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Clinical Trial

Comparison of the Efficacy of Topical Sucralfate with New Dressings in the Treatment of Bedsores Grade 1 and 2: A Randomized Single-Blind Clinical Trial

Running Title: Topical Sucralfate Versus. Advanced Dressings for Pressure Ulcers

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Abstract

Introduction: A pressure ulcer is a lesion caused by pressure, tension, and friction, leading to skin and tissue damage. Due to its high prevalence in hospitalized patients, especially in the ICU, it affects physical and mental health, prolongs hospitalization, and may cause disability. Various treatments exist, including pressure relief, repositioning, nutritional support, and different types of dressings. This study compared the effects of topical sucralfate and a new dressing on wound healing to identify the most effective, economical approach.

Materials and methods: This single-blind clinical trial was conducted on 30 ICU patients at Shahid Sadoughi Hospital, Yazd, with grade 1 and 2 pressure ulcers. Patients with immunodeficiency, diabetes, or kidney disorders were excluded. Participants were randomly divided into two groups: 15 received topical sucralfate (25% gel) and 15 received a new dressing. Data were collected using patient questionnaires and the PUSH tool, and analyzed with SPSS v24.

Result: The study found that 63.3% of patients were male. Treatment duration in women was significantly longer in the new dressing group than with sucralfate. No significant age-related difference was found. For ulcers ≤ 8 cm, sucralfate reduced treatment time compared with a new dressing, whereas for ulcers > 8 cm, a new dressing was more effective. In non-secreting or low-secreting wounds, the new dressing group had a significantly longer treatment duration than the local sucralfate group. Conversely, for wounds with moderate secretion, the mean treatment duration was significantly longer in the sucralfate group than in the new dressing group. Treatment duration for all wound tissues (closed, epithelial and granulation, slough and necrotic) was shorter with the new dressing.

Conclusion: In patients with grade 1 and 2 pressure ulcers, except in wounds > 8 cm or with moderate secretions, topical sucralfate, compared with the new dressing, decreased treatment duration and led to improvement within a short time.

Keywords: Pressure ulcer, Topical sucralfate, New dressing.

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Introduction

Pressure ulcers (also known as pressure sores or bedsores) are lesions resulting from prolonged pressure, stretching, or friction that damage the skin and its underlying tissues (1). The pathological changes at the site of a pressure ulcer occur following the collapse of blood vessels. When blood circulation is blocked, cellular nutrition is impaired, toxic substances accumulate, and cell death occurs, which ultimately leads to ulcer formation (2).

The most common sites for pressure ulcers are the sacrum (30-49%) and the heels (19-36%). Overall, about 60% of pressure ulcers occur in the pelvic region (3). Multiple reports show that the prevalence of pressure ulcers in ICU patients has varied from 16.9% to 23.8% (4).

More than 100 risk factors for pressure ulcer development in general hospitals have been identified in the literature (5). Potential contributing factors include malnutrition, neurological disorders, reduced mobility and activity, advanced age, urinary and fecal incontinence, skin moisture, mental status, skin condition, and medication use, as well as pressure, friction, and shear force (6). The most significant cause of pressure ulcers is increased pressure (7).

Pressure ulcers (PUs) are a complication that severely affects patients' quality of life (8). Various interventions for the management of pressure ulcers include: pressure relief, repositioning, nutritional support, and different types of dressings (9).

Among the standard dressings for treating pressure ulcers, hydrocolloid dressings are widely used. This type of occlusive dressing is designed to provide a moist environment and accelerate the healing process of pressure ulcers. This dressing absorbs wound exudate, which also helps to relieve patient pain. Another advantage is the patient's comfort while using it. The disadvantages of this treatment include its high cost, the risk of allergies or severe reactions to this type of dressing, and its contraindication for use in direct contact with muscle, tendons, or bone. The healing rate with this dressing is reported to be 50%, with an average healing time of 5 weeks (10).

Sucralfate is composed of sucrose octasulfate and aluminum hydroxide. The oral form of this medication is used to treat gastric and duodenal peptic ulcers and to prevent stress-induced peptic ulcers. This medication is also effective in wound treatment. Sucralfate increases the concentration of epidermal growth factor (EGF) and fibroblast growth factor (FGF) in the wound and prevents the release of cytokines from damaged skin cells, thereby preventing inflammation (11, 12). Therefore, in this study, the effects of sucralfate gel were compared with those of new dressings on the healing of bedsores in ICU patients.

