Original Research Article

A Hospital Based Prospective Study to Evaluate the Effect of Collagen Dressing in Diabetic Foot Ulcer Patients

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Abstract

Background: Diabetic foot is one of the most significant and devastating complications of diabetes and is defined as a foot affected by ulceration that is associated with neuropathy and/or peripheral arterial disease of the lower limb in a patient with diabetes. The aim of this study to estimate the efficacy of Collagen dressing in patients with diabetic foot ulcer.**Materials & Methods:** A hospital based prospective study done on 30 patients with diabetic foot ulcer, who reported at department of general surgery in district hospital Dholpur during two year periods. All diabetic foot ulcer patients, with ulcer size less than 150 sqcm attending the Surgery Department were invited to participate in the study. All patients underwent a standard clinical and laboratory evaluation. Briefly, information about age, known DM duration, smoking habits, arterial blood pressure, and anthropometric measurements were collected. Critically ill patients and patients with underlying bone osteomyelitis or malignancy were excluded. In all patients, wound size was measured before treatment initiation.**Results:** In our study, overall, the chronic leg ulcer was found most commonly in elder age group above 50yrs. A significant reduction in healing was seen in patient presented with infection, with a mean percentage reduction in ulcer size of (45.42 ± 16.67), when compared to (68.56 ± 14.23) in patient who had no infection. P-value was <0.05* which is statistically significant. Pearson correlation test was used to test the correlation between percentage reduction in ulcer size with duration of diabetes, ulcer, antibiotics, hospital stay and duration of healing, all showing negative correlation. **Conclusion:** The use of newer dressings with collagen dressing may increase the wound-healing potentials of these new treatments, and further studies will be required to evaluate the effects of the combined treatments.

Keywords: Diabetic Foot Ulcer, Collagen Dressing, Wound Healing, Infection.

Introduction

Diabetic foot is defined as the presence of infection, ulceration and/or destruction of deep tissues associated with neurologic abnormalities and various degrees of peripheral arterial disease in the lower limb in patients with diabetes. It is estimated that about 5% of all patients with diabetes present with a history of foot ulceration, while the lifetime risk of diabetic patients developing this complication is 15%. The majority (60–80%) of foot ulcers will heal, while 10–15% of them will remain active, and 5–24% of them will finally lead to limb amputation within a period of 6–18 months after the first evaluation. 40–70% of all nontraumatic amputations of the lower limbs occur in patients with diabetes[1]. Furthermore, many studies have reported that foot ulcers precede approximately 85% of all amputations performed in diabetic patients[2].The prevention of diabetic foot is crucial, considering the negative impact on a patient's quality of life and the associated economic burden on the healthcare system.

Collagen components, such as fibroblast and keratinocytes, are a major part of skin development. Collagen may be harvested from living and nonliving bovine, porcine, and equine skin. Once harvested, a native collagen bioscaffold matrix is created that stabilizes the vascular and cellar components, which become incorporated into the wound bed[3]. Cullen et al[4] reported that after using the (oxygenised regenerated cellulose) ORC/collagen dressing, researchers analyzed wound fluid and found a significant decrease in collagenase-like activity; gelatinase, matrix metalloproteinase (MMP)-2, and MMP-9 levels; and increased scavenged free radicals and binding of growth factors. Normal wound healing maintains a balance of extracellular matrix degradation and formation.

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Nonhealing diabetic foot wounds maintain a chronic inflammatory state with lack of extracellular matrix formation[4,5]. Bacteria are believed to play a role in chronic extracellular matrix degradation. Analysis of wound fluid has found increased levels of proteases, inflammatory cytokines, and decreased growth factors.[5] Many gram positive pathogens commonly found in diabetic foot ulcers, such as Staphylococcus aureus, Enterococcus faecalis, and Streptococcus equi, are able to bind to collagen by utilizing collagen-binding adhesins of the microbial surface component recognizing adhesive matrix molecules family[6-8].The aim of this study to estimate the efficacy of Collagen dressing in patients with diabetic foot ulcer.

Materials & Methods

A hospital based prospective study done on 30 patients with diabetic foot ulcer, who reported at department of general surgery in district hospital Dholpur during two year periods. All diabetic foot ulcer patients, with ulcer size less than 150 sqcm attending the Surgery Department were invited to participate in the study. All patients underwent a standard clinical and laboratory evaluation. Briefly, information about age, known DM duration, smoking habits, arterial blood pressure, and anthropometric measurements were collected. Critically ill patients and patients with underlying bone osteomyelitis or malignancy were excluded. In all patients, wound size was measured before treatment initiation.

Methods

A collagen dressing was applied to wound, and all patients were followed as per standard post-application treatment protocol. Patients underwent dressing changes every 3 to 4 days until wound healing or for maximum period of 12 weeks. Changes in wound size was recorded when the dressing was removed; and at 4 and 12 weeks. Healing time, follow up period was noted. All patients were followed up for adverse events.

Statistical Analysis

Statistical analysis was performed with the help of statistical package SPSS (Statistical Package for the Social Sciences) version 21. Pearson

correlation test was used to find the correlation of two continual variables. Significance was defined by P values less than 0.05 using a two-tailed test.

Results

In our study, overall, the chronic leg ulcer was found most commonly in elder age group above 50yrs, with 66.67% in the age group between 51 to 70yrs, 6.66% in >71 yrs and 26.66% in <50 yrs (Table 1). On comparing the ulcer size before and after collagen dressing there was a significant reduction in ulcer size after collagen dressing, with a p value of <0.05*(Table 2).

High incidence of diabetic ulcers was found in males when compared to females, with comparable reduction in ulcer size in both the sexes (Table 3).

