Journal of Cardiovascular Disease Research
ISSN: 0975-3583,0976-2833 VOL 16, ISSUE 7, 2025

A COMPARATIVE STUDY OF TOPICAL SUCRALFATE AND NORMAL SALINE DRESSINGS IN THE MANAGEMENT OF DIABETIC FOOT ULCERS

Dr. R Parameshwaran Unnithan[1], Boopesh S[2], Dr. Jaya Sakthi[3]

1. Professor, Department of General Surgery, Sree Mookambika Institute of Medical Sciences, Kanyakumari, Tamil Nadu

2. Junior Resident, Department of General Surgery, Sree Mookambika Institute of Medical Sciences, Kanyakumari, Tamil Nadu

3. Assistant Professor, Department of General Surgery, Sree Mookambika Institute of Medical Sciences, Kanyakumari, Tamil Nadu

***Corresponding Author – Dr Boopesh S,** Junior Resident, Department of General Surgery, Sree Mookambika Institute of Medical Sciences, Kanyakumari, Tamil Nadu*

ABSTRACT

Background: Diabetic foot ulcers (DFUs) are a serious complication of diabetes mellitus, often leading to prolonged hospitalization, infection, and lower limb amputation. Effective local wound management plays a critical role in promoting healing and preventing complications. Normal saline is commonly used for wound dressing due to its safety and availability. However, topical sucralfate, with its mucoprotective and tissue-regenerative properties, may offer enhanced wound healing benefits.

Aim: To compare the efficacy of topical sucralfate versus normal saline in the management of DFUs.

Materials and Method: The present study prospective, randomized study was conducted on 70 patients with diabetic foot ulcers (Wagner Grade I–III) attending the surgical outpatient department. Patients were randomly assigned into two equal groups of 35 each. Group A received daily dressings with topical sucralfate, while Group B received dressings with normal saline. Wound assessment was performed weekly for four weeks, evaluating ulcer size, granulation tissue formation, and signs of infection. Patients with critical limb ischemia, osteomyelitis, or uncontrolled systemic illness were excluded. Data were analyzed using appropriate statistical tests to compare outcomes between the two groups, with $p < 0.05$ considered statistically significant.

Results: Baseline characteristics including age, gender, HbA1c levels, and wound stage were comparable. By week 4 and 8, the sucralfate group showed significantly greater wound size reduction ($p = 0.042$ and $p = 0.039$, respectively). Healthy granulation tissue was more prevalent in the sucralfate group at both time points ($p < 0.05$). Additionally, slough presence was significantly lower in the sucralfate group by week 8 ($p = 0.024$). These findings highlight the superior healing efficacy of topical sucralfate over normal saline dressings.

Conclusion: Topical sucralfate is more effective than normal saline in promoting healing of diabetic foot ulcers, enhancing granulation tissue formation, and controlling infection. Its use may represent a cost-effective and safe adjunct in the management of DFUs.

Keywords: Diabetic foot ulcer, Granulation tissue, Normal saline, Sucralfate dressing, Wound healing.

INTRODUCTION

Diabetes mellitus (DM) comprises a spectrum of metabolic disorders characterized by chronic hyperglycemia due to impaired insulin secretion, resistance, or both. It represents a

growing global health burden, affecting over 422 million people worldwide, with the majority residing in low- and middle-income countries.[1] Diabetes contributes to approximately 1.5 million deaths annually.[2] In India alone, current estimates from the Indian Council of Medical Research (ICMR) indicate that 11.4% of adults, or about 101 million individuals, are living with diabetes.[3]

The chronic complications associated with diabetes are numerous and often severe. These include diabetic nephropathy, retinopathy, peripheral neuropathy, and a significantly increased risk of cardiovascular events such as myocardial infarction and stroke. In advanced stages, diabetes can lead to disabling outcomes like kidney failure, vision loss, and lower extremity amputations. Among these, diabetic foot ulcers (DFUs) are particularly concerning, as they involve progressive tissue breakdown and are a leading cause of non-traumatic lower limb amputations.[4,5]

