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THE EFFECT OF SUCRALFATE DRESSING IN DIABETIC FOOT ULCER PATIENTS.

General Surgery

Dr. Malluru Srividya* PG student (3rd Year), Department of Surgery, Dr.D.Y. Patil Medical College, Hospital &Research Institute, Kolhapur. *Corresponding Author

Dr. Rekha Khyalappa Professor, Department of Surgery, Dr.D.Y.Patil Medical College, Hospital &Research Institute, Kolhapur.

ABSTRACT

Introduction-Diabetic foot ulcers are most commonly occurring complication in patients of diabetes mellitus who have poor glycaemic control. It's also the common cause for osteomyelitis of foot, amputation of lower extremities. About 60% of patients develop neuropathy eventually leads to formation of foot ulcers. Staphylococcus is common infective organism which cause ulcers over the foot. **Objective-**To study efficacy of topical Sucralfate in healing of diabetic ulcer, in terms of number of days needed for healing, rate of reduction in mean ulcer surface area. Also, to assess the bacterial load by culture & sensitivity of wound swabs before and after application of Sucralfate and conventional dressing. **Methodology-**The present prospective study was conducted at Dr. D.Y. Patil Medical College Hospital Research Institute, Kolhapur. A total of 30 patients from OPD & IPD with diabetic foot ulcers of Wagner grade- I&II having size less than 15x15cm were included in study. All patients were evaluated and investigated by a standard protocol for the management of the ulcer. The dressings were changed everyday morning in both groups for 6-weeks and appearance of the healthy granulation tissue is observed daily. The final area is measured on 43rd day by planimetry using a transparent graph sheet and subjected to statistical analysis. **Result-**Sucralfate on daily application to wounds increases thickness of granulation tissue and promotes rapid epithelialization of second-degree burns. An ideal dressing that promotes chronic ulcer healing without any complications. **Conclusions-**The results of the study showed significant effect in area of reduction, negative culture rate and weeks for recovery are seen in study group, suggesting that topical Sucralfate dressing can effectively increase the wound healing in diabetic foot ulcer compared to conventional dressing.

KEYWORDS

Diabetes, foot ulcer, wound, Sucralfate, dressing

INTRODUCTION-

Worldwide Diabetic Foot Ulcer (DFU) is severe public health problem that is affecting 9.1 to 26.1 Million people with Diabetes. According to International Diabetes Federation (IDF), India is second largest country consisting of diabetic patients (69.1 Million) with an overall prevalence of 9.3%, among which 15% of patients suffer from DFU during their lifetime.[1-5] Major Multifaceted complications are associated with Diabetes which include Retinopathy, Neuropathy, Atherosclerosis, Nephropathy and foot ulcers. These complications are outcomes of defect in the vascular system leading to inappropriate circulation. This exposes the foot to higher risk of all the complications of diabetes.[7,8] About 85% of lower extremity amputations are preceded by non-healing foot ulcers. DFU particularly non-healing types are one of the most frequently encountered common surgical problems which cause more hospital admissions than any other long-term complications of diabetes and results in increased morbidity and mortality.[9-11]

According to National Institute for Health and Clinical Excellence (NICE) strategies, early effective organization of diabetic foot ulcer can reduce the severity of problems such as preventable amputations and possible mortality, and improve overall quality of life. The management of DFU involves Blood Sugar control, wound debridement, advanced dressings, offloading modalities. Surgery to heal Chronic Ulcers and prevention of reappearance should be considered a vital component of management in some cases. Hyperbaric Oxygen Therapy, Electrical stimulation, Negative pressure wound therapy(NPWT), Bio-Engineered skin and growth factors could be used as adjunct therapies for the rapid healing of DFU. Among all modalities of management of DFU Wound care and management are very important. Treatment of a DFU require proper Wound care and appropriate Antibiotic therapy. The essentials of good clinical care include regular debridement, offloading, moist wound care, treatment of infection and revascularization of the ischemic limb. In addition, wound healing can be enhanced by the appropriate choice of topical therapy (a mixed range of standard and advanced topical therapies). Many factors including assessment of the wound, its classification and need for debridement including sharp surgical, mechanical, and chemical, etc., must be taken into consideration before proceeding with the appropriate selection of topical regimen.[14,15] Various topical agents such as Sucralfate dressing, Mupirocin dressing, Haemocoagulase dressing, Oxum solution,etc., have been used for DFU. Among all, Sucralfate is one of the economical and abundant methods of dressing used for DFU. It illustrates potential effectiveness in healing of skin wounds. Sucralfate induces proliferation of dermal fibroblasts & keratinocytes. Also enhances prostaglandin E2 synthesis in basal keratinocytes and enhances interleukin-1-stimulated interleukin-6 release from fibroblasts. Sucralfate increases the thickness of granulation tissue on daily application. A series of studies have shown that the application of Sucralfate to wound enhances the wound repair process. Sucralfate has been demonstrated in preclinical studies to promote granulation tissue formation and thus, promote cutaneous ulcer healing. Effective wound dressing should keep the wound moist and free from complications like Infection, Maceration and Allergy.[5,16-18] Hence, this study was conducted to compare the efficacy of topical Sucralfate and Conventional dressing in the healing of DFU.

MATERIALS AND METHODS-

The present randomized prospective study was performed at Dr. D.Y. Patil Hospital and Research Centre, Kolhapur from December 2020-2022 after institutional ethical approval. A total of 30 patients from OPD & IPD with DFU of Wagner grade-I&II having size less than 15x15cm were included in the study. Whereas, patients receiving other modalities of wound dressing and those who are already amputated to a certain level of limb, pulseless limb, immunocompromised patients, associated with Septicaemia, Osteomyelitis, Skin Malignancies and Diabetic Ketoacidosis were excluded from the study.

