

Topical Solutions for Chronic Lower Limb Ulcers: A Comparative Study of Sucralfate and 5% Povidone-Iodine

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Abstract

Background: Sucralfate (Aluminum hydroxide salt of the disaccharide sucrose octasulfate) is a medication primarily used to treat active peptic ulcers in the gastrointestinal tract. It is also been found to have potential benefits in wound healing. Studies have shown that sucralfate can promote the growth and repair of skin tissue by stimulating the proliferation of dermal fibroblasts and keratinocytes. In addition, sucralfate has been found to enhance the synthesis of prostaglandin E2 in basal keratinocytes and the release of interleukin-6 from fibroblasts. Applying sucralfate daily to full-thickness wounds has been shown to increase the thickness of granulation tissue, which can help facilitate healing. While sucralfate is primarily used to treat peptic ulcers and gastroesophageal reflux disease, its potential benefits in wound healing warrant further investigation.

Objectives: To compare the efficacy of topical sucralfate with that of a control group using 5% povidone-iodine dressing, in the healing of chronic lower limb ulcer.

Methods: From October 2020 to November 2022, a comparative study was conducted at BLDE DU Shri BM Patil Medical College Hospital and Research Center, Vijayapura. The study included 224 patients, with 112 assigned to the control group and 112 assigned to the study group. Patients in both groups received daily dressings for 2 weeks, and their progress was monitored for changes in ulcer size, appearance of granulation tissue, and culture sensitivity. The study aimed to compare the outcomes between the two groups using an interventional approach.

Results: In our study, complete granulation tissue fill-up was shown in 100 (89.3%) patients in the study group and 71 (63.4%) patients in the control group. In this study, at first visit, positive culture is seen in 89 patients in the study group and 96 patients in the control group and negative culture is seen in 23 patients in the study group and 16 patients in the control group after 14 days. Negative culture is seen in 105 patients in the study group and 51 patients in the control group. Study outcomes were better in the study (Sucralfate) group as compared to the control (Betadine) group. The study group showed a significant reduction in mean ulcer surface area (71.8%) as compared to the control group (24.8%).

Conclusion: The results suggest that sucralfate dressing may be a promising option for the treatment of chronic lower limb ulcers. Its effectiveness in facilitating wound contraction and promoting early granulation tissue fill-up make it a viable alternative to traditional Betadine dressings.

Key words: 5% povidone iodine solution, Chronic lower limb ulcers, Dressings, Sucralfate

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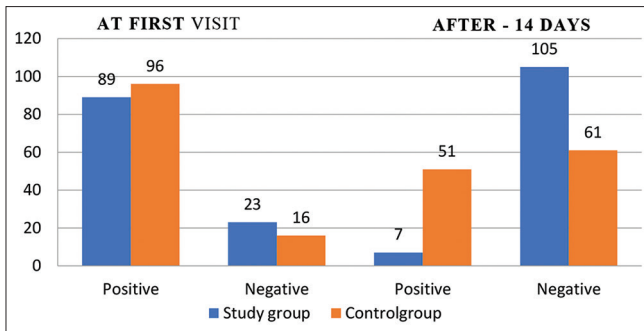
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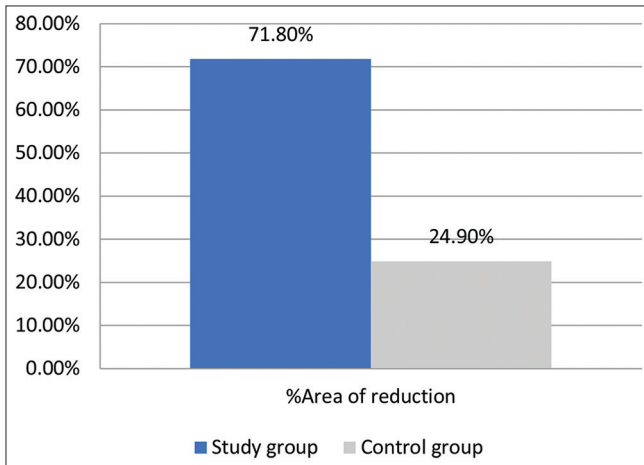
INTRODUCTION

