



A COMPARATIVE STUDY OF COLLAGEN DRESSING AND CONVENTIONAL DRESSING IN THE TREATMENT OF DIABETIC FOOT ULCER

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ABSTRACT

Background: Diabetic foot ulcer treatment is a challenging health care issue where amputation of lower limbs is common. Though there are various modalities of investigation and treatment available we compared the efficacy of collagen based dressing against conventional dressing in diabetic foot ulcer treatment especially in Indian scenario.

Method: A total of 100 diabetic foot ulcer patients admitted in the department of General Surgery M.K.C.G.MCH, Berhampur from August 2014 to July 2016 divided in two groups namely Collagen and Conventional groups and subjected to collagen sheet and Betadine with gauze respectively. With start of treatment, appearance of granulation tissue, completeness of healing, need for skin grafting, were compared in both groups.

Results: With two weeks of treatment, 56% of the 'collagen group' wounds and only 36% of the 'conventional group' wounds were sterile (P=0.043). Healthy granulation tissue appeared earlier over collagen-dressed wounds than over conventionally treated wounds (P=0.035). After six weeks, 41 (82%) of 'collagen group' wounds and 32 (64%) of 'conventional group' wounds were >75% healed (P=0.042). Nine patients in the 'collagen group' and 18 in the 'conventional group' needed partial split-skin grafting (P=0.04). Collagen-treated patients enjoyed early and more subjective mobility.

Conclusion: Significant better results in terms of completeness of healing of Diabetic foot ulcer is found in collagen dressing. Collagen dressing may avoid the need of skin grafting, and provides additional advantage of patients' compliance and comfort.

KEYWORDS : Diabetic foot ulcers, collagen dressing.

Introduction

The knowledge about Diabetes mellitus is important because of its high prevalence. The prevalence of diabetes constituted chiefly by type2 diabetes (T2D), is a global public health threat. Foot problems in patients with diabetes remain a major public health issue and are the commonest reason for hospitalization of patients with diabetes. The human foot is a remarkable mirror of systemic disease. The American Diabetes Association consensus group identified increased risk in patients with diabetes for >10 years, which are males, having poor glucose control or having cardiovascular, retinal, or renal complications.[1] Diabetics have foot problems secondary to neuropathy and microvascular changes. Diabetics are at increased risk of ulceration and trauma can lead to collapse of foot also known as Charcot neuroarthropathy.[2] Peripheral vascular disease is common among patients with diabetes. American Diabetic association recommends ABI screening every 5 years in patients with diabetes.[3] Among people with diabetes, 15% will experience foot ulcers in their lifetime.[4] New biological dressings like Collagen has many advantages over conventional dressings in terms of nonimmunogenic, nonpyrogenic being natural, easy application, hypoallergic and pain free.[5]

The use of collagen dressing has been to inhibit the action of metalloproteinase that delays wound healing by increasing proteolytic activity and inactivating growth factors.[6] Moreover, it is easy to apply and has the additional advantage of stopping bleeding.[7] Regular surveillance of bacterial profile and their antibiotic susceptibilities should also be a part of overall management strategy of wound care units, so as to guide appropriate antibiotic therapy while the dressings are doing their part.[8]

This study was conducted to compare the wound healing with collagen dressing and conventional dressing with Betadine and gauze.

Materials and methods :

This prospective study was conducted in the Department of general surgery of M.K.C.G. Medical College & Hospital Berhampur from August 2014 to July 2016. The study included all the diabetic foot ulcer patients admitted to the indoor surgical ward after applying inclusion and exclusion criteria.

Exclusion criteria:

1. A condition that may have interfered with wound healing (e.g. carcinoma, connective tissues disease, uncontrolled diabetes

mellitus, chronic liver or renal disease).

2. Current treatment with dialysis, corticosteroids, immunosuppressive agents, radiation therapy, chemotherapy.
3. Known hypersensitivity to any of the dressing components.
4. Those who are not willing to take part in study.

Inclusion criteria:

1. Age of the patient 18 years or above
2. An area of at least 1 cm.
3. Patient with adequate peripheral pulses of limbs.
4. A wound that was debrided of necrotic/ non-viable tissue at enrolment.

