INPLASY PROTOCOL

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Support: **None.**

Review Stage at time of this submission: **Formal screening of search results against eligibility criteria.**

Conflicts of interest:
None declared.

Differences in corneal nerve parameters in type 1 and type 2 diabetic peripheral neuropathy: A protocol for a meta-analysis

Zhang, N[1]; Yang, JY[2]; Ou, CY[3]; Chen, X[4]; Cheng, P[5]; Liu, BY[6]; Wu, J[7].

Review question / Objective: **The aim of this systematic review is to analyze the differences of corneal nerve parameters between type 1 and type 2 diabetic peripheral neuropathy to better understanding of how DPN occurs.To this end, the proposed systematic review will address the following question: What are the differences in corneal nerve parameters in peripheral neuropathy patients with type 1 diabetes mellitus and type 2 diabetes mellitus?**
Eligibility criteria: **The inclusion criteria of this study are: (1) Research subjects: patients with diabetes who have been diagnosed, both type 1 and type 2 are included in the study, and each group of research subjects included in each study is more than 10 cases. (2) CCM is used to detect patients, and at least one of the reported parameters is included (CNFD, CNBD, CNFL, TC, IWL). (3) Type of research: observational research or interventional research. Interventional research extracts data before intervention. Reviews, case reports, systematic reviews, and meta-analyses need to be excluded. For some cohort studies, multiple articles were published during the study, and the most recent article was selected for inclusion. There are no restrictions on the language, region, and country of published articles.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 May 2022 and was last updated on 27 May 2022 (registration number INPLASY202250153).

INTRODUCTION

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end, the proposed systematic review will address the following question: What are the differences in corneal nerve parameters in peripheral neuropathy patients with type 1 diabetes mellitus and type 2 diabetes mellitus?

Condition being studied: Diabetic neuropathy (DN) is one of the most common chronic complications of diabetes, of which Diabetic peripheral neuropathy (DPN) accounts for 75%, DPN includes large fiber neuropathy (LFN), small fiber neuropathy (SFN) and mixed small- and large-fiber neuropathy (MFN), Type 1 diabetes mellitus (T1DM) and Type 2 diabetes mellitus (T2DM) DPN may occur. Epidemiological data show that about 10%-50% of diabetic patients will eventually develop DPN, and the prevalence of DPN varies widely depending on the survey population and neuropathy assessment methods.More and more studies have found many differences in the peripheral neuropathy of the two types of diabetes, and speculate that T1DM-DPN and T2DM-DPN may be different diseases. Several studies on CCM have demonstrated differences in corneal neural parameters between T1DM-DPN and T2DM-DPN.This led us to ponder how corneal nerve damage differs between T1DM-DPN and T2DM-DPN.Based on the inconsistency of the differences in corneal nerve parameters between T1DM-DPN and T2DM-DPN patients in different studies, and there is no systematic review or meta-analysis published on the differences in corneal nerve parameters between the two. Therefore, this meta-analysis evaluate the total effect of the differences in corneal nerve parameters between T1DM-DPN and T2DM-DPN in the included studies, in order to provide more clinical references.

METHODS

Search strategy: We have searched, with no language restrictions, and the publications until October 21, 2021: PubMed (MEDLINE), Embase, Web of Science,China National Knowledge Infrastructure, Wanfang Data,China Science and Technology Journal Database,China Biology Medicine disc.The search string will be built as follows: (neuropathy OR neuropathies OR diabetic neuropathy) and (diabetes OR diabetic) and (corneal confocal microscopy OR CCM).The electronic database search will be supplemented by a manual search of the reference lists of included articles.

Participant or population: Type 1 diabetic peripheral neuropathy and type 2 diabetic peripheral neuropathy.

Intervention: None.

Comparator: Control group (without diabetic peripheral neuropathy).

Study designs to be included: Observational research or interventional research. Interventional research extracts data before intervention. Reviews, case reports, systematic reviews, and meta-analyses need to be excluded. For some cohort studies, multiple articles were published during the study, and the most recent article was selected for inclusion.

Eligibility criteria: The inclusion criteria of this study are: (1) Research subjects: patients with diabetes who have been diagnosed, both type 1 and type 2 are included in the study, and each group of research subjects included in each study is more than 10 cases. (2) CCM is used to detect patients, and at least one of the reported parameters is included (CNFD, CNBD, CNFL, TC, IWL). (3) Type of research: observational research or interventional research. Interventional research extracts data before intervention. Reviews, case reports, systematic reviews, and meta-analyses need to be excluded. For some cohort studies, multiple articles were published during the study, and the most recent article was selected for inclusion. There are no restrictions on the language, region, and country of published articles.

Information sources: A total of 7 electronic databases were searched for all published articles from the establishment of the database to October 21, 2021, including

three English databases:Pubmed, Web of science (WOS), Embase, four Chinese databases: China National Knowledge Infrastructure (CNKI), Wanfang database (wanfang), China Science and Technology Journal Database (VIP), China Biology Medicine disc (CBM). In addition, conference papers and dissertations were supplemented by searches.

Main outcome(s): CNFL(corneal nerve fiber length); CNFD (corneal nerve fiber density); CNFD (corneal nerve fiber density).

Additional outcome(s): Accmetric VS. Ccmetric.

Data management: Document management software: Endnote; Data analysis and processing software: Revman 5.4.

Quality assessment / Risk of bias analysis: The risk of bias assessment of the study was completed following Cochrane's Bias Assessment Tool, a total of seven items were included, including selection bias, implementation bias, measurement bias, missing bias, incomplete data reporting, and other biases. The included studies were assessed as high-quality, moderate-quality, and low-quality according to the results of the bias assessment.

Strategy of data synthesis: 1.The type of outcome data which will be synthesised: continuous data. 2.Effect measure be applied: WMD with 95% confidence interval. 3. Effect model: random-effects model will be performed. 4. Hierarchical methods:Stratification was performed depending on the confocal microscopy image analysis software used.

Subgroup analysis: Subgroup analysis was performed depending on the confocal microscopy image analysis software used: Accmetric VS. Ccmetric.

Sensitivity analysis: Remove studies individually from the overall analysis results, assess the relationship between the analysis results and the original results, further assess the robustness of the results and explore sources of heterogeneity.

Language: English.

Country(ies) involved: China.

Other relevant information: None.

Keywords: diabetic peripheral neuropathy (DPN), type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus(T2DM), corneal confocal microscopy (CCM), meta-analysis.

Dissemination plans: Publish paper in journal.

Contributions of each author:

Author 1 - Nan Zhang - 1. Propose an idea. 2. Develop an overall research plan and make a data extraction table. 3. Analysis and processing of results. 4. Article writing. 5.Database search.
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