The problem of managing chronic wounds continues to be a challenge despite the thousands of years that have passed since mankind first succeeded in deciphering the human genetic code. One of the most frequent surgical conditions a surgeon encounter is chronic wounds, especially those that

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Graph 1: Culture and sensitivity



Graph 2: Percentage reduction of ulcer

do not heal. Doctors have been experimenting with various techniques to heal these types of wounds for a long time.

During the last 20 years, many innovative dressings were introduced in wound healing, such as collagen,^[1] crystal violet, insulin, mercurochrome, and oxygen therapy. Recent literature says that an ulcer is epithelialized more rapidly when treated with a dressing that allows moist wound healing.^[2,3]

Studies have shown that topical sucralfate is a superior method for treating diabetic ulcers, as well as decubitus ulcers, venous stasis ulcers, traumatic wounds, burns, and trophic ulcers.^[4] In preclinical studies, sucralfate has been found to encourage the growth of granulation tissue which in turn encourages the healing of cutaneous ulcers.

Sucralfate is an oral gastrointestinal medicine used primarily to treat active peptic ulcers. It is the aluminum hydroxide salt of the disaccharide sucrose octa sulfate. Peptic ulcers and gastroesophageal reflux disease are both treated with sucralfate.^[5]

Additionally, it suggests a potential role in the recovery of skin injuries. Dermal fibroblast and keratinocyte proliferation are promoted by sucralfate. Sucralfate increases interleukin-1-stimulated fibroblasts' release

Table 1: Diabetes mellitus

| Present/absent | Group | | | | Total | |
|----------------|---------------|------------|-------------|------------|-------|------------|
| | Control group | | Study group | | | |
| | Count | % in group | Count | % in group | Count | % in group |
| Absent | 84 | 75% | 84 | 75% | 168 | 75% |
| Present | 28 | 25% | 28 | 25% | 56 | 25% |
| Total | 112 | 100% | 112 | 100% | 224 | 100% |

Table 2: Culture & sensitivity – after 14 days

| Pus culture sensitivity (after) (positive/negative) | Group | | | | Total | |
|---|---------------|------------|-------------|------------|-------|------------|
| | Control group | | Study group | | | |
| | Count | % in group | Count | % in group | Count | % in group |
| Negative | 51 | 45.5% | 105 | 93.8% | 156 | 69.6% |
| Positive | 61 | 54.5% | 7 | 6.2% | 68 | 30.4% |
| Total | 112 | 100% | 112 | 100% | 224 | 100% |

Table 3: Amount of granulation Tissue fill up

| Granulation tissue fill up in 2 weeks (complete/partial) | Group | | | | Total | |
|--|---------------|------------|-------------|------------|-------|------------|
| | Control group | | Study group | | | |
| | Count | % in group | Count | % in group | Count | % in group |
| Complete | 71 | 63.4% | 100 | 89.3% | 171 | 76.3% |
| Partial | 41 | 36.6% | 12 | 10.7% | 53 | 23.7% |
| Total | 112 | 100% | 112 | 100% | 224 | 100% |

of interleukin-6 and basal keratinocytes' production of prostaglandin E2.^[6] Sucralfate enhanced the thickness of granulation tissue when a daily application was made to full-thickness wounds.^[7]

Numerous types of research demonstrated the effectiveness of sucralfate,^[8] which resulted in the wound being completely closed and shrinking in size.

Because of new research regarding the effectiveness of sucralfate in treating lower limb ulcers, we undertook this study to ascertain if sucralfate administered topically over chronic lower limb ulcers reduces the size of the lesion more effectively than 5% Povidone-iodine treatment.

