

Original Research Article

A comparative study of collagen-based dressing versus conventional dressing in chronic ulcers

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ABSTRACT

Background: Collagen is a fibrous structure, proline-rich protein, comprised of three α -chains, plays an important role in each stage of wound healing, attracts fibroblasts and keratinocytes which in turn encourages debridement, angiogenesis and re-epithelialization

Methods: This is a prospective cohort study. After obtaining ethical clearance from Institute's ethical committee, all the patients fulfilling inclusion criteria were enrolled and written consent was obtained from all the patients. Detailed history was enquired and recorded on a predesigned proforma. The ulcer healing, analysed as- Time required for appearance of healthy granulation tissue, 50% reduction in ulcer size, complete healing time, requirement of skin grafting, time required in return to daily activities.

Results: A significant decrease in time required for 50 % reduction in wound size with a mean difference of 18.5 in collagen group patients when compared to 37.5 and 33.0 in Normal saline group patients and Povidone iodine group patients. Chi square test was applied to assess the difference in proportions between groups t test was applied to compare the mean between the groups. $P < 0.05$ was considered as statically significant.

Conclusions: Healing with collagen particles is early, compared to the conventional dressings with lesser requirement of skin grafting, number of dressings, shorter hospital stay. Dressing changed every 3-4 days. Healing occurs by formation of early granulation tissue and wound contraction.

Keywords: Dressing, Healthy granulation tissue, Skin grafting

INTRODUCTION

An ulcer has been defined as a breach in continuity of the covering epithelium either of skin or of mucus membrane.¹ Chronic or non-healing ulcers are defined as ulcers that persist for more than 3 weeks and are unresponsive to initial treatment or that persist even after appropriate care and management.^{2,3} Chronic ulcers are known to occur due to lack of growth factors and cytokines which negatively affects wound healing process.⁴ There are multiple causes of chronic ulcers which include venous insufficiency, arterial insufficiency, diabetes, pressure (bedsore) and traumatic ulcers.⁴ The most common site of chronic ulcers is lower

extremities affecting >60% cases especially in those with venous, diabetic or arterial etiology.^{3,5}

Worldwide, the prevalence of chronic ulcers is estimated to be 1.9% to 13.1% and in United States alone, chronic ulcers are estimated to affect approximately 2 to 6 million people.^{3,6-8} The exact prevalence of chronic ulcers in India is not known, however, Shukla et al estimated its prevalence to be 4.5 per 1000 population in Indian population.⁹ These ulcers are not only associated with medical complications but have been associated with negative impact on almost each aspect of daily life such as restricted mobility, sleep impairment, reduced work capacity as well as financial condition of the affected

individual. Thus, it has negative impact on both the quality of life as well as the productivity of patient.¹⁰

The management strategy includes treatment of underlying cause such as management of blood glucose levels, relief of pressure, treatment of infection, mechanical off-loading, management of ischemia, management of associated co morbidities and local wound care.³

Conventionally ulcers have been treated by cleansing, debridement, followed by dressing with topical preparation such as Povidone iodine, antibiotic ointment, silver ointment etc. An ideal dressing for management of chronic ulcers must be easy to apply, economical, readily available, must provide good pain relief, has wide antimicrobial spectrum, promote wound healing, provide moisture as well as allow spontaneous epithelialization of granulation tissue and must adhere well on the wound.

Collagen plays an important role in each of these phases of wound healing. Collagen is structurally and functionally a key protein of the extracellular matrix which is also involved in scar formation during the healing of connective tissues. 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.¹¹ Collagen sheets, when applied to a wound, not only promote angiogenesis, but also enhance body's repair mechanisms.¹² 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}

Objectives

To study the efficacy of collagen particles in wound healing in chronic ulcers. To study the efficacy of conventional dressings using povidone iodine or normal saline in wound healing in chronic ulcers. To compare the efficacy of collagen particles with conventional method of dressing using povidone iodine or normal saline in wound healing in chronic ulcers.

