

ORIGINAL RESEARCH

Comparing the Clinical Outcomes of Collagen Dressing with Povidone Iodine Dressing in the Treatment of Acute Diabetic Foot UlcerDr. Shanjeev K.M.¹, Dr. Anokha Jagadish², Dr. Anand I.P.³¹Senior Resident, Department of General Surgery, A. J. Institute of Medical Sciences, Mangalore, Karnataka, India.²Senior Resident, Department of General Surgery, Kempegowda Institute of Medical Sciences, Bangalore, Karnataka, India.³Associate Professor, Department of General Surgery, A. J. Institute of Medical Sciences, Mangalore, Karnataka, India.**Corresponding Author**

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ABSTRACT**BACKGROUND:** In this study, we wanted to analyse the wound healing efficacy of collagen dressings as compared to povidone iodine dressings in acute diabetic foot ulcer patients, evaluate the difference in wound size between the two dressing groups along with the difference in the wound healing duration between the two groups.**MATERIALS AND METHODS:** This was a hospital based prospective comparative observational study conducted among 102 patients who presented with acute diabetic foot ulcers to the Department of General Surgery or from any other department in a Tertiary Care Referral Hospital in Mangalore, Karnataka, over a period of 2 years from October 2019 to September 2021, after obtaining clearance from Institutional Ethics Committee and written informed consent from the study participants.**RESULTS:** Males had a higher incidence of diabetic ulcers; this is statistically significant with a p value of 0.03. The quality of the ulcer bed was better in group A with 43 out of 51 patients having healthy granulation tissue and satisfactory ulcer bed (84.31 %) when compared to group B patients which had only 19 out of 51 patients who had satisfactory wound healing (37.25 %) on day 21; p = 0.004, which is statistically significant with collagen group showing better results. The collagen group had faster wound healing rates in comparison with the povidone iodine group, which is statistically significant. (p = 0.035)**CONCLUSION:** Collagen is a more efficient and readily available alternative to topical povidone iodine in patients with acute diabetic ulcers.**KEYWORDS:** Clinical Outcomes, Collagen, Dressing, Povidone Iodine, Treatment, Acute Diabetic, Foot Ulcer**INTRODUCTION**Diabetic foot ulcer (DFU) is considered as one of the most frequently encountered complications, in patients suffering from diabetes mellitus. It is estimated that DFUs affect about 15 % of the patients who have diabetes mellitus; thereby causing significant morbidity, disability and leading on to mortality.^[1,2]With India, being the country with second highest diabetic population in the world,^[3] the extent of DFUs and managing them has turned out to be a challenging task, for the health-care system. The DFU, thus impose an enormous financial burden on the diabetic population. In a survey it was estimated, that the expenditure incurred in managing a DFU by average Indian diabetic patient on an annual basis is around and 1750 - 2000 US dollars (appr.1,45,000INR).^[4]

The healing of diabetic ulcer is protracted, as compared to those who are non-diabetic owing

to other factors like poor macrophage function, reduced growth factors and chemokines.^[5] And other co morbid prevailing conditions affecting the individual at the time of treatment including financial and psychological support. The concept of wound healing has been well known to mankind since time immemorial, till date there is no dressing that is claimed to be perfect and ideal in all aspects.

The most commonly employed dressing in the management of diabetic foot wounds are moist saline gauze dressings or povidone iodine solution-soaked gauze. Dressings (medicated) that maybe used as and when appropriate depending upon the individual preference or as suggested by the treating physician based on the clinical experience.^[6,7]

In order to achieve the goal of an ideal wound management, novel wound dressing techniques, which would augment this slow wound healing, are being tested continuously. One such dressing technique employs collagen, for accelerating diabetic wound healing. Various studies have demonstrated the efficacy of collagen-based dressing in diabetic ulcers. As they achieve faster wound healing rates, therefore reducing the duration of hospitalization and the related morbidity and the health care expenditure, the present study has been undertaken, in an attempt to analyse the effective use of collagen dressings in DFU treatment, of patients, attending a tertiary care referral centre by a single treating physician.

Aims and Objectives

- To analyse the wound healing efficacy of collagen dressings as compared to povidone iodine dressings in acute diabetic foot ulcer patients.
- To evaluate the difference in wound size between the two dressing groups.
- To evaluate the difference in the wound healing duration between the two groups.

