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A COMPARATIVE STUDY OF COLLAGEN DRESSINGS VERSUS CONVENTIONAL DRESSINGS IN CHRONIC NON HEALING ULCERS : RANDOMISED TRIAL

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ABSTRACT

Introduction : The care of wounds is a particularly difficult issue in the field of medicine. Chronic ulcers, also known as non-healing ulcers, are those that do not heal in a predetermined amount of time despite receiving adequate therapy. In order to manage chronic non-healing ulcers, the current study compares the effectiveness of collagen with traditional (saline, betadine, magnesium sulphate, vinegar) dressings.

Methods: Following clearance from the institutional ethics committee, sixty patients with chronic, non-healing ulcers were included in a prospective, randomised clinical trial. The ulcers were clinically examined and a thorough history was taken. A test group of 30 patients and a control group of 30 patients were assigned to the patients at random. Relevant research was conducted. While cases in the control group received conventional dressings and mechanical debridement, patients in the test group received collagen dressings. At days 21, 35, and 42, patients were followed up for longer periods of time than at 2 and 3 months.

Results: It was discovered in the current study that men had more chronic non-healing ulcers than women (78.33% vs. 21.67%). The third and fourth decades are when chronic non-healing ulcers are most frequently observed (31.66%), and trauma is the leading cause of these ulcers (56.67%). The number of dressings needed (p-value 0.0001), ulcer healing time (p-value 0.001), ulcer size reduction by more than 90%

(83.33% vs 16.67%), pain scores (p-value 0.005), and hospital stay (p-value 0.044) were all significantly lower in the collagen dressing group when compared to the conventional dressing group.

Conclusion: When compared to conventional dressings, collagen dressings are non-allergic, secure, encourage early healing, lessen pain and the need for analgesics, lessen associated complications like infections, reduce the frequency of dressing changes and antibiotic use, and shorten hospital stays.

Keywords: Chronic ulcers, non-healing ulcers, collagen dressing, skin.

Introduction

Inflammatory, proliferative, and remodelling phases are often used to categorise wound healing, which is a complex and dynamic physiological phenomenon.[1,2,3,4].

Inflammation is the first reaction to tissue damage, with the aim of promoting fast hemostasis and starting the process that results in tissue regeneration.

The injured, necrotic tissue is eliminated during the proliferative phase and replaced by live tissue that is unique to the local tissue environment (such as bone, cartilage, fibrous tissue, etc.).

Remodelling is the process through which freshly formed tissue changes its shape and organisation to more closely match the old tissue [2,3].

Normal wound healing concludes with full wound closure after it has started.

Lack of growth factors and cytokines can cause an ulcer to become chronic in nature when the normal healing process is interrupted [5]. Non-healing ulcers come in a variety of forms, such as venous, arterial, diabetic, pressure, and traumatic ulcers.

Chronic wounds are defined as those that have either not through the ordered process that results in appropriate anatomical and functional integrity or have undergone the repair process but have not yet yielded a sufficient anatomical and functional outcome[6]. Chronic wounds are those that do not heal after three months (7).

Non-healing ulcers are often treated with wound cleaning, necrotic tissue removal, infection prevention, diagnosis, and therapy, mechanical off-loading, blood glucose control, and local ulcer care with dressing application[8,9,10].

The creation of dressings that provide a moist environment for healing has recently been a key focus of chronic wound care. Patients gain from occlusive dressings because they lessen discomfort and increase usability, cost effectiveness, and convenience.

Traditional dressings are thought of as passive devices that shield the wound from additional harm while wound healing occurs spontaneously underneath. Modern wound care focuses on interactive dressings that may modify the immediate wound environment, a topic of significant research.

Collagen makes almost 25% of the body's total protein pool and is the main fibrous protein of extracellular connective tissues. Collagen dressing causes neovascularization which is an important step in proliferation phase of wound healing. Type I collagen, which is present in collagen dressing, promotes the formation of healthy granulation tissue. Therefore, there is a perceived need to investigate the efficacy of collagen dressings in contrast to traditional dressings in

chronic ulcer.

