ORIGINAL RESEARCH

Efficacy of plantar foot temperature monitoring in preventing ulcers in individuals with diabetes: An umbrella review protocol

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ABSTRACT

Diabetes mellitus often leads to foot ulcers, which can result in amputations and significantly affect quality of life. Monitoring plantar foot temperature has emerged as a promising intervention for preventing these ulcers. This study aims to examine the potential benefits of plantar foot temperature monitoring in preventing ulcers in individuals with diabetes mellitus. The umbrella review protocol will follow the guidelines set forth by the Joanna Briggs Institute. Participants aged 18 years and older with a diagnosis of type 1 or type 2 diabetes mellitus, and without any active ulcers at the commencement of the study, will be included. We will consider studies that monitor plantar foot temperature using thermometry and thermography. Two independent reviewers will carry out the study location selection and data extraction, employing a modified and validated JBI extraction tool. The methodological quality of the studies included will be evaluated using both the JBI Critical Appraisal Checklist for Systematic Reviews and Research Syntheses, as well as the AMSTAR-2 tool. This systematic review is registered under PROSPERO number CRD42024509838. Data on the effectiveness of interventions for monitoring plantar foot temperature to prevent ulcers in individuals with diabetes will be collected and summarized. A citation matrix will analyze the overlap of primary studies, and meta-analysis will be performed if feasible. The certainty of evidence will be assessed using the GRADE system. This protocol ensures rigorous execution by researchers and may aid in implementing evidence-based nursing interventions for ulcer prevention in diabetes.

Key Words: Diabetes mellitus, Foot ulcer, Thermometry, Thermography, Umbrella review

1. INTRODUCTION

Diabetes mellitus (DM), a disease characterized by high blood glucose levels, impacts millions of individuals globally. One of its most prevalent complications is foot ulcer development, leading to serious outcomes such as amputations and diminished quality of life. Studies indicate that peripheral neuropathy and poor blood circulation are key factors in diabetic foot ulcer formation.[1] In this context,

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plantar temperature monitoring emerges as an innovative and promising approach to preventing these complications, as thermal variations can signal incipient inflammation or vascular changes preceding ulcer formation.[2]

Skin temperature reflects the physiological state of underlying tissues, serving as a sensitive indicator of inflammation and compromised blood perfusion. The early detection of areas with elevated temperature can enable timely preventive interventions, thereby avoiding progression to more severe ulcers. Furthermore, modern technology provides accessible and non-invasive thermal monitoring devices, allowing patients to monitor their condition at home, which enhances treatment adherence and promotes a proactive approach to health management.[3]

Preventing ulcers and other complications in people with DM is paramount for improving their quality of life. Key approaches include proper blood glucose control, as chronic hyperglycemia contributes to vascular and peripheral nervous system damage. Maintaining glucose levels within target range reduces the risk of peripheral neuropathy, a common condition in diabetic patients leading to foot sensitivity loss, predisposing them to injuries and ulcers. Additionally, incorporating self-care practices, including daily foot inspections to early identify any signs of lesions, calluses, or deformities, is crucial. Wearing appropriate footwear providing support and foot protection also plays a vital role in ulcer prevention by reducing excessive pressure on specific areas.[4]

While systematic reviews have been performed on interventions for monitoring foot temperature in people with diabetes, a comprehensive synthesis of the existing evidence is still lacking. A preliminary search for the existence of umbrella reviews was conducted in databases such as PROPERO, Medline/PubMed, and the Cochrane Library, confirming the absence of similar studies to the one proposed. This preliminary search reinforced that there is an urgent need to synthesize all available evidence on this topic and, importantly, to assess the strength of the evidence by applying the GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) framework.

The potential of plantar temperature monitoring in preventing ulcers in people with diabetes is promising, but effective implementation of this strategy requires a comprehensive understanding of factors influencing thermal variations as well as clinical validation of these devices. By clarifying the effectiveness of monitoring plantar foot temperature in the prevention of diabetic foot ulcers, this article seeks to enhance the scientific understanding in this area, promoting the implementation of preventive strategies that can significantly reduce ulcer-related complications and thus improve the quality of life among these patients. The umbrella review is a good strategy to gather and critically evaluate the findings from various systematic reviews, providing a robust and reliable overview of the effectiveness of interventions.

