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RESEARCH ARTICLE

"ANALYSIS OF EFFICACY OF COLLAGEN DRESSING VERSUS CONVENTIONAL DRESSING IN CHRONIC WOUND"

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Abstract

A breach in continuity of the covering epithelium either of skin or of mucus membrane is defined as ulcer. Chronic or non-healing ulcers are defined as ulcers that are unresponsive to initial treatment or that persist for more than 3 weeks after appropriate care and management. Chronic nonhealing ulcers not only have a medical challenge but have social, economical and occupational effects on the patient. Ulcers have been treated conventionally by cleansing, debridement and removal of necrotic and infected tissue which was followed by dressing with topical antiseptic like Povidone iodine, antibiotic ointment, silver ointment, etc. Collagen is a group of naturally occurring proteins found in all phases of wound healing. Collagen is a key component of extracellular matrix which plays critical roles in the regulation of the phases of wound healing in its native fibrillar conformation or as a soluble component.Collagen helps wound healing through deposition and organisation of freshly formed fibres and granulation tissue in the wound bed which creates a good environment for wound healing.Collagen sheets when applied to a wound promote angiogenesis and also enhance body' s repair mechanisms Our Aim is To compare the efficacy of the conventional dressing and collagen dressing in chronic wound in terms of Average time required for appearance of Granulation tissue, Requirement of Skin Grafting and mean Hospital Stay. Based on the type of dressing used, patients were divided into 2 groups, Group A(49) patients were dressed with conventional dressing, Group B patients (51) were dressed with collagen making a total of 100 patients. Appearance of healthy granulation tissue was observed to be significantly earlier among patients of collagen dressing group as compared to other group .The observed difference between number of days of hospital stay of patients with collagen dressing was statistically significant as compared to other group Thus Collagen based dressing were observed to be superior from conventional dressings in terms of aspects of healing viz. appearance of healthy granulation tissue.

Introduction:-

A breach in continuity of the covering epithelium either of skin or of mucus membrane is defined as ulcer.[1] Ulcer can be classified as either acute or chronic depending on the duration of ulcer. Chronic or non-healing ulcers are

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defined as ulcers that are unresponsive to initial treatment or that persist for more than 3 weeks after appropriate care and management.[2,3]

Chronic ulcers occur due to various causes and are known to occur due to lack of growth factors and cytokines which negatively affects wound healing process[4]. Other causes of chronic ulcers include venous insufficiency, arterial insufficiency, diabetes, pressure (bedsore) and traumatic ulcers. Most commonly the lower extremities are affected in >60% cases, especially in patients having venous, diabetic or arterial etiology[5,6]. The worldwide prevalence of chronic ulcers is estimated to be 1.9% to 13.1%.[7] The prevalence of chronic ulcers in India is not known, but Shukla et al estimated the prevalence of chronic ulcers in India to be 4.5 per 1000 population in Indian population[8]

Chronic nonhealing ulcers not only have a medical challenge but have social, economical and occupational effects on the patient. The physician and patients desire minimal duration of treatment, hospital stay, expenses and early return to work.

Ulcers have been treated conventionally by cleansing, debridement and removal of necrotic and infected tissue which was followed by dressing with topical antiseptic like Povidone iodine, antibiotic ointment, silver ointment, etc. An ideal dressing for chronic ulcers is a dressing which is easy to apply, economical, readily available, promote wound healing, provide moisture and antimicrobial spectrum as well as allow spontaneous epithelialization of granulation tissue and must adhere well on the wound.

Wound healing progresses through 4 phases; haemostasis, inflammatory, proliferative, maturation in response to tissue injury. These normal processes of wound healing are disrupted in chronic wounds due to underlying pathology like diabetes, trauma, infection, arterial or venous insufficiency and need some form of intervention to guide the process back to completion.[9,10]

Collagen is a group of naturally occurring proteins found in all phases of wound healing. Collagen is a key component of extracellular matrix which plays critical roles in the regulation of the phases of wound healing in its native fibrillar conformation or as a soluble component.[11-16] The factors creating the hostile environment of a chronic wound are persistent inflammation, increased destruction of extracellular matrix components caused by elevated metalloproteinases and other enzymes and improper activation of soluble mediators of the wound healing process.