This study compared the healing times for chronic non-healing ulcers treated with collagen dressings against standard dressings, and evaluated the results in terms of ulcer surface area reduction and length of hospital stay.

MATERIAL AND METHODS:

From May 2022 to November 2022, this randomised prospective Controlled Trial was carried out in the General Surgery Department of the Mahatma Gandhi Hospital, Dr. SN Medical College, Jodhpur. All 60 consecutively eligible male and female outpatient department patients who had a chronic, non-healing ulcer and met the inclusion criteria were enrolled.

Patients of either sex (male or female) with chronic ulcers (>3 months after injury) and ulcer floor has pale granulation tissue and whose age is between 20 and 60 years are included in the inclusion criteria. Patients having a collagen dressing allergy, malignant ulcers, critical illness, or any indication of underlying bone osteomyelitis were not allowed to participate in the trial. Patients were divided at random into test (comprised of 30 patients) and control (comprised of 30 patients) groups after undergoing a thorough clinical examination and comprehensive history. The size of the ulcer was measured using a standard tape or sterile gauze. Relevant investigations was conducted. Patients in the test group received dressings made of collagen. While patients under control group were subjected to Conventional dressings and mechanical debridement. Patients were monitored for periods of 2 months (60 days) and 3 months (90 days) starting at day 21, 35, and 42.

All statistical analysis was conducted using social science-specific statistical software, IBM SPSS version 20.0, Chicago, USA. Student t test (independent, two tailed) was used to find the significance of wound size between two groups, and paired t test was used to find the significance of wound size before and after dressings. Chi square test or Fisher Exact test have been used to find the significant association of study characteristics between control and test groups.

OBSERVATIONS AND RESULTS:

In the present study it was seen that men had increased number of chronic nonhealing ulcers (78.33%) as compared to females (21.67%). Chronic non healing ulcers are most commonly seen in 3th-4th decades (31.66%), while 28.33% were affected in 5rd-6th decade.

TABLE I : MEAN AGE DISTRIBUTION IN both GROUPs

Group	N	Mean age	Standard deviation	Minimum age	Maximum age
Test	30	39.1	19.3	6	67
Control	30	34.76	19.08	6	72

The mean age group was 39.1 ± 19.3 in the test group and in the control group the mean

age was 34.76 ± 19.08 years. (Table 1)

In study group 46.67% of ulcers were in the foot respectively in the test group and control group, while 20% and 33.33% were over the leg in test and control group respectively. There was no significant difference in both groups. **P value 0.466 (NS) (figure1)**

