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Original Research Article

A Comparative Study on Topical Sucralfate Dressing versus Conventional Dressing in the Management of Chronic Diabetic Foot Ulcers

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Abstract

Background: The incidence of diabetes and its complications are increasing day by day. Lifetime risk of developing a foot ulcer is up to 25% in diabetic patients. The course of healing in chronic diabetic foot ulcers is unpredictable and resistant to treatment. Various modalities of treatment have been developed to aid the faster healing of diabetic foot ulcers however none proved to be gold standard. Sucralfate is a drug primarily used to treat GIT ulcers, has proved to be effective in reducing the size of wound and aids in complete healing of wounds in various studies. Our study intends to compare the efficacy of sucralfate with conventional dressing in treating diabetic ulcers.

Materials and methods: This randomised comparative study was done in the Department of General Surgery. 100 patients with chronic diabetic foot ulcers, divided into two groups of 50 each were studied. One group received topical sucralfate dressing and the other group received treatment in the form of conventional therapy. Comparison between two groups was made regarding the percentage decrease in wound area, duration taken for complete healing, effect when associated with varicose veins and effect on bacterial load of ulcer.

Results: The majority of patients were aged more than 50 years, Females (58%) were more affected than males (42%). The plantar aspect (46%) was the most common site. The sucralfate group mean area of reduction after 21 days was 42.3% (S.D;7,5) and in the conventional group was 17.9 (S.D;12.7). which is observed to be statistically significant. The ulcer's mean duration for complete healing was 2.7 weeks in the topical sucralfate group and 5.9 weeks in the conventional dressing group.46 patients in the study group, whereas 49 patients in the control group still had a positive culture at the end of 21st day of dressing.

Conclusion: In this study, it was perceived that the category receiving topical sucralfate dressing had better wound contraction as compared to the category receiving only conventional treatment Sucralfate helps in wound healing better than conventional dressing for chronic diabetic ulcers and is better even if it is associated with varicose veins.

Keywords: Dressing, Ulcer, Sucralfate, Diabetic Foot, Healing.

Introduction

India is set to be the diabetic capital centre with a projected 109 million individuals with diabetes by 2035. The prevalence of Diabetes in India is 9.6%, and, as of 2020, more than 1.5 million Indians die each year because of diabetes-related causes [1]. Diabetic foot is the most common complication imposing admissions and causing a tremendous medical and financial burden on our health care system. In a lifetime of a diabetic patient, the probability of developing a foot ulcer is 25% [2] .5 It is the main reason for the admission in hospital for diabetic patients (about 30%) and absorbs about 20% of the total healthcare cost, more than all other diabetic complications [3]. Diabetic ulcers, particularly non-healing types, are the common surgical issue and continues to be enigmatic challenge even in this era of deciphering genetic code.

Diabetic ulcers are chronic ulcers in the inflammatory phase and have cessation of epidermal growth factors that may lead to prolonged time for healing. The standard treatment for diabetic ulcers includes debridement of necrotic tissue, infective control, local ulcer care, mechanical offloading, management of blood glucose levels, and education on wound care. As the recurrence rate and non-healing remains high, many other modalities have been tried in recent times, including negative pressure therapy, antimicrobial dressings, and multistage surgeries. The procedures often termed "advanced wound care therapies" includes debridements, reconstructions with skin grafting, rotational flapor free flap [1]. Such modalities are associated with further morbidities of the donor site, risk and side effects of pharmacological agents and antibiotic resistance.

To treat a simple and complex diabetic foot ulcer in low-Income countries like India, it can be equivalent to 5.8 years of average annual income [4]. Sucralfate, primarily used for the treatment of ulcers in the mucosa of the stomach and ulcers of the small intestine. Sucralfate induces proliferation of dermal fibroblasts and keratinocytes, enhances prostaglandin e2 synthesis in basal keratinocytes, enhances interleukin-1 stimulated interleukin-6 release from fibroblasts and neovasculrisation. Studies have proven that topical Sucralfate promotes healing of decubitus ulcers, venous stasis ulcers, traumatic wounds, and trophic ulcers lesion.In recent times, sucralfate dressing has become a successful treatment and is cost-effective and affordable for the patient in developing countries like India [5].

Our study aims to compare the efficacy of topical sucralfate with that of a conventional dressing in the management of chronic diabetic ulcers. The effectiveness of management of chronic diabetic ulcers was assessed, in terms of the number of days required for healing, role of reduction in surface area of ulcer and by comparing the bacterial load before and after the sucralfate dressing using culture and sensitivity report.

Methodology

This is a prospective randomized interventional study conducted on all the patients satisfying the inclusion criteria, admitted to the Department of general surgery. Total 100 cases were studied .Out of which 50 cases were treated with conventional dressing and 50 cases treated with sucralfate dressing. Lottery method was used for sampling. No topical antibiotics were used and off-loading of pressure from the affected area was done

in both groups. We obtained samples for culture and sensitivity on the day of admission and again at the end of 21st day in both groups and compared.