Collagen is central in the regulation of several of these processes and has been utilised as an adjunct wound therapy in chronic wounds to promote healing. In our study we have used collagen granules and sheet. As a biomaterial for dressing of chronic wounds, collagen offers several advantages over traditional dressings, growth hormones and biological coverings

Collagen helps wound healing through deposition and organisation of freshly formed fibres and granulation tissue in the wound bed which creates a good environment for wound healing[17]

Collagen sheets when applied to a wound promote angiogenesis and also enhance body's repair mechanisms.[18]. These sheets also act as a mechanical support and reduce loss of fluid from wound site which maintains the moisture while facilitating the migration of fibroblasts into wound which enhances the metabolic activity of the granulation tissue[19]

Aim and Objectives of this Study:-

Aim and Objectives:-

Aim:-

To compare the efficacy of the conventional dressing and collagen dressing in chronic wound.

Objectives:-

1. To analyseaverage time required for appearance of granulation tissue on wound in conventional and collagen dressing.
2. To assess the requirement of skin grafting in conventional and collagen dressing.
3. To analyse the mean hospital stay in conventional dressing and collagen dressing of a wound

Materials and Methods:-

Source of Data

1. Type of study: Prospective comparative study.
2. Place of study: MGM Medical college and hospital, Navi Mumbai.
3. Period of study: March 2021 to December 2022
4. Sample type: Random sampling
5. Sampling method: Convenient sampling
6. Sample size: $\mathbf{N=(Z^2 \text{ x } p \text{ x } q)L^2}$ **;** where p=prevalence of chronic wounds, q=prevalence of other wounds , z=standard deviation, L=margin of error : $\mathbf{[(1.96)^2 \text{ x } 0.6 \text{ x } 0.4] \div (0.1)^2 = 100}$
7. For the study purpose, two groups of equal size(i.e. 50 patients each) will be constitute to provide statistically most precise results(Group A & Group B)
8. Sampling technique: Simple random sampling (i.e randomly picking up of Unnamed card by patients) will be used to select study subject in each group.

Ethical Considerations:

Prior approval of the Institutional Ethics Committee was taken before conducting the study.

Written Informed Consent:

Written informed consent was taken from all the patients who were included the study. The consent form is attached in Annexure. The consent form was prepared in the vernacular language (English, Hindi and Marathi).

For the patients who could not read and write, the consent form was explained to them in their vernacular language in the presence of an unbiased, non-related witness, provided the witness was literate. Adequate time was provided to the participants to ensure their proper understanding of the nature of the study and the degree of participation. Confidentiality was maintained throughout the study and would be further maintained during any future sharing or publication of the result. Patients were given adequate time for raising any queries regarding the study or participation. Any queries raised by them were solved best to the knowledge of the investigator.

A copy of the Information Sheet of the Informed Consent Form was provided to the patients. The signature of the witness and the thumb impression of the patient (illiterate) or the signature of the patient (literate) was taken on the consent form.

Thus, the participation in the study was fully informed, voluntary and without any coercion.

Inclusion criteria:

All patients presenting with chronic wound and admitted under Department of General Surgery

Exclusion criteria:

1. Patients having malignant ulcers.
2. Patients with allergy to collagen dressing.
3. Patients who are critically ill.
4. Patient with any evidence of underlying bone osteomyelitis.
5. Patients presenting to the outpatient department will not be included.

All the data was recorded in excel and analysed.

Figures

Day 0 of Collagen Dressing

Day 7 of Collagen Dressing

Day 21 of Collagen Dressing.

Fig 5:- Collagen Granule used for Dressing.

Results:-

Our study titled "A comparative study of Collagen Dressing Versus Conventional Dressing in Chronic Wound" was conducted on a total of 100 patients presenting with chronic ulcers in the Department of General Surgery, MGM hospital, Navi Mumbai.

Based on the type of dressing used, patients were divided into 2 groups, Group A patients (49) were dressed with conventional dressing, Group B patients (51) were dressed with collagen making a total of 100 patients.

Table 1:- Showing Age wise distribution of Study Population in two groups.

Age group (years)	Conventional dressing(%)	Collagen dressing(%)	Total(%)
18-25	4(8.1)	5(9.8)	9 (9)
26-35	2(4.0)	6(11.76)	8(8)
36-45	9(18.36)	6(11.76)	15(15)
46-55	6(12.24)	8(15.68)	14(14)
56-65	17(34.69)	12(23.52)	29(29)
>65	11(22.44)	14(27.45)	25(25)
Total	49	51	100
Mean age	53.63	54.09	
Range	18-78	18-89	
	p=0.114		

Distribution of patients according to age:
In our study, majority of patients dressed with conventional dressing belonged to 56-65 years of age whereas majority of patients dressed with collagen dressing belonged to more than 65 years of age. Test of significance (chi-square test) observed no statistically significant difference in age composition of two groups and thus comparable with respect to age (p>0.05)

Graph 1:- Showing Age wise distribution of study Population in two groups.

