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The Efficacy of Topical Sucralfate for Skin Ulcer: A Systematic Review of Randomized Control Trials and Cohort Studies

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Abstract:
Wound care in ulcers often poses significant challenges due to prolonged healing time and frequently unsatisfactory outcomes. The use of topical modalities to maintain a moist wound environment continues to be developed. Sucralfate, as a cytoprotective agent for gastric mucosa, has shown potential in the management of ulcers. This systematic review aims to determine the efficacy of topical sucralfate in ulcer wound healing. A comprehensive literature search was conducted across databases including PubMed and Google Scholar, for nine clinical studies published between 2008 and 2023 across multiple countries. The present study included randomized controlled trials (RCTs) and cohort studies that compared sucralfate dressing with conventional dressing. Outcomes of interest included reduction area, healing time, healing rate, and rate of granulation tissue formation. Nine studies fulfilled the eligibility criteria, assigning topical sucralfate as the intervention and conventional modalities (saline, mupirocin, povidone iodine) or placebo as comparators. The study duration ranged from 10 days to 3 months, during which topical sucralfate achieved superior outcomes, with a statistically significant reduction in healing time and greater wound area reduction compared with controls. These results indicate that topical sucralfate is effective in ulcer wound management, exerting cytoprotective effects and promoting epithelial regeneration, thereby enhancing the overall quality of wound healing. While primarily considered an adjunctive agent, the evidence demonstrates that sucralfate exerts clinically relevant effects on epithelialization and tissue recovery. Its cytoprotective properties underscore a therapeutic role that extends beyond supportive care, reinforcing its value as a complementary strategy in wound management.

Keywords: *sucralfate, ulcer, topical, efficacy*

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INTRODUCTION

The skin is the largest organ of the human body and plays an essential role in maintaining physiological homeostasis, including protection against infection, regulation of fluid balance, and thermoregulation (Sorg et al., 2017). When its continuity is disrupted, a wound occurs, which may progress into a chronic ulcer if healing does not occur within the expected timeframe of approximately three to four months. Chronic ulcers such as pressure, diabetic, venous, arterial, neuropathic, and inflammatory ulcers represent a major global health concern. Pressure ulcers alone have a prevalence of up to 41–44%, while diabetic ulcers account for more than 90% of lower-limb amputations and contribute significantly to mortality (Zuniga et al., 2024). Venous ulcers also remain common, affecting up to 50–55% of women and 40–50% of men. The chronicity of these wounds, combined with their lengthy healing times, highlights the need for effective and patient-tolerable wound-care strategies (Fernandes et al., 2005; Panuncialman & Falanga, 2010).

Advances in wound-care science have expanded available treatment options, transitioning from traditional dry dressings to modern moist wound healing approaches (Kolimi et al., 2022; Saifullah &

Sharma, 2024; Weigelt et al., 2022). Contemporary wound management now encompasses hydrocolloid dressings, foam dressings, alginate dressings, and various topical agents such as sucralfate, mupirocin, silver-based antimicrobials, growth factors, and enzymatic debriding agents. Previous systematic reviews have demonstrated the superiority of moist wound healing over traditional dry dressings in accelerating re-epithelialization and reducing healing time. Studies by Tumino et al. (2008) established the efficacy of topical sucralfate in venous ulcers through randomized placebo-controlled trials, while Masuelli et al. (2010) provided mechanistic insights into sucralfate's cytoprotective and wound healing properties. More recent investigations have explored combination therapies, such as sucralfate with platelet-rich plasma and growth factor modulation. . Among these, topical sucralfate has gained interest for its ability to promote re-epithelialization and enhance wound healing. Sucralfate, an aluminum hydroxide complex of octasulfate sucrose, is widely known as a cytoprotective agent for gastrointestinal disorders but has also been used for perineal excoriations, stomatitis, pressure ulcers, and radiation-induced injuries (Preethi & Dhanasekaran, 2019). Its potential benefits in reducing pain, accelerating granulation tissue formation, and improving healing outcomes have been reported across various clinical contexts (Masuelli et al., 2010).

Despite these encouraging findings, the adoption of topical sucralfate in ulcer management remains variable. Differences in study quality, small sample sizes, and heterogeneous methodologies have made it difficult to establish clear clinical guidance. Evidence synthesis is therefore necessary to determine its true therapeutic value and comparative effectiveness against standard wound dressings. Given the increasing burden of chronic ulcers worldwide and the need for accessible treatment options, this systematic review aims to systematically evaluate the current evidence on the efficacy of topical sucralfate in promoting ulcer wound healing. Specifically, the objectives of this review are to: (1) assess the effectiveness of topical sucralfate in reducing wound area and accelerating healing time compared to conventional wound dressings, (2) evaluate the impact of sucralfate on granulation tissue formation and epithelialization rates, (3) analyze the safety profile and adverse effects associated with topical sucralfate use, (4) compare the cost-effectiveness of sucralfate with standard wound care modalities, and (5) identify gaps in current evidence to guide future research directions. By addressing these objectives, this review seeks to provide evidence-based guidance for clinicians regarding the appropriate use of topical sucralfate in chronic wound management, potentially improving patient outcomes and healthcare resource utilization.