Methods

Study Design: This study was a randomized, single-blind, clinical trial.

Participants: The studied population of 30 patients hospitalized in the ICU department of Shahid Sadoughi Hospital, Yazd, who had bedsores of 1st and 2nd degree, was randomly divided into two groups using the method of sealed envelopes, with the studied group assigned a number and one group

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treated with sucralfate. The other group received a new dressing. Determination of sample size: The sampling method was simple random sampling, using envelopes sealed with the study group number.

Volume sample based on the formula below:

(2-1) $n = [(Z\alpha/2 + Z\beta)2 \times \{(p1\ (1-p1) + (p2\ (1-p2))\}] / (p1 - p2)2$

P1 = 62%

P2 = 93%

P = 0.775

q = 0.225

α = 5%

β = 80%

Based on results from similar studies and the criteria for determining sample size, approximately 15 people were selected for each group.

Outcome Measures: The present study was a single-blind randomized clinical trial (RCT). People who met the inclusion criteria were included in the study, and patients with diabetes, renal impairment, or immunodeficiency were excluded. Random faces were placed into two groups: topical sucralfate and a new dressing. The information needed for this study was collected through interviews and a questionnaire, as well as clinical evaluations and examinations of the patient's wounds at the desired time points. Data on age, gender, as well as wound size, amount of secretion (none, low, moderate, high), type of wound tissue (close, epithelial and granulation, slough and necrosis), wound grade (1 and 2), duration of treatment (days) and group type were recorded. It was possible to record and collect the mentioned information quantitatively **(Table 1)**. The wounds of the patients were followed up daily for 3 weeks using the PUSH tool. In this scale, the surface area of the wound, the presence of secretion, and the condition of the wound in terms of the presence of necrosis or granulation tissue are evaluated and scored. The decrease in the score of this tool is used as a measure of improvement (13). Routine care of bedsores, such as using a wavy mattress and regularly changing patient position, was provided in both groups. Also, sucralfate gel was applied once a day to the wound, and, in some patients, the new dressing was used as needed, up to 2 times a day, depending on the wound's grade.

Inclusion and exclusion Criteria:

Inclusion Criteria

1. Bedsore in the 1st and 2nd
2. Age 15 to 75 years

Exclusion Criteria

1. Diabetes
2. Immunocompromised patients
3. Kidney failure

Statistical Analysis

After collecting the data in SPSS version 24, using descriptive statistics (frequency, percentage, mean, and standard deviation), and performing Chi-square tests, the t-test was used to analyze the data. The Mann-Whitney test was used to evaluate parametric bread data. The confidence level of 95% was considered to interpret the obtained results.

Questionnaire

Name: ……. Age: ……

Sex: Male ☐ Female ☐

Bedsore degree: 1st degree ☐ 2nd degree ☐

Treatment: Sucralfate topical ointment ☐ New dressings ☐

Underlying diseases: Diabetes ☐ Renal failure ☐ Other diseases ☐

Duration of treatment: ……. days.

Table 1. Pressure Ulcer Scale for Healing (PUSH Tool 3.0)

LENGTH X WIDTH (cm2)	0 0	1 < 0.3	2 0.3 – 0.6	3 0.7 – 1.0	4 1.1 – 2.0	5 2.1 – 3.0	Sub-score
		6 3.1 – 4.0	7 4.1 – 8.0	8 8.1 – 12.0	9 12.1 – 24.0	10 > 24.0	
EXUDATE AMOUNT	0 None	1 Light	2 Moderate	3 Heavy			Sub-score
TISSUE TYPE	0 Closed	1 Epithelial Tissue	2 Granulation Tissue	3 Slough	4 Necrotic Tissue		Sub-score
							TOTAL SCORE

Results

This study aims to investigate the effect of sucralfate topical gel compared to new dressings on the healing of 1st and 2nd-degree bedsores in patients hospitalized in the ICU. This study was conducted on 30 patients with bedsores of the 1st and 2nd degree admitted to the ICU of Shahid Sadoughi Hospital in Yazd in the form of two groups of 15: case (sucralfate) and control (new dressing) **(Figure 1).** The results of our study showed that out of 30 patients, 19 (63.3%) were men.

