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Study of Collagen Dressings in Patients with Chronic Non: Healing Ulcers

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ABSTRACT
Wounds that do not heal within 3 months are often considered chronic. Collagen dressing causes neovascularization which is an important step in proliferation phase of wound healing. Eight Present study was aimed to study collagen dressings in patients with chronic non-healing ulcers. Present study was single-center, prospective, observational study, conducted in patient above 14 years age, with chronic ulcers including diabetes and burns. Patients were subjected to Collagen dressings. A total of 100 patients were recruited in the study with chronic non healing nonmalignant ulcers. Majority were from 51-60 years age group (41%) and were male (51%). 62 patients had purulent discharge and 21 had serous discharge in the study group. It was observed that only two patients developed positive growth at the end of 21 days. It was observed that 39 patients underwent debridement of the ulcer at the start of treatment in study group. On a scale of 0-10 pain scoring was done after 24 hrs of applying the dressing and pain was considerably low in study group with 47 patients having minor pain and 43 patients having moderate pain. It was observed that in collagen dressing 66 patients required antibiotic only for 5 days and 23 patients required antibiotics for 6-7 days. It was observed that with collagen dressings 64 patients stayed for 2-3 weeks and 28 patients stayed for 3-4 weeks. It took 6 months for ulcer healing in 44 patients in study group and 3 months for 8 patients. 78 patients had good compliance and 22 patients had bad Compliance. Collagen dressings may be used as an adjunct in management of chronic non healing ulcers.

INTRODUCTION

Chronic wounds are defined as wounds that have failed to proceed through the orderly process that produces satisfactory anatomic and functional integrity or that have proceeded through the repair process without producing an adequate anatomic and functional result[1]. Wounds that do not heal within 3 months are often considered chronic[2]. Chronic wounds seem to be detained in one or more phases of wound healing. In acute wounds, there is a precise balance between production and degradation of molecules such as collagen: in chronic wounds this balance is lost and degradation plays too large a role[3,4]. Chronic wounds mostly affect people over 60 years age[5]. The incidence is 0.78% of population and prevalence ranges from 0.18-0.32%[6]. If a standardized treatment is applied with a multi disciplinary foot care team, major amputation can be avoided in about 80-90%[7]. Thus the key to success is a complete wound healing which is accomplished by meticulous wound care and optimization of wound healing capacity.

Traditional wound dressings are regarded as passive devices that protect the wound from further injury, while wound healing takes place naturally beneath. Recent concept of wound care concentrates on interactive dressings, which can alter the local wound environment, which is a subject of intense research. Collagen dressing causes neovascularization which is an important step in proliferation phase of wound healing[8]. Present study was aimed to study collagen dressings in patients with chronic non-healing ulcers

MATERIALS AND METHODS

Present study was single-center, prospective, observational study, conducted in department of General surgery, C.U. Shah Medical College and Hospital, Surendranagar, India. Study duration was of 1 years 6 months (June 2021 to December 2022). Study approval was obtained from institutional ethical committee.

Inclusion criteria

- Patient above 14 years age, with chronic ulcers including diabetes and burns, willing to participate in present study

Exclusion criteria:

- Patient with allergy to collagen dressing
- Patient who are critically ill
- Patient with any evidence of underlying bone osteomyelitis
- Malignancy
- Patients who are unable to buy materials required

Study was explained to patients in local language and written consent was taken for participation and study. All patients who presented to the hospital with complaints of chronic non healing non-malignant ulcers were taken into the study. A detailed history and clinical examination were done and the size of the ulcer was measured with a standard tape. Relevant investigations were done. Patients were subjected to Collagen dressings. Patients were followed up for a period of 3-10 months duration. Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Statistical analysis was done using descriptive statistics.

