

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

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BACKGROUND

Diabetes is associated with a significant risk of LEA (lower extremity amputation) [1]. LEA rates vary between communities, 46-9,600 per 10⁵ 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 Dorrestiejn et al have looked at lower extremity amputation in patients with diabetes as an outcome [21 22]. In 2009, Dorrestiejn 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

Inclusion Criteria:	Exclusion Criteria:
<ul style="list-style-type: none">• Any time	<ul style="list-style-type: none">• Cross-sectional studies
<ul style="list-style-type: none">• English language	<ul style="list-style-type: none">• Review articles
<ul style="list-style-type: none">• Any Country	<ul style="list-style-type: none">• Non-systematic reviews
<ul style="list-style-type: none">• Any age	<ul style="list-style-type: none">• Chart reviews /Case series
<ul style="list-style-type: none">• Patients with a diagnosis of diabetes – either type 1 or type 2	

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)

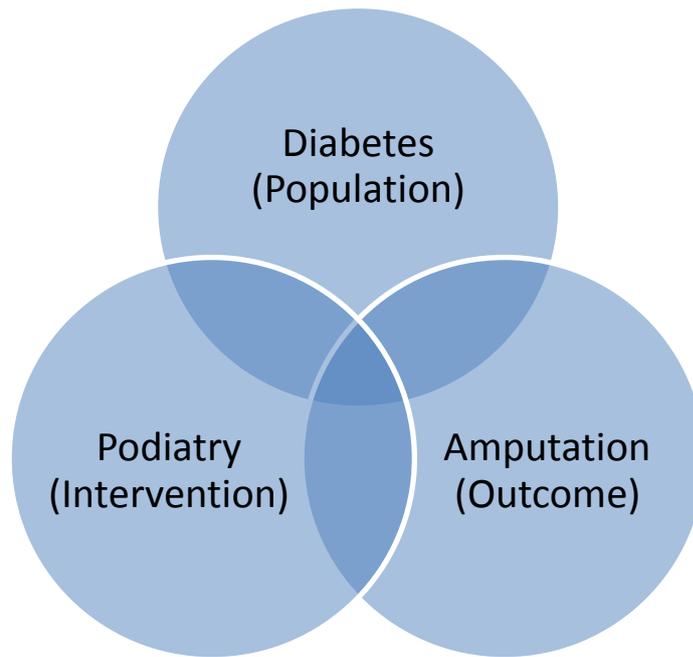


Figure 1 Venn diagram of key terms for search strategy

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.

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