METHODS

A comprehensive literature search on the efficacy of topical sucralfate was conducted using the PubMed and Google Scholar databases. The collected literature included randomized controlled trials (RCTs) and cohort studies comparing the effectiveness of topical sucralfate with conventional wound dressings, with or without placebo. The keywords used in the search were “sucralfate” OR “topical sucralfate” OR “sucralfate dressing” AND “ulcer” OR “skin ulcer”.

Only abstracts reporting the use of topical sucralfate for the management of skin ulcers in humans were included. Eligible study designs consisted of primary research articles such as cohort studies, RCTs, and cross-sectional studies. The studies included in this systematic review met the following criteria: (1) original research articles, (2) written in English or Indonesian, and (3) focused on outcomes and the effectiveness of topical sucralfate in the healing of skin ulcers. The outcomes of interest included reduction in wound area, healing time, healing rate, and the formation of granulation tissue. Systematic reviews, narrative reviews, preclinical animal studies, and meta-analyses were excluded.

Titles and abstracts of articles that met the search criteria were screened, and duplicates were removed. Each study was then independently examined to determine whether it fulfilled the inclusion and exclusion criteria.

Two reviewers independently assessed the eligibility of the articles to be included. Extracted data from each study consisted of the publication year, study design, participant age (mean or range), sample size, intervention and comparison groups, and reported clinical outcomes.

Screening and selection of studies were conducted meticulously, and the quality of the included studies was assessed using the Risk of Bias (RoB 2) tool developed by the Cochrane Risk of Bias Assessment. Risk-of-bias analysis was performed for all nine eligible articles. Five domains were evaluated: the randomization process, deviations from the intended interventions, missing outcome data, measurement of outcomes, and selection of the reported results. To ensure consistency, one reviewer independently performed the risk-of-bias assessment for all included studies.

RESULT AND DISCUSSION

A total of 175 studies were identified during the identification phase, consisting of 164 studies retrieved from Google Scholar and 11 from PubMed. After the initial assessment, 17 duplicate articles were excluded prior to screening. The screening phase was then conducted on 158 articles, which were subsequently evaluated for eligibility based on predefined criteria. A total of 9 articles met the inclusion and exclusion criteria and were ultimately included in this systematic review (Figure 1).

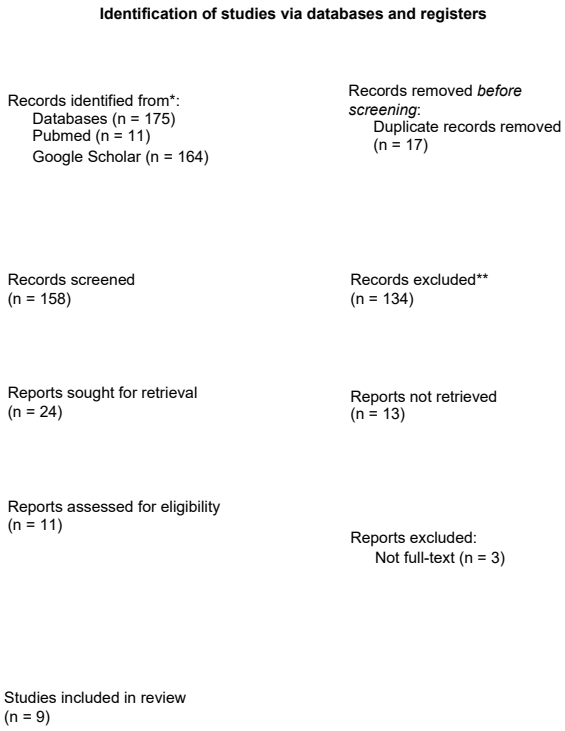

Figure 1. PRISMA flow diagram for eligible articles assessment regarding topical sucralfate for skin ulcer.
Source: Author Documentation

The risk-of-bias assessment summarizes five methodological domains (D1–D5) across all included studies. Overall, most studies demonstrated a low risk of bias in nearly all domains, indicated by the predominance of green markers. Several studies showed some concerns (yellow markers).

Despite these isolated concerns, the majority of the evidence base was rated as methodologically sound, with consistent low-risk evaluations. This pattern indicates generally robust internal validity among the included studies, with only a few requiring cautious interpretation due to specific methodological limitations (Figure 2).

