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

C M Buckley,[1,2] I J Perry,[2] C P Bradley,[1] P M Kearney[2]

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[1]Department of General Practice, University College Cork, Cork, Ireland
[2]Department of Epidemiology and Public Health, University College Cork, Cork, Ireland

Correspondence to
Dr Claire Buckley;
Claire.buckley@ucc.ie

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 heterogenous 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.

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.

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 9600/10^5 people with diabetes.[2] A number of factors influence the occurrence of an LEA in people with diabetes; including

hypertension, obesity and hyperglycaemia.[3 4] In the foot, previous ulceration, infection and ischaemia are proven risk factors.[5] Nearly 85% of amputations begin as foot ulcers among persons with diabetes.[6] Protective factors include control of clinical parameters and screening to identify those people at high risk and many LEAs are preventable.[7 8] The effects of clinical and sociodemographic risk factors on the occurrence of an LEA have been well documented in people with diabetes.[9–12]

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.[13] 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.[14] Podiatry is practiced as a specialty in many countries and in many English-speaking countries, the older term of 'chiropodist' may still be used. According to the National Health Service in the UK, there is no difference between a chiropodist and a podiatrist.[15] 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*[16 17] 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.[16] 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.[17] 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.[18] 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 substudies. 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 χ^2 distribution with k−1° of freedom (where k is the number of studies).[19] 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).[20]

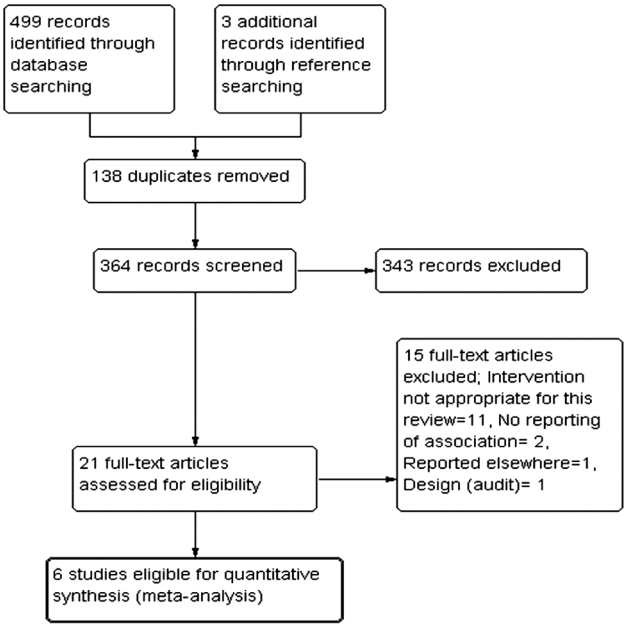

Figure 1 PRISMA flow chart: selection of studies for inclusion in review.

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).[14] 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).[21] 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, Ronnemaa *et al*[22] recruited patients with diabetes from the national drug imbursement register in Finland which is representative of the total population with diabetes. However, Plank *et al*[23] 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*[24] 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.[25] 'A priori'

Table 1 Characteristics of included studies

Study (author, country, year)	Type of study	Participants	Interventions	Source of data used in study	Length of follow-up	Baseline risk as per diabetic foot risk stratification[14]	Outcomes
Ronnemaa, Finland, 1997[22 16]	RCT	530 patients with diabetes randomised Intervention: 267 Control: 263	Intervention: 45 min individual patient education Podiatric care visits as necessary Control: Written information	Clinical report forms	1 and 7 years	Low	Primary: Patient knowledge about foot care Secondary: ulcer incidence Amputation rate
Plank, Austria, 2003[23]	RCT	91 patients with diabetes randomised Intervention: 47 Control: 44	Intervention: Chiropodist visit at least once a month Control: chiropodist treatment not specifically recommended	Clinical report forms	386 days (368–424, 25th–75th percentile)	High (healed foot ulcers)	Primary: Recurrence rate of ulcers Secondary: Amputation rate Death
Sowell, USA, 1999[24]	Cohort	255 256 with diabetes or PVD or gangrene followed over time	Intervention: Podiatric Medical care—receipt of any M0101 services Comparison: Did not receive podiatry (M0101) services	Medicare claims database	1 year	Unknown	Number of amputations
Lipscombe, Canada, 2003[37]	Cohort	132 patients with diabetes on peritoneal dialysis (PD)	Intervention: Assessment, education and footcare by chiropody	Medical charts	3 years	High	Number of amputations
Lavery, USA, 2010[21]	Cohort	300 high-risk patients with diabetes 150 with an ulcer history 150 on dialysis followed over time	Intervention: Podiatry services—number of visits to podiatrist for prevention, ulcer treatment of other pathology	Claims data and electronic medical records	30 months	High (history of foot ulcer)	Amputation rate Ulcer incidence
Sloan, UK, 2010[38]	Cohort	189 598 patients with diabetes followed over time Participants grouped into different stages (1–4) of disease depending on severity of symptoms and signs	Intervention: Care provided by podiatrist Comparison: Care provided by 'other health professional'—GP/internist/endocrinologist/nurse/physician assistant	Medicare claims database	6 years	Stage 1: Moderate Stage 2: High Stage 3: Active Stage 4: Active	Amputation rate

