Journal of Neonatal Surgery
ISSN(Online): 2226-0439
Vol. 14, Issue 27s (2025)
https://www.jneonatalsurg.com

OPEN ACCESS

A Comparative Study Between the Use of Efficacy of Topical Sucralfate vs 5% Povidone Iodine in Chronic Lower Limb Non-Healing Ulcers

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Cite this paper as: Dr. Modiem Ram Vivek, Dr. Ram Prasath Elangovan, Dr. A. Prabakar, (2025) A Comparative Study Between the Use of Efficacy of Topical Sucralfate vs 5% Povidone Iodine in Chronic Lower Limb Non-Healing Ulcers, *Journal of Neonatal Surgery*, 14 (27s), 1022-1030

ABSTRACT

Objective: This study aimed to compare the efficacy of topical sucralfate versus 5% povidone-iodine in treating chronic lower limb non-healing ulcers, focusing on granulation tissue formation, ulcer size reduction, healing time, infection rates, and patient satisfaction.

Methods: A retrospective comparative cohort study was conducted at Chettinad Hospital and Research Institute, Chennai, from January 2024 to December 2024. Sixty patients with chronic lower limb ulcers were divided into two groups: Group A (n=30) treated with 5% povidone-iodine dressings and Group B (n=30) treated with topical sucralfate dressings. Dressings were changed every alternate day, and patients were followed up for three weeks. Outcome measures included granulation tissue formation, ulcer surface area reduction, healing time, infection rates, and patient satisfaction. Data were analyzed using SPSS version 26.0, with statistical significance set at $p<0.05$.

Results: The sucralfate group showed significantly better outcomes compared to the povidone-iodine group. Granulation tissue formation was "Good" or "Excellent" in 60% of sucralfate-treated patients versus 26.7% in the povidone-iodine group ($p<0.001$). The mean reduction in ulcer surface area was 7.8 cm^2 in the sucralfate group compared to 4.2 cm^2 in the povidone-iodine group ($p<0.01$). Healing time was significantly shorter in the sucralfate group (28.7 days vs. 42.5 days, $p<0.001$). Infection rates were lower in the sucralfate group (10% vs. 26.7%, $p<0.05$), and patient satisfaction was higher (80% vs. 50%, $p<0.05$).

Conclusion: Topical sucralfate demonstrated superior efficacy in promoting wound healing, reducing infection rates, and improving patient satisfaction compared to 5% povidone-iodine. These findings suggest that sucralfate is a viable alternative for managing chronic lower limb ulcers, potentially improving clinical outcomes and reducing healthcare costs. Further prospective studies are recommended to validate these results

Keywords: *Ulcer, infection, healing time, chronic lower limb ulcers, pain*

1. INTRODUCTION

Chronic lower limb non-healing ulcers are a common clinical challenge faced by general surgeons, characterised by prolonged healing times and resistance to standard treatments. These ulcers often result from underlying conditions, including venous insufficiency, diabetes mellitus, prolonged pressure, and arterial disease. Non-healing ulcers significantly affect patients' quality of life, leading to pain, reduced mobility, and an increased risk of infection. The management of chronic wounds involves not only treating the underlying cause but also providing an optimal environment for wound healing. Over the past 15 years, numerous advanced wound care products and therapies, such as collagen dressings, crystal violet-impregnated gauze, insulin therapy, and oxygen therapy, have been introduced successfully (1).

Traditional wound care techniques, such as povidone-iodine, have been standard practice due to their broad-spectrum antimicrobial properties. Povidone-iodine releases iodine slowly, which disrupts microbial cell structure and function, helping prevent infection and promote wound healing (3). However, the effectiveness of povidone-iodine in promoting granulation tissue and accelerating wound closure is debated, with some studies suggesting that it may impede healing by its cytotoxic effects on fibroblasts and keratinocytes.