Inclusion Criteria:

- Patient between 12 and 75 years of age.
- Duration of the ulcer more than 4 week.
- The size of ulcer less than 15 x 15 cm.
- Patient giving consent for topical sucralfate therapy.

Exclusion Criteria:

- Patients with peripheral vascular disease.
- Patients who are Immunocompromised.
- Associated with septicemia and osteomyelitis.
- Skin Malignancies.
- Exposed bones and Charcot Joint.
- Diabetic foot grade 4 and 5 (as defined by Wagner's classification).

On conventional dressing, normal saline was used to clean the ulcer and soaked gauze piece was kept over the ulcer followed by covering with pad and roller bandage. In Study Group the ulcer was cleaned with normal saline, a single one gram sucralfate tablet was crushed and powdered and placed in sterile normal saline to form a suspension. Sterile Gauze was soaked in the suspension and placed over the wound at 20mg/sq.cm TBSA. The dressings will be changed everyday morning in both control and study groups. Appearance of granulation tissue will be observed and final area will be measured on 21st day by planimetry using a transparent graph sheet and subjected to statistical analysis. At the end of 21 days the wounds in both the groups will be inspected and the wounds will be compared based on rate of granulation tissue formation, Present dimension and surface area of the ulcer.

We have applied the following formula to calculate the % reduction in area of wound after 21 days period in both cases and control groups.

Rate of contraction of wound after 21 days of treatment = (Initial area – Final Area) X 100

The analysis and Interpretation of this study was based on the data collection by using group. Descriptive and inferential statistics were used to compare the results. The data were compared into excel sheets and analyzed by using STATA14.1. A probability of less than 0.05 was considered as significant.

Figure1: Conventional dressing(day 0 and day 21)

Figure 2: Sucralfate dressing (day 0 and day 21)

Results

In the present study we have taken 100 patients suffering from diabetic footulcers (>4 weeks). Patients were taken up for study based on inclusion and exclusion criteria. Out of 100 patients, 50 (24 males, 26 females) were study cases and 50 (18 males and 32 females) were control. The mean age in the study group was 64.04 years and, in the controlgroup was 58.03 years.

The mean FBS levels (table1), site of ulcer (table2), onset of ulcer (table 3) and associated with varicose veins (table 4) on admission were charted and compared.

Table 1: Comparison of fbs factors between dressing

Group	F.B.S.		P-value
	Mean	Standard deviation	
Normal	137.1	6.4	0.0419*
Sucralfate	156.9	7.2	

*P<0.05 Statistically significant

Table 2: Distribution of study subjects according to site of ulcer

SITE	Group N=100				P-value
	Normal		Sucralfate		
	N=50	%	N=50	%	
Dorsum of foot	16	32%	16	32%	0.777
Lateral malleoli	3	6%	3	6%	
Median malleoli	5	10%	8	16%	
Plantar aspect	25	50%	23	46%	
Sole of foot	1	2%	0	0%	
Total count	50	100%	50	100%	

Table 3: Association of ONSET between the groups

ONSET	Group N=100				P-value
	Normal		Sucralfate		
	N=50	%	N=50	%	
Spontaneous	30	60%	32	64.0%	0.680
Traumatic	20	40%	18	36.0%	
Total	50	100%	50	100%	

Table 4: Association of varicose veins between the groups

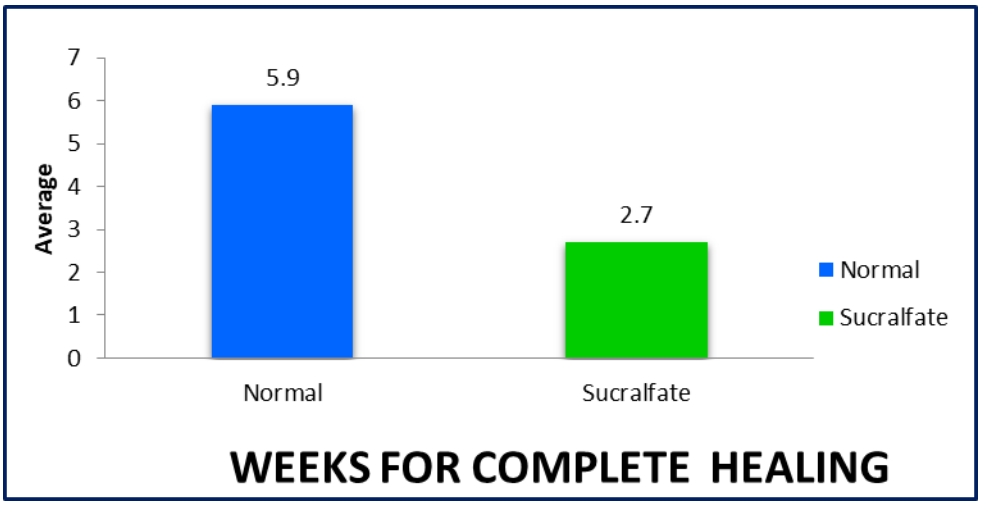
Comorbidity	Group N=100				P-value
	Normal		Sucralfate		
	N=50	%	N=50	%	
Only Diabetes	48	96%	42	84%	0.046*
Associated with Varicose veins	2	4%	8	16%	
Total	50	100%	50	100%	

All 100 patients selected and grouped as study and control complied for the 21 days period of treatment. The initial area measurement of ulcer was taken on day 01 and final area measurement on day 21 was taken on transparent sheet. The area of reduction (table5) and weeks taken for complete healing (table 6) in each group are compared.