The average length of the treatment period of the patients according to the demographic variables (age and sex) in the two investigated groups: The results of our study on the average length of the treatment period of the patients according to gender in the two investigated groups showed that in men, the average length of the treatment period in the sucralfate group was 10.00±6.00 days and in the new dressing group it was 13.00±9.00 days (P> 0.05).

The analysis of the data using the Mann-Whitney nonparametric test showed a statistically significant difference in the average treatment period length between women in the new dressing group (13.00±5.00) and the sucralfate group (5.00±1.00) (P<0.05).

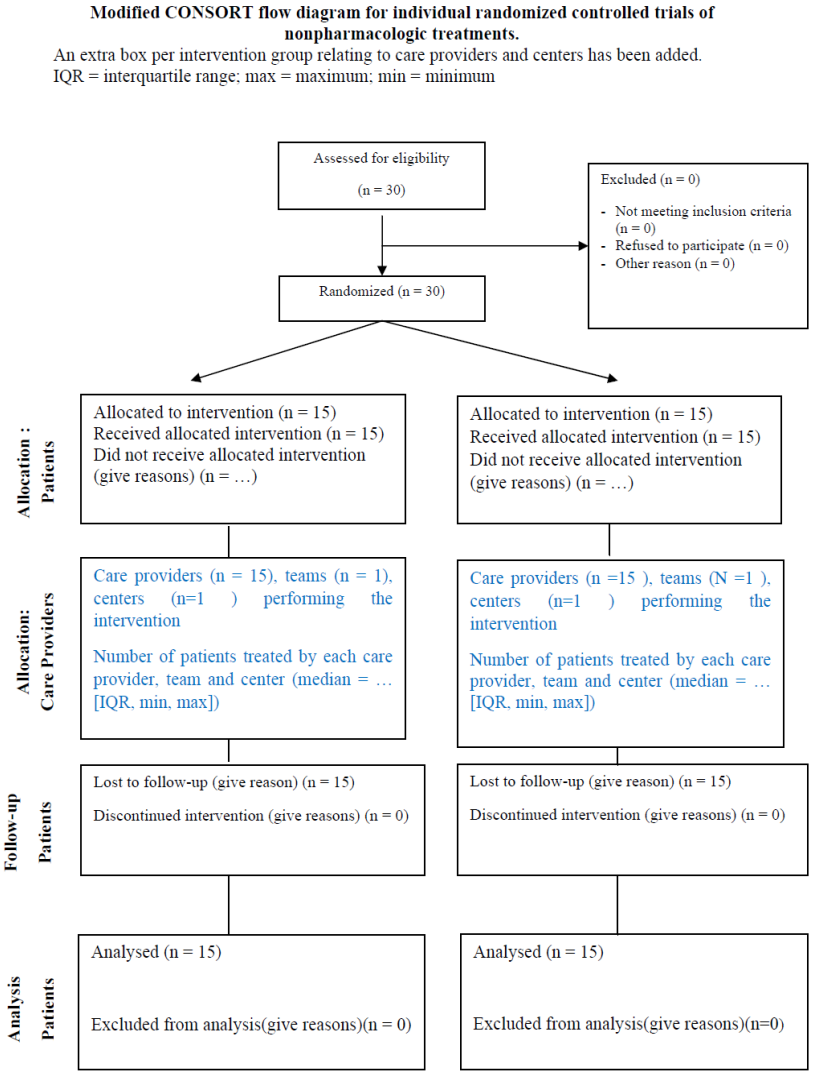

Figure 1. Details of the enrollment, allocation, and analysis of the population (consort form)

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The results of our study on the average length of the treatment period of the patients according to age in the two investigated groups showed that in people <60 years old, the average length of the treatment period in the sucralfate group was 13.00±5.00 days, and in the new dressing group, it was 14.00±7.00 days. Other information is given in **Table 2.**

Table 2. The average length of the treatment period of the patients according to age in the two investigated groups

Age	Number	Group		P-value
		New	Sucralfate	
> 60 years	12	14.00±7.00	13.00±5.00	0.811
< 60 years	18	11±5.00	8.00±3.00	0.160

Analysis of the above table using the Mann-Whitney nonparametric test showed that there is no statistically significant difference in the average treatment period length by age between the two investigated groups.