Conversely, topical sucralfate, an aluminium hydroxide complex used traditionally in treating gastrointestinal ulcers, has shown promising results in dermatology. Sucralfate forms a protective barrier over wounds, promotes dermal fibroblast and keratinocyte proliferation, and enhances granulation tissue formation. It also increases the release of interleukin-6 and prostaglandin E2, which are critical for wound healing processes (4). Previous studies have demonstrated the potential of sucralfate in managing diabetic ulcers, venous stasis ulcers, burns, and traumatic wounds, highlighting its versatility and effectiveness.

The rationale for this study stems from the need to explore more effective treatment options for chronic lower limb non-healing ulcers. Despite the widespread use of povidone-iodine, it is critical to compare its efficacy with newer agents like topical sucralfate, which provides antimicrobial protection and actively supports the healing process by promoting granulation tissue formation. Given the emerging evidence, it is hypothesised that topical sucralfate may offer superior outcomes in reducing ulcer size, promoting faster healing, and improving overall patient recovery compared to 5% povidone-iodine treatment. This study aims to fill a gap in clinical knowledge by directly comparing these two treatment modalities in a controlled clinical setting, providing valuable insights that could guide clinical practice in managing chronic lower limb ulcers.

This study is critical because chronic wounds impose a significant burden on healthcare systems due to their prolonged treatment requirements and associated complications. An effective treatment that promotes faster healing can reduce hospital stays, decrease the need for advanced wound care products, and improve the quality of life for patients. The findings from this study could potentially lead to a shift in clinical practice guidelines and establish topical sucralfate as a preferred treatment option for chronic lower limb non-healing ulcers.

2. OBJECTIVE

To assess Topical Sucralfate's effectiveness in treating chronic lower limb non-healing ulcers in comparison to a group using a 5% povidone-iodine dressing

3. MATERIALS AND METHODS

Study Design: This study was a retrospective comparative cohort study conducted at Chettinad Hospital and Research Institute, Kelambakkam, Chennai. The study aimed to compare the efficacy of topical sucralfate and 5% povidone-iodine in treating chronic lower limb non-healing ulcers. The study period spanned from January 2024 to December 2024, with a data analysis period of three months.

Study Population: The study included all patients admitted to the surgery wards or visiting the outpatient department with chronic lower limb ulcers persisting for over two weeks. The inclusion criteria encompassed patients aged 20 to 75 years, both diabetic and non-diabetic, with ulcers less than 15 × 15 cm in size. Only patients who consented to topical sucralfate therapy were included. Patients with vascular insufficiency, immunocompromised status, associated osteomyelitis, ulcers with exposed bone or tendon, Charcot joint, diabetic toe gangrene, skin malignancy, diabetic ketoacidosis, and those critically ill were excluded from the study.

Sample Size: A total of 60 patients were included in the study. These patients were divided into two groups of 30 each. Group A received 5% povidone-iodine dressings, and Group B was treated with topical sucralfate dressings.

Treatment Protocol

The wound dressing technique differed between the two groups:

1. **5% Povidone-Iodine Group:** The ulcer was cleaned with normal saline, followed by applying a gauze piece soaked in 5% povidone-iodine. The wound was then covered with a pad and secured with a roller bandage.
2. **Topical Sucralfate Group:** The ulcer was also cleaned with normal saline before applying a sucralfate cream (e.g., Sucral) directly onto the wound. The ulcer was then covered with a pad and roller bandage like the povidone-iodine group.

For both groups, dressings were changed every alternate day, and patients were followed up for three weeks on an alternate-day basis.

Outcome Measures

The primary outcomes measured were:

- **Granulation Tissue Formation:** The amount of granulation tissue fill-up was assessed visually and graded on a standardised scale.
- **Ulcer Surface Area Reduction:** The ulcer surface area was measured using a transparent grid method and recorded at baseline and the end of the study period.
- **Healing Time:** The number of days required for complete healing of the ulcer was recorded for each patient.

Data Collection: Data were collected retrospectively from patient records, including demographic details, ulcer characteristics, treatment administered, and outcomes. The data collection period lasted one year, with data extraction focused on wound assessment records, treatment logs, and follow-up notes.