Method:

For the sake of analysis the patients were divided into two groups i.e. Group A (Collagen Dressing group) and Group B (Conventional Dressing group). The patients numbered serially from one to hundred in the study group. The patients bearing odd study group serial numbers subjected to Collagen dressing and the patients bearing even study group serial numbers subjected to Conventional dressing.

In both the groups data regarding characteristics of ulcers such as size, edge, floor characteristics, slough, granulation tissue, pathogenic organisms and wound swab or pus culture sensitivity results noted and analysed. Wound swab done every five days interval and also when specifically required. Fasting blood sugar and 2hr PPBS done every three days interval and result noted. Before applying dressing, the affected area thoroughly cleaned for removal of external contamination and infected wound debrided properly. Both groups treated with antibiotics based on pus culture sensitivity reports.

In Group A i.e. "Collagen dressing Group" one or more collagen sheets of appropriate size were selected. Collagen sheets rinsed in NS (normal saline) before application. Sheets applied firmly so as to cover the whole raw area of ulcer with necessary care taken to remove any air bubble.

Dressing was dried before covering it with gauze bandage and tape. The day of first application of collagen dressing taken as day 0. The gauze and bandage removed on day 3 and the collagen sheet observed for soakage. If the collagen sheet fully soaked or if the exudative fluid reached within one inch of edge of collagen sheet then it is replaced with a new one otherwise the sheet is left in place and gauze and bandage reapplied over the sheet. Thereafter the above process

repeated on Day 6, Day 9, and Day 12 and so on up to six weeks or until the collagen sheets peeled off of its own in a dried state resulting in complete wound healing requiring no further wound treatment, whichever was earlier. If the collagen sheets continued to be soaked up upto six weeks, then that was removed and patient subjected to skin grafting of the remaining raw area.

In Group B i.e. “Conventional dressing group” isotonic sodium chloride and liquid povidone iodine moistened gauze applied over wound area and covered with gauze bandage and tapes. The conventional dressings changed every alternate day till the end of study.

The patients in both the groups studied for six weeks. After completion of six weeks, those patients who did not achieve complete wound healing were subjected to split skin grafting.

Response to treatment and patient's outcome were noted in terms of progression of wound healing, granulation tissue formation, changes in edges of wounds and need of skin grafts. Both groups followed till discharge and its results noted. The patient were followed up for three months after discharge and any morbidity or mortality factors recorded.

Results :

Table 1: Age and Sex distribution in Group A and Group B:

		Group A (no of pts)	Group B (no of pts)	P value
Age group (in years)	20-40	12(24%)	8(16%)	0.532
	40-60	28(56 %)	33(66%)	
	>60	10 (20%)	09(22%)	
		Total50 (100%)	Total 50 (100%)	
Sex	M	38(76 %)	34(68%)	0.373
	F	12(24 %)	16(32%)	
		Total50 (100%)	Total50 (100%)	

There is no significant difference in age (P=0.532) and sex (P=0.373) distribution in the experimental study groups. Most patient are male and in the age group 40 to 60 years in both the study groups. No definite relationship or association could be established between age, sex with the duration and severity of the disease and ulcer.

Table 2: Size of ulcer of patients in Group A and Group B:

Size of ulcer in cm ²	Group A (no.of patients)	Group B (no.of patients)	P value
1-5	26(52%)	28(56%)	0.702
6-10	15(30%)	16(32%)	
11-15	9 (18%)	6 (12%)	
	Total 50(100%)	Total 50(100%)	

There is no significant difference in the size of ulcer in patients included in both the groups of study (P=0.732). Most patients having ulcer size in between one to five cm² in both the study groups. The average ulcer size in both the study groups is four cm².

Table-3: Duration of ulcer in Group A and Group B :

Duration of ulcer in days	Group A (no of patients)	Group B (no of patients)	P value
1-10	8 (16%)	12 (24%)	0.289
11-20	32(64%)	33 (66%)	
21-30	10 (20 %)	5 (10 %)	
	Total 50 (100%)	Total 50 (100%)	

There is no significant difference in the duration of ulcers (p=0.289) in both the study groups under comparison. Most ulcers are ten to twenty days old in both the study groups. Eighty to ninety percent patients present before 20 days of onset of ulcer. Average duration of ulcer is 15 days in both collagen and conventional groups. It was observed that larger ulcers were comparatively longer duration in onset in both the study groups.