The average length of the treatment period of the patients according to the characteristics of the wound (excretion rate, wound size, tissue type) based on the criteria PUSH in two investigated groups: The results of our study on the average length of the treatment period of the patients according to the size of the wound in the two investigated groups showed that in the wounds of ≤3cm, the average length of the treatment period in the sucralfate group was 5.00±2.00 days and in the new dressing group it was 9.00±5.00 days. Other information is given in **Table 3.**

Table 3. The average length of the treatment period of the patients according to the size of the wound in the two investigated groups

Wound size (cm)	Number	Group		P-value
		New	Sucralfate	
≤3	10	9.00±5.00	5.00±2.00	0.000
3-8	13	16.00±9.00	9.00±5.00	0.000
>8	7	15.00±9.00	16.00±7.07	0.000

Analysis of the above table using the T-test parametric test showed that there is a statistically significant difference between the average length of the treatment period according to the size of the wound in the two investigated groups (P=0.0); so the average length of the treatment period in wounds ≥ 3 and 3-8 cm in the new dressing group was significantly higher than the sucralfate group. However, in wounds > 8 cm, the average treatment period in the sucralfate group was significantly longer than in the new dressing group.

The results of our study on the average treatment duration in patients according to the amount of wound secretion in the two investigated groups showed that in wounds without secretion or with a small amount of secretion, the average treatment duration in the sucralfate group was 7.00±3.03 days. In the new dressing group, it was 9.00±4.00 days. Other information is given in **Table 4.**

Table 4. The average length of the treatment period of the patients according to the amount of wound discharge in the two investigated groups

The amount of secretion wound	Number	Group		P-value
		New	Sucralfate	
No-Mild	21	9.00±4.00	7.00±3.03	0.000
Moderate	8	16.00±7.00	21.00±0.00	0.000
Intense	1	30	0	……..

Analysis of the above table using the T-test parametric test showed that there is a statistically significant difference between the average length of the treatment period in terms of the amount of wound secretion in the two investigated groups (P<0.05); so the average length of the treatment period in wounds without secretion or with a small amount of secretion in the group The new dressing was significantly

more than the sucralfate group. However, in wounds with moderate discharge, the average treatment period in the sucralfate group was significantly longer than in the new dressing group.

In cases with a high amount of secretion, it was not possible to perform a statistical comparison due to the zero value in the Sucralfate group. The results of our study on the average treatment period for patients by wound tissue type in the two investigated groups showed that in closed wounds, the average treatment period was 4.00±0.00 days in the sucralfate group and 5.00±2.00 days in the new dressing group. Other information is given in **Table 5.**

Table 5. The average length of the treatment period of the patients according to the type of wound tissue in the two investigated groups

Texture type wound	Number	Group		P-value
		New	Sucralfate	
Closed	6	5.00±2.00	4.00±0.00	0.000
Epithelial+Granulation	14	11.00±5.00	8.00±2.00	0.000
Slough + Necrotic	10	18.00±8.00	14.00±7.00	0.000

Analysis of the above table using the T-test parametric test showed that there is a statistically significant difference between the average length of the treatment period according to the type of wound tissue in the two investigated groups ($P<0.05$); so the average length of the treatment period in all three types of wound tissue was significantly higher in the new dressing group than in the sucralfate group.

Discussion

Treatment duration in women was 13.00±5.00 days in the new dressing group and 5.00±1.00 days in the sucralfate group (p=0.040). No significant age-related difference was found. The average length of the treatment period in wounds ≤ 3 and 3-8 cm in the new dressing group was 9.00±5.00 and 16.00±9.00 days, respectively. On the other hand, the duration of wound healing in the sucralfate group was 5.00±2.00 and 9.00±5.00 days for these two wound sizes, respectively, yielding a p-value of 0.000. In contrast, for ulcers > 8 cm, the new dressing was more effective, with recovery times of 15.00±9.00 and 16.00±7.07 days in the sucralfate group (p= 0.000). In non-secreting or low-secreting wounds, the new dressing group had a significantly longer treatment duration than the local sucralfate group. Conversely, for wounds with moderate secretion, the mean treatment duration was significantly longer in the sucralfate group than in the new dressing group. Treatment duration for all wound tissues (closed, epithelial and granulation, slough and necrotic) was shorter with the new dressing.