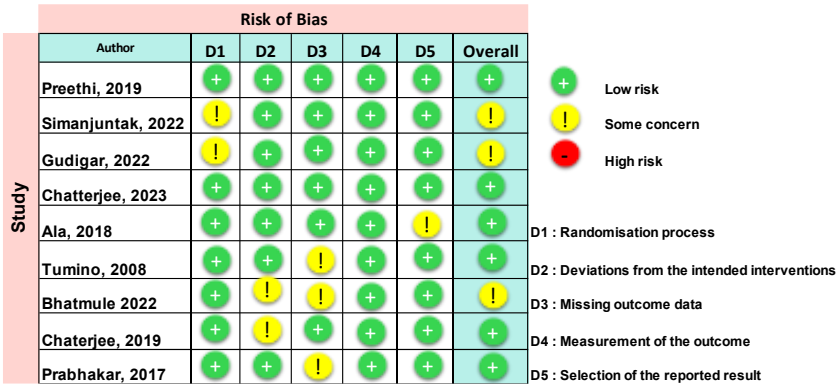

Figure 2. Risk of bias analysis
Source: Author Documentation

The studies included in this review comprised randomized controlled trials and prospective clinical investigations involving adult to elderly populations. Sample sizes ranged from 20 to 108 participants. Across these studies, topical sucralfate was evaluated in various formulations such as dressing, gel, or combined ointment—and compared with standard treatments such as povidone iodine and hydrogen peroxide dressings, normal saline drainage, phenytoin dressing, mupirocin, and placebo. The randomized trials assessed sucralfate alone or in combination with agents like platelet-rich plasma or mupirocin, with mean participant ages generally between the mid-40s and late-60s. Prospective studies further examined sucralfate against alternative dressing options in broader age ranges. Collectively, the included studies represented diverse clinical contexts and comparison groups, allowing for a comprehensive assessment of sucralfate's therapeutic potential in chronic wound care (Table 1).

Table 1. Characteristics of included studies

Study (years)	Study types	Age	Sample size	Intervention and comparison	Outcome
Preethi (2019)	RCT	58	50	• Intervention: Topical sucralfate dressing • Comparison: Conventional dressing with 5% povidone iodine solution and hydrogen peroxide wash	• Significant mean area reduction of 34.995% in Sucralfate dressing vs 14.682% in conventional dressing • Higher percentage reduction in wound area of 70.4% vs 29.6% in conventional group • Cost effective and shortened duration of hospital stay
Simanjuntak (2022)	RCT	52	20	• Intervention: Sucralfate and PRP therapy • Comparison: Normal saline drainage	• Mean VEGF expression is higher in treatment group of 98.18+10.96 vs 66.69+23.79 in control group • No significant difference in wound area

Gudigar (2022)	Prospective study	20-80	60	• Intervention: sucralfate dressing • Comparison: phenytoin dressing	• Wound reduction rate is better in Sucralfate (65) compared to phenytoin (30.3) • Greater rate of tissue formation in phenytoin (58.65) vs sucralfate (52.76)
Chatterjee (2023)	Prospective study	51	108	• Intervention: topical sucralfate and mupirocin • Comparison: topical mupirocin	• Higher healing rates in the sucralfate and mupirocin group (16.2±7.3%) vs in control (14.5±6.6%,)
Ala (2018)	RCT	68±18	40	• Intervention: sucralfate gel • Comparison: placebo	• Pressure Ulcer Scale for Healing (PUSH Score) is higher in sucralfate gel group (6.36) vs in control (5.89) • Shortened average healing time (days) in sucralfate gel group (6.05) vs in control (7.78)
Tumino (2008)	RCT	64.918±12.076	50	• Intervention: topical sucralfate (SUC-LIS 95) • Comparison: Placebo	• Daily application of SUC-LIS 95 led to compleye healing in 95.6% of patients vs 10.9% in placebo
Bhatmule (2022)	Prospective comparative study	60.74±8.85	100	• Intervention: Saline dressing (• Comparison: Traditional normal saline dressings	• Higher mean percentage reduction of area of 43.59±7.81 sucralfate vs saline dressing 21.85±5.84 • Shorten healing time of 2.78+1.12 weeks in the sucralfate group as opposed to 6.12+2.63 weeks in saline dressing
Chatterjee (2019)	RCT	46.0±15.70	96	• Intervention: Mupirocin 2% and sucralfate 7% ointment • Comparison: Mupirocin 2%	• Significant median ulcer area reduction in intervention group • Complete healing of 41.3% participants in intervention group vs 18.18% in control group • Few adverse event (all local, mild, and tolerable)
Prabhakar (2017)	RCT	Not defined	99	• Intervention: Sucralfate dressing • Comparison: Phenytoin dressing and saline dressing	• Significant reduction in ulcer size (Sucralfate by 2.12x2.3 cm; phenytoin by 2.1x2.12 cm; and normal saline 1.2x1.5cm

