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Protocol

Current ulcer care practices among leprosy patients: a systematic review protocol

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ABSTRACT

Background: Leprosy, or Hansen's disease, is a chronic infectious condition caused by *Mycobacterium leprae* or *Mycobacterium lepromatosis*, predominantly affecting the skin, peripheral nerves, and mucous membranes. Despite being curable, it continues to result in significant morbidity due to delayed diagnosis, stigma, and complications such as chronic trophic ulcers (CTUs). While multiple treatment options exist ranging from debridement and protective footwear to growth factor therapies but their comparative effectiveness remains unclear.
Methods: This systematic review and meta-analysis aim to evaluate the effectiveness of various ulcer care practices for individuals affected by leprosy, focusing on outcomes such as healing rates and ulcer recurrence. This systematic review will follow the PRISMA-P 2015 guidelines and is registered in PROSPERO (CRD420251010372). A thorough search will be conducted in databases such as PubMed, Google Scholar, and grey literature from 2005 to 2024. Studies included will be randomized controlled trials (RCTs) and cross-sectional studies that report on ulcer care practices in people affected by leprosy. We will include interventions like wound dressings, debridement, medications, use of footwear, and traditional methods. The quality of the studies will be assessed using standard tools: the Cochrane RoB 2 tool for randomized trials and the Joanna Briggs Institute (JBI) checklist for cross-sectional studies. Data will be analysed using R software.
Conclusions: The review will synthesize evidence on the effectiveness of ulcer care interventions in leprosy, guiding clinical decision-making and informing policy to improve healing outcomes and quality of life among affected individuals.
Trial Registration: Current control trial registration number is CRD420251010372.

Keywords: Leprosy, Chronic ulcers, Wound healing, Ulcer care, Meta-analysis

INTRODUCTION

Leprosy, or Hansen's disease, is a chronic but treatable infection caused by *Mycobacterium leprae* and/or *Mycobacterium lepramatosis* affecting the skin, nerves, and mucous membranes. Beyond physical deformities, it often leads to stigma and discrimination. Early treatment can cure the disease and prevent disability. In 2023, 182,815 new leprosy cases were reported worldwide, with 39.8% affecting females and 5.6% involving children. Additionally, 9,729 new cases of grade 2 disability were identified, including 266 in children. The highest burden of new cases is concentrated in the WHO South-East Asia and African regions.[1-3]

Plantar ulcers are a significant complication of leprosy and are classified by the world health organization as a grade 2 disability, indicating visible deformity or damage. These ulcers are challenging to heal and often become chronic due to factors such as sensory loss, muscle

paralysis, nerve dysfunction, callus formation, and infection. They affect approximately 10% to 20% of individuals with leprosy.[4,5]

CTUs in individuals with leprosy typically develop on the foot, over bony prominences, and are influenced by factors such as loss of sensation, unprotected walking, muscle paralysis, nerve damage, poor circulation, inadequate scar tissue, and persistent infections. These ulcers are difficult to heal and often become chronic.

Various treatments, including debridement, wound dressings, proper rest, protective footwear, topical antibiotics, growth factor applications, negative pressure wound therapy (NPWT), and reconstructive surgeries, have been used. However, despite options like plaster cast immobilization, collagen dressings, and topical agents such as phenytoin or metronidazole, healing remains slow. The exploration of growth factors like platelet-derived and epidermal growth factors offers hope, but more effective and safer methods are needed to reduce treatment time, dressing frequency, and hospital stays, ultimately improving the patient's quality of life.[6,7]

While various medical and surgical interventions are used in practice, no single therapy has shown consistent effectiveness, and consolidated evidence on their comparative success in healing, reducing recurrence, and improving quality of life remains limited. Continued research is needed to establish more reliable and effective treatment strategies.[8,9]

This systematic review and meta-analysis aim to bridge this gap by evaluating and synthesizing evidence from studies published over the last 20 years. The findings will offer insights into which interventions are most effective and under what conditions, thereby guiding clinical practice, supporting evidence-based care, and informing policy and future research for the management of leprosy-related ulcers.

Objectives

The objective of this systematic review and meta-analysis is to evaluate the effectiveness of various ulcer care practices in leprosy

METHODS

Design and protocol registration

This systematic review and meta-analysis follow the guidelines established by the preferred reporting items for systematic reviews and meta-analyses protocols (PRISMA-P 2015).[10] The protocol for this study has been registered in the PROSPERO international prospective register of systematic reviews with the registration number CRD420251010372. This registration ensures transparency and methodological rigor in the review process.