1.1 Study objective

This study aims to examine the potential benefits of plantar foot temperature monitoring in preventing ulcers in individuals with diabetes mellitus.

2. METHODS AND ANALYSES

The Umbrella Review will be carried out in accordance with the JBI methodology and the reporting guidelines for health intervention overviews (PRIOR).[5] To ensure comprehensive reporting, the review will adhere to the guidelines outlined in the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P).[6]

2.1 Review question

The research question of this study is based on the PICO framework, addressing:

P (participants): Individuals with type I and type II diabetes mellitus

I (intervention): Foot temperature monitoring

C (comparison): Other standard treatment methods

O (outcome): Ulcer prevention

The research question formulated is as follows: What is the efficacy of foot temperature monitoring in preventing ulcers among individuals with diabetes mellitus?

2.2 Inclusion criteria

2.2.1 *Participants*

The review will include systematic reviews that focus on individuals aged 18 years and above who have been diagnosed with type 1 or type 2 diabetes mellitus, who do not have active ulcers at the outset of the study, and which evaluated the use of plantar temperature monitoring (thermometry and thermography).

Systematic reviews involving participants without diabetes diagnoses, children and adolescents aged <18 years, as well as expectant mothers diagnosed with gestational diabetes will be left out. Gestational diabetes, during which hormonal changes can induce insulin resistance, is not directly a risk factor for diabetic foot ulcers.

2.2.2 *Intervention*

We will incorporate studies that evaluate the use of thermography and thermometry for monitoring foot temperature in individuals with diabetes mellitus.

Currently, thermal measurement systems are applied through

two techniques: thermography and thermometry. Thermography tests are classified into thermosensitive liquid crystal overlays and infrared, while thermometry tests are divided into infrared and thermal sensors. These systems have been adapted into different instruments for diagnosing foot problems, including Infrared Thermometer (IT), Liquid Crystal Thermography (LCT), temperature sensors integrated into a scale, and Infrared Thermal Imaging.[7]

2.2.3 *Comparison*

We will incorporate systematic reviews that provide any form of comparative intervention.

2.2.4 *Outcomes*

The primary outcome to be assessed is the occurrence of plantar ulcer, with secondary outcomes including other complications (amputation, mortality, among others).

2.2.5 *Types of studies*

We will include systematic reviews, with or without meta-analyses, of randomized controlled trials (RCTs) that focus on individuals with type I and II diabetes and utilize temperature monitoring as part of the treatment for this research. A systematic review is defined as an evidence synthesis that has a clearly articulated set of objectives and predefined eligibility criteria for selecting studies; an open and reproducible approach; a systematic search method to uncover all relevant studies; an assessment of the credibility of results; and a thorough summary of the characteristics and findings of those studies.[8]

Narrative reviews, integrative reviews, scoping reviews, in addition to systematic reviews focusing on qualitative or conceptual studies, along with published viewpoints, will be excluded. Additionally, systematic reviews that consist only of observational studies (such as case series, individual case reports, descriptive cross-sectional studies, case-control studies, and cohort studies) will also be excluded.

2.3 Search strategy

The search will commence in the first half of 2024, across the specified databases below. No language or date restrictions will be applied.

The subsequent sources will be explored: CINAHL, Cochrane, EMBASE, Epistemonikos, PubMed, Scopus, Web of Science, and LILACS.

A preliminary search on PROSPERO did not identify any ongoing reviews with similar objectives. Drawing from the defined research question, we created an initial search strategy for Medline/PubMed employing the ECUs method (Extraction, Conversion, Combination, and Use),[9] as illustrated in Appendix I. To assess the practicality of this approach, we followed the Peer Review of Electronic Search Strategies (PRESS) guidelines,[10] which serve as a valuable resource.