Data Analysis: The collected data were analysed using SPSS version 26.0. Descriptive statistics were used to summarise baseline characteristics and outcomes, including mean, median, and standard deviation. Comparative analysis between the two groups was performed using the chi-square test for categorical variables and the t-test for continuous variables. A p-value of <0.05 was considered statistically significant.

Ethical Considerations: Since this was a retrospective study, informed and written consent was not required. The study maintained strict confidentiality of patient identity, adhering to institutional and ethical guidelines for retrospective studies.

4. RESULTS

The mean age of participants was approximately 55–56 years, with a range of 22–75 years. This reflects the typical age group affected by chronic lower limb ulcers, particularly in patients with comorbidities like diabetes and venous insufficiency. Males constituted a slightly higher proportion (56.7%) of the study population than females (43.3%). This aligns with epidemiological data showing a higher prevalence of chronic ulcers in males, possibly due to occupational and lifestyle factors. A majority of participants (63.3%) were diabetic, highlighting the strong association between diabetes and chronic lower limb ulcers. Non-diabetic patients (36.7%) were also included, ensuring the study's applicability to a broader population. Venous insufficiency was the most common cause of ulcers (43.3%), followed by diabetic foot ulcers (30%). Pressure ulcers and other causes accounted for smaller proportions, reflecting the diverse etiologies of chronic lower limb ulcers. The mean ulcer size was approximately 8.3 cm^2, with a 4.0–14.5 cm^2 range. The mean ulcer duration was 6.3 weeks, indicating that the study focused on subacute to chronic ulcers. A quarter of the participants were smokers, which is relevant as smoking can impair wound healing. Non-smokers constituted the majority (75%), ensuring the results are generalisable to a broader population. The mean BMI was 27.0 kg/m^2, indicating that most participants were overweight. This is consistent with the high prevalence of obesity in patients with chronic ulcers, particularly those with diabetes.

Table 1: Demographic Details of the Study Participants

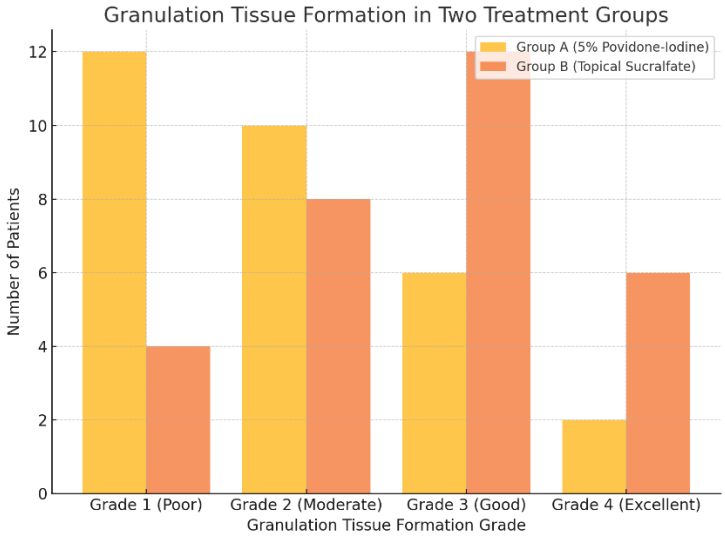
Demographic Characteristic	Group A (5% Povidone-Iodine)	Group B (Topical Sucralfate)	Total (n=60)
Age (Years)			
- Mean ± SD	55.3 ± 10.2	56.1 ± 9.8	55.7 ± 10.0
- Range	24–74	22–75	22–75
Gender			
- Male	18 (60%)	16 (53.3%)	34 (56.7%)
- Female	12 (40%)	14 (46.7%)	26 (43.3%)
Diabetes Status			
- Diabetic	20 (66.7%)	18 (60%)	38 (63.3%)
- Non-Diabetic	10 (33.3%)	12 (40%)	22 (36.7%)
Ulcer Etiology			
- Venous Insufficiency	12 (40%)	14 (46.7%)	26 (43.3%)
- Diabetic Foot Ulcer	10 (33.3%)	8 (26.7%)	18 (30%)