Table 4 : Overall response to treatment in Group A and Group B :

	Group A (n=50)	Group B (n=50)	P value
Sterile wound swab culture at 2 weeks	28(52%)	18(36%)	0.043+

Sterile wound swab culture at 4 weeks	44(88%)	36(72%)	0.045+
Avg. time for healthy granulation tissue	7 days	15 days	0.035*
Complete ulcer healing at 6 weeks	41(80%)	32(64%)	0.042+
Ulcers that required Split Skin Graft (SSG)	9(20%)	18(36%)	0.042+

* Mann-whitney test
+ Pearson chi-square test

It was found that out of 50 patients of the collagen group, 41(82%) ulcers showed complete closure with collagen dressing in six weeks or lesser time. Collagen sheets in these patients were found almost fully incorporated in the ulcers. The remaining 9(Nine) ulcers achieved less than 75% healing and underwent split-skin grafting (SSG).

In the conventional group, a total of 32 patients (64%) showed complete closure at the end of the sixth week while the remaining were less than 75% closed and thus required SSG. Therefore, a statistically significant (P=0.042) number of collagen-treated ulcers achieved complete healing after six weeks (41 versus 32). Also significantly less (P=0.04) number of collagen-treated ulcers required SSG when compared with conventional dressing group. Diabetic foot ulcers of different patients did not show a similar healing pattern, progression of healing, appearance of granulation tissue etc in both the study groups. Grossly smaller wounds healed faster.

Discussion:

Collagen is a biomaterial that encourages wound healing through deposition and organization of freshly formed fibres and granulation tissue in the wound bed thus creating a good environment for wound healing.[9] Collagen sheets, when applied to a wound, not only promote angiogenesis, but also enhance body's repair mechanisms. [10,11]While acting as a mechanical support these reduce oedema and loss of fluids from the wound site, along with facilitation of migration of fibroblasts into the wound and enhancing the metabolic activity of the granulation tissue.[12,13] Moreover, it is easy to apply and has the additional advantage of stopping bleeding. Other commonly used biological dressings include amniotic membrane and homograft skin.[14] Human amniotic membrane is easy to obtain, has a low price and provides good wound coverage and has distinct advantages compared with other biologic dressings.[15]

Regarding healing of the wounds, in a study done by Veves et al[6] on 276 patients of diabetic foot ulcer divided equally into two groups, 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). We found also significant difference in the number of wounds that achieved complete closure at six weeks of either treatment(P=0.042).

In a similar study done by Onkar et al[5] on 120 patients 60 patients suffering from wounds of varied aetiology given collagen dressing and 60 patients subjected to other dressing materials. They found significant difference in sterile wound swab culture status (P=.03), at 2 weeks and 4weeks (P=.04), average healthy granulation tissue time taken (P=.03), number of patients undergone split skin grafting (P=.04). As in Onkar et al study period of study was eight weeks so the number of patients undergone split skin graft were less as compared to this study where study period is taken six weeks. But the difference in collagen dressing group and conventional dressing group patients undergone split skin grafting in both the studies are significant (p<0.05).

In another study by Harish Raote al[16] regarding collagen dressings versus conventional dressings in wound healing of 100 patients with diabetic foot ulcer. In 75 patients collagen dressing was applied, whereas conventional dressing in 25 patients. On enrollment, the median wound size was 33.5 cm2 in collagen dressing group and 48 cm2 in conventional dressing group. Healing time (4.02 ± 0.59 Vs 7.6 ± 1.38), duration of antibiotic therapy (15.12±4.55 Vs 24.08± 6.5) and mean follow up period (2.40 ± 0.61 Vs 2.96 ± 1.2) were significantly less in collagen dressing group as compared to conventional dressing group (P<0.001). No adverse event was reported in both the groups. Collagen dressing is safe and effective in the treatment of foot ulcer

and significantly reduces healing time, duration of antibiotic therapy and follow up time.

Conclusion:

Collagen sheet dressings offer significant better results over conventional dressings in terms of completeness of healing of chronic ulcers. Through our study we could prove that collagen dressing is better in comparison with conventional dressings considering early granulation tissue formation, early sterile wound swab culture and decreasing need of split skin grafting. However, collagen based dressings may avoid the need of skin grafting, this finding needs further substantiation by appropriately designed randomized studies of large groups.

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