>Plank, Austria, 2003&lt;sup&gt;23&lt;/sup&gt;</td>
<td>RCT</td>
<td>91 patients with diabetes randomised</td>
<td>Intervention: Chiropodist visit at least once a month Control: chiropodist treatment not specifically recommended</td>
<td>Clinical report forms</td>
<td>386 days (368–424, 25&lt;sup&gt;th&lt;/sup&gt;–75&lt;sup&gt;th&lt;/sup&gt; percentile)</td>
<td>High (healed foot ulcers)</td>
<td></td>
</tr>
<tr>
<td>Sowell, USA, 1999&lt;sup&gt;24&lt;/sup&gt;</td>
<td>Cohort</td>
<td>255 256 with diabetes or PVD or gangrene followed over time</td>
<td>Intervention: Podiatric Medical care—receipt of any M0101 services Comparison: Did not receive podiatry (M0101) services</td>
<td>Medicare claims database</td>
<td>1 year</td>
<td>Unknown</td>
<td></td>
</tr>
<tr>
<td>Lipscombe, Canada, 2003&lt;sup&gt;27&lt;/sup&gt;</td>
<td>Cohort</td>
<td>132 patients with diabetes on peritoneal dialysis (PD)</td>
<td>Intervention: Assessment, education and footcare by chiropody Comparison: Did not receive podiatry (M0101) services</td>
<td>Medical charts</td>
<td>3 years</td>
<td>High</td>
<td>Number of amputations</td>
</tr>
<tr>
<td>Lavery, USA, 2010&lt;sup&gt;21&lt;/sup&gt;</td>
<td>Cohort</td>
<td>300 high-risk patients with diabetes 150 with an ulcer history 150 on dialysis followed over time</td>
<td>Intervention: Podiatry services—number of visits to podiatrist for prevention, ulcer treatment of other pathology</td>
<td>Claims data and electronic medical records</td>
<td>30 months</td>
<td>High (history of foot ulcer)</td>
<td>Amputation rate Ulcer incidence</td>
</tr>
<tr>
<td>Sloan, UK, 2010&lt;sup&gt;28&lt;/sup&gt;</td>
<td>Cohort</td>
<td>189 598 patients with diabetes followed over time Participants grouped into different stages (1–4) of disease depending on severity of symptoms and signs</td>
<td>Intervention: Care provided by podiatrist Comparison: Care provided by ‘other health professional’—GP/internist/endocrinologist/nurse/physician assistant</td>
<td>Medicare claims database</td>
<td>6 years</td>
<td>Stage 1: Moderate Stage 2: High Stage 3: Active Stage 4: Active</td>
<td>Amputation rate</td>
</tr>
</tbody>
</table>

RCT, randomised controlled trial.
Table 2  Quality assessment of included RCTs

<table>
<thead>
<tr>
<th>Study (author, country, year)</th>
<th>Type of study</th>
<th>Base population</th>
<th>Randomisation</th>
<th>Blinding</th>
<th>Confounding</th>
<th>Losses to follow-up</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ronnemaa, Finland, 199722</td>
<td>RCT</td>
<td>Community-based care in Finland, receiving antidiabetic drug treatment from the national drug reimbursement register</td>
<td>Randomisation performed separately for men/women and patients &lt; 20 years. Method of randomisation not described</td>
<td>Outcome assessor blinded to baseline characteristics but no further information on blinding provided</td>
<td>Baseline characteristics not described</td>
<td>Follow-up completed by 63% of patients in intervention group and 62% patients in control group at 7 years</td>
<td>No intention to treat analysis undertaken</td>
</tr>
<tr>
<td>Plank, Austria, 200323</td>
<td>RCT</td>
<td>All in routine outpatient care at hospital diabetic foot clinic in Austria</td>
<td>Subjects were assigned a patient number in ascending order and randomly allocated to the intervention or control group</td>
<td>Allocation concealment ensured</td>
<td>Similar baseline characteristics</td>
<td>All patients followed up</td>
<td>Intention to treat and per protocol analysis</td>
</tr>
</tbody>
</table>

RCT, randomised controlled trial.