MATERIALS AND METHODS

This was a hospital based prospective comparative observational study conducted among 102 patients who presented with acute diabetic foot ulcers to the Department of General Surgery or from any other department in a Tertiary Care Referral Hospital in Mangalore, Karnataka, over a period of 2 years from October 2019 to September 2021, after obtaining clearance from Institutional Ethics Committee and written informed consent from the study participants.

Inclusion Criteria

- 1- Patients above 18 years and below 70 years of age.
- 2- Patients who have acute diabetic foot ulcers (less than 4 weeks of duration)
- 3- Patients who were willing to give informed consent.

Exclusion Criteria

- 1- Patients with diabetic foot ulcers, who belongs to grade 3 and above of the Meggitt– Wagner's grading of diabetic foot ulcers.
- 2- Patients with any malignant changes in ulcers and co-existing varicose veins.
- 3- Patients who are critically ill due to any underlying cause.

Sample Size Estimation

Based on the study conducted by Shimikore S S, Pawar G B, it was observed that there was a difference of about 15 sq.mm at 2nd observation between the collagen dressing group and the povidone iodine dressing for diabetic foot ulcers. In order to detect a minimum difference of 10 sq.mm in the wound size, using collagen dressing in comparison to povidone iodine dressing, assuming a pooled standard deviation of 18 sq.mm with 95 % confidence interval and 80 % power, the sample size estimated for the study was 51 subjects in each group.

Statistical Methods

Quantitative data was represented using descriptive statistics. Z test was used to test the statistical significance in the wound size and wound healing time between the two groups. Chi-square test was used to test the significant difference in qualitative characteristics between two groups. Analysis of variance (ANOVA) was used to compare improvement in the same group over time.

RESULTS

Gender	Group A	Group B	TOTAL	Group A	Group B	Total
Males	30	29	59	58.82 %	56.86 %	57.84 %
Females	21	22	43	41.18 %	43.14 %	42.16 %
N	51	51	102	100.00 %	100.00 %	100.00 %
(Between the groups p = 0.93) <i>Gender</i>						
Group	Group A	Group B	The two-tailed P value equals 0.5538, not statistically significant.			
Mean	140.40	137.60				
SD	20.87	15.08				
SEM	3.81	2.75				
<i>FBS</i>						
Group	Group A	Group B	The two-tailed P value equals 0.1084, not statistically significant.			
Mean	176.70	165.37				
SD	32.59	24.08				
SEM	5.95	4.40				
<i>PPBS</i>						
<i>Table 1</i>						

59 males and 43 females with a male to female ratio of 1.37 : 1. There was no statistical significance between the two groups (p = 0.93). Hence, the two groups are comparable. Overall, males had a higher incidence of diabetic ulcers; this is statistically significant with a p value 0.03. The mean FBS in the Group A was 140.4 SD \pm 20.87 mg/dl and in the Group B was 137.60 SD \pm 15.8 mg/dl. There was no statistical significance between the two groups with a p value of 0.55. Hence, the two groups are comparable.

The mean PPBS in the Group A was 176.7 SD \pm 32.59 mg/dl and in the Group B was 165.37 SD \pm 24.08 mg/dl. There was no statistical significance between the two groups with a p value of 0.108. Hence, the two groups are comparable.

Group	Group A	Group B	The two-tailed p value equals 0.8774, not statistically significant.				
Mean	8.117	8.173					
SD	1.250	1.374					
SCM	0.228	0.251					
N	25	25					
<i>hba1c</i>							
Group	Group A	Group B	Total	Group A	Group B	Total	p value equals 0.6624, not statistically significant.
No growth	46	44	90	90.20 %	86.27 %	88.24 %	
Growth	5	7	12	9.80 %	13.73 %	11.76 %	
<i>Pus Culture on -Day 0</i>							
Group	Group A	Group B	Total	Group A	Group B	Total	P = 0.7784, not statistically significant
Good	4	6	10	7.84 %	11.76 %	9.80 %	
Not							
Satisfactory	47	45	92	92.16 %	88.24 %	90.20 %	
<i>Quality of Ulcer Bed on Day 0</i>							
Group	Group A	Group B	Total	Group A	Group B	Total	P = 0.004
Good	43	19	62	84.31 %	37.25 %	60.78 %	
Not satisfactory	8	32	40	15.69 %	62.75 %	39.22 %	
<i>Quality of Ulcer Bed on Day 20</i>							
<i>Table 2</i>							

The mean HbA1c in the Group A was 8.11 SD ± 1.2 % and in the Group B was 8.17 SD ± 1.3 %. There was no statistical significance between the two groups with a p value of 0.88. Hence, the two groups are comparable.