The pathogenesis of DFUs is multifactorial, involving peripheral neuropathy, ischemia due to microvascular and macrovascular disease, and a compromised immune response, all of which contribute to poor wound healing. The high incidence, prolonged healing time, and risk of complications make DFUs a major contributor to diabetes-related morbidity, healthcare expenditure, and loss of productivity.[6,7]

Successful DFU management requires a multidisciplinary and comprehensive approach, including glycemic control, infection management, wound debridement, pressure offloading, and appropriate wound care. Among various dressing options, normal saline is frequently used due to its accessibility and safety, though it lacks intrinsic healing properties.[8] On the other hand, sucralfate, traditionally used for peptic ulcers, has demonstrated promising results in wound healing due to its cytoprotective action, stimulation of angiogenesis, and promotion of granulation tissue formation when applied topically.[9]

This study is novel in its direct clinical comparison of topical sucralfate versus normal saline in the management of diabetic foot ulcers in an Indian patient population. While previous research has explored the use of sucralfate in other chronic wounds, few controlled studies have systematically evaluated its efficacy in DFUs. By assessing outcomes such as wound size reduction, granulation tissue formation, infection control, and healing time, this study provides important evidence on the cost-effective, safe, and potentially superior role of sucralfate dressings.

AIMS

This study aimed to compare the efficacy of topical sucralfate versus normal saline in

the management of DFUs.

MATERIALS AND METHODS

This prospective, hospital-based comparative study was conducted in the Department of General Surgery at a tertiary care hospital in Kanyakumari District, over a period of 12 months, from March 2024 to February 2025. The study was designed to evaluate and compare the healing efficacy of topical sucralfate versus normal saline dressings in patients with Wagner Grade I to III DFUs. The study enrolled a total of 70 in-patients diagnosed with diabetic foot ulcers, based on predefined inclusion and exclusion criteria. All patients provided informed consent prior to participation.

Inclusion Criteria

Patients were eligible for inclusion if they met the following criteria:

- Diagnosed with Type 2 diabetes mellitus and under regular treatment
- Age between 18 and 75 years**.**
- Presence of Wagner Grade 1 to 3 diabetic foot ulcers persisting for more than 2 weeks.
- Willingness to undergo topical sucralfate dressing as part of the study protocol

Exclusion Criteria

Patients were excluded from the study if they had:

- A history of coronary artery disease**,** cerebrovascular accidents (stroke)**, or** peripheral arterial disease**.**
- Presence of septicemia**,** osteomyelitis**,** malignant skin lesions**,** exposed bone**,** or Charcot's neuroarthropathy**.**
- Known allergy to sucralfate or any component of the dressing materials.

Eligible participants were randomly allocated into two equal groups using a simple randomization method:

- **Group 1 (Sucralfate Group):** Received topical sucralfate application directly over the ulcer, followed by conventional dressing**.**
- **Group 2 (Control Group):** Received normal saline dressing only, without the addition of any topical agent.

Group 1 was administered topical sucralfate directly onto the ulcer bed, subsequently covered with a typical sterile gauze bandage. Group 2, designated as the control group, was

administered standard dressing with only normal saline. All dressings were conducted on alternate days following aseptic protocols. Before each dressing, wounds were cleansed with regular saline in both groups. Surgical debridement was performed as necessary to eliminate slough and necrotic tissue, so providing a sterile wound bed for optimal healing. Both groups persisted in receiving routine supportive treatment, encompassing optimal glycaemic management, antimicrobial therapy as warranted, nutritional supplementation, and pressure unloading through suitable footwear or assistive equipment.