Table 3  Quality assessment of included cohort studies

<table>
<thead>
<tr>
<th>Study (author, country, year)</th>
<th>Type of study</th>
<th>Base population</th>
<th>Confounding</th>
<th>Losses to follow-up</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sowell, USA, 199924</td>
<td>Cohort</td>
<td>All Medicare population at risk for lower extremity amputation in 1993–1994</td>
<td>Not addressed—only looked at 1 variable—acknowledged as a limitation</td>
<td>No losses to follow-up</td>
<td>Amputation incidence rates with and without exposure to podiatry</td>
</tr>
<tr>
<td>Lipscombe, Canada, 200337</td>
<td>Cohort</td>
<td>Patients in Peritoneal Dialysis program at University Health Network, between January 1997 and December 1999</td>
<td>Data on confounding variables collected</td>
<td>No losses to follow-up</td>
<td>Descriptive stats</td>
</tr>
<tr>
<td>Lavery, USA, 201021</td>
<td>Cohort</td>
<td>Patients with diabetes attending Scott and White Health Plan, Texas, USA</td>
<td>Data on confounding variables collected</td>
<td>150 consecutive patients with at least 30 months follow-up from the time of diagnosis recruited so no losses to follow-up</td>
<td>Descriptive stats</td>
</tr>
<tr>
<td>Sloan, UK, 201038</td>
<td>Cohort</td>
<td>All individuals with a DM-related LEC diagnosis between 1994 and 2001</td>
<td>Data on confounding variables collected</td>
<td>No losses to follow-up</td>
<td>HRs adjusted for Medicare expenditures from care received from non-study health professionals</td>
</tr>
</tbody>
</table>
sensitivity analyses were planned for different levels of baseline risk but there were insufficient data.

Sources of potential bias should be considered in relation to the observational studies. Although information was collected on potential confounders in many of the included observational studies, the analyses were not adjusted for potential confounders and sources of bias. Clinical practices may vary per individual and per location. Guidelines have been recently developed to standardise referral of patients with diabetes to podiatry.\textsuperscript{14}

Healthcare-seeking behaviours are complex and multifactorial and ethnicity and socioeconomic position can influence attendance at podiatry.\textsuperscript{26, 27} Level of disease may also influence a patient’s decision to attend the podiatrist and create a self-selection bias in the patients with diabetes who visit the podiatrist. Patients who received healthcare services in early stages of disease may be more likely to engage in other healthy lifestyle behaviours, for example, healthy diet, not smoking and this phenomenon of ‘healthy user bias’ has been previously documented.\textsuperscript{28} In their retrospective cohort study, Sowell et al\textsuperscript{24} reported 20 LEAs in the intervention group and 130 in the control group (noting that the population at risk in this study is patients with diabetes and/or gangrene and/or PVD). This study described the majority of included participants with the outcome of LEA. However, their analysis did not adjust for important potential confounders which limit the conclusions that can be drawn from this study.

The issues of bias and confounding are minimised by the gold standard technique of randomisation in RCTs. However, there is a lack of RCTs in this area. The two