MATERIALS AND METHODS

This was a prospectively conducted comparative intervention study done during a period of October 2020 to November 2022

Patients who have been hospitalized in surgery wards or who visited outpatient department with lower limb ulcers that have persisted for more than 2 weeks at BLDE[DU] Shri B.M. Patil Medical College, Hospital, and Research

Table 4: Wound contraction

| Variables | Group | n | Mean | SD | Mann-Whitney U-test value | P-value |
|--|---------------|-----|--------|--------|---------------------------|---------|
| Initial area of ulcer in cm ² | Control group | 112 | 36.116 | 19.984 | 6947 | 0.164 |
| | Study group | 112 | 33.795 | 21.883 | | |
| Final area of ulcer in cm ² | Control group | 112 | 28.188 | 17.051 | 10610 | <0.001 |
| | Study group | 112 | 10.696 | 9.63 | | |
| % area reduction | Control group | 112 | 0.249 | 0.16 | 459 | <0.001 |
| | Study group | 112 | 0.718 | 0.129 | | |

Table 5: Wound contraction comparison with other studies

| Wound contraction | Study group (%) | Control group (%) |
|--------------------|-----------------|-------------------|
| Our study | 71.8 | 24.9 |
| Preethi et al. | 70.4 | 29.6 |
| Nagalakshmi et al. | 41.97 | 18.37 |

Center, Vijayapur after obtaining Institutional ethical committee clearance.

Aim of the Study

To assess Topical Sucralfate's effectiveness in treating chronic lower leg ulcers in comparison to a control group using a 5% povidone-iodine dressing.

Inclusion Criteria

1. Patients in the age range of 12–75
2. Lower limb ulcers that have been present for more than 2 weeks
3. <10 × 10 cm in size
4. Both diabetic and non-diabetic patients.

Exclusion Criteria

1. Vascular insufficiency patients
2. Immunocompromised patients
3. Osteomyelitis associated with it, ulcers with exposed bone or tendon, or the presence of a Charcot joint, diabetic toe gangrene
4. Skin malignancy
5. Diabetic ketoacidosis and critically ill patients.

Patients were randomized into two groups of study and control group based on alternate numbers. Out of 224, patients, 112 took treatment in the form of 5% povidone iodine dressings, and 112 took treatment with sucralfate dressing.

The nature of the study was explained to the patients, and written informed consent was obtained from them before enrollment. Photographs of the ulcers both before and after dressing were taken.

The wound area was calculated by multiplying the length by the width following a comprehensive clinical evaluation and ongoing research (the ulcer should be <10 cm × 10 cm).

For both groups, the dressings were changed every other day. 2 weeks of alternate-day follow-up were given to the patients in both groups. Planimetry was used to measure the result, or the area of the target ulcer, using a clear graph sheet. Results were calculated by using the student's *t*-test.

The wounds in both groups were inspected at the time of the first visit and after 14 days, and the wounds were compared in terms of:

- The amount of granulation tissue fill-up
- Reduction in mean ulcer surface area
- Wound culture and sensitivity.

Sampling

Sample size: 224.

With the anticipated proportion of area reduction of the wound in conventional dressing and sucralfate in diabetic ulcers at 14.6% and 35% respectively, the study would require a sample size of 112 per group. (i.e., a total sample size of 224 assuming equal group sizes), to achieve a power of 95% for detecting a difference in proportions between two groups at a two-sided $P = 0.05$.

Statistical Analysis

- The data obtained were entered into a Microsoft Excel sheet, and statistical analysis was performed using a statistical package for the social sciences (version 20).
- Results were presented as Mean ± SD, counts and percentages, and diagrams.
- For normally distributed continuous variables between two groups were compared using an independent t-test for not normally distributed variables Mann Whitney U test was used. Categorical variables between the two groups will be compared using the Chi-square test/ fisher's exact test.
- $P < 0.05$ was considered statistically significant.

