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Original Research Article

Outcome of normal saline versus collagen dressing in management of diabetic foot ulcer – A comparative study

G. Rajendran[1], Uma. D[1], Prasanna Venkatesh[1], Ramesh. A[1,*]

[1]*Dept. of General Surgery, K.A.P. Viswanatham Government Medical College, Tiruchirappalli, Tamil Nadu, India*

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ABSTRACT

Introduction: Diabetic Foot ulcer is a major disease-causing disability to many patients around the world. Treatment of diabetic foot ulcers (DFU), which is the most common reason for lower-extremity amputation, remains a serious healthcare problem.
Aim: To compare the normal saline dressing with collagen dressing in diabetic foot ulcer treatment.
Materials and Methods: This comparative study was conducted on 100 patients, randomised into 50 patients in each group, Normal saline dressing and Collage dressing. The ulcer was evaluated after every 3 days to reduce the size, formation of granulation tissue and epithelisation until the ulcer healed completely or up to 8 weeks, whichever is earlier.
Results: In both, groups male patients were more than female, i.e. CG group with 60% and NS group with 66%. The mean wound size was 47.93 cm^2 for CG and 45.45 $cm^2$for the NS group. The mean percentage improvement of ulcer size (73.43% VS 54.50% in 5^{th} week), presence of granulation tissue (90% VS 0% patients in1^{st} week) and presence of epithelial tissue (74% VS 4% patients in 1^{st} week) were significantly better in CG than in NS group.
Conclusion: From the above study, the collagen dressing is superior compared to normal saline dressing in management of diabetic foot ulcers.

1. Introduction

Wound healing is the effort when the body tries to restore the structural and functional integrity of the injured part. Foot ulcers affect 15% of diabetics at any point during their lives. Foot ulcers are a major reason for lower extremity amputation in patients with diabetes foot ulcer.[1] Almost 14- 24% of diabetes patients needed an amputation. Wound healing depends on several factors, including site of injury, structure involved, mechanism of injury, contamination, loss of tissue, local and systemic condition. A key concept is that wound healing undergoes the same series of events following specific stages. With the knowledge of the steps of wound healing, one can manipulate healing to achieve optimal results in a short period of time.[2,3]

Wound management has become a burden in society and it is growing day by day. Delayed wound healing adds to the burden mentally, physically and financially both to the individual and the health care system. Among them, diabetic foot ulcer contributes a major part.[4]

Diabetic is a systemic disease, which can impair wound healing through various mechanisms if not controlled. It can cause microangiopathy affecting microcirculation, increased glucose level in wound precipitating infection, increased glycosylated hemoglobin reducing the caring oxygen capacity and glycosylated tissue reducing oxygen utilisation capacity of the tissue. It can also cause diabetic neuropathy and atherosclerosis, which further dampened

* *Corresponding author*.
E-mail address: drrameshms21@gmail.com (Ramesh. A).

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wound healing.[5]

For the wound to heal properly, there should be a favorable environment where the entire negative factor which interferes with wound healing is removed.[6] We can also provide an external factor that promotes wound healing like using insulin, antibiotics, normal saline dressing, collagen dressing, etc.

Normal saline dressings are physiologically normal, isotonic and provide a moist environment for the wound to heal. They are useful adjuncts in the treatment of open wounds and are used in clinical practice with great success. They are cheaply available and easy to apply.[7,8]

The collagen-based dressing is a newer entity in treating diabetic ulcer. Collagen is an endogenous substance and an essential structural element of connective tissue. Collagen dressing is believed to elevate the fibroblast development, which in turn raises the uptake of fibronectin, helps deposition of collagen fibers, and preserves leukocytes, macrophages and epithelial cells and helps in maintaining the microenvironment of the wound.[9,10]

2. Materials and Methods

This Comparative study was conducted at KAPV Government medical college, MGMGH, Trichy, from May 2018 to October 2019 in 100 patients with diabetic foot ulcers. Patients were randomised into two groups, Normal saline and Collagen sheets. Prior approval from the Ethical Committee and written consent were obtained.

2.1. *Inclusion criteria*

1. 20 years or older with ulcer duration of at least 4 weeks.
2. Wound area of at least 2*2cm.
3. Wound debrided of necrotic and nonviable tissue at the time of enrollment.

2.2. *Exclusion criteria*

1. Clinical signs of wound infection.
2. Wound with exposed bone or capsule.
3. Comorbid condition affecting wound healing.
4. Taking treatment, which interferes, wound healing within 4 weeks of enrollment.

2.3. *Study procedure*

The initial condition of the ulcer was recorded considering the inclusion and exclusion criteria in mind. The patient's in-group CG underwent collagen sheets dressing once a week, whereas the patient's in-group NG underwent a daily normal saline dressing.

During dressing and examination of patients, observations were made. Data was recorded on every 7^{th} day from admission until the 8^{th} weeks or until the ulcer is completely healed, whichever is earlier. The efficacy of the dressing was based on the reduction of the size of ulcers, presence of granulation tissue and epithelialisation at the site of the wound.