<table>
<thead>
<tr>
<th>Study (author, country, year)</th>
<th>Type of study</th>
<th>Primary outcome</th>
<th>Baseline risk as per diabetic foot risk stratification\textsuperscript{14}</th>
<th>Relative risk of amputation with contact with a podiatrist compared with no contact with a podiatrist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ronnemaa, Finland, 1997\textsuperscript{22, 16}</td>
<td>RCT</td>
<td>Diabetes-related amputation: One year follow-up: Intervention: 0 Control: 0 7-years follow-up: Intervention: 1 Control: 0</td>
<td>Low</td>
<td>2.96</td>
</tr>
<tr>
<td>Plank, Austria, 2003\textsuperscript{23}</td>
<td>RCT</td>
<td>Diabetes-related amputation: 1-year follow-up: Intervention: 2 Control: 1</td>
<td>High (healed foot ulcers)</td>
<td>0.92</td>
</tr>
<tr>
<td>Sowell, USA, 1999\textsuperscript{24}</td>
<td>Cohort</td>
<td>Amputation related to diabetes/gangrene/PVD 1-year follow-up: Intervention: 20 Control: 130</td>
<td>Unknown</td>
<td>0.25</td>
</tr>
<tr>
<td>Lipscombe, Canada, 2003\textsuperscript{37}</td>
<td>Cohort</td>
<td>Diabetes-related amputation: Amputation during any of the 3 years of the study: Intervention: 11 Control: 4</td>
<td>High</td>
<td>2.16</td>
</tr>
<tr>
<td>Lavery, USA, 2010\textsuperscript{21}</td>
<td>Cohort</td>
<td>Diabetes-related amputation: Actual number of amputations not outlined Amputation incidence density: 58.7 in Dialysis Group per 1 000 person-years 13.1 in Ulcer Group per 1 000 person-years</td>
<td>High (history of foot ulcer)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Sloan, UK, 2010\textsuperscript{38}</td>
<td>Cohort</td>
<td>Diabetes-related amputation: 6-year follow-up: actual number of amputations not outlined</td>
<td>Stage 1: Moderate Stage 2: High Stage 3: Active Stage 4: Active</td>
<td>Stage 1 disease: 2.20 Stage 2 disease: 0.85 Stage 3 disease: 0.44 Stage 4 disease: 0.36</td>
</tr>
</tbody>
</table>

RCT, randomised controlled trial.
available RCTs have a lack of power as few participants had the outcome of LEA. The most likely cause of the low numbers of outcomes in the included studies is length of follow-up. LEA takes years to develop, especially from the time-point when a patient is classified as low risk. In the first included RCT, Plank et al described two LEAs in the intervention group and one in the control group. In the second RCT, Ronnemaa et al noted no LEA after 1 year of follow-up and one LEA in the intervention group after 7 years of follow-up. Neither RCT was designed to assess LEA as a primary outcome and thus, had insufficient power to detect a significant difference for the outcome of LEA.

CONCLUSIONS AND IMPLICATIONS
Two Cochrane reviews have looked at the outcome of LEA in patients with diabetes. These reviews concluded that there is insufficient evidence that brief educational interventions or complex interventions reduce the risk of LEA. This systematic review concludes that there is insufficient evidence that contact with a podiatrist reduces the risk of LEA in patients with diabetes. Thus, this review cannot make any recommendations about practice. To detect the true effect, adequately powered RCTs and longer follow-up studies are needed to examine the effect of contact with a podiatrist on
LEA in patients with diabetes. Perhaps, podiatry programmes could be rolled out in a manner designed to answer the question of effect on outcomes such as LEA. Such studies could also assess the impact of the timing and intensity of the podiatry intervention on outcomes. Perhaps studies focusing on high-risk participants are too close in timing to the LEA event and studies of lower-risk participants would be better to detect an effect in LEA prevention.

International standards recommend a multidisciplinary team should manage the footcare of a patient with diabetes.14 Many studies have looked at the effects of a multidisciplinary team of which podiatry serves as a useful. Teams which include contact with a podiatrist would be useful. Buckley CM, Perry IJ, Bradley CP, et al. Comprehensive foot examination and risk assessment. Diabetes Care 2008;31:1679–85.