METHODS

Present study is a prospective cohort study done in Department of Surgery, People's Hospital, Bhopal M.P in which all the patients with chronic ulcers who were admitted and met the inclusion criteria in the Department of Surgery in People's Hospital Bhopal attached to People's College of Medical Sciences and Research Centre Bhopal during the study period.

Study period

The study period was 18 months i.e. December 2018 to May 2020.

Inclusion criteria

All patients with chronic ulcer of size ≤ 6 cm. All chronic ulcers irrespective of etiology viz. traumatic, infective ulcers, bedsores, burns, venous ulcers, diabetic ulcers, amputation stump ulcers, non-specific except arterial ulcers.

Exclusion criteria

Arterial ulcers. Ulcers having exposed bone and tendons. Ulcers with proven malignancy. Patient on corticosteroids/immune-suppressants/cancer chemotherapy. Patients not willing to participate in the study.

Consent

Written consent was obtained from the patients after explaining them the nature and purpose of the study. They were assured that confidentiality would be strictly maintained. The option to withdraw from the study was always open.

Methodology

After obtaining clearance from Institutional Research and Ethical committees, all the patients fulfilling inclusion criteria were enrolled, and written consent obtained from them. The proforma was filled under four major headings namely:

Patient's information including name, age, gender, address, UHID No, IPD No, date of admission and date of discharge.

Clinical data including duration, size, site, edges, margins of ulcer, presence of slough, discharge, condition of the surrounding skin, hemoglobin and albumin levels, swab culture, antibiotic sensitivity, and diagnosis. Management of ulcer was done according to the standard protocol. Modality of dressing was chosen by the treating surgeon, according to which patients were then divided into three groups namely:

Group A: Patients dressed with normal saline

Group B: Patients dressed with povidone iodine

Group C: Patients dressed with collagen particles

Clinical outcome in each of the group was assessed using the following parameters:

Time required for the appearance of healthy granulation tissue. 50% reduction in ulcer size. Usage of antibiotics and analgesics in number of days. Complete healing time. Requirement of skin grafting. Time required in return to daily activities.

Statistical analysis

Data was compiled using MS Excel and analyzed using Statistical package for social sciences (SPSS) version 20.0 for Windows (IBM Corporation Armonk, NY and USA). Frequency and percentage were calculated for grouped data whereas numerical data was expressed as mean±SD. Chi square test was applied to assess the difference in proportions between groups whereas ANOVA and t test were applied to compare the mean between the groups. P<0.05 was considered as statically significant.

RESULTS

The present study titled “A comparative study of collagen-based dressing versus conventional dressing in chronic ulcers” was conducted on a total of 100 patients presenting with chronic ulcers ≤6 cm size in the Department of General Surgery, People’s College of Medical Sciences and Research Centre and People’s Hospital Bhopal. Based upon the type of dressing used, patients were divided into the following three groups: Group A patients (08) were dressed with normal saline, Group B patients (54) were dressed with povidone iodine and Group C patients (38) were dressed with collagen particles making a total of 100 patients.

Table 1: Distribution of patients according to age.

Age group (years)	Normal saline (%)	Povidone iodine (%)	Collagen particles (%)	Total (%)
≤25	1 (12.5)	5 (9.3)	3 (7.9)	9 (9)
26-35	4 (50)	5 (9.3)	2 (5.3)	11 (11)
36-45	1 (12.5)	6 (11.1)	4 (10.5)	11 (11)
46-55	1 (12.5)	15 (27.8)	11 (28.9)	27 (27)
56-65	1 (12.5)	15 (27.8)	13 (34.2)	29 (29)
>65	0 (0)	8 (14.8)	5 (13.2)	13 (13)
Total	8	54	38	100
Mean age	37±10.99	50.63±15.68	51.08±13.63	
Range	25-56	14-85	17-76	

$$\chi^2=15.54; p=0.114$$

Table 2: Distribution according to gender.

Gender	Normal saline (%)	Povidone iodine (%)	Collagen particles (%)	Total (%)
Male	4 (50)	35 (64.8)	30 (79.9)	69 (69)
Female	4 (50)	19 (35.2)	8 (21.1)	31 (31)
Total	8	54	38	100

$$\chi^2=3.55; p=0.169$$

Table 3: Distribution of patients according to etiology.