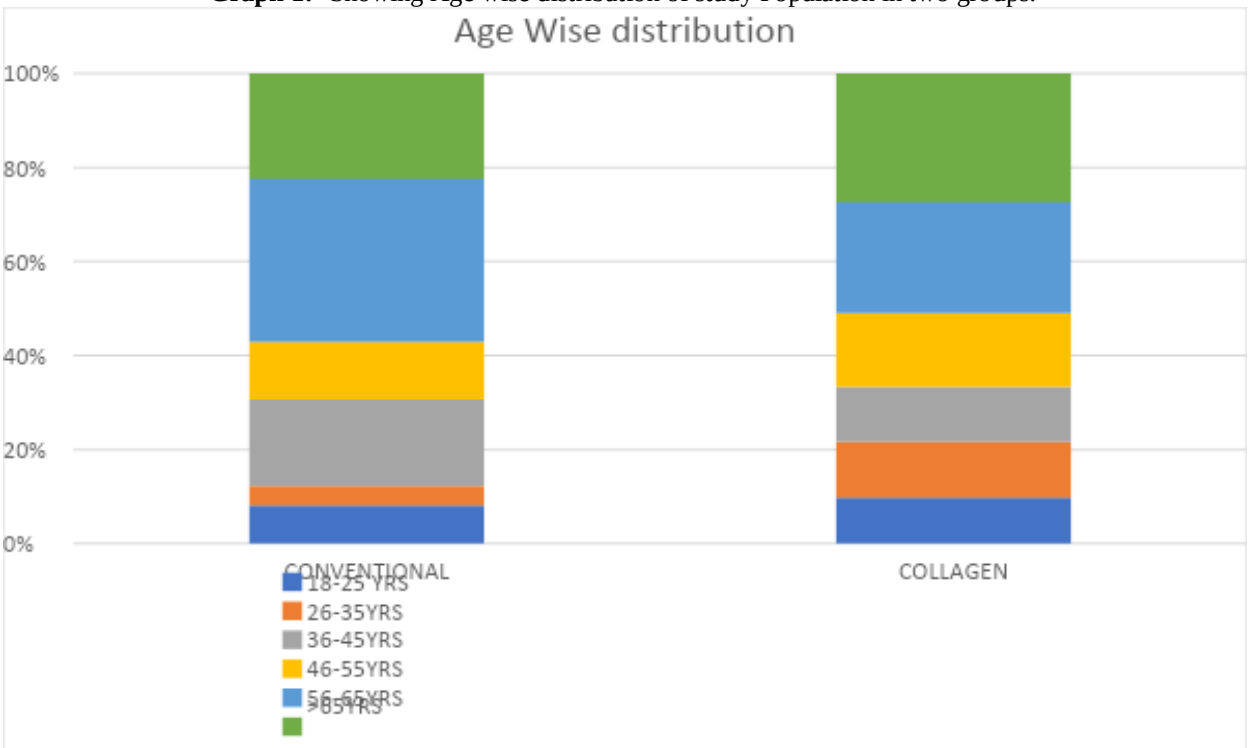


Table 2:- Showing Sex wise distribution of study Population in two groups.

Gender	Conventional dressing(%)	Collagen dressing(%)	Total(%)
Male	42(85.71)	39(76.47)	81(81)
Female	7(14.28)	12(23.52)	19(19)
Total	49	51	100
	p=0.169		

Distribution according to gender:
Our study comprised of 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 both groups (p>0.05).

Graph 2:- Showing Sex wise distribution of study Population in two groups.