Search strategy

The search string will use Boolean operators and may include: ("Hansen's Disease" OR Leprosy OR "Mycobacterium leprae" OR Leprotic) AND ("foot ulcer" OR ulcer OR "chronic wounds" OR "wound care") AND ("wound healing" OR "ulcer care" OR "wound management" OR dressing OR "topical therapy" OR debridement OR antibiotic OR surgery OR "foot care").

The search will be restricted to studies published between 2005 and 2024, and those in English, but translations will be sought for non-English studies if necessary.

Study selection and quality appraisal

Two independent groups of reviewers will screen the identified articles. First, titles and abstracts will be assessed for relevance. The second stage will involve full-text screening to assess whether the articles meet the inclusion criteria for this review. Disagreements will be resolved through discussion, and if necessary, a third reviewer will adjudicate. Studies that do not meet the inclusion criteria will be excluded.

Risk of bias assessment

For RCTs, we will use the Cochrane risk of bias 2 (RoB 2) tool.[11] It assesses the risk of bias in randomized trials through five domains. It focuses on the randomization process, deviations from intended interventions, missing outcome data, outcome measurement, and selection of reported results. Each domain helps determine whether bias affects validity of the trial results. For cross-sectional studies, we will apply the Joanna Briggs Institute (JBI) critical appraisal checklist.[12,13] It evaluates sample representativeness, measurement accuracy of exposures and outcomes, and handling of confounding factors.

The certainty of evidence will be assessed using the GRADE approach, which evaluates five domains: risk of bias, inconsistency, indirectness, imprecision, and publication bias.[14] Appropriate tools will be used to assess study quality. Heterogeneity, relevance to the review question, confidence intervals, and potential reporting bias will also be considered. Each outcome will be rated as high, moderate, low, or very low certainty.

PICO framework

To guide the systematic review and meta-analysis, the PICO (Population, intervention, comparison and outcome) framework was utilized to frame the research question and define eligibility criteria.

Population (P)

The population of interest includes individuals diagnosed with leprosy (Hansen's disease) who have developed chronic ulcers, particularly plantar or foot ulcers. These

ulcers often result from nerve damage, sensory loss, and repeated trauma, and are commonly classified as grade 2 disabilities by the World Health Organization (WHO).

Intervention (I)

The review considers a broad range of ulcer care interventions employed in the management of leprosy-related ulcers. These include: Wound dressings (e.g., collagen, hydrocolloid, alginate), topical antibiotics and antiseptics, surgical interventions (e.g., wound closure, skin grafts), debridement (mechanical, enzymatic, or autolytic), pressure relief and protective footwear and advanced therapies such as platelet-based applications (e.g., platelet-rich plasma), stem cell therapies, and topical agents like phenytoin, metronidazole, or herbal preparations (Ayurveda, Siddha).

Comparison (C)

The interventions will be compared against: Standard care practices (e. g., basic cleaning and dressing, conventional wound care), placebo/no treatment, alternative treatments (e. g., traditional medicine vs. modern therapies).

This comparison allows for the assessment of effectiveness between commonly used, evidence-backed methods and other experimental or alternative strategies.

Outcomes (O)

The primary outcomes of interest are:

Healing rate

Defined as the proportion of ulcers that completely heal or significantly reduce in size over a specified treatment period, assessed through clinical evaluation or wound measurements.

Ulcer recurrence

Defined as the reappearance of ulcers at the same or new site following initial healing, typically evaluated during follow-up periods ranging from 6 months to 1 year.

This structured approach ensures clarity in identifying and selecting studies and facilitates a focused analysis of the effectiveness of various ulcer care interventions in leprosy patients.

Inclusion criteria

We will include RCTs and cross-sectional studies published in the past 20 years (i.e., from 2005 onwards) that assess ulcer care practices in individuals affected by leprosy. Eligible studies must report on interventions such as dressings, antibiotics, protective footwear, surgery, pressure relief, infection control, debridement, or alternative treatments (e.g., Ayurveda, Siddha, herbal medicine), with outcomes related to healing rate, quality of life, or ulcer recurrence. Only studies published in the English language will be included. Studies from clinical and community-based settings such as hospitals, clinics, leprosy care centers, and community health programs providing ulcer care for leprosy patients.

Exclusion criteria

We will exclude case reports, case series, editorials, opinion pieces, and reviews that do not contain original data. Studies published before 2005, those that do not specifically address ulcer care in leprosy patients, or those focusing on general wound care unrelated to leprosy will also be excluded. Additionally, studies that do not report the specified outcomes (healing rate, quality of life, or ulcer recurrence) will not be considered and studies from laboratory or experimental settings without human participants, and those focused on non-leprosy ulcers, will be excluded.