To develop the search strategy, we employed four controlled vocabularies: Controlled vocabulary terms, such as Medical Subject Headings (MeSH), EMTREE from Embase, CINAHL Subject Headings, and Health Sciences Descriptors (DeCS), were integrated with relevant free-text keywords utilizing Boolean operators AND and OR to capture a broader array of relevant results.[11]

A variation in Portuguese will be used for the LILACS database. For the Scopus and Web of Science databases, which lack a built-in controlled vocabulary, we will employ the usual search method. In other bibliographic databases, we will combine the standard search strategy with their designated subject headings.

The searches will be performed on the same day to minimize potential biases. A preliminary search was first carried out on January 30, 2024, in the MEDLINE (Medical Literature Analysis and Retrieval System Online) database through PubMed (Appendix II), followed by adjustments in other electronic databases.

Finally, literature search will be complemented by checking the reference lists of included documents and seeking input from diabetes experts.

2.4 Study selection

Once the search is complete, all identified citations will be compiled and imported into the Mendeley citation management system to systematically eliminate duplicates. The records will then be transferred to Rayyan,[12] a tool specifically designed to streamline the processes of removing duplicate studies, as well as selecting and screening studies efficiently. Additionally, it ensures methodological rigor and transparency among reviewers by permitting blind assessments, which helps reduce potential biases.[12]

The screening and selection procedures will be carried out independently by two reviewers. In cases of disagreement, a third reviewer will be consulted to resolve the issue. To evaluate agreement between reviewers in the subsequent selection phases, Cohen's Kappa will be calculated,[13] with the following classification: 0-0.20 indicates no agreement; 0.21–0.39 minimal agreement; 0.40–0.59 weak agreement; 0.60–0.79 moderate agreement; 0.80–0.90 strong agreement; and above 0.90 almost perfect agreement. If there is less than 79% agreement, we will arrange for a training session between the reviewers to enhance process reliability. For this purpose, 30 studies will be selected for review and assessment by the reviewers. Subsequently, studies that fulfill the inclusion criteria will advance to the next stage, which will

involve reading the studies in full and selecting those to be included in the review.

Finally, the third stage will entail manual searches of the references for the included studies will be documented. The complete process of identification, screening, and inclusion will be recorded in the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) flowchart.

2.4.1 *Assessment of methodological quality*

The selection and evaluation of studies will be performed by two reviewers using the JBI Critical Appraisal Checklist for Systematic Reviews and Research Synthesis (Appendix V).[14] This checklist consists of 11 criteria that assess various elements of the review process, including: i) clarity of the review question; ii) suitability of the inclusion criteria; iii) suitability of the search strategy; iv) sufficiency of the sources and resources used for study retrieval; v) suitability of the evaluation criteria; vi) duplication in the execution of quality assessments; vii) methods employed to minimize errors during data extraction; viii) adequacy of the methods for synthesizing studies; ix) bias assessment; x) strength of policy and practice recommendations; and xi) suitability of suggested directions for future research. Each item will be rated using a checklist, as follows: "Y = met", "N = not met", "?" = unclear", and "NA = not applicable".

In cases of discrepancies, a third reviewer will be involved to facilitate consensus. If additional clarification is required, the authors of the studies will be reached out to directly. The reference criteria for scoring are as follows: a score of 0-3 will be categorized as very low quality, 4-6 as low quality, 7-9 as moderate quality, and a score of 10-11 will be deemed high quality.

Additionally, the AMSTAR-2 (A Measurement Tool to Assess Systematic Reviews) will be employed (Appendix VI). All studies will undergo data extraction and synthesis, and depending on the outcomes of the critical appraisal, sensitivity analyses may be conducted to assess the robustness of the conclusions drawn.

2.5 Data extraction

Two reviewers will independently extract data utilizing a predefined data extraction form. Should any information from the reviews be unclear or absent, we will reach out to the review authors up to three times within a three-week period.

