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Original Article

Comparative Study of Topical Sucralfate and Normal Saline Dressing for Diabetic Ulcer-A Quasi-Experimental Study

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ABSTRACT

Objective: To compare the effect of topical Sucralfate versus normal saline dressing in wound healing of diabetic ulcers.
Study Design: Quasi-experimental.
Place and Duration of Study: Department of Surgery, Combined Military Hospital, Multan Pakistan from Jan to Jun 2023.
Methodology: The study included 64 diabetic patients aged 25-75 years with long-standing diabetic grade 1 and 2 ulcers. Participants were distributed in 2 equal Groups by lottery method. Group-A patients were planned for topical Sucralfate dressings, whereas Group-B patients received normal saline dressings. The mean reduction in wound area and healing time were assessed and compared in both Groups.
Results: Out of 64 patients, 56 patients were included in the final analysis and eight were excluded due to death or complications. The mean age was 56.21±9.58 years in the topical Sucralfate Group and 57.70±12.01 years in the normal saline Group. The mean wound surface area was 185.24±22.01 cm^2 in Group-A and 186.67±19.17 cm2 in Group-B (p=0.907). In weeks 1 and 3, the Sucralfate dressing Group showed more reduction in surface area, 12.31±2.23% and 72.69±9.54 %, respectively, whereas the normal saline Group had 10.59±2.56% and 47.44±6.99% reduction in wound size respectively (p<0.005). Healing time in the topical Sucralfate Group was less than in the normal saline Group, 26.38±2.63 days vs 36.96±3.79 days, respectively (p<0.005).
Conclusion: Topical Sucralfate dressings have been shown to be more successful and effective in treating diabetic ulcers than conventional normal saline dressings.

Keywords: Diabetic foot, Dressings, Sucralfate, Saline solution, Wound healing.

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INTRODUCTION

Diabetes mellitus (DM) is a major global health issue and its prevalence is on the rise in Pakistan.[1] A devastating complication of diabetes is diabetic foot ulcers (DFUs) which can complicate to osteomyelitis, gangrene and the most feared outcome of amputation.[2] The overall lifetime risk of diabetic ulcers in the diabetic population is as high as 34%, and at least two-thirds of all non-traumatic amputations occur in diabetics.[3] Lower limb complications of diabetes constitute a top ten conditions in terms of years lived with disability and also associated with increased rates of depressive illness.[4] The global prevalence of DFUs is 6.3% (95% CI: 5.4-7.3%), which is higher in males than females (4.5% vs 3.5%) and higher in type 2 diabetes mellitus (T2DM) 6.4% than in type 1 diabetes mellitus (T1DM) 5.5%.[5]

There are three types of DFUs namely neuropathic, ischemic and neuroischemic.[6] Different modalities to treat DFUs include debridement and wet-to-dry normal saline dressings, topical Sucralfate dressing, negative pressure wound therapy (NPWT) or Vacuum-assisted closure (VAC), shock wave therapy, and skin grafts.[7] Conventionally repeated wet-to-dry wound dressings are being done for DFUs post-debridement till complete granulation.[8] Topical Sucralfate is an alternative and effective technique that is widely used for diabetic ulcers.[9] It promotes angiogenesis, enhances tissue granulation, and promotes quick wound healing.[10]

The rationale for conducting this study was to compare the two known treatment techniques for diabetic foot ulcers, normal saline wound dressing, and topical Sucralfate dressing, in terms of granulation formation, healing time, and post-op complications. The objective of this study was to compare the effects of Topical Sucralfate versus normal saline dressing in wound healing of diabetic ulcers.

METHODOLOGY

This Quasi experimental study was carried out in the Department of surgery, Combined Military

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Hospital Multan, Pakistan from January to June 2023, over a period of 6 months following approval from the Institutional Ethical Review Committee (ERC No. 139/2023 dated 20 Dec 2022). Using WHO sample size calculator, with level of significance 5% and power of test at 80%, and 47% reduction in surface area of wound with topical Sucralfate dressing compared to 18% reduction of area with Conventional normal saline dressings,[11] a total sample size of 64 patients was calculated with 32 patients in each Group. A total of 72 patients with diabetic foot ulcers presented to the surgical department of CMH Multan during the study period. Five patients with underlying osteomyelitis and three with gangrene were excluded, and 64 diabetic patients with foot ulcers who fulfilled the inclusion criteria were enrolled in the study after informed consent.