There was no statistical significance between the two groups, in terms of growth of organism from the pus culture on day 0; with Group A 46 cases had positive growth and Group B 44 cases had a positive growth (p = 0.66). Hence, the two groups are comparable.

On day 0, both the groups had comparable ulcer bed quality without any statistical difference between the control and collagen group. (p = 0.77)

The quality of the ulcer bed was better in group A with 43 out of 51 patients having healthy granulation tissue and satisfactory ulcer bed (84.31 %) when compared to group B patients which had only 19 out of 51 patients who had satisfactory wound healing (37.25 %) on day 21; p = 0.004, which is statistically significant with collagen group showing better results.

Group	Group A	Group B	Group	
Mean	14.75	14.6	P value equals 0.8848, not statistically significant.	
SD	2.00	2.48		
SEM	0.366	0.454		
Ulcer Size on Day 0				
Mean duration of healing	Group A	Group B	TOTAL	P = 0.035
	18.65	22.3	26	
Mean Duration of Wound Healing				
Table 3				

There was no statistical significance between the two groups, in terms of size of the ulcer on day 0; with group A mean ulcer size being 14.75 sq. cms and group B mean ulcer size of 14.6 sq.cms, with a p value of 0.88. Hence, the two groups are comparable.

The mean duration of wound healing was 18.65 weeks in those who got the collagen dressing and it was 22.365 weeks in the control group. Thus, the collagen group had faster wound healing rates in comparison with the povidone iodine group, which is statistically significant. (p = 0.035)

MEGGITTWAGNER'S GRAD		Day 0	Day 3	Day 5	Day 7	Day1 0	Day1 2	Day1 4	Day1 7	Day2 0
COLLAGEN	Grade 1	32	32	32	32	32	33	33	39	42
	Grade 2	19	19	19	19	19	18	18	12	9
IODINE	Grade 1	30	30	30	30	30	30	30	30	30
	Grade 2	21	21	21	21	21	21	21	21	21
COLLAGEN	Grade 1	62.75 %	62.75 %	62.75 %	62.75 %	62.75 %	64.71 %	64.71 %	76.47 %	82.35 %
	Grade 2	37.25 %	37.25 %	37.25 %	37.25 %	37.25 %	35.29 %	35.29 %	23.53 %	17.65 %
'IODINE	Grade 1	58.82 %	58.82 %	58.82 %	58.82 %	58.82 %	58.82 %	58.82 %	58.82 %	58.82 %
	Grade 2	41.18 %	41.18 %	41.18 %	41.18 %	41.18 %	41.18 %	41.18 %	41.18 %	41.18 %
P value		0.08	0.08	0.08	0.08	0.08	0.076	0.076	0.038	0.001
Meggitt - Wagner's Grades of the Ulcer Sizes on Serial Observation										
Group		Group A	Group B	Total	Group A	Group B	Total			
Less than 2 debridement		8	18	26	15.69 %	35.29 %	25.49 %			
More than 2 debridement		12	32	44	23.53 %	62.75 %	43.14 %			
STSG		2	9	11	3.92 %	17.65 %	10.78 %			
Flaps		0	1	1	0.00 %	1.96 %	0.98 %			
Requirement of Secondary Procedures										
Table 4										

There was no statistical significance between the two groups with regards to the Meggitt - Wagner's grades of the ulcer till day 14 with p values more than 0.05. Hence the two groups are comparable till day 14. The difference began on day 17 and day 21, with p values less than 0.05, showing that collagen granules take time to act, to help in healing the ulcer but has better and earlier wound healing rates when compared to the conventional povidone iodine dressing when the complete wound healing duration is taken into consideration.

The requirement of secondary procedures was much lesser in patients who got the collagen dressing when compared to the control group. The number of subjects that needed more than 2 debridements in the collagen group was less (12), when compared to the control group (32). Split thickness skin graft (STSG) was done for 2 patients in the collagen group and for 9 patients in the control group during the follow-up period to augment the wound healing. 1 patient from the control group underwent a local flap reconstruction procedure for the ulcer, while no flap reconstruction was done in the collagen group. Overall, the collagen group had undergone lesser secondary procedures to help wound healing when compared to the povidone iodine group, which further reduces the cost incurred in the procedure as well as the length of hospital stay.