Table 5: Comparison of area of reduction between dressing

Group	Area of Reduction		P-value
	Mean	Standard deviation	
Normal	17.9	12.7	<0.0001*
Sucralfate	42.3	7.5	

*P<0.05 Statistically significant



Graph 1: Weeks for complete healing

In our study the culture and sensitivity of the ulcers before the commencement of sucralfate dressings were positive for many microorganisms. In the study group 18 were positive for Staph. aureus, 7 patients for Proteus mirabilis, 6 for Pseudomonas aeroginosa, 1 patient showed E. Coli and 18 of them did not show any growth. In the control group 17 of them were positive for Staph.aureus,12 of them for Proteus mirabilis, 4 for Pseudomonas aeroginosa, 6 for Klebsiella Pneumoniae and 2 of them for E. Coli and 9 patients did not show any growth. After sucralfate dressings were given, culture obtained on the 21st day surprisingly showed negative culture in 46 patients in the study group, whereas 49 patients in the control group still had a positive culture.

Discussion

A diabetic foot ulcer is one of the most common complications in diabetic patients. Successful dressing of diabetic foot ulcers is challenging and associated with unpredictable outcome. The objective of an ideal dressing which is every surgeon's desire, is to promote ulcer healing without any complications [2]. In recent times, sucralfate dressing has also

come to the forefront as a successful treatment option.

In the present study it was seen that the incidence of diabetic ulcers was more in males (42%) as compared to females (58%). This was observed in a study conducted by john amalan [6], Preethisp [7]. Whereas in this study and studies conducted by Gogineni Mahesh, the incidence was more in female patients [8]. The mean age group in the study group with diabetic ulcers were 59 years and in the control group were 62 years. The older the patient, the more chances of having a diabetic foot ulcer. There is a 2 to 4 folds risk of ulceration and amputation with the progression of age and duration of diabetes. The mean FBS value in the test group was 137.1, and the mean FBS value in the control group was 156.9. Diabetic foot are not only a manifestation of neurogenic and atherosclerotic long- term effects of diabetes but could also be the direct effect of hyperglycemia.

In this study, 27.00% of the ulcers were traumatic in origin, trauma being the triggering factor secondary to neuropathy. 73.00% were spontaneous in origin secondary to blister rupture or unnoticed trivial trauma. This clearly shows that diabetic patients were more prone to develop spontaneous ulcers than traumatic ulcers. This study found that diabetic foot more commonly occurs on the foot's plantar aspect (46%) than the foot's dorsum aspect (32%). Study conducted by Edmonds et al in 1986, (Edmonds) showed more foot ulcers were on plantar and fore foot areas. Most of the diabetic foot ulcers are invariably shoe related and due to gait abnormalities. They can be prevented by appropriate sized footwear. However in our study the incidence of ulcers over the plantar aspect of the foot were not as high as postulated by Edmonds et al [9].

Study group had better area of reduction of 42.3% (S.D: 7.5) as compared to the control group, the mean area of reduction was 17.9% (S.D ;12.7). These were found to be statistically significant on independent sample T test ($p<0.0001$). The mean time taken for complete healing of the ulcers were 2.7 weeks in the study group as compared to 5.9 weeks in the control group. Diabetic ulcers are chronic wounds, stuck in inflammation phase and shows cessation of epidermal growth. Sucralfate actions are, increase the blood flow to the tissues and vasculature integrity, thereby leading to quick repairing of superficial defects. Sucralfate stimulates angiogenesis, epithelization and formation of granulation tissue by binding to FGF and EGF2.Shorter duration of hospital stay was observed in the topical Sucralfate dressing group [10].

In a study group out of 50 patients, 8 patients along with chronic diabetic foot ulcers, also had varicose veins, but the area of wound reduction is the same as that of the diabetic patients, it also suggests that sucralfate action of wound healing in chronic diabetic ulcers is better even if it is associated with varicose veins. Considerable effect on bacterial load was seen with the topical Sucralfate compared to conventional dressing group. This may account for the antimicrobial activity of Sucralfate. [11]

Conclusion

This study emphasizes that topical sucralfate is an effective modality to facilitate wound contraction compared to conventional dressing in patients suffering from chronic diabetic foot ulcers and can be used as an adjunct to conventional treatment for chronic diabetic foot ulcers. The limitation of our study is it was institution-based; a multicentric trial can provide better results. Large sample size can increase the potential of the study by increasing the sample size.

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