All patients were observed for 8 weeks, with assessments performed at baseline (day of admission), at the end of the 4th week, and again at the end of the 8th week. The principal outcome measures comprised the decrease in ulcer dimensions (quantified in square centimetres via a standardised wound tracing technique), the degree of granulation tissue development, and the occurrence of slough or indicators of infection, including erythema, exudate, or malodour. Secondary outcomes encompassed the duration until observable wound enhancement and any adverse effects linked to the treatments. Wound healing advancement was recorded photographically at each evaluative step. The presence and quality of granulation tissue were visually assessed by the same investigator throughout the trial to minimise observer variability.

All collected data were entered into Microsoft Excel and analyzed using SPSS 20.0. Categorical variables, including the presence or absence of slough and infection, were reported as frequencies and percentages. Continuous variables, such as ulcer size and granulation tissue scores, were presented as mean ± standard deviation (SD). The Chi-square test was employed for categorical data, while the Mann-Whitney U test was utilised for continuous, non-parametric data to compare treatment outcomes between the two groups. A p-value below 0.05 was deemed statistically significant, signifying a substantial difference between the treatment and control groups.

RESULTS

Among the total study population, 27 patients (38.6%) were male, and 43 patients (61.4%) were female. The mean age of the study population was 58 ± 7.34 years, with Group A having a mean age of 59.3 ± 7.76 years and Group B 56.7 ± 6.74 years. In terms of diabetic management, 37 patients (52.9%) were on insulin therapy, while 33 patients (47.1%) were receiving oral hypoglycemic agents. The mean HbA1c level across the study population was 8.0 ± 1.09%, with no statistically significant difference between the two groups (Group A: 7.96 ± 0.96; Group B: 8.03 ± 1.20; $p = 0.805$), confirming comparable baseline glycemic

control. There were no statistically significant differences between groups in terms of age, sex, diabetes treatment, or HbA1c levels between the groups. (Table 1)

Parameter		Group A (n=35)	Group B (n=35)	p-value
Mean Age (years)		59.3 ± 7.76	56.7 ± 6.74	0.114
Gender	Male	13 (37.1%)	14 (40.0%)	0.80
	Female	22 (62.9%)	21 (60.0%)	
Treatment	Insulin Therapy	18 (51.4%)	19 (54.3%)	0.81
	Oral Hypoglycemics	17 (48.6%)	16 (45.7%)	
Mean HbA1c (%)		7.96 ± 0.96	8.03 ± 1.20	0.805

Table 1: Comparison of baseline Characteristics of the Study Population

The HbA1c distribution was identical in both groups, with 71.4% of patients in each group having moderate control (6–9%) and 28.6% having poor control (>9%), indicating comparable glycemic status. There was no statistically significant difference in the distribution of wound stages between the two groups ($p = 0.973$), confirming baseline comparability.

At admission, the mean wound sizes in both groups were comparable. However, by week 4 and week 8**,** Group A (sucralfate) showed significantly greater reduction in wound size compared to Group B.(Table 2)

Time Point	Group A (Mean ± SD)	Group B (Mean ± SD)	p-value
Admission	61.8 ± 44.7	76.6 ± 77.2	1.000
Week 4	28.9 ± 27.1	58.3 ± 57.7	0.042*
Week 8	12.7 ± 18.7	8.8 ± 20.7	0.039*

Table 2: Comparison of mean wound sizes (cm^2) between groups

At admission, both groups had a comparable distribution of granulation tissue type ($p = 0.65$). However, by weeks 4 and 8, pink (healthy) granulation tissue was significantly more prevalent in the sucralfate group ($p < 0.05$), indicating better healing.(table 3)

Time Point	Granulation Type	Group A (n=35)	Group B (n=35)	p-value
Admission	Pale	22 (62.9%)	19 (54.3%)	0.65
	Pink	13 (37.1%)	16 (45.7%)	
Week 4	Pale	12 (34.3%)	17 (48.6%)	0.037*
	Pink	23 (65.7%)	18 (51.4%)	
Week 8	Pale	3 (8.6%)	9 (25.7%)	0.034*
	Pink	32 (91.4%)	26 (74.3%)	