DISCUSSION

Sex distribution

In the present study, the age group of the subjects ranged between 36 years and 80 years and the most commonly affected age group was found to be, between the age group of 61 - 70 years, with 15 cases. There was a positive co-relation between the age of the patient and the incidence of ulcer; as the age increased there was an increase in the incidence of ulcers which was statistically significant with a p value 0.046.

Our study included 59 males and 43 females with a male to female ratio 1.37 : 1. There was no statistical significance between the two groups. Hence, the two groups were comparable. Overall, males had a higher incidence of diabetic ulcers; this is statistically significant with a p value of 0.03. In a study by Bansal et al.,^[8] among those patients with diabetic foot ulcer, 56.31 percent were in the age group of 51 - 70 years, which is comparable to our study, in which the most common age group affected by diabetic ulcers is 51 - 70 years (50 percent).

Glycaemic control

The mean FBS in the Group A was 140.4 SD \pm 20.87 mg/dl and in the Group B was 137.60 SD \pm 15.08 mg/dl. In a study by Munish et al.^[9] the mean FBS was 213.60 \pm 73.17 in group A and 223.20 \pm 63.55. There was no statistical significance between the two groups in both our study as well as the reference study, with a p value more than 0.05 and the glycaemic control were similar in both control and study group.

Effect of Collagen on the Wound Bed

Secondary Procedures:

Rao et al.^[10] noted that, the requirement of secondary procedures like wound debridement, STSG and skin flaps, etc, were significantly lower in collagen dressing patients (64.47 %) when compared to the conventional dressing patients (100 %). Similarly, in our study also, the requirement of secondary procedures was much lesser in the collagen group than in the control group. The number of patients that needed more than 2 wound debridements were lesser in the collagen group (23.53 %), than in the control group (62.75 %) which needed more than 2 debridements. Also, 3.92 % of patients in the collagen group and 17.65 % of patients in the control group needed STSG later, for complete wound healing. One patient in the control group also underwent a flap reconstruction while no flap reconstruction was done in the collagen group patients.

Infection Rates

Rao et al.^[10] noted that the infection rates, as evidenced by the culture and sensitivity were comparable in patients receiving conventional dressing (100 %) and in patients receiving collagen dressing (89.47 %). This is comparable to the present study, with 14 cases (27.45 %) in group A and 32 cases (62.75 %) in group B patients showed no growth in culture and 37 cases (72.55 %) in group

A and 19 patients (37.25 %) in group B showed positive culture on day 21.

Healing Time

Veves et al.^[11] also noted that of the patients who were managed with collagen, had complete closure of the wound closure while only 39 (28.3 %) in whom conventional dressings were done healed completely which is comparable to the present study. Rao et al noted^[10] that the healing time was significantly lower in patients receiving collagen dressing (4.63 ± 1.18 weeks) as compared to conventional dressing (7.79 ± 1.61 weeks). The mean duration of wound healing was 18.65 weeks in those who got collagen and 22.365 weeks in the control group in the present study.

BayramColak et al.^[12] noted that complete wound closure before 12 weeks was achieved in 17 (56.6 %) of the control group patients, while 25 (73.5 %) of the patients in collagen group had complete wound closure before 12 weeks. This is comparable to the present study.

CONCLUSION

We noted that the use of collagen dressings increases the chances of faster healing along with reducing the duration required for complete wound healing and the need for secondary procedures. We also noted that the use of collagen helped in improving the quality of granulation tissue, which was much better than those who received povidone iodine dressing. It has to be kept in mind that in patients who received collagen dressing, there was no significant wound infection. Although the need for secondary procedures like debridement or grafting for the same ulcer size area was much lesser in the collagen group as compared to the control group, the success rate of secondary procedures like split thickness, in terms of graft take up was also better in those whom collagen was used. Hence, it can be concluded that collagen is a more efficient and readily available alternative to topical povidone iodine in patients with acute diabetic ulcers. Here, we have not included the chronic diabetic ulcer patients, as there have been not enough studies that have proven the efficacy of collagen use in these ulcers. Further studies are recommended with larger sample size and longer duration, to see the long-term benefits and adverse effects between collagen application in chronic diabetic ulcers.

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