RCT, randomised controlled trial.

Table 2 Quality assessment of included RCTs

Study (author, country, year)	Type of study	Base population	Randomisation	Blinding	Confounding	Losses to follow-up	Analysis
Ronnemaa, Finland, 1997[22]	RCT	Community-based care in Finland, receiving antidiabetic drug treatment from the national drug reimbursement register	Randomisation performed separately for men/women and patients </> 20 years. Method of randomisation not described	Outcome assessor blinded to baseline characteristics but no further information on blinding provided	Baseline characteristics not described	Follow-up completed by 63% of patients in intervention group and 62% patients in control group at 7 years	No intention to treat analysis undertaken
Plank, Austria, 2003[23]	RCT	All in routine outpatient care at hospital diabetic foot clinic in Austria	Subjects were assigned a patient number in ascending order and randomly allocated to the intervention or control group	Allocation concealment ensured	Similar baseline characteristics	All patients followed up	Intention to treat and per protocol analysis

RCT, randomised controlled trial.

Table 3 Quality assessment of included cohort studies

Study (author, country, year)	Type of study	Base population	Confounding	Losses to follow-up	Analysis
Sowell, USA, 1999[24]	Cohort	All Medicare population at risk for lower extremity amputation in 1993–1994	Not addressed—only looked at 1 variable—acknowledged as a limitation	No losses to follow-up	Amputation incidence rates with and without exposure to podiatry
Lipscombe, Canada, 2003[37]	Cohort	Patients in Peritoneal Dialysis program at University Health Network, between January 1997 and December 1999	Data on confounding variables collected	No losses to follow-up	Descriptive stats
Lavery, USA, 2010[21]	Cohort	Patients with diabetes attending Scott and White Health Plan, Texas, USA	Data on confounding variables collected	150 consecutive patients with at least 30 months follow-up from the time of diagnosis recruited so no losses to follow-up	Descriptive stats
Sloan, UK, 2010[38]	Cohort	All individuals with a DM-related LEC diagnosis between 1994 and 2001	Data on confounding variables collected	No losses to follow-up	HRs adjusted for Medicare expenditures from care received from non-study health professionals

Table 4 Results of included studies

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

RCT, randomised controlled trial.

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.[14] Healthcare-seeking behaviours are complex and multifactorial and ethnicity and socioeconomic position can influence attendance at podiatry.[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.[28] In their retrospective cohort study, Sowell *et al*[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