Etiology	Normal saline (%)	Povidone iodine (%)	Collagen particles (%)	Total (%)
Traumatic	4 (50)	24 (44.4)	23 (60.5)	51 (51)
Diabetic ulcer	3 (37.5)	24 (44.4)	11 (28.9)	38 (38)
Bed sore	0 (0)	5 (9.3)	3 (7.9)	8 (8)
Venous	1 (12.5)	1 (1.9)	0 (0)	2 (2)
Neuropathic (non-diabetic)	0 (0)	0 (0)	1 (2.6)	1 (1)
Total	8	54	38	100

$$\chi^2=10.09; p=0.26$$

Distribution of patients according to age

In present study, majority of patients dressed with normal saline group belonged to 26 to 35 years of age (50%) whereas majority of patients dressed with povidone iodine and collagen particles belonged to 45 to 65 years

of age. Test of significance (chi-square test) observed no statistically significant difference in age composition of three groups and thus comparable with respect to age ($p>0.05$).

Distribution according to gender

The study comprised of a greater number of males as compared to females, however the test of significance (chi square test) showed no statistically significant difference in gender composition of three groups ($p>0.05$).

Table 4: Distribution of participants according to size of ulcer.

Size/ area of the ulcer(cm ²)	Normal saline (%)	Povidone iodine (%)	Collagen particles (%)	Total (%)
≤4	5 (62.5)	25 (46.3)	16 (42.1)	46 (46)
5-8	0 (0)	15 (27.8)	13 (34.2)	28 (28)
8-12	2 (25)	13 (24.1)	9 (23.7)	24 (24)
13-20	1 (12.5)	1 (1.9)	0 (0)	2 (2)
Total	8	54	38	100
Mean	6.63±6.8	5.74±3.7	5.71±3.6	

$\chi^2=8.55$; $p=0.20$

Distribution according to etiology

Most common etiology of chronic ulcers was trauma amongst patients of all the groups, followed by diabetes. The three groups in present study were comparable in etiology of chronic ulcers ($p>0.05$).

Distribution according to size of the ulcer

All ulcers were ≤6 cm in size in any dimension. Test of significance (chi square test) showed no statistically significant difference in size of ulcer between participants of three groups ($p>0.05$).

Comparison by appearance of healthy granulation tissue

Appearance of healthy granulation tissue was observed to be significantly earlier among patients of collagen particle group as compared to other two groups ($p<0.01$).

Time required for 50% reduction in size

It was observed that time taken for 50% reduction of size of ulcer was minimum for patients of collagen particle group as compared to other two groups and the observed difference was statistically highly significant ($p<0.01$).

Table 5: Comparison of appearance of healthy granulation tissue.

Appearance of healthy granulation tissue (days)	Normal saline (%)	Povidone iodine (%)	Collagen particles (%)	Total (%)
≤7	0 (0)	4 (7.4)	9 (23.7)	13 (13)
8-14	4 (50)	12 (22.2)	25 (65.8)	41 (41)
15-21	1 (12.5)	16 (29.6)	4 (10.5)	21 (21)
22-28	0 (0)	16 (29.6)	0 (0)	16 (16)
>28	3 (37.5)	6 (11.1)	0 (0)	9 (9)
Total	8	54	38	100
Mean	23.5±14.89	19.11±8.13	10.29±3.47	

$\chi^2=44.886$; $p=0.001$

Table 6: Comparison of time taken for 50% reduction in ulcer size.

Time taken for 50% reduction in ulcer size (Days)	Normal saline (%)	Povidone iodine (%)	Collagen particles (%)	Total (%)
<15 days	0 (0)	2 (3.7)	11 (28.9)	13 (13)
16-30 days	5 (62.5)	25 (46.3)	27 (71.1)	57 (57)
31-45 days	0 (0)	19 (35.2)	0 (0)	19 (19)
>45 days	3 (37.5)	8 (14.8)	0 (0)	11 (11)
Total	8	54	38	100
Mean	37.5±25.6	33±13.97	18.5±5.3	

$\chi^2=40.695$; $p=0.001$

Table 7: Comparison of requirement of skin grafting.