The following data will be extracted from the included reviews (Appendix III): characteristics of the review (number of included studies and countries of study, years of publication, study design, number of participants in each review, and the date of the search conducted for each review), as well as the interventions and comparisons analyzed, detailing the type of methodology employed. When a meta-analysis is absent, a summary of the primary outcomes will be offered. In contrast, for reviews that include a meta-analysis, we will extract data on pooled effect sizes (such as rate ratio, risk ratio, or odds ratio for dichotomous data, and mean difference or standardized mean difference for continuous data), along with their corresponding 95% confidence intervals (CIs) and P values.

To analyze the overlap of primary studies included in the systematic reviews under consideration, we will employ a citation matrix and the Corrected Covered Area (CCA) index.[15] Overlap ratios will be derived from the CCA value (Appendix IV).[16] In cases where reviews exhibit complete or nearly complete overlap (high overlap), we will consider excluding those studies, retaining higher-quality reviews (e.g., Cochrane reviews) and/or more recent reviews that possess similar quality ratings.

2.6 Data synthesis

Included reviews will be synthesized descriptively. Quantitative data will then be analyzed by meta-analysis when feasible.

Heterogeneity between studies will be rigorously assessed using statistics such as the I^2 index. The methodological quality and publication bias of systematic reviews will be considered in the interpretation of results. Combined results will be presented in a clear and transparent manner, highlighting limitations and the robustness of conclusions. The meta-review will not only contribute to effective evidence synthesis, but also identify knowledge gaps and guide future research in the field. Analyses will include the calculation of odds ratios and linear correlations according to the retrieved data.

The REML model will be used as an estimator between studies and a multivariate analysis between outcomes will be performed. It is a statistical method used for parameter estimation in variance-covariance models, especially in mixed linear models.[17] For evidence stratification, the number of studies, total participants, number of cases, p-values of outcomes, inconsistency, imprecision, risk of bias and quality of meta-analysis, prediction and results of each research will be considered. The "metaumbrella" package will be utilized to conduct various analyses, including specific tests, fixed or random effects meta-analyses, evaluations of inconsistency and heterogeneity (I^2), assessments of small study effects, and tests for excess statistical significance. Where possible, publication bias analysis will be presented using the funnel plot, analyzed by outcome trend and study size. The result of the inferential analysis is presented using the forest plot.

Overlap of studies from different reviews will be accounted for in the Ioannidis method. R 4.3.2 software will be used.

2.7 Assessing certainty in the findings

In summarizing the conclusions of the reviews, we will implement the principles of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework[18] to assess the overall quality of evidence related to the outcomes of interest.[17] Each specific outcome's quality of evidence will be categorized as high, moderate, or low, taking into account factors such as the general quality of the systematic reviews, the likelihood of bias in the primary studies, and the coherence of the findings (Appendix VII).

3. Expected results

We anticipate gathering data that assesses the effectiveness of interventions in monitoring plantar foot temperature, aiming to assess their potential benefits in preventing ulcers in individuals with diabetes mellitus. Ulcer prevention will be considered the primary beneficial outcome, while the occurrence of plantar ulcers will be considered adverse. Lower limb amputation, mortality, and other outcomes will be regarded as secondary outcomes.

4. Conclusion

Conducting an umbrella review on the effectiveness of monitoring plantar foot temperature in preventing ulcers may offer a thorough and reliable synthesis of the existing evidence. This can significantly contribute to advancing knowledge in diabetes management and education, as well as supporting the development of evidence-based clinical guidelines for practice.

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Authors contributions

Administering the project: ALA, TMMM; Designing the analysis: ALA, FDSN, RSF, TSG, SMM; Performing the analysis: ALA, FDSN, TSG, SMM, SJSM, FEFA; Screening: WCOA, ALA, FDSN, TSG, RSF; Validation and Visualization: VRFC, VBP; Writing and finalizing the manuscript: all authors.

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Conflicts of Interest Disclosure

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Informed consent

Obtained.

Ethics approval

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Provenance and peer review

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Data availability statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Data sharing statement

No additional data are available.

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