In our study, out of 30 patient 21 (70%) had hypertension, and showed a statistically significant lesser percentage reduction in ulcer size (44.62 ± 18.11) as compared to (59.38 ± 14.67) in patients without hypertension, with a p-value of <0.05*. A significant reduction in healing was seen in patient presented with infection, with a mean percentage reduction in ulcer size of (45.42 ± 16.67), when compared to (68.56 ± 14.23) in patient who had no infection. P-value was <0.05* which is statistically significant (Table 3).

In our study 80% of the patients required SSG after collagen dressing. Patient who was not in a need for SSG, had a mean percentage reduction in ulcer size of about 75.17± 6.15 and those who needed SSG had 42.38± 14.23 percent reduction in ulcer size. Patient with adequate glycemic control had statistically significant more percentage reduction in ulcer size (53.42± 17.28) than patient without adequate glycemic control (37.56 ± 12.3), with a p-value of <0.05* (Table 3).

Pearson correlation test was used to test the correlation between percentage reduction in ulcer size with duration of diabetes, ulcer, antibiotics, hospital stay and duration of healing, all showing negative correlation (Table 4).

Table 1: Age distribution

Age	Frequency	Percent
<50	8	26.66%
51-70	20	66.67%
>71	2	6.66%
Total	30	100.0

Table 2: Reduction of ulcer size

	N	Mean	SD	P value
Initial ulcer size	30	52.26	29.17	<0.0001
Final ulcer size	30	28.45	22.43	

Table 3: Characteristics vs percentage reduction

Characteristics	N	Mean	SD	P value
Gender				
Male	20	46.54	18.24	>0.05
Female	10	50.96	15.64	
Hypertension				
No	9	59.38	14.67	<0.05*
Yes	21	44.62	18.11	
Infection				
No	4	68.56	14.23	<0.05*
Yes	26	45.42	16.67	
SSG requirement				
No	6	75.17	6.15	<0.05*
Yes	24	42.38	14.23	
Glycemic control				
No	9	37.56	12.3	<0.05*
Yes	21	53.42	17.28	

Table 4: Pearson Correlation Test

	Percentage reduction of ulcer size		
	Pearson Correlation	Sig. (2-tailed)	N
Duration of DM	-0.714	<0.0001	30
Duration of Ulcer	-0.286	.013	30
Duration of Anitbiotics	-0.523	<0.0001	30
Duration of Hospital stay	-0.36	.002	30
Duration of Healing	-0.862	<0.0001	30
Age group	-0.565	<0.0001	30

Discussion

Wound healing is a complex process that involves the timely expression of numerous growth factors that promote cellular migration and proliferation, production of new connective tissue matrix, and collagen deposition[9,10]. In addition, diabetic foot ulcers are chronic wounds that are stuck in the inflammation phase and show a cessation of epidermal growth or migration over the wound surface[11,12].

There is a clear association between age and chronic leg ulceration. Data suggest that the prevalence of leg ulceration progressively increases with increasing age. In our study, overall, the chronic leg ulcer was found more in older age, with 66.67% in the age group between 51 to 70yrs, 6.66% in >71 yrs and 26.66% in <50 yrs. The finding is in the line with published literature. Studies by Cornwall et al[13]; Callam et al[14]; Baker et al[15]; Baker and Stacey[16]; O'Brien et al[17] reported prevalence estimates in age bands and all show an increase in prevalence with each decade of life.

In our study the mean wound surface area was 52.26 ± 29.17 cm. Extensive debridement, control of infection, adequate off-loading of the ulcerated foot, and lower extremity revascularization when required are the cornerstones of treatment for the ulcer[18-20]. Collagen plays a relevant role in cutaneous tissue repair and

represents a valid therapeutic option when used as a bioactive advanced dressing in chronic wound management. It improves fibroblast deposition in the dermal matrix and stimulates angiogenesis, granulation tissue formation, and re-epithelization[21]. Fibroblasts mainly participate in the biosynthesis of collagen, which acts as a mold, precursor, plastic material, and cementing substance in the wound healing process.

In a study by Veves in 276 patients with diabetic foot ulcer, after 12 weeks of treatment, 51 (37.0%) Promogran'-a collagen/oxidized regenerated cellulose dressing-treated patients had complete wound closure as compared to 39 (28.3%) patients of control group (moistened gauze), but this difference was not statistically significant (P=0.12). In this study, author found an overall benefit of collagen on the rate of wound healing compared with moistened gauze. Donaghue compared the efficacy of a collagen-alginate topical wound dressing with that of regular gauze moistened with normal saline in 75 patients diabetic foot ulcers. The mean percent reduction of the wound area was 80.6% in the collagen-alginate dressing group and 61.1% in the gauze-dressing group. Complete healing was achieved in 48% of the collagen-alginate dressing group and 36% of the gauze-dressing group[22].

The presence of infection affected the healing time and the percentage reduction in ulcer size. Patients who presented with infection, had prolonged hospital stay and duration of antibiotic therapy. In our study, patient who presented with hypertension, had lesser percentage reduction in ulcer size as compared to patients without hypertension. Twenty one patients in our study had adequate glycemic control, and showed a better healing and better reduction in ulcer size when compared with patient who had poor glycemic control. This study shows that there is significant reduction in ulcer size after collagen treatment (p value <0.0001).

Conclusion

The use of newer dressings with collagen dressing may increase the wound-healing potentials of these new treatments, and further studies will be required to evaluate the effects of the combined treatments.

However, despite the limited studies, and the need for improved study designs and increased number of randomized controlled trials, wound dressings containing collagen do appear to have some benefit in the treatment of diabetic foot ulcers and should be carefully considered by clinicians that manage wounds. There has not been sufficient evidence to prove the superiority of a particular collagen biological source or combination. Future work should further consider the inclusion of biofilm activity and the potential enhancement of extracellular targets.

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