

Clinical Study of Comparison Between Efficacy of Topical Sucralfate and Conventional Dressing in the Management of Diabetic Ulcer

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Abstract

Introduction: In this millennium where man has succeeded in deciphering human genetic code, the issue of management chronic wound continues an enigmatic challenge. Diabetic ulcers, particularly non-healing types, are one of the most common surgical issues. From time, immemorial doctors are trying different methods to treat this kind of ulcers. The difficulty in a chronic ulcer is its refusal to heal, whatever management given, especially diabetic ulcers.

Aim: To compare the efficacy of topical sucralfate with that of a control group using conventional dressings, in the healing of diabetic ulcers.

Materials and Methods: A total of 100 patients with diabetic foot ulcer participated in the present study. After undergoing a detailed clinical examination, and relevant investigations, the initial wound area was recorded after sharp debridement by measuring length x width (ulcer should be <15 cm x 15 cm). Both groups were subjected to once daily dressings. The patients were followed up on a daily basis for 3 weeks in both groups.

Results: In our study, it was observed that participants receiving sucralfate dressing had a better area of reduction of 41.97% (standard deviation [SD]: 7.41) as compared to the control group receiving only conventional dressing (normal saline dressing) in whom the mean area of reduction was 18.37 (SD: 13.43).

Conclusion: Sucralfate dressing is an effective modality to facilitate area of reduction of wound in patients suffering from diabetic foot ulcers and can be used as an adjunct to conventional mode of treatment (conventional dressings and debridement) for faster and better healing of diabetic ulcers.

Key words: Culture and sensitivity, Diabetic ulcer, Sucralfate dressing

INTRODUCTION

In this millennium where man has succeeded in deciphering the human genetic code, the issue of management chronic wound continues an enigmatic challenge. Diabetic ulcers,¹ particularly non-healing types, are one of the most common surgical issues. From time, immemorial doctors

are trying different methods to treat these kinds of ulcers. The difficulty in a chronic ulcer, is its refusal to heal,² whatever management given, especially diabetic ulcers. The notion that ulcers should be kept dry, although still held by a considerable number of clinicians, is steadily losing ground. We now know that ulcers re-epithelialize³ much faster or develop granulation tissue faster when treated with dressings which allow moist wound healing.⁴ We recognize that occluding ulcers does not lead to infection. An ulcer care revolution is currently in the making. Many techniques have been tried over the centuries to heal diabetic leg ulcers. Although wound dressings have been used for at least two millennia, there exists no ideal dressing. Surgical dressing of wounds depends on tradition, training, and the surgeons

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own philosophy. During the past 2½ decades, a wide range of innovative dressings has been introduced. People have tried various non-conventional topical therapies in wound healing, such as *Aloe vera*, benzoyl peroxide, collagen,^{5,6} gentian violet, impregnated gauze, topical phenytoin, mercurochrome, oxygen therapy,⁷ sugar, and vinegar. Studies have also proven that topical sucralfate promotes healing of decubitus ulcers, venous stasis ulcers,⁸ traumatic wounds, burns, trophic ulcers and was seen to be superior management of diabetic ulcers.

Aim

To compare the efficacy of topical sucralfate with that of a control group using conventional dressings, in the healing of diabetic ulcers.

MATERIALS AND METHODS

This prospective study was conducted in Department of Surgery, Tirunelveli Medical College Hospital, Tirunelveli. Patients with long-standing diabetic ulcers (>2 weeks) were included, 50 patients in the study group, 50 patients in control group were randomly allocated.

Inclusion Criteria

Patients between 12 and 75 years of age, duration of the diabetic ulcer more than 2 weeks, the size of ulcer <15 cm × 15 cm, patients giving consent for topical sucralfate therapy.

Exclusion Criteria

Pulseless limb, immunocompromised patients, associated septicemia and osteomyelitis, skin malignancies, diabetic ketoacidosis, exposed bones, tendon, and charcot joint. Of 100 patients, 50 took treatment in the form of conventional normal saline dressings, and 50 took treatment with sucralfate dressing. Off-loading of pressure from the affected area and no antibiotics were used in both groups. Photographs of the ulcers before and after the dressings were taken, along with culture and sensitivity of the ulcers before and after the dressings. After undergoing a detailed clinical examination, and relevant investigations, the initial wound area was recorded after sharp debridement by measuring length x width (ulcer should be <15 cm × 15 cm). Both groups were subjected to once daily dressings. The patients were followed up on a daily basis for 3 weeks in both groups. The outcome that is the area of the target ulcer was measured by planimetry using a transparent graph sheet. Results were calculated using Student's test.