PROTOCOL FOR SYSTEMATIC REVIEW

DOES CONTACT WITH A PODIATRIST PREVENT THE OCCURRENCE OF A LOWER EXTREMITY AMPUTATION IN PEOPLE WITH DIABETES? A SYSTEMATIC REVIEW AND META-ANALYSIS

Authors:
Dr Claire M. Buckley
Professor Ivan J. Perry
Professor Colin P. Bradley
Dr Patricia M. Kearney
BACKGROUND

Diabetes is associated with a significant risk of LEA (lower extremity amputation) [1]. LEA rates vary between communities, 46-9,600 per 10^5 people with diabetes, for many reasons [2]. A number of factors influence the occurrence of a LEA in patients with diabetes; including hypertension, obesity and hyperglycaemia [3-7]. In the foot, previous ulceration, infection and ischaemia are proven risk factors [8]. Nearly 85% of amputations begin as foot ulcers among persons with diabetes [9]. Protective factors include control of clinical parameters and screening to identify those patients at high risk [10]. Many LEAs are preventable [11]. Thus, the effects of clinical and socio-demographic risk factors on the occurrence of a lower extremity amputation have been well documented in patients with diabetes in previous studies [12] [13] [14]. However, the effect of patient contact with a podiatrist on the occurrence of LEA in patients with diabetes is less well explored.

In 1998, the ADA (American Diabetes Association) published a technical review and position statement on preventive foot care in people with diabetes, highlighting the importance of foot care in people with diabetes to prevent adverse outcomes [15-16]. An updated position statement by the ADA in 2003 stated that early recognition and management of independent risk factors for ulcers and amputations can prevent or delay the onset of adverse outcomes [17]. However, these statements did not specify the role of podiatry. In 2005, the Standards of Medical Care of Diabetes issued by the ADA advised that problems involving the feet, especially ulcers and wound care, may require care by a podiatrist [18]. And in 2008, a task force report by the Foot Care Interest Group of the ADA stated that all patients with diabetes should be assigned to a foot risk category. These categories were designed to direct referral and subsequent therapy by the speciality clinician or team [19]. This report did not outline the role of podiatry but panel members included podiatric medicine representatives, suggesting that podiatry does have a place in footcare of patients with diabetes. It is now being recognised across the globe that podiatry has a role in the management of the diabetic foot. Guidelines from Scotland, Europe outline a diabetic risk stratification and triage tool, highlighting which patients need podiatry referral [20] (Appendix 1).

The management of diabetes is a complex process involving many healthcare professionals, including podiatrists. Two previous Cochrane reviews by Dorrestijn et al have looked at lower extremity amputation in patients with diabetes as an outcome [21-22]. In 2009, Dorrestijn et al concluded that there is no high quality evidence evaluating complex interventions (complex intervention defined as an integrated care approach) and insufficient evidence of benefit in preventing diabetic foot ulceration [21]. The second Cochrane review in 2010 concluded that there is insufficient robust evidence that limited patient education alone is effective in achieving clinically relevant reductions in ulcer and amputation incidence [22]. Individual patient contact with a podiatrist was not examined as an intervention in either review. To the best of our knowledge, the effect of contact with a podiatrist on the occurrence of a LEA in patients with diabetes has not been previously examined in any systematic review.

This review will look at contact with a podiatrist as an intervention to prevent LEA in patients with diabetes. Randomised and non-randomised studies will be included.

Objectives

To conduct a systematic review of international literature to determine if contact with a podiatrist has an effect on the occurrence of LEA in patients with diabetes.
METHODS

Criteria for considering studies for review

Types of study design
Randomised and non-randomised studies that allow analysis of the effect of patient contact with a podiatrist in preventing LEAs will be included.

Types of participants
People with type 1 or type 2 diabetes mellitus in any health care setting.

Types of interventions
Studies of patients with diabetes attending a podiatrist for treatment alone or for treatment and education to prevent the occurrence of LEA will be included. Comparison groups will be those that were not in contact with podiatrists or received written instructions only.

