

COMPARATIVE STUDY OF THE OUTCOME OF ANTIBIOTIC COATED COLLAGEN GRANULES VS ANTIBIOTIC DRESSING IN CHRONIC ULCERS

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Abstract

Background: Chronic non-healing leg ulcers are a major health problem worldwide and greatly impact the people at personal, professional and social levels. The present study compared the outcome of antibiotic-coated collagen granules' outcome vs conventional antibiotic dressing in chronic ulcers. **Materials and Methods:** The prospective randomized cross-sectional study was conducted on 60 patients with more than six weeks of ulcers. The study was carried out from May 2018 to May 2019. Patients were categorised into two groups. Group A (collagen granule dressing) and group B (conventional antibiotic dressing or control group), each with 30 patients. The wound surface area was measured before and after the application of both dressings. Wounds were assessed in all patients before and after each dressing for a reduction in surface area, the duration between the first debridement and skin cover with grafting (SSG), the need for skin grafting in small wounds, and education duration of hospital stays. **Results:** Male predominance was observed in both groups of patients. In group A, a maximum of patients, 10 (33.33%), were in the age group of 51 to 60 years, whereas in group B majority, 11(36.66%), were in the age group of more than 60 years. There was a significant ($p<0.05$) decrease in mean wound surface area before and after dressing for group A patients. The Group A patients with collagen granules dressing showed a significant decrease ($p<0.001$) in mean hospital stay, no of wound dressing, and mean difference between the duration of the first dressing and SSG application than in group B patients. **Conclusions:** We found collagen granule dressing significantly impacts chronic ulcers' outcome (healing).

INTRODUCTION

Skin and subcutaneous tissue loss on the leg or foot that takes longer than six weeks to cure is a chronic non-healing leg ulcer. The lower leg, especially the foot, is frequently affected by chronic ulceration, which is common, painful, uncomfortable in social settings, and expensive.^[1] It is widely established that the prevalence of leg ulcers ranges from 0.18 to 1%.² Diabetic, venous, arterial, and neuropathic conditions are the main causes of ulcers in the lower extremities.^[2]

Chronic wounds are characterised by a protracted inflammatory phase preventing regenerative wound healing. Persistent wounds provide a severe health risk, particularly for those with diabetes mellitus (DM). The objective of wound care in chronic ulcers is to promote healing and avoid lower extremity

amputation using standardised wound care procedures.^[3]

Wounds that are difficult to treat include diabetic ulcers, venous ulcers, trophic ulcers, pressure sores and necrotizing fasciitis.^[4] An ideal dressing used in wound management should be economical, easy to apply, and readily available. It will provide good pain relief, protect the wound from infection, promote healing, keep moisture, be elastic, and non-antigenic and adhere well to the wound while waiting for spontaneous epithelisation and healthy granulation tissue.^[5]

Among the newer type of wound dressings - Biological Dressings like Collagen create the most physiological interface between the wound surface and environment and are impervious to bacteria. Collagen, the most abundant protein in the body, plays a critical role in the successful completion of adult wound healing. Its deposition, maturation, and

subsequent remodelling are essential to the functional integrity of the wound.^[6] Collagen granule dressing has a better advantage over conventional dressing in terms of collagen formation, with a greater reduction in inflammatory cells during healing days resulting in decreased days of healing. In contrast, conventional dressing has minimal collagen formation and a high grade of inflammation during the healing days, with maximum exudate formation resulting in increased days of healing.^[7] A collagen granule dressing has another advantage over conventional dressing: non-immunogenic, non-pyrogenic, natural, easy applicant, hypo allergic and pain-free.⁸

Hence the present study was performed to compare the outcome of antibiotic-coated collagen granules dressing with antibiotic dressing in treating chronic ulcers.

MATERIALS AND METHODS

This prospective randomized cross-sectional study was conducted on 60 patients presenting with more than six weeks of ulcers in GRH, Madurai OPD and casualty. The study was carried out from May 2018 to May 2019. Both outpatient and inpatients were diagnosed and included in the study. Patients were categorised into two groups based on collagen application and normal dressing. Institutional ethical committee approval and written consent were taken before the start of the study.

Inclusion Criteria

All non-healing chronic ulcers, including diabetic ulcers, traumatic ulcers, pressure sores, amputation stump ulcers, and post-surgical wound gaping of at least six weeks, were included.

Exclusion Criteria

Patients with Ulcers having bone exposed raw area. Patients with Malignant ulcers, connective tissue disorders, immune system disorders, and ulcers with reduced vascularity. Patients with and. Patients on immunosuppressive drugs, steroids, chemotherapy and radiotherapy and any known allergy to the dressing materials were excluded.

Patients were categorised into group A (collagen granule dressing) and group B (conventional antibiotic dressing or control group), with 30 patients. Complete blood count, renal function tests, serum proteins, pus culture, and sensitivity were

studied. All the patients were started on empirical intravenous antibiotics and changed after obtaining the culture report. One group received collagen granule dressing; the other received the conventional antibiotic dressing with metronidazole and povidone iodine-soaked gauze.

In study group A, collagen granules were applied, and the wound dressing was done after giving a saline wash. In the control group, after giving a thorough wound wash, the antibiotic dressing was done with povidone-iodine and metronidazole. The wound was inspected after three days. The wound surface area was documented before and after applying collagen granules dressing. Wound surface area was measured with the help of a paper with multiple squares, each having a surface area of 1 sq. cm. Wound surface area was noted down in the proforma. Wounds were assessed in all patients before and after each dressing. Parameters such as reduction in surface area of the wound, decreased time duration between the first debridement and skin cover with grafting, decreased need for skin grafting in small wounds, and reduced hospital stays were measured.