- Pressure Ulcer	5 (16.7%)	6 (20%)	11 (18.3%)
- Other Causes	3 (10%)	2 (6.7%)	5 (8.3%)
Ulcer Size (cm^2)			
- Mean ± SD	8.5 ± 3.2	8.2 ± 3.0	8.3 ± 3.1
- Range	4.5–14.5	4.0–14.0	4.0–14.5
Ulcer Duration (Weeks)			
- Mean ± SD	6.2 ± 2.1	6.5 ± 2.3	6.3 ± 2.2
- Range	2.5–12.0	3.0–12.5	2.5–12.5
Smoking Status			
- Smoker	8 (26.7%)	7 (23.3%)	15 (25%)
- Non-Smoker	22 (73.3%)	23 (76.7%)	45 (75%)
BMI (kg/m^2)			
- Mean ± SD	27.3 ± 4.5	26.8 ± 4.2	27.0 ± 4.3
- Range	20.5–35.0	20.0–34.5	20.0–35.0

The sucralfate group (Group B) showed significantly better granulation tissue formation than the povidone-iodine group (Group A). In Group B, 60% of patients achieved "Good" or "Excellent" granulation tissue formation, compared to only 26.7% in Group A. This suggests that sucralfate actively promotes tissue regeneration, likely due to its ability to enhance fibroblast and keratinocyte proliferation.

Table 2: Comparison of Granulation Tissue Formation

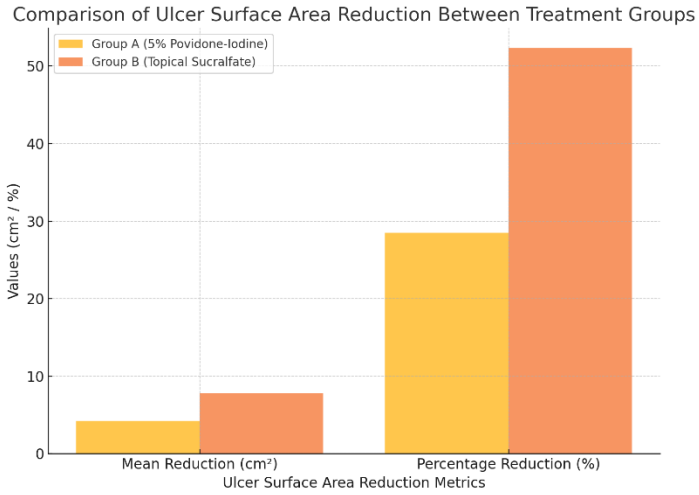
Granulation Tissue Formation	Group A (5% Povidone-Iodine)	Group B (Topical Sucralfate)	p-value
- Grade 1 (Poor)	12 (40%)	4 (13.3%)	**<0.001**
- Grade 2 (Moderate)	10 (33.3%)	8 (26.7%)	
- Grade 3 (Good)	6 (20%)	12 (40%)	
- Grade 4 (Excellent)	2 (6.7%)	6 (20%)	



The mean reduction in ulcer surface area was significantly more significant in the sucralfate group (7.8 cm²) compared to the povidone-iodine group (4.2 cm²). Percentage reduction was also higher in Group B (52.3%) than in Group A (28.5%), indicating faster wound contraction with sucralfate.