Types of outcome measures
Primary: LEA (first or repeat)
Secondary: N/A

Table 1 Inclusion & Exclusion Criteria

<table>
<thead>
<tr>
<th>Inclusion Criteria:</th>
<th>Exclusion Criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Any time</td>
<td>• Cross-sectional studies</td>
</tr>
<tr>
<td>• English language</td>
<td>• Review articles</td>
</tr>
<tr>
<td>• Any Country</td>
<td>• Non-systematic reviews</td>
</tr>
<tr>
<td>• Any age</td>
<td>• Chart reviews /Case series</td>
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<tr>
<td>• Patients with a diagnosis of diabetes – either type 1 or type 2</td>
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</tbody>
</table>

Search strategy for identification of studies
Published studies will be identified through searches of PUBMED, CINAHL, EMBASE (Excerpta Medica), and Cochrane databases. No time-limits will be implemented. Where a study is reported in more than one article, data will be extracted from the most relevant report. The key search terms will be ‘podiatry’, ‘amputation’ and ‘diabetes’. (Figure 1)
A comprehensive search strategy will be devised with the advice of the librarian. Key terms will be searched as MeSH (Medical Subject Heading) terms e.g. ‘diabetes - MeSH term’ and as free text with/without truncation as appropriate e.g. ‘Diabet*(this symbol is used for identifying all words starting with Diabet, e.g. diabetes, diabetic etc.). The search will include case-control studies, cohort studies, retrospective and prospective studies, articles, clinical trials and RCTs. The strategy will be adapted as per database requirements. In addition, hand searches will be conducted of the reference lists of all articles retrieved to identify other potentially eligible articles.

Methods - data collection and analysis

Selection of studies
Full copies of potentially eligible studies will be obtained and two review authors (CMB and PK) will decide independently on inclusion or exclusion (table 1). In the case of disagreement, consensus will be reached by discussion between four review authors (CMB, PK, CB and IJ).

Data extraction and management
Data on eligible studies will be extracted and summarised using a pre-agreed data extraction summary form. This form will include study design, baseline characteristics of participants including number of participants, age, gender, ethnicity, type of diabetes, information on exposure, outcome measure (lower extremity amputation) and other relevant data. Risk of foot disease at baseline will be assessed using the Diabetic foot risk stratification and triage system from the SIGN (Scottish Intercollegiate Guidelines Network) guidelines (Appendix 1). If the data required for the review is missing from the published article, the authors will be contacted.
Assessment of quality in included studies
A modified version of a checklist developed by Downs and Black for assessing the methodological quality of both randomised and non-randomised studies of health care interventions will be used to critically appraise the studies in this review [23].

Assessment of heterogeneity
All eligible studies will be included in the data analysis. If data are too scarce or the quality of the studies is inadequate or results are too varied to present in numerical form, the authors will perform a narrative qualitative summary. If appropriate, meta-analysis will be attempted to pool outcome data. Either a fixed or random effects model will be used depending on the heterogeneity between studies. The most suitable model will be chosen after assessing the I^2 statistic for heterogeneity.

Pilot Results
Preliminary searches of the electronic databases have yielded approximately 500 titles & abstracts for initial screening.

REFERENCES
9. Apelqvist J, Larsson J. What is the most effective way to reduce incidence of amputation in the diabetic foot? Diabetes/metabolism research and reviews 2000;16(S1):S75-S83


18. ADA. Standards of Medical Care in Diabetes. Diabetes Care 2005;28(suppl 1):s4-s36 doi: 10.2337/diacare.28.suppl_1.S4[published Online First: Epub Date]


Appendices
Appendix 1 Diabetic foot risk stratification and triage

**Diabetic Foot Risk Stratification and Triage**

- **Active**
  - **Definition**: Presence of active ulceration, spreading infection, critical ischaemia, gangrene or unexplained hot, red, swollen foot with or without the presence of pain.
  - **Action**: Rapid referral to and management by a member of a Multidisciplinary Foot Team. Agreed and tailored management/treatment plan according to patient needs. Provide written and verbal education with emergency contact numbers. Referral for specialist intervention if/when required.