In Mehrabani's study, which compared the effects of honey dressings and hydrocolloid dressings on the healing of pressure ulcers in patients hospitalized in special departments, both types of dressings were shown to promote the healing of bed ulcers (14). In this study, the gender factor in wound healing was investigated, and no significant difference was observed; the healing process was the same in both male and female groups. However, the honey dressing has been shown to reduce wound secretions better than the hydrocolloid dressing. However, in the study we conducted, sucralfate had a better effect in women than the new dressing, and no statistical difference was observed in men, which could have occurred by chance. Also, in our study on wound

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healing, the sucralfate group showed a better effect, which was statistically significant.

Our study was conducted to investigate the effect of sucralfate topical ointment compared with modern dressings on the healing of 1st- and 2nd-degree bedsores in patients hospitalized in the ICU. The results of our study showed that, except in the cases of wounds >8 cm and wounds with moderate secretion, in other cases in patients with bedsores of the 1st and 2nd degree hospitalized in ICU, the use of topical sucralfate compared to the new dressing reduces the length of the treatment period and heals the bedsores faster. In a study conducted by Koch et al. with the title of investigating the healing power of chitosan dressing containing saprophyte on an experimental wound in rats, three groups of rats were included: a control group without dressing, a group receiving chitosan, and a group receiving chitosan + sucralfate. It was found that wound-healing speed increased significantly on the 11th and 14th days after surgery in both the chitosan and chitosan + sucralfate groups compared with the control group. However, there was no difference between the chitosan and chitosan + sucralfate groups. No significant statistics were observed (15). In this study, factors such as wound size and the amount of wound secretion were not taken into account, which may explain the lack of statistical difference. However, in our study, the effect of sucralfate on wound treatment and healing was statistically significant. This finding is consistent with the results of a 2010 study by Mahim Koshariya et al. They showed that topical sucralfate increased the rate of re-epithelialization compared with silver sulfadiazine and accelerated wound healing (16).

In a 2010 review, Maxwell et al investigated the effect of topical sucralfate on epithelial wound healing. In this study, topical sucralfate is effective in the healing of epithelial lesions, including wounds, inflammatory dermatitis, mucous inflammation, and burn wounds (17). It was not considered, and no comparison was made between the recoveries of epithelial lesions; all were treated equally. In our studies, taking into account dressing, exit criteria, age, and gender, it was observed that, in addition to the above, sucralfate can be effective for 1st- and 2nd-degree bed sores.

Limitations of the study

1- Reducing the referral of patients with bedsores of the 1st and 2nd degree to medical centers and hospitals.

2- Early discharge of patients with 1st and 2nd degree bedsores in these medical centers.

3- Non-cooperation of some patients and their companions in following up on treatment after being discharged.

Conclusion

According to the results, it can be concluded that, except for wounds >8 cm and wounds with medium discharge, in other cases in patients with bedsores, the use of topical sucralfate compared to a new dressing reduces the treatment period. Also, according to the results, healing of bedsores did not differ between age groups or between men, but in women, sucralfate reduced treatment duration compared with a new dressing. In general, the proper

use of topical sucralfate in patients with 1st- and 2nd-degree bedsores hospitalized in the ICU can reduce treatment duration, accelerate wound healing, shorten the patient's hospital stay, and lower treatment costs.

Suggestions

According to the results, it is suggested:

1. Investigating the effect of sucralfate on wounds of higher-grade beds (3 and 4).
2. In future studies, the effectiveness of topical sucralfate in treating bedsores will be compared with other dressings (such as hydrocolloid dressings) to determine the most appropriate treatment for these patients.
3. In future studies, the influence of other factors such as the depth of the wound, history of underlying disease (especially diabetes and vascular collagen diseases), duration of the disease, etc.
4. Conducting a study on more samples (increasing the study population).

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Conflict of interest: The authors declared no conflict of interest.

Ethical considerations: The drug used in this plan does not cause serious and dangerous side effects. In this study, the patient was not charged an additional cost over the standard costs. Informed consent was obtained from the patients. The subject was registered in the clinical trial registration database of the Ministry of Health (IRCT.ir), and the ethical code was obtained from the Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd. Code of Ethics (IR.SSU.MEDICINE.REC.1396.199).

Authors' contribution: B.H. and M.J. were involved in the conception and design of the study. M.J. and Z.L. evaluated the patients and collected the data. M. L analyzed the data, and B.H drafted the first manuscript. All authors read and approved the final manuscript.

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