The evaluation and assessment of patients receiving sucralfate dressing was done regularly and progress was documented. All the patients were assessed and investigated by standard protocol for management of the Ulcer. The investigations done were-Routine laboratory investigations, Renal parameters, Vascular and Venous studies, Liver Function tests, Lipid Profile, Diabetic Profile and other radiological studies as indicated. The ulcer was evaluated by the Wagner grading system. The planimetry was performed on day one and at subsequent one-week interval (the maximum length, width and depth will be measured in centimeter). Pus culture and sensitivity was sent before any dressing being applied and then after three weeks. After sending the culture sample a broad spectrum antibiotic was started as per hospital antibiotic policy and it was changed according to sensitivity report. For every patient wound dressing protocol was followed. Strict aseptic precautions were taken every time when the wound dressing was done. At the end of the study period of six weeks, the patient was categorized according to status of Healing parameters.

Complete Improvement – complete healing of an ulcer.

Significant Improvement – healing with reduction of more than 50%

of ulcer dimension.

Partial Improvement – healing with reduction of up to 50% of ulcer dimension.

No Improvement – no reduction in ulcer area (or) increase in dimension (or) any other ablative measure required.

The results were tabulated, analysed, presented and discussed after compilation of the data.

Wagner's Ulcer Grade System:
Grade-I: Superficial ulcers
Grade-II: Deep ulcers up to subcutaneous tissue exposing soft tissue or bone
Grade-III: Abscess formation underneath/osteomyelitis.
Grade-IV: Gangrene of part of tissue/limb/foot.

RESULTS:

FBS:
Mean FBS in was found to be 156.96mg/dl. There was no correlation between the area of reduction and FBS(P=0.136)

Onset:
23 subjects (93%) are spontaneous onset & 7 subjects (7%) are traumatic onset.

Site
8 subjects (26.66%) had ulcers on the dorsal surface of the forefoot, 17 subjects (56.66%) on plantar surface, 3 (10%) on Medial malleoli, and 2 (6.66%) on lateral malleoli (Table-1).

Table-1. Site Of The Ulcer

Site	Dorsal surface (n)	Plantar (n)	Medial malleoli (n)	Lateral malleoli (n)
	8	17	3	2

Culture test
The culture test showed negative culture in 27 (97%) patients.

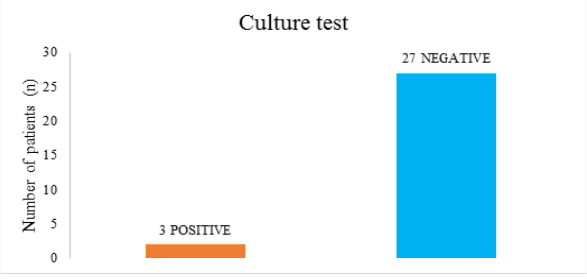

Figure 2: Culture Test

Area Of Reduction
Study shows significant area of reduction of 41.97±7.41%

Table-3.1 Area Of Reduction

Area of reduction	Mean (%)	S. D.	P value
	41.97	8.41	<0.0001

Area Of Reduction According To Site:
Area of reduction when assessed with respect to site, a significant improvement in the area of reduction was observed in dorsal (43.62±9.49%), plantar (40.75±5.63%), and medial malleoli (42.71± 9.62%) site Dorsal, plantar and medial malleoli (P<0.0001) (Table-3.2).

Table-3.2 Area Of Reduction According To Site

Area of reduction			P value
Site	Mean (%)	S.D.	
Dorsal	43.62	9.49	<0.0001
plantar	40.75	5.63	<0.0001
Medial malleoli	42.71	9.62	<0.0001
Lateral malleoli	42.5	3.63	0.003

Weeks for recovery:
The mean time taken for complete healing of the ulcers was 2.68±0.47weeks (P<0.0001) (Table-4).

Table-4. Weeks Required For Recovery

Mean (weeks)	S.D.	P value
2.68	0.47	<0.0001

DISCUSSION

This study is aimed to study the efficacy of Sucralfate dressing for the treatment of DFU. Statistically significant findings of the study were, the area of reduction was significant in Sucralfate dressing co. Moreover, culture-positive rates decreased with Sucralfate dressing. These findings suggested that Efficacy of Sucralfate dressing in DFU is better.

When the site of a foot ulcer is observed, it showed a higher percentage of ulcers at the plantar surface(56.66%).[20] A close observation of the localization of lesions discovered that calluses developed at zones of high pressure and is reliable to previous reports.[22] Patients with Diabetes and Peripheral Neuropathy are at higher risk of plantar ulcers due to excessive localized pressures. Higher peak pressure has been related to a higher risk of ulceration in the forefoot.[23] In this study the culture and sensitivity of the ulcers before the beginning of Sucralfate dressings were positive for many microorganisms.

Sucralfate on daily application to wounds increases the thickness of granulation tissue and promotes rapid epithelialization of second-degree burns.[19,20] Sucralfate has been shown in preclinical experiments to increase the synthesis of granulation tissue, which helps in the healing of cutaneous ulcers as evidenced by the results of this study reporting healing in 2.68±0.47 weeks by Sucralfate. [20]. Sucralfate dressing was found to be less expensive and easily applicable.

CONCLUSION

The study was conducted to evaluate the effect of Sucralfate dressing in DFU patients. We conclude that the DFU was more predominant in males than females. The results of Sucralfate dressing showed significant effect in area of reduction, negative culture rate and weeks for recovery which suggest that topical Sucralfate dressing can effectively increase the wound healing in diabetic foot ulcers.

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