- **High**
  - **Definition**: Previous ulceration or amputation or more than one risk factor present e.g. loss of sensation or signs of peripheral vascular disease with callus or deformity.
  - **Action**: Annual assessment by a specialist podiatrist. Agreed and tailored management/treatment plan by specialist podiatrist according to patient needs. Provide written and verbal education with emergency contact numbers. Referral for specialist intervention if/when required.

- **Moderate**
  - **Definition**: One risk factor present e.g. loss of sensation or signs of peripheral vascular disease without callus or deformity.
  - **Action**: Annual assessment by a podiatrist. Agreed and tailored management/treatment plan by podiatrist according to patient needs. Provide written and verbal education with emergency contact numbers.

- **Low**
  - **Definition**: No risk factors present e.g. no loss of sensation, no signs of peripheral vascular disease and no other risk factors.
  - **Action**: Annual screening by a suitably trained Health Care Professional. Agreed self-management plan. Provide written and verbal education with emergency contact numbers. Appropriate access to podiatrist if/when required.

*These risk categories relate to the use of the SCI-DC foot risk stratification tool.*

1. Diabetes mellitus (MeSH)
2. Diabet*
3. 1 or 2
4. Amputation (MeSH)
5. Amput*
6. 4 or 5
7. Podiatry (MeSH)
8. Podiatr*
9. 7 or 8
10. Case-control study (MeSH)
11. Case-control* (free text)
12. Cohort studies (MeSH)
13. Cohort* (free text)
14. Retrospective Studies (MeSH)
15. Prospective Studies (MeSH)
16. Journal Article (Publication type)
17. Clinical Trial (Publication Type)
18. Randomized Controlled Trial (Publication Type)
19. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
20. 3 and 6 and 9 and 19

Results: 184

1. (MH "Diabetes Mellitus+") OR (MH "Diabetes Mellitus, Insulin-Dependent") OR (MH "Diabetes Mellitus, Non-Insulin-Dependent")

2. Diabet*

3. 1 or 2

4. (MH "Amputation+") OR (MH "Above-Knee Amputation") OR (MH "Amputation Stumps") OR (MH "Amputation Care (Iowa NIC)")

5. Amput*

6. 4 or 5

7. Podiatric Assessment") OR (MH "Education, Podiatry") OR (MH "Surgery, Podiatric+") OR (MH "Podiatric Care")

8. Podiatr*

9. 7 or 8

10. (MH "Case Control Studies+")

11. Case-control* (free text)

12. Cohort studies (MeSH)

13. Cohort* (free text)

14. (MH "Retrospective Panel Studies") OR (MH "Retrospective Design")

15. (MH "Prospective Studies") OR (MH "Concurrent Prospective Studies") OR (MH "Nonconcurrent Prospective Studies")

16. (MH "Electronic Publications+") OR (MH "Electronic Journals") OR (MH "Publication Formats+")

17. Article (free text)

18. (MH "Clinical Trials+")

19. (MH "Randomized Controlled Trials")

20. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19

21. 3 and 6 and 9 and 20

Results: 43

1. 'diabetes mellitus'/exp
2. diabet*
3. 1 or 2
4. 'amputation'/exp
5. amput*
6. 4 or 5
7. 'podiatry'/exp
8. podiatr*
9. 7 or 8
10. 'case control study'/exp – (mesh/emtree)
11. 'case control study'/exp OR 'case control study' – (case control*)
12. 'cohort study'/exp – (mesh/emtree)
13. Cohort*
14. 'retrospective study'/exp
15. 'prospective study'/exp
16. 'article'/exp
17. 'clinical trial'/exp
18. 'randomized controlled trial'/exp
19. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
20. 3 and 6 and 9 and 19