RESULTS

A total of 100 patients were recruited in the study with chronic non healing nonmalignant ulcers. Majority were from 51-60 years age group (41%) and were male (51%). It was observed 55 patients had associated systemic illnesses in study group and 21 had diabetes mellitus and 18 patients were hypertensive in study group. In present study, common ulcer site was over the leg (34%), in foot (32%) and over ankle (32%). Trauma is the most common cause of origin of chronic non healing ulcer accounting for 72 patients while only

Table 1: General characteristics

Age groups (years)	No. of patients	Percentage
<20	4	4
21-30	4	4
31-40	08	08
41-50	09	09
51-60	41	41
61-70	22	22
>70	12	12
Mean age (mean±SD)		
Gender		
Male	51	51
Female	49	49
Systemic illness		
Diabetes Mellitus	21	21
Hypertension	18	18
Vasculitis	07	07
Chronic renal failure + Hypertension	03	03
Diabetes Mellitus + Hypertension	02	02
Chronic renal failure	02	02
Gout	02	02

Table 2: Chronic non healing ulcer characteristics

Ulcer site	No. of patients	Percentage
Leg	34	34
Foot	32	32
Ankle	15	15
Gluteal Region	7	7
Forearm	5	5
Arm	3	3
Others	2	2
Groin	1	1
Hand	1	1
Onset		
Traumatic	72	72
Spontaneous	28	28
Type of discharge		
Purulent	62	62
Serous	21	21
No Discharge	17	17

Table 3: Culture findings on day 0 and day 7

Organism	On day of admission	On day-7 after admission
E.coli	35	26
S.aureus	10	22
Klebsiella	16	9
Pseudomonas	08	13
Citrobacter	09	4
S. epidermidis		4
Acinetobacter	07	7
Enterobacter	05	4
Enterococci		5
No Growth	10	6

Table 4: Culture findings on day-21 post admission in study group

	Results on day 21 post admission		
	Negative	Positive	Total
No. of patients	98	2	100

Table 5: Dressings and patient characteristics

	No. of patients	Percentage
Debridement		
Done	39	39
Not done	61	61
Pain scale after 24 hours post 1st dressing		
No pain	0	0
Mild (1-3)	47	47
Moderate (4-6)	43	43
Severe (7-10)	10	10
Duration of antibiotics		
5 days	66	66
6-7 days	23	23
8-10 days	9	9
>10 days	2	2
No antibiotic	0	0
Duration of hospital Stay		
1-2 weeks	3	3
2-3 weeks	64	64
3-4 weeks	28	28
>4 weeks	5	5
Dressings required		
1-5	0	0
6-10	27	27
11-15	26	26
16-20	13	13
21-25	20	20
26-30	12	12
>30	2	2

Table 6: Ulcer healing characteristics

	No. of patients	Percentage
% Reduction of ulcer size		
<50	0	0
51-60	0	0
61-70	2	2
71-80	12	12
81-90	35	35
>90	51	51
Ulcer healing time		
3 Months	8	8
4 Months	18	18
5 Months	30	30
6 Months	44	44
Compliance		
Good	78	78
Bad	22	22

28 patients had spontaneous onset. 62 patients had purulent discharge and 21 had serous discharge in the study group. On day of admission, 35 patients had *E.coli,* 10 patients had *S.aureus* and 16 patients had Klebsiella in their culture findings. On day-7 after admission, 26 patients had *E.coli* , 22 patients had *S.aureus* and 13 patients had Pseudomonas in their culture findings . It was observed that only two patients developed positive growth at the end of 21 days. It was observed that 39 patients underwent debridement of the ulcer at the start of treatment in study group. On a scale of 0-10 pain scoring was done after 24 hours of applying the dressing and pain was considerably low in study group with 47 patients having minor pain and 43 patients having moderate pain. It was observed that in collagen dressing 66 patients required antibiotic only for 5 days and 23 patients required antibiotics for 6-7 days. It was observed that with collagen dressings 64 patients stayed for 2-3 weeks and 28 patients stayed for 3-4 weeks. It was observed that in study group 27 patients required collagen dressings between 6-10, while only 26 patients required between 11-15.

51 patients had percentage reduction of ulcer between 91-99%, 35 patients had percentage reduction between 81-90%, 12 patients had percentage reduction between 71-80% in study group. It took 6 months for ulcer healing in 44 patients in study group and 3 months for 8 patients. 78 patients had good compliance and 22 patients had bad Compliance.

DISCUSSIONS

Successful wound dressings are those which keep the wound moist and are devoid of any adverse reactions such as infection, maceration and allergic reactions. It has been well documented that the incidence of infection and degree of wound contraction are considerably reduced when wounds are dressed with biologic materials rather than left exposed or dressed with non-biologic materials during healing process. Chronic wounds are those wounds which are stuck in inflammatory phase and shows cessation of epidermal growth. The incidence of chronic non healing ulcer is increasing in the present medical era because of sedentary life style, change in dietary habits, increase in stress, and increasing life span of human beings. These wounds have been managed by local dressings with various agents like Povidone Iodine, EUSOL, Acetic acid, hydrogen peroxide, Silver sulfadiazine, local antibiotic ointments or powders etc. since long time[9].