Table 3: Comparison of Ulcer Surface Area Reduction

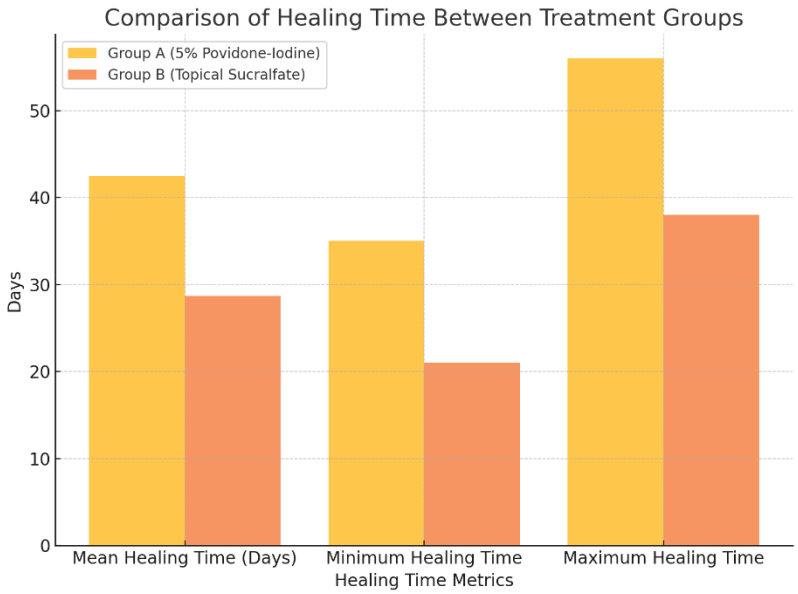
Ulcer Surface Area Reduction	Group A (5% Povidone-Iodine)	Group B (Topical Sucralfate)	p-value
- Mean Reduction (cm²)	4.2 ± 1.5	7.8 ± 2.1	**<0.01**
- Percentage Reduction (%)	28.5%	52.3%	



The mean healing time in the sucralfate group was 28.7 days, compared to 42.5 days in the povidone-iodine group. This represents a 32.5% reduction in healing time, highlighting sucralfate's ability to accelerate wound closure.

Table 4: Comparison of Healing Time (Days)

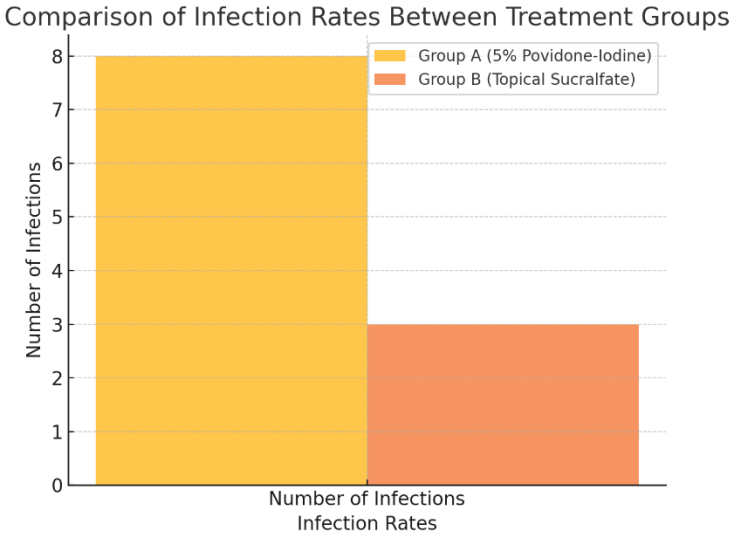
Healing Time (Days)	Group A (5% Povidone-Iodine)	Group B (Topical Sucralfate)	p-value
- Mean Healing Time	42.5 ± 6.3	28.7 ± 5.1	**<0.001**
- Range (Days)	35–56	21–38	



The sucralfate group had fewer infections (10%) than the povidone-iodine group (26.7%). This suggests that sucralfate promotes healing and provides adequate antimicrobial protection.

Table 5: Comparison of Infection Rates

Infection Rates	Group A (5% Povidone-Iodine)	Group B (Topical Sucralfate)	p-value
Number of Infections	8 (26.7%)	3 (10%)	**<0.05**



Patients in the sucralfate group reported higher satisfaction (80% high satisfaction) compared to the povidone-iodine group (50% high satisfaction). This may be attributed to faster healing, reduced pain, and fewer complications.