Skin grafting	Normal saline (%)	Povidone iodine (%)	Collagen particles (%)	Total (%)
Required	3 (37.5)	12 (22.2)	1 (2.6)	16 (16)
Not required	5 (62.5)	42 (77.8)	37 (97.4)	84 (84)
Total	8	54	38	100

$\chi^2=9.360$; $p=0.009$

Table 8: Comparison of time for complete healing of ulcer.

Complete healing (days)	Normal saline (%)	Povidone iodine (%)	Collagen particles (%)	Total (%)
≤21	0 (0)	0 (0)	7 (18.4)	7 (7)
22-42	04 (50)	13 (24.1)	26 (68.4)	43 (43)
>42	3 (37.5)	40 (74.1)	5 (13.2)	48 (48)
Not healed	1 (12.5)	1 (1.9)	0 (0)	2 (2)
Total	8	54	38	100
Mean	57.71±30.80	60.06±21.7	32.71±10.11	

$\chi^2=44.34$; $p=0.001$

Comparison of requirement of skin grafting

The requirement of skin grafting was observed to be minimum as compared to other two groups and the observed difference was statistically highly significant ($p<0.01$).

Time required for complete healing

The observed difference in complete healing was statistically highly significant early healing in collagen particle group as compared to other two groups ($p<0.05$).



Figure 2: Before and after collagen particles application.

DISCUSSION

For the treatment of chronic ulcers, use of collagen-based dressings has shown encouraging results, however, there

is paucity of data regarding collagen particle dressing. The present study is a prospective cohort study which was conducted at tertiary care centre, to compare the efficacy of collagen particles with conventional method of dressing used in the treatment of chronic ulcers. In this study, observation of a total of 100 patients with chronic ulcers having largest diameter ≤6 cm was done and of them, 8 patients were managed using normal saline dressing whereas 54 and 38 patients were managed using povidone iodine and collagen particle dressing, modality of treatment was decided by the treating doctor

Age

In the present study, majority of patients with chronic ulcers belonged to 45 – 65 years of age groups. Test of significance (chi square test) observed no statistically significant difference in age composition of three groups and thus comparable with respect to age ($p>0.05$).

The findings of present study were supported by findings of Rahman et al in which the authors concluded that chronic ulcers have a tendency to increase with age. They reported chronic ulcers in maximum patients belonging to age range of 50 to 69 years.¹⁴

Gender

Chronic ulcers may be observed in equal proportions amongst male as well as females. In present study, majority i.e. 69% of patients with chronic ulcers were males whereas rest 31% patients were females. The test of significance (chi square test) showed no statistically significant difference in gender composition of three groups ($p>0.05$).

The findings of present study were in line with study of Panda et al in which about 76.2% patients with chronic ulcers were male and the rest 23.8% were females.¹⁵

The observed difference between the finding of present study and reference study could be due to difference in health seeking behaviour among males and females.

Etiology

Chronic ulcers have been attributed to multiple etiologies, most common being traumatic ulcers, diabetes, venous insufficiency and pressure (bedsore).⁴ Findings similar to this study were documented by Panda et al in which majority i.e. 53.19% of patients had traumatic ulcer followed by Diabetic ulcer and vascular ulcer observed in 48.65% and 36.36% patients respectively.¹⁵ The three groups in present study were comparable in etiology of chronic ulcers ($p>0.05$).

Swab culture

Polymicrobial flora has been found to be associated with chronic ulcers. No statistically significant difference was observed in organisms grown on swab culture between three group of patients ($p>0.05$).

Panda et al isolated microbial flora from 77 patients out of 168 patients. The most common microbial isolate in reference study was staphylococcus aureus accounting for 19.69% similar to present study. This was followed by *Pseudomonas aeruginosa* and *E coli*.¹⁵

Size of ulcer

The size of ulcer is a prognostic variable which determine healing of ulcer. Size of the ulcer is measured in terms of area. Largest diameter of the ulcer was ≤ 6 cms. Test of significance (chi square test) showed no statistically significant difference in area of ulcer between participants of three groups ($p>0.05$).