Collagen dressings is a newer concept in the wound management. xenogenous collagen membrane had good comfort ability in lining skin i.e. it was supple and adapted to the wound no matter what the contour was. No reaction or complication has been reported with collagen. In this study, we selected chronic non healing ulcer and used Collagen wound dressings as local agent for cleansing and sterilizing with mechanical debridement. In this study 47% ulcers were

noted in foot and ankle. In Study conducted by Edmonds *et al*.[10] it was proven that 93% of the foot ulcers were on plantar and fore foot area. Most of the diabetic ulcers are invariably shoe related and due to gait abnormalities. They can be prevented by appropriately sized footwear. In the present study, 39% of patients underwent debridement so as to have clean ulcer base. It has been proven by Bergstorm W, Benett *et al*.[11] and Goode *et al*.[12] that the presence of necrotic and devitalized tissue may prevent or delay wound healing.

All patients (23 in number) were on insulin for control of sugar. In a study conducted by Airsides Veves13 patients having blood sugar levels more than 300 mg percentage were put on insulin therapy. This reversed the defect in endogenous insulin secretion and action and restored euglycemia. In the present study, the percentage reduction of wound area in collagen dressing of >90% was seen in 51% in study group. In the study conducted by Donahue *et al*.[14] where collagen dressings were compared to conventional dressings, at end of study, percentage reduction of wound areas was 80.60% in collagen dressing and 61% in conventional dressing group. It has been reported that collagen dressing in the treatment of chronic non- ulcers was beneficial and enhanced the healing[14]. Another study conducted to evaluate the efficacy and cost effectiveness shows that treatment with collagen with good wound care resulted in 12% reduction in cost over 1 year of treatment compared with good wound care alone[15]. In the study which mentions wound healing as carefully controlled balance between destructive processes necessary to remove damage tissue and repair process which leads to new tissue formation, collagen inactivates potentially harmful factors such as proteases, oxygen free radicals, excess metal ions present in chronic wound fluid, while simultaneously protecting positive factors such as growth factors and delivering them back to wound[16].

In our study numbers of collagen dressings required per patient were reduced significantly. In a study done by Aristidis Veves *et al*.[17] showed that average number of dressings were same in both groups, 12 per week vs. 11.2 per week. In a study, it was seen that collagen dressings were changed significantly less frequently than gauze dressings. 87% of collagen dressings were changed once daily compared to 52.7% of gauze dressings. The remaining gauze dressings were changed twice daily[18].

In our study, though not proven financially cost effective over short span, it is found more effective clinically and had a better compliance. Study conducted by Aristidis Verve *et al*.[17] proved that Promogran dressings had better patient ratings and clinical ratings compared to normal gauze dressing. Patient ratings (8.6 vs. 7.6) and clinical ratings (9.3 vs. 7.4) respectively. Collagen by its properties act like a second skin to the wounds and provides the ideal dressing in chronic non healing ulcers. Collagen dressings are non-allergic, safe, promoter of wound healing, are more patient compliant in terms of less pain while changing the dressing, also in terms of less number of dressings. It also reduces microbial load and decreases healing time without damaging the normal tissue or producing complications. The moistening effect and minimum toxicity found with the use of collagen dressings makes it a good choice for chronic ulcer management. Pain was drastically reduced after application of collagen dressings. Collagen dressings also controlled the infection rate by forming a temporary barrier between the wound and the environment. Thus reduced the duration of antibiotic therapy and also the duration of hospital stay.

CONCLUSION

Majority of patients were healed with complete epithelization in short span of time with compare to less number of dressings. Also the percentage reduction of ulcer over a definitive period of time and the ulcer healing time were relatively good. Collagen sheet promotes early healing, reduces pain and decreases the need of analgesics and decreases associated complications like infections. Because of simple application and good tolerance of the membrane, collagen membrane can be advocated as a temporary biological material in management of chronic non healing ulcers. Thus, collagen dressings may be used as an adjunct in management of chronic non healing ulcers.

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