The collected data were analysed with IBM SPSS Statistics for Windows. Percentage analysis was used for categorical variables, and the mean & S.D were used for continuous variables to describe the data descriptive statistics frequency analysis. The probability value of 0.05 is considered significant and Y.

RESULTS

The prospective randomized cross-sectional study was conducted on 60 patients presenting with more than six weeks of ulcers in GRH, Madurai OPD and casualty.

Patients were categorised into groups A (study group) and B (control group), each with 30 patients. Male predominance was observed in both groups of patients. In group A, a maximum of 10 patients (33.33%) were reported in the age group of 51 to 60 years, whereas in group B most patients, 11(36.66%), were in the age group of more than 60 years. There was a significant ($p < 0.05$) decrease in mean wound surface area before and after dressing for group A patients, 48.03 cm² to 43.16 cm², respectively [Table 1, Figure 1].

Table 1: Observation of different variables of patients among both groups

Parameters	Observation N (%)		P-value
	Group A (N=30)	Group B (N=30)	
Gender			
Male	24	18	-
Female	4	12	-
Age group (years)			
<40	8	5	-
41-50	7	5	-
51-60	10	9	-
>60	5	11	-
Wound surface area (cm ²) mean ± SD			
Before	48.03±17.31	43.60±12.67	p=0.047

After	43.17±14.97	39.57±13.62	
Hospital stays (days) mean ± SD	32.10±5.52	45.57±7.05	p<0.001
Number of dressings mean ± SD	5.40±0.86	8.20±1.77	p<0.001
Difference between the duration of first dressing and SSG application. mean ± SD	22.23±3.49	36.13±6.79	p<0.001

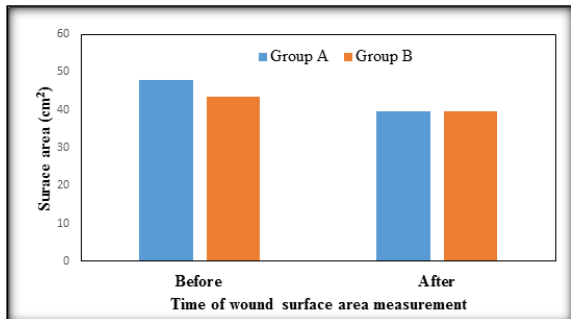


Figure 1: Observation of mean wound surface area before and after dressing in both groups

There was a significant ($p<0.05$) reduction in the duration of mean hospital stay observed among the case group (group A) who received the collagen dressing than the control group. The mean hospital stays for the case group was 32.10 days, and among the control group, it was 45.57 days. The mean number of wound dressings was also found to be significantly ($p<0.001$) less in group A patients (5.4 ± 0.86) than in group B patients (8.2 ± 1.77). The mean difference between the duration of the first dressing and split-thickness skin graft (SSG) application was also reported significantly ($p<0.001$) less in group A (22.23 ± 3.49) than in group B patients (36.13 ± 6.79) [Table 1].

DISCUSSION

Male predominance was observed in both groups of patients. In group A, a maximum of patients, 10 (33.33%), were reported in the age group of 51 to 60 years, whereas in group B, most patients, 11 (36.66%), were in the age group of more than 60 years. Jaiswal et al., in 2006 in their study showed a similar male: female ratio. Males are more involved in physical work and labour. In the present study, the mean wound surface area reduction in the study group was significantly higher than in the control group.^[9] In a study by Driver et al., the mean difference in the decrease in wound size was $43.16\pm 15.16\%$ in the experimental group, whereas in the control group, it was $2.28\pm 2.54\%$.^[10]

Collagen dressing group patients also showed a significant reduction in the mean duration of hospital stay, the mean number of wound dressings and the mean difference between the duration of the first dressing and SSG. Jegoda et al. also reported a similar finding in their investigations. Collagen dressings have very good results in our study.^[11] Collagen favours the outcome because of increased defence mechanisms by stimulating and

differentiation of early and late granulocytes, erythroid and megakaryocyte precursor cells. Side effects of collagen are generally infrequent and mild and can be well tolerated by the patients.^[12]

Due to several potential stimuli (local tissue ischemia, bioburden, and necrotic tissue), wounds can stall the inflammatory phase, contributing to the chronicity of the wound. One key component of chronic wounds is elevated matrix metalloproteinases (MMP); at elevated levels, MMPs degrade nonviable collagen and feed on viable collagen.⁸ In addition, fibroblasts in a chronic wound may not secrete tissue inhibitors of MMPs at an adequate level to control the activity of MMPs. These events prevent the formation of the scaffold needed for cell migration and ultimately prevent the formation of the extracellular matrix and granulation tissue.^[13]

Collagen granules act as a sacrificial substrate for MMPs, and MMPs will act upon it. Collagen breakdown products are chemotactic for various cell types required to form granulation tissue. It can absorb wound exudates and maintain a moist wound environment. Since it contains antibiotics that will counteract the micro-organisms, providing a tissue and vascular growth matrix.^[14]

No doubt today, collagen is a costly affair in our country. Still, if we consider the cost of hospitalization and if we prevent amputation, then this therapy seems to be logical. Hence, collagen can be a good option for chronic non-healing diabetic ulcers. This study has limitations, such as a small cohort and the cost of treatment. More studies in a large cohort are required to confirm our results.

CONCLUSION

The present study concludes that antibiotic-coated collagen granule dressing is more advantageous than conventional. In terms of decreased wound surface area, duration between the first dressing and SSG application, number of dressings required before the application of skin grafting and shorter hospital stay.

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