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ADMINISTRATIVE INFORMATION

Support - None.
Review Stage at time of this submission - Preliminary searches.
Conflicts of interest - None declared.
INPLASY registration number: INPLASY202570116

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 July 2025 and was last updated on 29 July 2025.

INTRODUCTION

Review question / Objective To identify and map the available management strategies for scleredema diabeticorum and to summarize their reported clinical outcomes across different study designs.

Background Scleredema diabeticorum is a rare cutaneous complication of diabetes mellitus, characterized by progressive skin thickening and induration, typically over the upper back and neck. Due to its rarity, there are no standardized treatment guidelines, and current management relies on diverse approaches reported in case-based literature. This scoping review aims to map the available treatments and summarize reported clinical outcomes to inform clinical practice and identify evidence gaps.

Rationale Due to the rarity of scleredema diabeticorum, evidence on its management is limited and scattered across case reports and small studies. No comprehensive synthesis

currently exists to guide clinicians on effective treatment strategies. A scoping review is therefore warranted to systematically map the available evidence on treatment modalities and associated clinical outcomes, and to identify knowledge gaps for future research.

METHODS

Strategy of data synthesis Data will be synthesized using a descriptive and narrative approach. Extracted information on study characteristics, treatment modalities, and clinical outcomes will be organized in summary tables and categorized by intervention type. Patterns of treatment response (e.g., improvement, no change, progression) will be mapped across studies. No meta-analysis will be conducted due to the expected heterogeneity in study design and outcome reporting.

Eligibility criteria This review will include studies involving patients diagnosed with scleredema diabeticorum that report any form of therapeutic

intervention beyond diabetes treatment alone. Eligible studies must report clinical outcomes such as symptom improvement, stabilization, or progression. Included study designs are randomized controlled trials, prospective studies, retrospective studies, case reports, case series, and letters. Only articles published in English between 2005 and 2025 and subjected to a peer-reviewed process will be considered. Exclusion criteria are conference abstracts, book chapters, books, review articles, studies that do not report treatment interventions, studies without clinical outcome data, and articles not peer-reviewed.

Source of evidence screening and selection

Relevant studies will be identified through a systematic search of Scopus, MEDLINE (via PubMed), and the Cochrane Library. All retrieved records will be screened in two stages: first by title and abstract, followed by full-text review to determine eligibility based on the predefined inclusion and exclusion criteria. The screening and selection process will be conducted independently by two reviewers, with discrepancies resolved through discussion or consultation with a third reviewer.

Data management All search results will be exported to a reference management software to remove duplicates. Eligible studies will then be organized and screened using Microsoft Excel. A standardized data extraction form will be developed to collect relevant information, including study characteristics, participant details, intervention type, treatment outcomes, and study design. Data will be independently extracted by two reviewers, with discrepancies resolved through discussion or consultation with a third reviewer.

Language restriction English.

Country(ies) involved Thailand.

Keywords Scleredema diabeticorum; diabetes mellitus; skin thickening; treatment; management; clinical outcome; scoping review.

Contributions of each author

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