Results: 246

1. MeSH descriptor Diabetes Mellitus explode all trees in all MeSH products
2. Diabet*
3. 1 or 2
4. MeSH descriptor Amputation explode all trees
5. Amput*
6. 4 or 5
7. MeSH descriptor Podiatry explode all trees
8. Podiatr*
9. 7 or 8
10. MeSH descriptor Case-Control Studies explode all trees in all MeSH products
11. Case control stud*
12. MeSH descriptor Cohort Studies explode all trees in all MeSH products
13. Cohort stud*
14. MeSH descriptor Retrospective Studies explode all trees in all MeSH products
15. MeSH descriptor Prospective Studies explode all trees in all MeSH products
16. Article
17. Clinical Trial
18. Randomised Control Trial
19. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
20. 3 and 6 and 9 and 19

Results: 25
13 Cochrane Reviews
2 Other Reviews
6 Clinical Trials
2 Technology Assessments
2 Economic Evaluations
1 Cochrane Group
# Appendix 6 Table of Excluded Studies

<table>
<thead>
<tr>
<th>Study (Author, Country, Year)</th>
<th>Exclusion criteria</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Driver, 2010[39]</td>
<td>Intervention</td>
<td>Podiatric lead limb preservation team - No data on contact with a podiatrist as the intervention available</td>
</tr>
<tr>
<td>Ellis, 2010[40]</td>
<td>Design / Outcome</td>
<td>Audit / Diabetic Foot Complication</td>
</tr>
<tr>
<td>Zayed, 2009[41]</td>
<td>Intervention</td>
<td>Podiatry as part of Multidisciplinary team - No data on contact with a podiatrist as the intervention available</td>
</tr>
<tr>
<td>Snyder, 2006[42]</td>
<td>Design</td>
<td>Chart review/case series, Intervention on subset of patients, comparison group not available for this subset</td>
</tr>
<tr>
<td>Robbins, 2006[43]</td>
<td>Intervention</td>
<td>Podiatry as part of Multidisciplinary team - No data on contact with a podiatrist as the intervention available</td>
</tr>
<tr>
<td>El Sakka 2006[30]</td>
<td>Intervention</td>
<td>Podiatry as part of Multidisciplinary team - No data on contact with a podiatrist as the intervention available</td>
</tr>
<tr>
<td>Schraer, 2004[44]</td>
<td>Intervention</td>
<td>Program</td>
</tr>
<tr>
<td>Dargis, 1999[31]</td>
<td>Intervention</td>
<td>Podiatry as part of Multidisciplinary team - No data on contact with a podiatrist as the intervention available</td>
</tr>
<tr>
<td>Van Gils, 1999[32]</td>
<td>Intervention</td>
<td>Podiatry as part of Multidisciplinary team - No data on contact with a podiatrist as the intervention available</td>
</tr>
<tr>
<td>Del Aguila, 1994[45]</td>
<td>No report of association</td>
<td>Number of podiatry visits in 12 months described - Unable to determine whom were not exposed to podiatry</td>
</tr>
<tr>
<td>Malone, 1989[46]</td>
<td>Intervention</td>
<td>Intervention involved education by podiatrists, not treatment</td>
</tr>
<tr>
<td>Crane, USA, 1999[47]</td>
<td>Intervention</td>
<td>Podiatry-established critical pathway</td>
</tr>
<tr>
<td>Carrington, UK, 2001[48]</td>
<td>Intervention</td>
<td>Program including podiatry</td>
</tr>
<tr>
<td>Source</td>
<td>Type</td>
<td>Description</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Hamalainen, Finland, 1998 [49]</td>
<td>Study</td>
<td>Study described in another paper</td>
</tr>
<tr>
<td>McCabe, UK, 1998 [50]</td>
<td>Intervention</td>
<td>Clinical foot screening programme, only subset of population seen by podiatrist, no comparison group involved</td>
</tr>
</tbody>
</table>