Source: Data processed from included studies

The findings compiled from the included studies demonstrate a consistent pattern indicating that topical sucralfate provides substantial benefits in the management of various chronic ulcers. In diabetic foot ulcers, several studies reported considerable reductions in wound size. One study documented a decrease of 34.995% mean area reduction, and higher in wound reductions reaching 70.4%,

accompanied by markedly faster healing times than in control groups (Preethi & Dhanasekaran, 2019). The superiority of sucralfate is further illustrated when compared with normal saline dressings: the reduction in ulcer area reached 43.59% in the sucralfate group versus 21.85% in the normal saline group, with strong statistical significance ($p = 0.0001$). The difference in complete healing time was also notable, with the sucralfate group achieving closure within approximately 2.78 weeks, compared to 6.12 weeks in conventional dressings (Bhatmule et al., 2022). In non-infected vascular ulcers, the therapeutic response was even more striking, with healing rates reaching 95.6% over 42 days, while the placebo group achieved only 10.9% (Tumino et al., 2008).

These clinical improvements are supported by well-established biological mechanisms. Sucralfate has been shown to stimulate the proliferation of fibroblasts and keratinocytes, and to enhance the synthesis of prostaglandin E2 as well as interleukin-6 production induced by interleukin-1 (Preethi & Dhanasekaran, 2019). Its role in angiogenesis is demonstrated by increased VEGF expression. In studies combining topical sucralfate with platelet-rich plasma, VEGF expression increased significantly ($p = 0.003$), suggesting enhanced formation of new blood vessels and improved granulation tissue quality (Simanjuntak et al., 2023). Sucralfate also binds to basic fibroblast growth factor, protecting it from degradation and preserving its angiogenic function. In addition to VEGF, increased EGF expression has been documented, providing strong biological support for accelerated tissue regeneration (Tumino et al., 2008).

Clinical parameters associated with wound quality also improved consistently. One study reported a significant reduction in ulcer size ($p < 0.001$) accompanied by decreased infection scores within the first three weeks of therapy ($p < 0.001$). Symptoms such as pain, erythema, discharge, foul odor, and edema also improved significantly ($p < 0.001$), reflecting overall enhancement of the wound environment. Adverse effects were minimal and did not necessitate treatment discontinuation, and adherence was reported to be good, with 32.61% of patients demonstrating very high compliance (Chatterjee, et al., 2019). Another study documented a reduction of 2.12 × 2.3 cm in ulcer dimensions following sucralfate dressing, further reinforcing its clinical value in accelerating wound healing (Prabhakar et al., 2017).

Several studies also highlighted the economic advantages of sucralfate. Total treatment costs were reduced by approximately 30% when using sucralfate compared with conventional dressings. This cost reduction was primarily attributed to a shorter duration of hospitalization of16.96 days in the sucralfate group versus 27.76 days in the conventional treatment group as well as reduced dressing consumption. Given the substantial burden of chronic ulcer care, these findings underscore the cost-effectiveness of sucralfate in clinical practice (Ala et al., 2018; Bhatmule et al., 2022; Prabhakar et al., 2017; Preethi & Dhanasekaran, 2019).

Although a small number of studies reported non-significant findings for example, a study showing faster healing with sucralfate gel but without statistical significance ($p = 0.07$) but the general trend still favored sucralfate (Ala et al., 2018). Such non-significant results were likely influenced by small sample sizes or variability in patient and wound characteristics rather than an absence of therapeutic effect (N. Chatterjee et al., 2023; Gudigar et al., 2022).

Overall, the available evidence provides a coherent picture that topical sucralfate holds considerable promise as an adjunctive therapy for chronic ulcers. Its proven clinical effectiveness, strong mechanistic foundation, consistent improvement in wound condition, favorable safety profile, and meaningful economic advantages all support its potential role in modern wound care strategies.

CONCLUSION

The evidence consistently shows that topical sucralfate significantly benefits chronic ulcer management, especially diabetic foot and vascular ulcers, by reducing ulcer size by approximately 35–44% and accelerating healing times to about 2.78 weeks versus over 6 weeks with conventional treatment. In non-infected vascular ulcers, sucralfate gel healed 95.6% of cases compared to 10.9% with placebo. Its mechanisms include promoting fibroblast and keratinocyte proliferation, enhancing prostaglandin E2 and interleukin pathways, and stabilizing growth factors crucial for angiogenesis and tissue repair. Although some improvements were not always statistically significant, sucralfate consistently reduced infection scores, relieved symptoms, and promoted wound progression, while also offering potential cost savings by lowering dressing changes and hospitalization duration. Future research should focus on large-scale, multicenter randomized trials to confirm these benefits across diverse patient populations and further explore sucralfate's molecular effects in chronic wound healing.

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