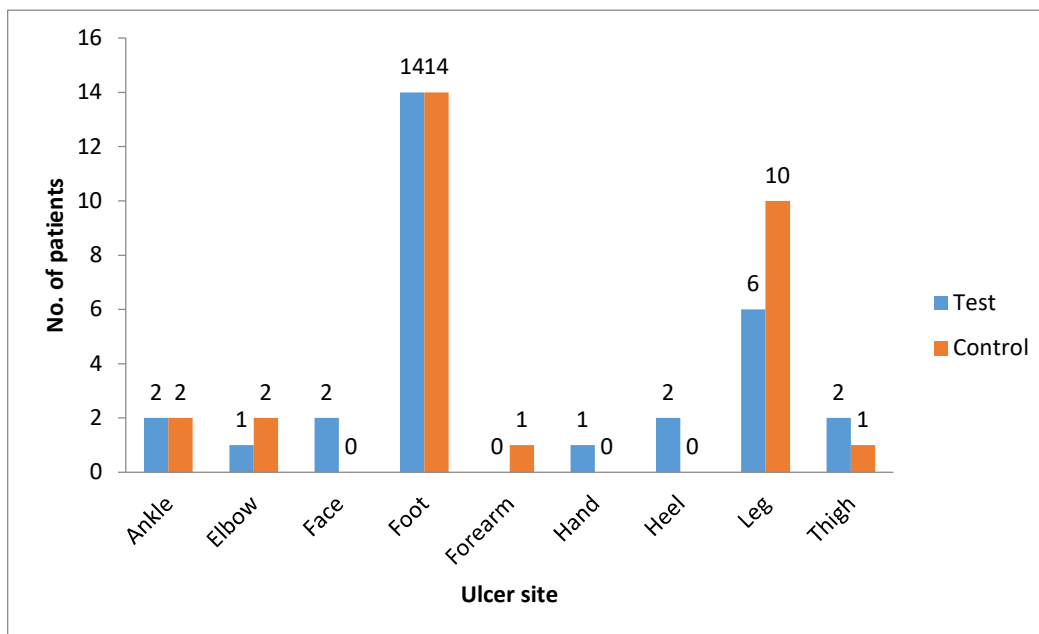


Fig. 1 : Ulcer site in both groups

TABLE 2 : COMPARISON OF MODE OF ONSET OF ULCER IN STUDY GROUPS

Onset	Test		Control		Total	
	No	%	No	%	No	%
Traumatic	16	53.33	18	60.00	34	56.67
Burn	4	13.33	6	20.00	10	16.67
Spontaneous	10	33.33	6	20.00	16	26.67
Total	30	100.00	30	100.00	60	100.00

Chi square 1.518, df 2, P value 0.468 (NS)

Trauma is the most common cause of origin of chronic non healing ulcer accounting for 56.67% while only 26.67% were spontaneous in origin. There was no significant difference in both group. (table 2)

TABLE 3 : COMPARISON OF PERCENTAGE REDUCTION OF ULCERSIZE IN STUDY GROUPS

Percentage reduction of ulcer size	Test		Control		Total	
	No	%	No	%	No	%
<70	0	0.00	2	6.67	2	3.33
75-80	1	3.33	6	20.00	7	11.67
85-90	4	13.33	17	56.67	21	35.00
>90	25	83.33	5	16.67	30	50.00
Total	30	100.00	30	100.00	60	100.00

Chi square 26.95, df 3, P value <0.0001 (S)

In test group 25 patients had percentage reduction between 91-99%, 4 patients between 85-90% and only 1 patient between 75-80%.

In control group 17 patients had percentage reduction of ulcer between 85-90%. 6 patients had percentage reduction between 75-80%. 5 patients had percentage of reduction 91-99% and 2 patients had percentage of reduction <70%.

There was a statistically significant difference in both groups and p value is <0.0001 highly significant. (table 3)

TABLE 4 : COMPARISON OF ULCER HEALING TIME IN STUDYGROUPS

Ulcer healing time (months)	Test		Control		Total	
	No	%	No	%	No	%
3	6	20.00	0	0.00	6	10.00
4	6	20.00	4	13.33	10	16.67
5	12	40.00	6	20.00	18	30.00
6	6	20.00	20	66.67	26	43.33
Total	30	100.00	30	100.00	60	100.00

Chi square 15.93, df 3, P value 0.001 (S)

In present study found it took 6 months for ulcer healing in 6 patients in test group and 4 months for 6 patients, while it took 6 months for ulcer healing in 20 patients in control groups and 4 months for 4 patients. There was a statistically significant difference in both groups and p value is 0.001 very significant. (Table 4)

TABLE 5 : COMPARISON OF NUMBER OF DRESSINGS REQUIRED IN STUDY GROUPS

Dressing required	Test		Control		Total	
	No	%	No	%	No	%
1-5	0	0.00	0	0.00	0	0.00

6-10	17	56.67	0	0.00	17	28.33
11-15	12	40.00	2	6.67	14	23.33
16-20	1	3.33	4	13.33	5	8.33
21-25	0	0.00	14	46.67	14	23.33
26-30	0	0.00	8	26.67	8	13.33
>30	0	0.00	2	6.67	2	3.33
Total	30	100.00	30	100.00	60	100.00