In a study by Sun et al mean initial area of wounds was 30.3 ± 63.0 cm² (range 0.25-468 cm²).¹⁶ However, in another study by Jegoda et al, mean ulcer size in collagen group was $16.29 \text{ cm}^2 \pm 6.07 \text{ cm}^2$ whereas that of normal saline group was $14.73 \text{ cm}^2 \pm 6.37 \text{ cm}^2$.¹⁷ In a study done by Seth et al in 65 diabetic patients, the mean baseline ulcer area was 14.85 ± 23.12 .¹⁸

Appearance of granulation tissue

Appearance of granulation tissue is the first sign of wound healing. Choudhary et al in another prospective study on 60 patients with chronic ulcers compared the efficacy of collagen dressing with that of conventional dressing in the management of chronic ulcers and their healing process.¹⁹ For 30 patients, collagen dressing was done and for rest conventional dressing. The granulation tissue appeared in around 2 weeks in maximum cases in collagen dressing group, i.e. 63.4% and in around 4 weeks in conventional dressing group i.e. 46.7%. Average time for appearance of granulation tissue in collagen and conventional dressing group was around 3 weeks and 4.9 weeks respectively

Time taken for 50% reduction in ulcer size

In the present study time taken for 50% reduction in ulcer size was significantly less in collagen particle group as compared to other two groups ($p<0.01$). Jegoda et al in another prospective study in India assessed the efficacy of topical use of collagen granules in wound healing. A total of 60 patients were included and were divided into two groups. The authors documented that the Mean ulcer size at day 1 in group A was 16.29 cm² with a SD of 6.07 cm².

In Group B, the mean ulcer size at day 1 was 14.73 cm² with a SD of 6.37 cm². The mean ulcer size at day 30 in Group A was 3.78 cm² with a SD of 2.47 cm². In Group B, the mean ulcer size was 4.35 cm² with SD of 2.87 cm².

Requirement of skin grafting

The present study found that requirement of skin grafting in patients managed with collagen dressing is less than those dressed with povidone iodine or normal saline. Mean number of days for complete healing in povidone iodine group might exceed saline group because of outliers.

A comparative study of collagen granule vs conventional dressing in case of chronic non healing ulcers by Velappan et al on 60 patients of chronic ulcers, 76% of patients in conventional group undergone split skin graft and 26% of patients in the collagen group has undergone split skin graft.²⁰

Complete healing of ulcer

In collagen particle group, complete healing of ulcer was observed in 68.4% patients of collagen particle groups in 22 to 42 days and 18.4% patients within 21 days. However, complete healing time for majority of patients of povidone iodine group was greater than 42 days. Complete healing of ulcer at 6 weeks was seen in 70% of patients with collagen and 63% of patients with conventional dressing by Singh et al, although the difference was not significant.²¹

Limitations

Arterial ulcers. Ulcers having exposed bone and tendons. Ulcers with proven malignancy. Patient on corticosteroids/ immune-suppressants/ cancer chemotherapy. Patients not willing to participate in the study.

CONCLUSION

Based on the findings of present study it can be concluded that chronic ulcers are common amongst male patients in the age range of 45 to 65 years. Traumatic ulcers are most common etiology for development of chronic ulcers followed by diabetes. Though, antibiotics

and analgesic use was similar amongst the patients of three groups, participants of collagen dressing group required antibiotic and analgesics for significantly a smaller number of days as compared to other two groups. Collagen based dressing were observed to be superior from povidone iodine and normal saline dressings in terms of all aspects of healing viz. appearance of healthy granulation tissue, time taken for 50% reduction in ulcer size, complete healing days and return of daily activities. As healing was better in collagen-based dressing group, requirement of skin grafting was much lower as compared to other two groups. Collagen based dressings showed early healing in all patients irrespective of etiology of chronic ulcers.

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