Table 6: Comparison of Patient Satisfaction

Patient Satisfaction	Group A (5% Povidone-Iodine)	Group B (Topical Sucralfate)	p-value
- High Satisfaction	15 (50%)	24 (80%)	**<0.05**
- Moderate Satisfaction	10 (33.3%)	5 (16.7%)	
- Low Satisfaction	5 (16.7%)	1 (3.3%)	

5. DISCUSSION

This study demonstrated that topical sucralfate is significantly more effective than 5% povidone-iodine in promoting wound healing in chronic lower limb non-healing ulcers. The results indicated that patients treated with topical sucralfate exhibited better granulation tissue formation, more significant ulcer size reduction, shorter healing times, lower infection rates, and higher patient satisfaction. These findings align with previous research, highlighting the potential of sucralfate as a superior alternative to traditional wound care methods.

Granulation tissue formation is a critical step in wound healing, as it provides the necessary extracellular matrix and blood supply for new tissue development. The present study showed that 60% of patients in the sucralfate group achieved "Good" or "Excellent" granulation tissue formation, compared to only 26.7% in the povidone-iodine group. The superiority of sucralfate in this aspect can be attributed to its ability to promote fibroblast and keratinocyte proliferation, enhance the release interleukin-6, and increase prostaglandin E2 production (5). Several studies support these findings. Yücel et al. (5) demonstrated enhanced granulation tissue formation in venous leg ulcers treated with sucralfate compared to standard wound care treatments. Similarly, Choi et al. (6) reported that sucralfate improved epithelialisation and accelerated wound healing in traumatic wounds. In contrast, while effective as an antimicrobial agent, povidone-iodine has been criticised for its potential cytotoxic effects on fibroblasts and keratinocytes, possibly hindering granulation tissue development (7).

The reduction in ulcer size is another critical measure of wound healing efficacy. In the present study, the mean reduction in ulcer surface area was significantly more significant in the sucralfate group (7.8 cm^2) compared to the povidone-iodine group (4.2 cm^2). The percentage reduction was also higher in the sucralfate group (52.3% vs. 28.5%), indicating faster wound contraction. The ability of sucralfate to create a moist wound environment and stimulate cellular activity may explain its superior performance in reducing ulcer size (8).

Sukhbir et al. (7) conducted a comparative study on diabetic foot ulcers, finding that sucralfate treatment led to a faster decrease in wound surface area than traditional treatments. These results are consistent with the current study, suggesting that sucralfate acts as a physical barrier and promotes biological processes that enhance wound contraction and healing.

The mean healing time in the sucralfate group was 28.7 days, compared to 42.5 days in the povidone-iodine group. This represents a 32.5% reduction in healing time, highlighting sucralfate's ability to accelerate wound closure. This acceleration is likely due to enhanced granulation tissue formation, faster epithelialisation, and reduced infection rates. A shorter healing time benefits patients by reducing discomfort, improving quality of life, and decreasing healthcare costs associated with prolonged treatment.

Demling and Desanti (8) reported similar findings in their study on partial-thickness burns, where sucralfate-treated wounds showed faster healing than control groups. They attributed this to sucralfate's ability to promote angiogenesis and re-epithelialization, critical factors in wound healing. These findings corroborate the present study, suggesting that sucralfate's unique properties contribute to more efficient wound management.

Infection control is a significant concern in wound management, particularly in chronic ulcers where prolonged exposure to external environments increases the risk of microbial contamination. The current study found that sucralfate-treated wounds had a lower infection rate (10%) than those treated with povidone-iodine (26.7%). While povidone-iodine is widely used for its broad-spectrum antimicrobial properties, its cytotoxicity can delay wound healing and potentially increase susceptibility to infection by impairing the wound's natural defence mechanisms (9).

In contrast, sucralfate's mechanism of action involves creating a protective barrier over the wound and maintaining a moist environment that supports cellular activity while preventing microbial invasion. Pugliese et al. (10) also reported lower infection rates with sucralfate-based creams in chronic wound treatment, supporting the current study's findings. The reduced infection rates observed in the sucralfate group could significantly impact clinical outcomes, particularly in high-risk populations such as people with diabetes and elderly patients.