Chi square 49.94, df 5, P value <0.0001 (S)

In test group, 17 patients required collagen dressings between 6-10, followed by 12 patients required between 11-15 and only 1 patient required between 16-20. Control group required much more conventional dressings as compared with collagen dressings. There was a statistically significant difference in both groups and p value is <0.0001 highly significant. (Table 5)

TABLE 6 : COMPARISON OF DURATION OF HOSPITAL STAY IN both GROUPS

Duration of hospital stay (days)	Test		Control		Total	
	No	%	No	%	No	%
≤14	3	10.00	0	0.00	3	5.00
15-21	19	63.33	18	60.00	37	61.67
22-28	8	26.67	7	23.33	15	25.00
>28	0	0.00	5	16.67	5	8.33
Total	30	100.00	30	100.00	60	100.00

Chi square 8.094, df 3, P value 0.044 (S)

In collagen dressings 63.33% patients stayed for 2-3 weeks and no patient was hospital stay in more than 4 weeks. While in conventional dressings 60% patients stayed for 2-3 weeks and 16.67% patients stayed for more than 4 weeks. There was statistically significant difference in both groups and p value is 0.044 significant. (Table 6)

TABLE 7 : COMPARISON OF DURATION OF ANTIBIOTIC TREATMENT IN both GROUPS

Duration of antibiotic treatment (days)	Test		Control		Total	
	No	%	No	%	No	%
5	24	80.00	14	46.67	38	63.33
6-7	5	16.67	8	26.67	13	21.67
8-10	1	3.33	6	20.00	7	11.67
>10	0	0.00	2	6.67	2	3.33
Total	30	100.00	30	100.00	60	100.00

Chi square 8.895, df 3, P value 0.030 (S)

Comparison of duration of antibiotic treatment in study groups. In collagen dressings group 80% required Antibiotics only for 5 days in comparison to 46.67% in Conventional dressing group. There was statistically significant difference in both

groups and p value is 0.030 significant. (Table 7)

TABLE 8 : COMPARISON OF PAIN SCALE AFTER 24 HOURS POST 1 st DRESSING IN STUDY GROUPS

Pain Scale	Test		Control		Total	
	No	%	No	%	No	%
No pain	0	0.00	0	0.00	0	0.00
Minor(1-3)	20	66.67	9	30.00	29	48.33
Moderate(4-6)	9	30.00	13	43.33	22	36.67
Severe(7-10)	1	3.33	8	26.67	9	15.00
Total	30	100.00	30	100.00	60	100.00

Chi square 10.34, df 2, P value 0.005 (S)

Comparison of Pain scores after 24 hr of 1st dressing in Test and Control groups. On a scale of 0 to 10 pain scoring was done after 24 hours of applying the dressing and pain was considerably low in collagen group with 66.67% patients having minor pain in test group compared to 30% in control group. There was statistically significant difference in both groups and p value is 0.005 significant. (Table 8)

Discussion:

A more recent idea in wound care is collagen dressings. When lining skin, xenogenous collagen membrane provided high comfort since it was flexible and conformed to any shape of wound. In this study, we employed collagen wound dressings as a local agent for cleaning and sterilising a chronic non-healing ulcer and compared them to conventional dressings with mechanical debridement.

In the current study, 83.33% of patients in the collagen dressing test group and only 16.67% of patients in the control group obtained a more than 90% decrease in wound area.

In a study of 75 patients, Donaghue et al.[12] compared the effectiveness of topical wound dressings using collagen-alginate to those using guaze and ordinary saline. In the collagen-alginate dressing group, the mean wound area was reduced by 80.6%, compared to 61.1% in the guaze-dressing group.

Collagen dressings were compared to conventional dressings in the Donahue VM et al.(11) study, which was done in 1998. At the end of the trial, the collagen dressing group had a percentage decrease in wound areas of 80.60%, compared to the conventional dressing group's 61%.