To measure the size of ulcers, sterile thread is used. The vertical and horizontal diameters of the ulcer are measured using the thread and later the thread is measured in centimetres using inch tape. The appearance of healthy pink granular tissue over the surface of the ulcer was taken as starting point of granulation. In addition, the point of epithelialisation was taken when a bluish rim of tissue appears at the periphery of the ulcer

The data were entered into the SPSS version 25 statistical software.

3. Results

Around 60% of the study population in the collagen group are males and 66% of the study population in the normal saline group are females. (p-value =0.534). (Figure 1)

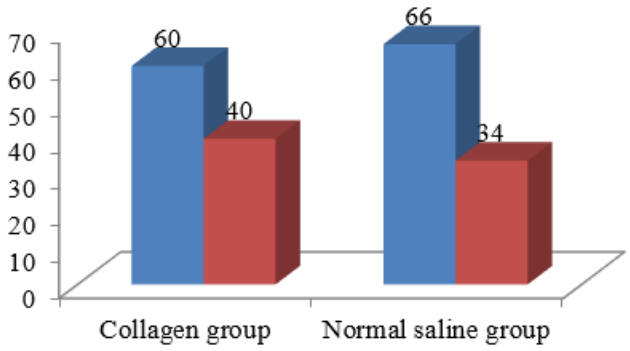

Fig. 1: Sex distribution of study population.

When age group data was evaluated, it was found that the maximum patients were of age group 51 to 60 years in both CG and NS. (P-value =0.874) (Figure 2)

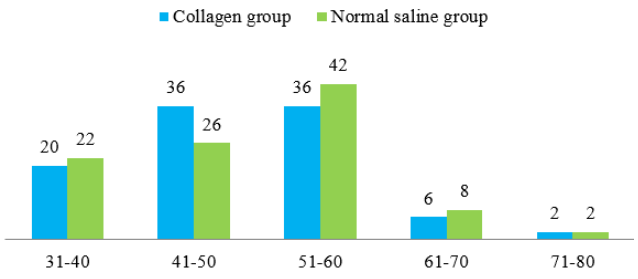

Fig. 2: Age distribution of study population.

The mean ulcer size at baseline for CG and NS group were 47.93 cm^2 and 45.45 $cm^{2,}$ respectively and after 8 weeks, it was found to be 3.33cm^2 and 3.82$cm^{2,}$ respectively. The mean size decreases each week, but the

Table 1: Comparison of overall mean ulcer size between two groups at different time intervals

Duration	Group	Mean	Std. Dev.	p-value
At baseline	Collagen	47.93	15.52	0.412
	Normal Saline	45.45	14.55	
At 1^{st} week	Collagen	42.16	14.48	0.836
	Normal Saline	41.57	13.95	
At 2^{nd} week	Collagen	35.47	13.72	0.534
	Normal Saline	37.14	13.02	
At 3^{rd} week	Collagen	28.01	13.16	0.215
	Normal Saline	31.17	12.10	
At 4^{th} week	Collagen	20.94	12.6	0.03
	Normal Saline	25.08	10.95	
At 5^{th} week	Collagen	14.6	11.45	0.05
	Normal Saline	18.84	9.68	
At 6^{th} week	Collagen	9.72	8.95	0.071
	Normal Saline	12.87	8.07	
At 7^{th} week	Collagen	6.69	7.31	0.479
	Normal Saline	7.67	6.59	
At 8^{th} week	Collagen	3.33	4.46	0.578
	Normal Saline	3.82	4.43	

Table 2: Comparison of the mean percentage improvement in ulcer size between two groups at different time intervals.

	Group	Mean	Std. Dev.	p-value
At 1^{st} week	Collagen	12.54	3.88	0.066
	Normal Saline	0.53	49.60	
At 2^{nd} week	Collagen	27.55	7.63	0.008
	Normal Saline	10.03	45.33	
At 3^{rd} week	Collagen	44.27	12.06	0.001
	Normal Saline	24.62	39.83	
At 4^{th} week	Collagen	59.97	16.06	0.0001
	Normal Saline	39.41	34.12	
At 5^{th} week	Collagen	73.43	17.35	0.0001
	Normal Saline	54.50	28.70	
At 6^{th} week	Collagen	82.54	14.88	0.001
	Normal Saline	68.86	22.711	
At 7^{th} week	Collagen	88.47	12.15	0.021
	Normal Saline	81.40	17.53	
At 8^{th} week	Collagen	94.26	7.67	0.037
	Normal Saline	90.66	11.42	

Table 3: Distribution of study population according to the presence of granulation tissue

Duration	Collagen group						Normal saline group					
	Present		Minimal		NIL		Present		Minimal		NIL	
	No	%	No	%	No	%	No	%	No	%	No	%
At baseline	0	0	48	96	2	4	0	0	50	100	0	0
At 1^{st} week	45	90	5	10	0	0	0	0	50	100	0	0
At 2^{nd} week	50	100	0	0	0	0	50	100	0	0	0	0
At 3^{rd} week	50	100	0	0	0	0	50	100	0	0	0	0
At 4^{th} week	50	100	0	0	0	0	50	100	0	0	0	0
At 5^{th} week	50	100	0	0	0	0	50	100	0	0	0	0
At 6^{th} week	50	100	0	0	0	0	50	100	0	0	0	0
At 7^{th} week	50	100	0	0	0	0	50	100	0	0	0	0
At 8^{th} week	50	100	0	0	0	0	50	100	0	0	0	0