Inclusion Criteria: Diabetic patients of either gender, 25-75 years old, with unilateral long-standing (> two weeks) foot ulcers of Wegner grade 1 and grade 2 with ulcer size of 15 x 15 cm or less, presenting to CMH Multan during the study period, were included in the study.

Exclusion Criteria: Non-diabetic patients or diabetics with traumatic foot ulcers, ulcer size more than 15 cm or bilateral ulcers, Wagner grade 3 or above ulcers involving one or both limbs, osteomyelitis, gangrene, acute limb ischemia, malignancy, coagulopathy, immune-compromised patients were all excluded from the study.

Diabetic foot ulcers (DFUs) are segregated into grades as per Wagner grading.[12,13] Grade 1: superficial ulcers—skin and subcutaneous tissue only; Grade 2: deep ulcers to tendon and muscle joint capsule; Grade 3: deep ulcers with abscess, osteomyelitis, and tendinitis; Grade 4: partial foot gangrene; Grade 5: whole foot gangrene.

All diabetic patients with long-standing ulcers of more than two weeks duration, Wagner grade 1 and 2 lower limb ulcers of size 15 cm or less, were admitted to the surgical ward for debridement followed by wet-to-dry dressings. Sampling was done by non-probability consecutive technique. All patients fulfilling inclusion criteria were divided into two Groups using a lottery method for the two interventions being studied. A total of 64 enrolled patients with Wagner grade 1 and 2 foot ulcers were divided into two equal Groups of 32(50%) participants in each Group. Patients treated with topical Sucralfate dressing were kept in Group-A, and patients treated with normal saline dressing were kept in Group-B as shown in Figure-1. Baseline investigations, including CBC, coagulation profile, LFTs, RFTs, HbA1c, and Hepatitis B & C serology were done in all patients. Pre-anesthesia assessment was sought in all patients (Figure-1).

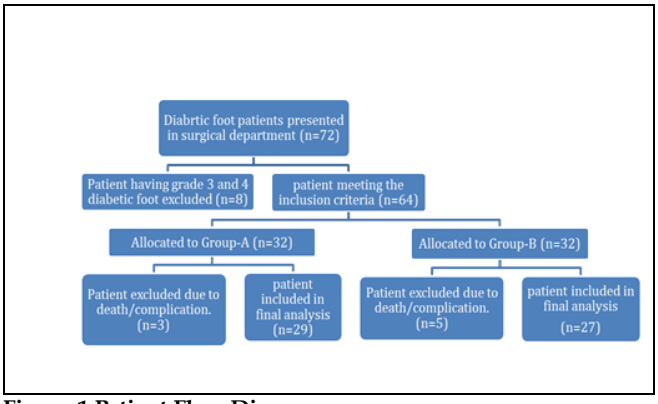

Figure-1 Patient Flow Diagram

Initial management was done by wound debridement under local anesthesia in the operation theatre, IV antibiotics were given, and strict glycemic control was performed on all patients. Repeated session of surgical debridement was done as per the requirement and condition of the wound. Same parenteral antibiotics were given to all patients, and no topical antibiotics were used for wounds in any patient included in the study. After complete debridement of wounds and declared clean wounds by the treating surgeon, Group-A participants underwent topical Sucralfate dressings once daily. Group-B participants underwent normal saline wet-to-dry dressings once daily.

The initial wound surface area was measured before surgical debridement in both Groups by measuring ulcer area (length x width) cm^2 by thorough clinical assessment and planimetry. Both Group participants had dressings once daily, and the wound was assessed daily during the dressing change with the measurement of wound surface area reduction. The mean percentage of weekly area reduction was calculated for the final analysis. Patients in both Groups were assessed indoors for three weeks or till at least 50-60% wound healing without any evidence of infection. Pre-decided parameters were noted in both Groups, including granulation tissue formation with reduced wound surface area, wound healing time, and the need for re-debridement. A total of 56 patients were included in the final analysis as

three patients from Group-A and one patient from Group-B expired during the course of treatment due to diabetic complications, and a further four patients from Group-B diagnosed to have osteomyelitis following initial debridement were also excluded from final analysis.