Collagen dressings were required for considerably fewer patients in our study than the traditional dressing group (p-value).In the test group, 12 patients needed a dressing between 11 and 15, 17 patients needed a dressing between 6 and 10, and only 1 patient needed a dressing between 16 and 20. In comparison to collagen dressings, the control group needed a lot more traditional dressings. Both groups showed a statistically significant difference (p value of 0.0001). A research found that collagen dressings were changed substantially less frequently than gauze dressings in comparison to other types of dressings (July 1998, issue number 0205 of Medical Science Bulletin).52.7%

of gauze dressings were changed daily against 87% of collagen dressings. The remaining gauze coverings had twice-daily replacements[13].

In a separate research, Graunlich et al.[14] examined the efficiency of collagen and hydrocolloid in the healing of pressure ulcers. There were 65 total patients, of which 35 received collagen dressing and 30 hydrocolloid dressing. In the collagen group, complete ulcer healing was seen in 8 weeks (51%) compared to (50%) in the control group, although the mean healing time remained the same.

According to the current study, ulcer healing took 6 months for 6 patients in the test group and 4 months for 6 other patients, compared to 6 months for 20 patients in the control groups and 4 months for 4 other patients. There was a statistically significant difference between the two groups, with a highly significant p value of 0.001.

Comparison of pain scores in the Test and Control groups 24 hours after the first dressing. In the collagen group, only 66.67% of patients reported slight pain, compared to 30% in the control group other patients in control group having moderate to severe pain. There was statistically significant difference in both groups and p value is 0.005 significant.

Comparison of the length of antibiotic therapy among study groups. 80% of those who used collagen dressings only needed antibiotics for 5 days, as opposed to 46.67% of those who used conventional dressings. There was a statistically significant difference between the two groups, with a p value of 0.030. Healing time (4.02 0.59 Vs 7.6 1.38), antibiotic therapy duration (15.12 4.55 Vs 24.08 6.5), and mean follow-up period (2.40 0.61 Vs 2.96 1.2) were all significantly shorter in the collagen dressing group as compared to the conventional dressing group in the study by Rao H et al. (P 0.001)[15].

With collagen dressings, 63.33% of patients stayed for a maximum of two to three weeks, with no patient having a stay longer than four weeks. While using standard dressings, 60% of patients stayed for two to three weeks, while 16.67% stayed for more than four weeks. There was a statistically significant difference between the two groups, with a p value of 0.044. According to a research by Chalimidi KR et al. titled "Efficacy of Collagen Particles in Chronic Non-Healing Ulcers," the collagen dressing group had a substantially higher mean difference in ulcer size (37.291 vs. 14.291) and a shorter hospital stay (16).

LIMITATIONS

Only 60 patients from each group were included, resulting in a smaller sample size. The cost of collagen dressing is not evaluated in this study, which is the second limitation of study.

CONCLUSION

By encouraging the development of early granulation tissue and wound contraction, collagen particles are helpful at accelerating the healing process. because of this, it shortens the healing process without causing difficulties or harm to healthy tissue. According to the current study, this can be done in order to decrease the number of dressings needed. With considerably less dressings than with standard dressings, the majority of patients healed completely epithelized at a quicker pace. Additionally, the

traditional dressings group fared substantially better in terms of the percentage of ulcer reduction over a specified period of time and the ulcer healing time.

By creating a temporary barrier between the wound and the surrounding environment, collagen dressings also reduced the risk of infection. As a result, both the length of the hospital stay and the duration of the antibiotic treatment were decreased.

By comparing collagen dressing to traditional dressings, we can state that collagen dressing improves early healing, lessens discomfort and the need for analgesics, and minimises related problems such as infections, the follow-up time, antibiotic usage, and hospital stay.

According to the data above, collagen dressings may be utilised as an additional tool in the treatment of persistent ulcers that won't heal. Further research will be needed to assess the outcomes of the collagen therapy because the study's sample size was not sufficiently big.

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