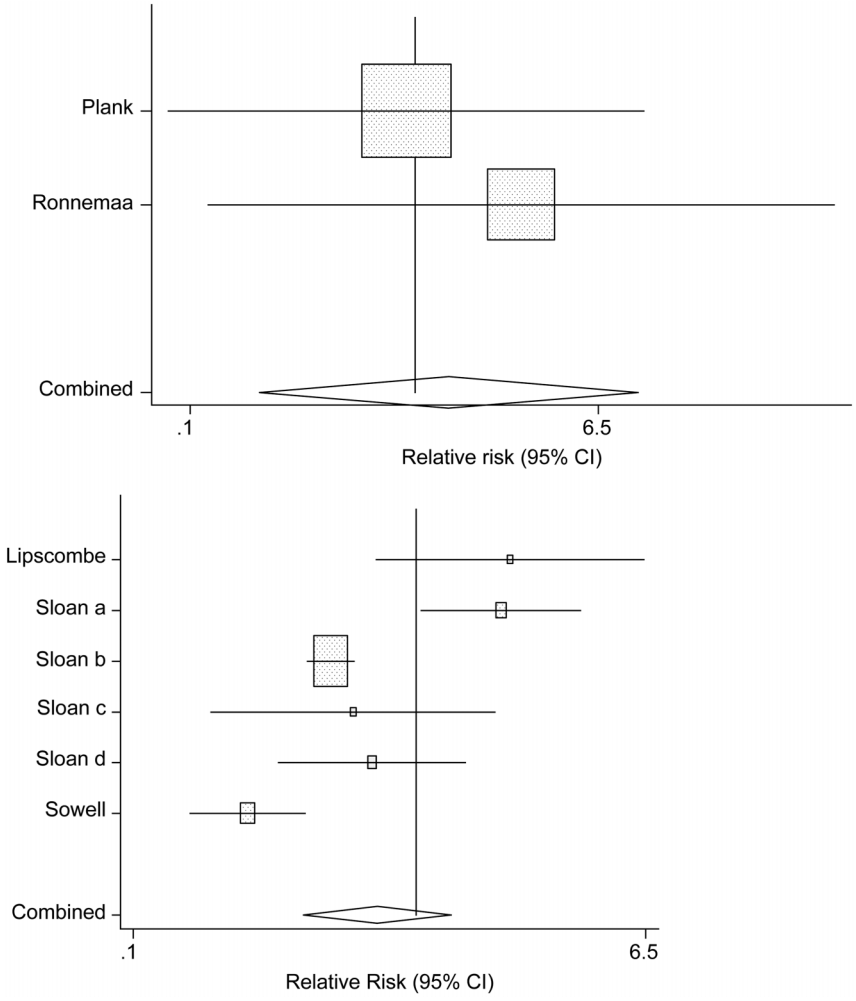

Figure 2 Forest plots of meta-analysis of randomised controlled trials (top) and cohort studies (bottom) with the intervention of contact with a podiatrist on left side of plot.

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*[23] described two LEAs in the intervention group and one in the control group. In the second RCT, Ronnemaa *et al*[22] noted no LEA after 1 year of follow-up and one LEA in the intervention group after 7 years of follow-up.[16] 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.

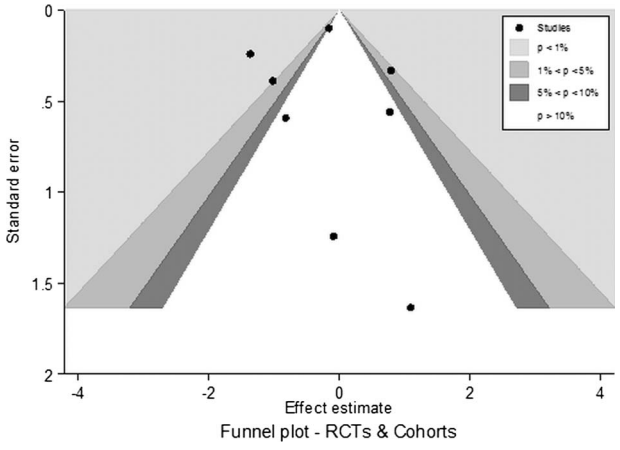

Figure 3 Funnel plot of included studies (randomised controlled trials and cohort studies).

CONCLUSIONS AND IMPLICATIONS

Two Cochrane reviews have looked at the outcome of LEA in patients with diabetes.[16 17] 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 member of the team and found positive effects on various outcomes.[29–36] This may be a more realistic reflection of how patients with diabetes are managed; looking at one service in isolation could be flawed as services are seldom delivered in isolation. According to the SIGN guidelines a multidisciplinary foot team should include a podiatrist, diabetes physician, orthotist, diabetes nurse specialist, vascular surgeon, orthopaedic surgeon and radiologist.[14] A systematic review of the literature looking at the effectiveness of multidisciplinary teams which include contact with a podiatrist would be useful.

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Notes