Outcomes

Main outcomes of this review will include healing rate and ulcer recurrence. Healing rate refers to percentage of ulcers that have completely healed or significantly reduced in size over a specified period, measured through clinical assessments or wound size evaluations. Ulcer recurrence will be defined as reappearance of ulcers following initial healing, typically measured during follow-up periods of 6 months to 1 year. These outcomes will be used to assess overall effectiveness of ulcer care practices in individuals affected by leprosy. No additional outcomes are planned for analysis.

Data extraction

Data will be extracted by two independent groups of reviewers. Information extracted will include study details (author, year of publication, study design), participant characteristics (age, gender, stage of leprosy), ulcer care interventions (type of wound care, frequency, duration), and outcomes (healing rates, complications, adverse events). Any disagreements between reviewers will be resolved through discussion, and a 3rd reviewer will be consulted if necessary. Data will be recorded in a Microsoft excel spreadsheet for analysis.

Data analysis

In this systematic review and meta-analysis, both narrative synthesis and quantitative analysis will be used. A meta-analysis will combine data on outcomes like healing rate and ulcer recurrence if the data across studies are consistent. Statistical analysis will be performed using R software, with random-effects models for high heterogeneity (I^2>50%) and Random-effects models for high heterogeneity.

A forest plot will display individual study results and pooled effect sizes, and sensitivity analysis will exclude high-bias studies to assess their impact. Publication bias will be assessed using funnel plots and Egger's test, and a Baujat plot will identify studies contributing to heterogeneity.

Additionally, a meta-regression will be conducted to explore how certain factors (such as the duration of intervention) might influence the results. The results from the meta-regression will be presented graphically and discussed to understand how they fit into the overall findings of the review.

DISCUSSION

To the best of our knowledge, this will be the first systematic review and meta-analysis focused specifically on examining the current practices in the care and management of ulcers among patients affected by leprosy. Ulcers associated with leprosy, particularly neuropathic and plantar types, pose a significant clinical challenge due to their chronic nature, risk of infection, recurrence, and potential to cause lasting disability. Despite the burden they represent, the treatment approaches remain diverse and fragmented, highlighting the need for consolidated evidence.

Several individual studies have explored different therapeutic options, each with varying degrees of clinical success. One such study by Gaikwad et al assessed the effectiveness of Ayurvedic treatment compared to conventional therapy in patients with longstanding plantar ulcers. The trial included 31 patients in each group. While the ulcers in the Ayurvedic group were initially larger in size, the outcomes were notably better, with nearly 77% improvement observed, in contrast to 43% in the conventional treatment group. Additionally, the majority of ulcers in the intervention group showed more than 50% healing, with the results being statistically significant.[15]

Another report by Montero et al highlighted the use of platelet-rich plasma (PRP) as a potential regenerative therapy for chronic neuropathic ulcers in leprosy. They described two cases involving four ulcers, all of which showed complete healing following PRP application. Although the findings are promising, the authors emphasized the need for more robust evidence to confirm its efficacy in broader clinical settings.[16]

Surgical interventions have also been employed as a means of treating persistent ulcers. Gahalaut et al conducted a study involving 40 leprosy patients with plantar ulcers, where different types of local superficial flaps such as advancement, rotation, transposition and 1st toe web flaps used. Majority of ulcers healed within four weeks, and patients were discharged within 6-8 weeks. Follow-up data indicated a relatively low recurrence rate of 25% over a period ranging from 6 months to 3 years, suggesting that flap-based surgical management may be an effective and sustainable approach.[17]

In terms of novel biomaterials, Nunes et al. evaluated the healing potential of a biomembrane incorporating latex proteins from the medicinal plant *Calotropis procera*. The membrane was applied to ulcers in 15 leprosy patients over a 56-day period. Compared to control groups treated with silver sulfadiazine or hydrocolloid dressings, the biomembrane showed superior outcomes, with approximately 88% of ulcers achieving complete healing. Importantly, no adverse effects were reported, and the efficacy appeared consistent regardless of patient age, ulcer duration, or disease status.[18]

Taken together, these studies demonstrate a range of evolving practices in the management of leprosy-related ulcers from traditional medicine and biologics to surgical and biomaterial-based interventions. However, the existing literature is limited by small sample sizes, heterogeneity in outcome measures, and lack of standardization. The planned systematic review and meta-analysis will therefore serve to consolidate the current evidence, identify effective treatment modalities, and inform future clinical and programmatic strategies for ulcer care in the context of leprosy.

CONCLUSION

This systematic review and meta-analysis aim to provide a comprehensive overview of ulcer care practices in leprosy, offering critical insights into the effectiveness of various treatments and identifying factors that influence healing outcomes. The findings will be valuable for healthcare providers and policymakers working to improve quality of life for individuals living with leprosy and reduce burden of leprosy-related complications.

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