Table 4: Distribution of study population according to the presence of epithelial tissue

Duration	Collagen group						Normal saline group					
	Present		Minimal		NIL		Present		Minimal		NIL	
	No	%	No	%	No	%	No	%	No	%	No	%
At baseline	0	0	0	0	50	100	0	0	0	0	50	100
At 1^{st} week	37	74	2	4	11	22	2	4	15	30	33	66
At 2^{nd} week	50	100	0	0	0	0	40	80	10	20	0	0
At 3^{rd} week	50	100	0	0	0	0	49	98	1	2	0	0
At 4^{th} week	50	100	0	0	0	0	50	100	0	0	0	0
At 5^{th} week	50	100	0	0	0	0	50	100	0	0	0	0
At 6^{th} week	50	100	0	0	0	0	50	100	0	0	0	0
At 7^{th} week	50	100	0	0	0	0	50	100	0	0	0	0
At 8^{th} week	50	100	0	0	0	0	50	100	0	0	0	0

difference in reduction of mean size is more or less similar and hence the results are not significant. The size of the ulcer and the margin varies to a maximum extent and hence comparing the mean size may lead to wide variation in the interpretation. Hence, the percentage difference in the improvement of each ulcer was calculated, keeping the measurement at baseline as constant. (Table 1)

When mean percentage improvement in ulcer size was compared between CG and NS, it was found that after 1^{st} week, there was a significant improvement in wound healing in CG than the NS, i.e. 12.54 % in CG and 0.53% in NS. (Table 2)

At baseline, nearly none had granulation tissue in the present study, but at the first week, around 90% improvement was seen in CG while no improvement in the normal saline group. Granulation tissue formation is early in the collagen group compared to the normal saline group (Table 3).

At baseline, nearly none had epithelialisation, but around 74 % improvement was seen in CG at the first week while only 4% improvement was observed in NS. Formation of Epithelialisation is early in the collagen group compared to the normal saline group (Table 4).

4. Discussion

Diabetic wound affects a large number of the population contributing to a significant burden in hospital. There is a steep increase in incidence due to changing urban lifestyle. Collagen dressing can be used to enhance wound healing due to its various properties. It helps in the formation of new collagen and stimulates fibroblast activity, thereby hasten the wound healing process. Normal saline is also known to improve wound healing since it is an isotonic solution keeping the wound moist, helping in the healing process. [1,2,4]

We found a high number of males (60% in CG and 66% in NS) had chronic leg ulcer compared to females (40% in CG and 34% in NS). However, the gender distribution was similar in both CG and NS ($p>0.05$). Hence, we can conclude that both groups were similar in composition before the start of the study. The study population was selected correctly so that there was equal representation in both groups.

The age group data suggest that there is a clear association between age and DF ulceration. There was an increasing prevalence of DF ulceration with an increase in age. In our study DF, ulceration was found more in older patients (51-60 years) in both groups (i.e. CG, NS). The finding is in accordance with Baker et al. 1994. [11]

When the reduction ulcer size was compared between the two groups, it was observed that both groups were comparable in reducing the ulcer size. However, when the percentage improvement in ulcer size was done, the CG group showed significantly better ulcer size than NS. The finding of our study is similar to the study done by, Shimikore et al. 2018, which showed at the end of 4 weeks, collagen dressing shows better results compared to conventional dressing in ulcer size reduction. [12]

In both, the group presence of granulation tissues was non at baseline, but at the first week, around 90% improvement was seen in CG while no improvement in NS, Formation of granulation tissue is early in CG compared to the NS group. This observation in our study is similar to Singh et al. 2011, where the average time for granulation treated with collagen dressing was eight-day whereas, for traditional dressing, it was 14 days. [13]

At baseline, nearly none group (CG and NS groups) had epithelialisation. Still, in the first week, around 74 % improvement was seen in the collagen group. In comparison, only 4% improvement was seen in the normal saline group, the formation of Epithelialisation is early in CG compared to the NS group. Nagaraj et al. 2019, reported similar findings in her study where she reported that epithelialisation was better in CG than in NS. [14]

5. Conclusion

Considering the formation of granulation tissue, epithelialisation, reduction in the size of the ulcer, we

can conclude that the collagen group has a consistent result and a reliable result compared to the normal saline group in reduction of ulcer size. Patients treated with either of the two dressing methods did not develop any complication during the study period. Hence, collagen dressing can be used safely with better reliable outcome in diabetic wound dressing.

6. Conflict of Interest

None.

7. Source of Funding

None.

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Author biography

G. Rajendran, Professor

Uma. D, Assistant Professor

Prasanna Venkatesh, Assistant Professor

Ramesh. A, Assistant Professor

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