Patient`s age, gender, hemoglobin, HbA1c, healing time, and wound surface area reduction were noted in all patients for analysis. Categorical data were presented as numbers and percentages, whereas continuous variables were as Mean±SD. Data were analyzed using Statistical Package for Social Sciences version 23 (SPSS v23). The normality of data was tested by the Kolmogorov-Smirnov test, the association between categorical variables was calculated using a chi square test and quantitative variables were compared by independent samples t-test, and a *p*-value of ≤ 0.05 was taken as statistically significant.

RESULTS

A total of 72 diabetic patients with DFUs presenting to CMH Multan during the study period were assessed for eligibility; 64 patients were enrolled after meeting inclusion criteria and 56 patients were included in the final analysis with 34 60.7%) males and 22(39.2%) females with a mean age of 56.21±9.58 years in topical Sucralfate Group and 57.70±12.01 years in normal saline dressing Group (*p*-value=0.572). Hemoglobin (Hb) levels and glycemic control assessed by complete blood count (CBC) and HbA1c were also noted, and no statistically significant difference was noted among both Group participants with mean Hb levels of 12.07±2.24 versus 11.47±2.69 mg/dl (*p*-value=0.338) and mean HbA1c 10.04±1.56 % versus 10.35±1.81 % (*p*-value=0.381) in Group-A and Group-B respectively (Table-I).

Table-I: Comparison of Baseline Characteristics of Studied Groups (n=72)

Baseline Characteristics		Group A Topical Sucralfate dressing (n=29)	Group B Normal Saline dressing (n=27)	*p*-value
Age (mean years±SD)		56.21±9.58	57.70±12.01	0.572
Gender	Male n(%)	19(65.5 %)	15(55.6 %)	0.376
	Female n(%)	10(34.5 %)	12(44.4 %)	
Hemoglobin (g/dl) (Mean±SD)		12.07±2.24	11.47±2.69	0.338
HbA1c (%) (Mean±SD)		10.04 ± 1.56	10.35±1.81	0.381
Wagner Grade	Grade 1 n(%)	13 (44.8 %)	16(59.3 %)	0.256
	Grade 2 n(%)	16 (55.2 %)	11(40.7 %)	

There was no statistically significant difference in mean wound surface area before debridement, with 185.24±22.01 cm² in Group-A and 186.67±19.17 cm² in Group-B participants (*p*=0.907). Following debridement, a percentage of weekly reduction in wound surface area was noted, which showed higher wound surface area reduction in topical Sucralfate dressings than regular normal saline dressings (*p*<0.005). (Tables II & III).

Table-II: Comparison of Wound Surface Area at Presentation (n=72)

Wound Surface Area	Group A Topical Sucralfate dressing (n = 29)	Group B Normal Saline dressing (n = 27)	*p*-value
Before Debridement (Mean CM²±SD)	185.24±22.01	186.67±19.17	0.907

Table-III: Comparison of Weekly Mean Percentage of Wound area Reduction and healing time in both Groups

Postoperative Progress	Group A Topical Sucralfate dressing (n=29)	Group B Normal Saline dressing (n=27)	*p*-value
Wound Area Reduction (%)			
Week 1 (Mean %±SD)	12.31±2.23	10.59±2.56	0.006
Week 2 (mean %±SD)	37.79±5.57	26.22±4.90	<0.005
Week 3 (Mean %±SD)	72.69 ± 9.54	47.44 ± 6.99	< 0.005
Healing Time			
Days (Mean±SD)	26.38±2.63	36.96±3.79	< 0.005

Time for complete healing was assessed in both Groups, which was considered as 90-100% healthy granulation tissue formation without evidence of infection, which was comparatively longer in Group-B participants who had regular normal saline dressings with mean 36.96±3.79 days in comparison to Group-A who received topical Sucralfate dressings 26.38±2.63 days (*p*-value <0.005). (Table-III).

During the course of treatment, the need for re-debridement after initial wound debridement was also compared in both Groups. It was observed that 7(24.1%) patients from the topical Sucralfate Group needed re-debridement, whereas 13(48.4%) patients from the normal saline dressing Group required re-debridement (*p*-value=0.030) (Figure-2).