Table 3: Comparison of Granulation Type between groups

By week 4 and 8, Group A had significantly fewer patients with slough**,** reflecting superior wound bed preparation and tissue regeneration. (Table 4)

Time Point	Slough Status	Group A (n=35)	Group B (n=35)	p-value
Admission	Present	20 (57.1%)	19 (54.3%)	0.66
	Absent	15 (42.9%)	16 (45.7%)	
Week 4	Present	12 (34.3%)	19 (54.3%)	0.034*
	Absent	23 (65.7%)	16 (45.7%)	
Week 8	Present	7 (20.0%)	14 (40.0%)	0.026*
	Absent	28 (80.0%)	21 (60.0%)	

Table 4: Comparison of Slough Status between groups

DISCUSSION

Diabetic foot ulcers are prevalent surgical complications necessitating efficient treatment approaches. Conventional techniques prioritise dry wound management; however, emerging innovations endorse moist wound healing. Sucralfate, originally utilised for gastrointestinal ulcers, has proven effective in facilitating wound healing through the promotion of granulation tissue production.[10]

The study group appeared equal at baseline, exhibiting no significant disparities in demographic or clinical attributes, including age, gender, treatment mode (insulin or oral medicines), or glycaemic control (HbA1c values). The average age of participants was 58 ± 7.34 years, with a predominance of females (61.4%). The analogous distribution of HbA1c values in both groups—71.4% of patients in each group had moderately controlled diabetes

(HbA1c 6–9%)—further substantiates that any observed outcome differences were likely attributable to the intervention rather than baseline variability.

Sucralfate, a disaccharide sucrose octasulfate complexed with aluminium hydroxide, facilitates wound healing by augmenting the production of growth factors, especially fibroblast growth factor (FGF), essential for angiogenesis and the proliferation of keratinocytes and dermal fibroblasts. It also promotes granulation tissue development and enhances the release of interleukin-1 and interleukin-6.[11]

The current study revealed that topical sucralfate dressings markedly expedited wound healing in comparison to normal saline. At the 4th and 8th weeks, the sucralfate group exhibited a more significant reduction in wound size ($p = 0.042$, $p = 0.039$), presumably attributable to its cytoprotective and reparative properties. The formation of granulation tissue was significantly enhanced in the sucralfate group, with a greater percentage of patients displaying healthy tissue at both time intervals ($p < 0.05$). Furthermore, slough removal in Group A was markedly improved by week 8 ($p = 0.026$), demonstrating enhanced wound bed preparation and less infection risk.

The results of this study were similar to those of Bhatmule A et al.[12] who documented a more significant reduction in wound size and enhanced healing using topical sucralfate.

The study noted enhanced granulation tissue production with sucralfate, paralleling the findings of Yuniati R et al.[13], who established its efficacy in expediting wound healing within 14 days.

Furthermore, sucralfate diminishes slough development, as indicated by Ganankkumar T et al.[14] who observed a 43.78% reduction in wound area with sucralfate dressings compared to 28.72% with normal saline ($p<0.0001$), underscoring its efficacy in expediting and enhancing ulcer healing.

The study conducted by Viramuthu DI et al.[15] demonstrated a statistically significant reduction in wound size in the sucralfate group at the 4th and 8th weeks of admission, along with a greater proportion of healthy granulation tissue observed among patients in this group.

Chatterjee N et al.[16] reported that the prevalence of diabetic foot was highest (50.9%) among individuals aged 50-59 years. The average age of the study population was 51 years. The prevalence of diabetic foot ulcers peaked throughout July and August at 42%. The mean ± standard deviation (SD) of the healing rates in the sucralfate and mupirocin combination group was 16.2 ± 7.3%, while in the control group it was 14.5 ± 6.6%. There was no statistically significant difference in the healing rates between the two groups, according to

the Student-test comparison of the means (p=0.201).