RESULTS

A total of 224 patients with lower limb ulcers were included in the study and were divided into two groups on an alternate basis; the Study group (Sucralfate group) and the Control group (Betadine group). The age distribution of patients was between 12 and 75 years of age with the

highest percentage of the patients belonging to 61–75 years followed by 51–60, 41–50, 31–40, and below 30 years of age groups.

In the present study, the incidence of chronic lower limb ulcers was more in males (81.2%) as compared to females (18.8%), with the maximum incidence of onset being spontaneous (71%) ulcers than traumatic (29%).

In this study, total of 56 (25%) individuals were diabetic and 168 (75%) individuals are non-diabetic with more male predominance [Table 1].

In the study group, 23 were positive for *Staphylococcus aureus* (SA), no patients for *Proteus mirabilis* (PM), 31 for *Pseudomonas aeruginosa* (PA), 8 patients showed *Escherichia coli* (EC), 25 patients showed *Klebsiella pneumonia* (KP), 2 patients showed *Enterococcus faecalis* (EF), and 23 of them did not show any growth. In the control group, 21 of them were positive for SA, 3 of them for PM, 23 for PA, 34 for KP, 1 for AB, 1 for EF, and 13 of them for EC. 16 of the patients did not show any growth on the first visit [Graph 1]. After 14 days, negative culture is seen in 105 patients in the study group and 51 patients in the control group [Table 2].

In this study, complete granulation tissue fill-up was shown in 100 (89.3%) patients in the study group and 71 (63.4%) patients in the control group [Table 3].

The study group had better wound contraction of 71.8% as compared to the control group, the mean wound contraction was 24.9% [Graph 2] (which is statistically significant with $P < 0.001$ [Table 4].

DISCUSSION

Every surgeon hopes to find the ultimate dressing, one that facilitates hassle-free chronic ulcer healing. Successful wound care must prevent unfavorable reactions including infection, maceration, and allergies while also keeping the wound moist. Lower leg ulcers are long-lasting lesions that have stopped growing on the surface of the skin.

The mean age group in the study group with chronic lower limb ulcers was 52.33 years and in the control group was 52.44 years. The study conducted by Narwade *et al.* on non-diabetic chronic leg ulcers:^[9] Etiology and management stated that chronic leg ulcers presented during the sixth decade with a male-to-female ratio of 5:1 which show similar results in this study.

In our study, the culture and sensitivity of the ulcers before the commencement of sucralfate dressings were positive

for many microorganisms. After sucralfate dressings were given culture obtained on the 14th day surprisingly showed –ve culture in patients in the study group, whereas patients in the control group still had a +ve culture.

This may account for the antimicrobial activity of Sucralfate. A series of experiments was conducted to determine the rate of bacterial growth in a human gastric juice at various pH values with the addition of sucralfate and antacid.

Whereas the addition of antacid resulted in bacterial growth in gastric juice, sucralfate showed an antibacterial effect. This may account for the decreased rate of pneumonia in intensive care.

In our study, it was observed that participants receiving Sucralfate dressing had better wound contraction of 71.8% as compared to the control group in whom the mean wound contraction was 24.9%. These were found to be statistically significant on Mann–Whitney U-test ($P < 0.001$) suggesting that Sucralfate enhances wound healing in chronic lower limb ulcers. This is similar to a study done by Nagalakshmi *et al.*^[10] In a study done by Preethi and Dhanasekaran^[11] on the comparative study of efficacy and cost-effectiveness of topical sucralfate and conventional dressings in diabetic ulcers in 100 patients shows about 70.4% reduction in ulcer surface area whereas control group shows only 29.6% reduction in ulcer surface area [Table 5].

CONCLUSION

The results suggest that sucralfate dressing may be a promising option for the treatment of chronic lower limb ulcers. Its effectiveness in facilitating wound contraction and promoting early granulation tissue fill-up, makes it a viable alternative to traditional betadine dressings.

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