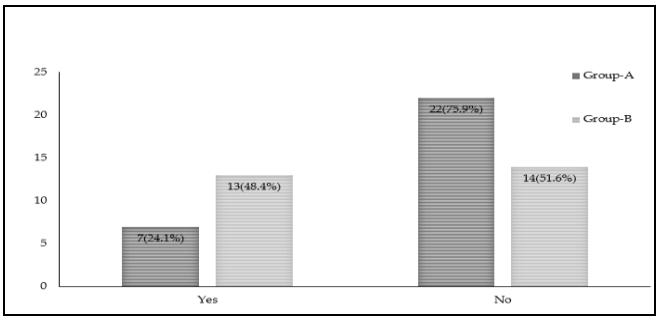

Figure-2: Comparison of Need for Re-Debridement in Both Groups

DISCUSSION

Diabetic foot ulcers (DFUs) are a debilitating complication of uncontrolled diabetes occurring in about 25% of the diabetic population and leading to non-traumatic amputations in up to 85% of DFUs in uncontrolled DM.[14] In our study, long-standing DFUs of Wagner grade 1 & 2 with size 15cm or less were studied, and no statistically significant difference between glycemic control in both studied cohorts was observed as evident by mean HbA1c of 10.04±1.56% vs 10.35±1.81 % (*p*-value=0.381) in Group-A and Group-B respectively. In a study done by Rani *et al.*,[15] it was shown that a greater mean percentage of wound area reduction was seen in topical Sucralfate dressing, 54.[17]±10.08 % in comparison to povidine and normal saline dressing Group 16.07±4.19%. Similarly, another study by Dr. Advait Bhatmule *et al.*,[11] from India concluded that diabetic ulcer wound area reduction in topical Sucralfate dressing was better, with a mean percentage of 43.59±7.81% when compared to the regular normal saline dressing Group with a mean percentage of 21.85±5.84%.

In regards to wound surface area reduction following treatment, it was observed in this study that the mean percentage of reduction in diabetic ulcer area from the initial ulcer area before debridement was higher in participants who had undergone topical Sucralfate dressing as compared to the normal saline dressing Group. At week 1, the Sucralfate dressing Group showed a 12.31±2.23% reduction in wound surface area, while the normal saline Group had only a 10.59±2.56% reduction in wound size (*p*=0.006). At the end of the 2nd and 3rd weeks, the topical Sucralfate dressing Group had greater granulation tissue formation with 37.79±5.57% & 72.69±9.54% reduction in wound area from the original wound. On the other hand, the normal saline Group had 26.22±4.90% & 47.44±6.99 % reduction in the targeted wound area, respectively (p<0.005).

Results of another comparative study by Kumar *et al.*,[16] also showed that participants who received topical Sucralfate dressing had better ulcer reduction of 41.97±7.41% with granulation tissue formation. In contrast, participants who underwent regular normal saline wet-to-dry dressing had wound area reduction of 18.37±13.43%. In this study, 29(51%) participants were found to have grade I diabetic ulcers, and 27(49%) had grade 2 ulcers as per Wagner`s grading scale of diabetic ulcers. Similar results were shown by Gnanakkumar.[17] where grade 1 ulcers were found in 45% of participants and grade 2 in 55% of diabetic patients included in the study. In addition, his research concluded that healing time was less in terms of weeks in the participants receiving topical Sucralfate dressing therapy, which was 3.12 weeks, compared to the normal dressing therapy Group, which was 6.29 weeks. We also observed complete healing time evident by granulation tissue, which was quicker in the topical Sucralfate Group at 26.38±2.63 days (3.7 weeks). In contrast, in the conventional normal saline Group, it was noted to be 36.96±3.79 days (5.2 weeks), similar to other studies. In a study by Nagalakshami *et al.*,[12] it was evident that the mean healing time was 2.68 weeks in the study Group (topical Sucralfate dressing) in comparison to 5.36 weeks in the control Group (normal saline dressing). In another randomized control trail by asd *et al.*, studied Group who underwent Sucralfate dressing showed mean healing rate of 16.2±7.3% whereas healing rate in control Group was 14.5±6.6%.[18]

LIMITATIONS OF STUDY

Studies including RCTs with larger sample sets involving diabetic patients from multi-centers including Wagner grade 3 or more, ulcer size > 15 cm, are to be done to compare topical Sucralfate with conventional normal saline dressing and other agents for more authentic results before implementation on a wide scale.

CONCLUSION

Topical sucralfate dressings have been shown to be more successful and effective than conventional normal saline dressings in treating diabetic ulcers. They achieve granulation tissue, reduce wound surface area quicker, and lessen healing time. Also, topical Sucralfate showed a lower rate of need for re-debridement and infection.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

SAA & NR: Data acquisition, data analysis, critical review, approval of the final version to be published.

AM & ZF: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

MWAB & ASA: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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