CONCLUSION

This comparative study demonstrated that topical sucralfate dressings are more effective than normal saline in the management of DFUs. Patients treated with sucralfate showed significantly greater wound size reduction**,** faster and healthier granulation tissue formation, and earlier slough clearance over an 8-week period. Both groups were comparable at baseline, ensuring that observed differences were attributable to the intervention. Sucralfate, being cost-effective and readily available, presents a promising adjunct in chronic wound care for diabetic foot ulcers, potentially improving outcomes.

REFERENCES

1. World Health Organization. Responding to non-communicable diseases during and beyond the COVID-19 pandemic. Geneva: World Health Organization; 2020 [cited 2024 Mar 23].
2. World Health Organization. Diabetes [Internet]. Geneva: World Health Organization; [cited 2024 Mar 23].
3. Anjana RM, Unnikrishnan R, Deepa M, Pradeepa R, Tandon N, Das AK, et al. Metabolic non-communicable disease health report of India: The ICMR–INDIAB national cross-sectional study (ICMR–INDIAB–17). Lancet Diabetes Endocrinol. 2023;11(7):474–89.
4. Wang X, Yuan CX, Xu B, Yu Z. Diabetic foot ulcers: classification, risk factors, and management. World J Diabetes. 2022;13(12):1049-65.
5. Pickwell KM, Siersma VD, Kars M, Holstein PE, Schaper NC. Diabetic foot disease: impact of ulcer location on ulcer healing. Diabetes Metab Res Rev. 2013;29:377-83.
6. Syafril S. Pathophysiology diabetic foot ulcer. InIOP Conference series: earth and environmental science 2018 Mar 1 (Vol. 125, No. 1, p. 012161). IOP Publishing.
7. Kim J. The pathophysiology of diabetic foot: a narrative review. Journal of Yeungnam Medical Science. 2023 Oct 31;40(4):328-34.
8. Wu L, Norman G, Dumville JC, O'Meara S, Bell-Syer SE. Dressings for treating foot ulcers in people with diabetes: an overview of systematic reviews. Cochrane Database Syst Rev. 2015;(7):CD010471.
9. Masuelli L, Tumino G, Turriziani M, Modesti A, Bei R. Topical use of sucralfate in epithelial wound healing: clinical evidence and molecular mechanisms of action. Recent patents on inflammation & allergy drug discovery. 2010 Jan 1;4(1):25-3.

10. Szabo S, Vattay P, Scarbrough E, Folkman J. Role of vascular factors, including angiogenesis, in the mechanisms of action of sucralfate. The American journal of medicine. 1991 Aug 8;91(2):S158-60.
11. Burch RM, McMillan BA. Sucralfate induces proliferation of dermal fibroblasts and keratinocytes in culture and granulation tissue formation in full-thickness skin wounds. Agents and Actions. 1991 Sep;34(1):229-31.
12. Bhatmule A, Janugade HB, Nangare N. A competitive study of topical sucralfate and ordinary saline for diabetic ulcer dressing. Journal of Pharmaceutical Negative Results. 2022 Oct 7;13.
13. Yuniati R, Innelya I, Rachmawati A, Charlex HJM, Rahmatika A, Khrisna MB, et al. Application of topical sucralfate and topical platelet-rich plasma improves wound healing in diabetic ulcer rats wound model. J Exp Pharmacol. 2021;13:797-806.
14. Gnanakkumar T. Efficacy of topical sucralfate and conventional dressing in the treatment of diabetic ulcer. Int J Health Clin Res. 2021;9(7).
15. Viramuthu DI, Selvakumar K, Sundararajan T, Sandirakumaran A. A Comparative Study of Topical sucralfate versus Normal Saline for Dressing of Diabetic Foot Ulcers at a Tertiary Care Hospital. European Journal of Cardiovascular Medicine. 2024 Dec 11;14:527-31.
16. Chatterjee N, Ekka NM, Mahajan M, Kumar B, Kumar N, Zia A et al. Effectiveness of Topical Sucralfate in the Management of Diabetic Foot Ulcers: An Open-Labeled Randomized Study. Cureus. 2023 Apr 14;15(4).