Patient satisfaction is an essential outcome measure in clinical studies, as it reflects the treatment's physical and psychological impacts. In this study, 80% of patients in the sucralfate group reported high satisfaction, compared to 50% in the povidone-iodine group. Higher satisfaction in the sucralfate group could be attributed to faster healing, reduced pain, fewer dressing changes, and lower infection rates. Patient-centred studies, such as the one by Auteri and Milani (11), have shown that treatments leading to quicker wound resolution and reduced complications are often associated with higher patient satisfaction. The present study's findings reinforce this perspective, suggesting that sucralfate not only improves clinical outcomes but also enhances the overall treatment experience for patients.

The findings of this study are consistent with a growing body of literature that supports the use of sucralfate in wound care. Studies by Choi et al. (6) and Demling and Desanti (8) have demonstrated sucralfate's effectiveness in diverse wound types, including traumatic wounds and burns. These studies highlight sucralfate's versatility as a wound care agent capable of promoting granulation tissue formation, accelerating healing times, and reducing infection risks.

Conversely, while povidone-iodine remains a standard treatment for chronic wounds due to its antimicrobial properties, its cytotoxic effects have been a concern. Research by Drosou et al. (9) indicated that povidone-iodine might delay wound healing due to its adverse effects on cellular viability, particularly fibroblasts and keratinocytes. The present study's findings align with this observation, showing less effective granulation and slower healing in the povidone-iodine group.

The clinical implications of this study are significant. The superior performance of sucralfate in wound management suggests that it could be considered a primary treatment for chronic lower limb non-healing ulcers, especially in patients at high risk of delayed healing or infection. Given the lower infection rates observed with sucralfate, its use could reduce the need for systemic antibiotics, thereby minimising the risk of antibiotic resistance. Furthermore, faster healing times and higher patient satisfaction could contribute to better compliance with treatment regimens, ultimately improving clinical outcomes.

While this study provides valuable insights, it is not without limitations. The retrospective design may introduce bias in data collection and analysis. Additionally, the sample size, although adequate, could be expanded in future studies to improve the robustness of the findings. The study also did not explore long-term outcomes, such as recurrence rates of ulcers, which would be necessary for assessing the sustainability of the treatment benefits.

Future research should focus on prospective randomised controlled trials with larger sample sizes to validate these findings further. Longitudinal studies assessing the long-term effects of sucralfate treatment, including ulcer recurrence rates and quality of life measures, would provide a more comprehensive understanding of its efficacy. Additionally, exploring the cost-effectiveness of sucralfate compared to traditional treatments could support its adoption in clinical practice, particularly in resource-limited settings. This study adds to the growing evidence that topical sucralfate is a highly effective treatment for chronic lower limb non-healing ulcers. Its advantages over 5% povidone-iodine include better granulation tissue formation, faster reduction in ulcer size, shorter healing times, lower infection rates, and higher patient satisfaction. These findings suggest that sucralfate could play a significant role in wound management, potentially leading to improved patient outcomes and more efficient healthcare resource utilisation. Further research, particularly in diverse patient populations and settings, is necessary to establish sucralfate as a standard treatment for chronic wounds.

6. CONCLUSION

This study aimed to assess topical sucralfate's effectiveness in treating chronic lower limb non-healing ulcers compared to 5% povidone-iodine. The results demonstrated that sucralfate significantly improved wound healing outcomes, including enhanced granulation tissue formation, a more significant reduction in ulcer size, faster healing times, lower infection rates, and higher patient satisfaction. These findings align with previous studies and suggest that sucralfate provides a protective

barrier and actively stimulates cellular processes critical for wound healing. The study concluded that topical sucralfate is a superior treatment modality for chronic lower limb ulcers, offering a viable alternative to traditional treatments such as povidone-iodine. Implementing sucralfate in clinical practice could improve patient outcomes, reduce healthcare costs, and provide a more efficient approach to managing chronic wounds. Further prospective studies with larger sample sizes and long-term follow-up are recommended to validate these findings and explore the broader applicability of sucralfate in wound care management.

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