RESULTS

The mean age in the study group was 58.88 years and in the control group was 62.28 years (Table 1).

Incidences of diabetic ulcers were more in males (57.00%) as compared to females (43.00%) (Table 2).

In this study, 27.00% of the ulcers were traumatic in origin. 73.00% were spontaneous in origin (Table 3).

30.00% of the patients had an ulcer on the dorsal surface of the forefoot, and 13.00% had ulcers on the medial malleoli. About 51.00% on the plantar aspect and about 6.00% on the lateral malleoli (Tables 4 and 5).

Negative culture in 46 patients in the study group whereas 49 patients in the control group still had a positive culture.

Diabetic ulcers in the study group had better mean percentage reduction of area 41.97% (standard deviation [SD]: 7.41) as compared to the control group which had mean percentage reduction of area was 18.37% (SD: 13.43) the difference in the mean 23.6% of reduction of area of the two groups where studied using independent sample T-test was found to be significant ($P < 0.0001$) (Table 6).

Table 1: Age distribution

| Age | Mean±SD |
|---------|-------------|
| Control | 62.28±6.94 |
| Study | 58.88±10.18 |

SD: Standard deviation

Table 2: Gender distributions

| Gender | Male | Female |
|---------|------|--------|
| Control | 31 | 19 |
| Study | 26 | 24 |

Table 3: Onset

| Onset | Spontaneous | Traumatic |
|---------|-------------|-----------|
| Control | 40 | 10 |
| Study | 33 | 17 |

Table 4: Area of reduction

| Onset | Mean±SD | | <i>P</i> value |
|-------------|-------------|------------|----------------|
| | Control | Study | |
| Spontaneous | 19.08±14.75 | 41.93±8.35 | <0.0001 |
| Traumatic | 15.54±5.35 | 42.05±5.33 | <0.0001 |

SD: Standard deviation

Table 5: Site

| Site | D | P | MM | LM |
|---------|----|----|----|----|
| Control | 16 | 26 | 5 | 3 |
| Study | 14 | 25 | 8 | 3 |

Table 6: Area of reduction

| Area of reduction | Mean±SD | P value |
|-------------------|-------------|---------|
| Control | 18.37±13.43 | <0.0001 |
| Study | 41.97±7.41 | |

SD: Standard deviation

Table 7: Weeks for recovery

| Weeks | Mean±SD | P value |
|---------|-----------|---------|
| Control | 5.36±0.59 | <0.0001 |
| Study | 2.68±0.47 | |

SD: Standard deviation

The mean time taken for complete healing of the ulcers was 2.68 weeks in the study group as compared to 5.36 weeks in the control group (Table 7).

DISCUSSION

Sucralfate,⁹ an oral gastrointestinal medication primarily indicated for the treatment of active duodenal ulcers, is also used for the treating gastroesophageal reflux disease and stress ulcers. It shows potential utility in the reduction healing of skin wounds. Sucralfate induces proliferation of dermal fibroblasts and keratinocytes. It also enhances prostaglandin E2 synthesis in basal keratinocytes, enhances interleukin-1-stimulated interleukin-6 release from fibroblasts.¹⁰⁻¹² When applied to full-thickness wounds daily, sucralfate increased the thickness of granulation tissue. It also promotes rapid epithelialization of 2nd degree burns. A series of studies has shown that application of sucralfate to a wound enhances the wound repair process. Sucralfate has been demonstrated in preclinical studies to promote the granulation tissue formation and thus, promoting cutaneous ulcer healing.¹³ An ideal dressing is every surgeon's desire, a dressing that promotes chronic ulcer healing without any complications. Successful wound dressing should keep the wound moist and be devoid of any adverse reactions such as infection, maceration, and allergy.

CONCLUSION

The wounds in participants treated with sucralfate dressing contracted more than wounds in the control group (41.97% vs. 18.37%; $P \leq 0.0001$ significant) which indicates sucralfate dressing is an effective modality to facilitate area of reduction of wound in patients suffering from diabetic foot ulcers and can be used as an adjunct to conventional mode of treatment (conventional dressings and debridement) for faster and better healing of diabetic ulcers.

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