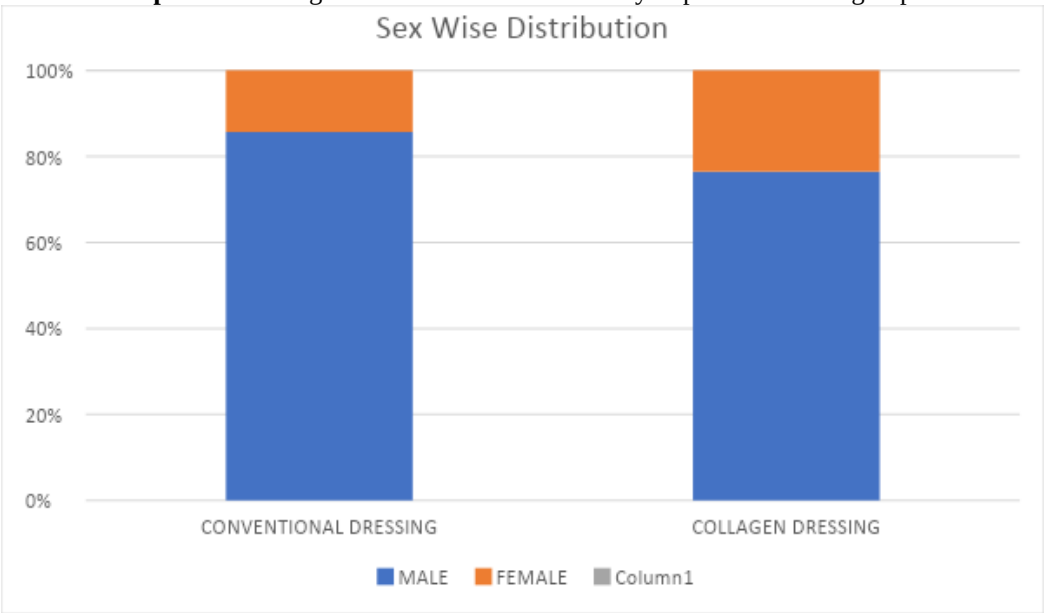


Table 3:- Distribution of study population in two groups according to Etiology.

Etiology	Conventional dressing(%)	Collagen dressing(%)	Total(%)
Traumatic	10(20.40)	15(29.41)	25(25)
Diabetic ulcer	37(75.51)	31(60.78)	68(68)
Bed sore	2(4.08)	5(9.80)	7(7)
Total	49	51	100
	p=0.26		

Distribution according to etiology:
Most common etiology of chronic ulcers was diabetic ulcer amongst patients of all the groups, followed by Trauma. Both the groups in the study were comparable in etiology of chronic ulcers (p>0.05).

Graph 3:- Distribution of study population in two groups according to etiology.

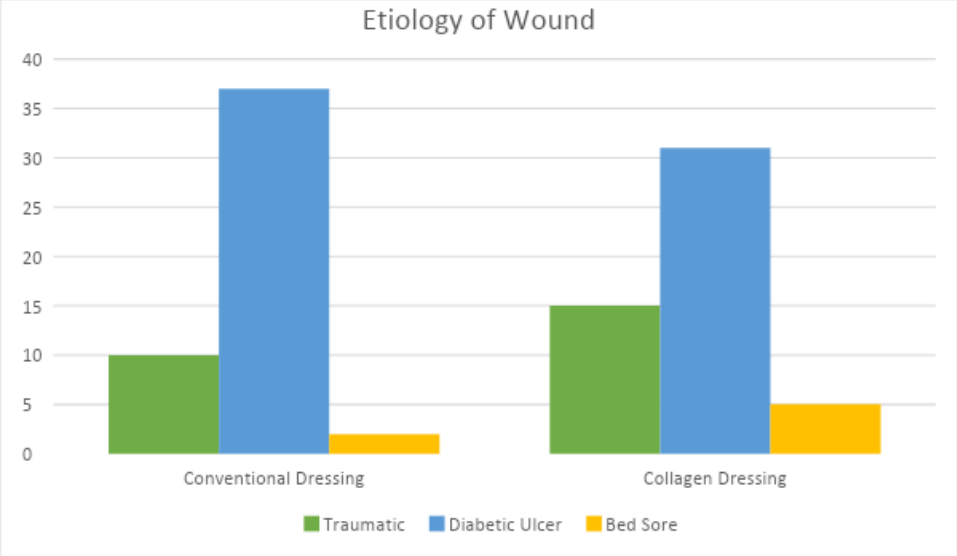


Table 4:- Distribution of study population in two groups according toSize/Area of the ulcer in Cm^2

Size/area of the ulcer(cm^2)	Conventional dressing(%)	Collagen dressing(%)	Total(%)
≤4	21(42.85)	19(37.25)	40(40)
5-8	14(28.57)	17(33.33)	31(31)
9-12	13(26.53)	13(25.49)	26(26)
13-20	1(2.04)	2(3.92)	3(3)
Total	49	51	100
Mean	6.1	6.7	
	p=0.20		

Distribution according to size of the ulcer:
Test of significance (chi square test) showed no statistically significant difference in size of ulcer between patients of both groups (p>0.05).

Graph 4:- Distribution of study population in two groups according toSize/Area of the ulcer in Cm^2

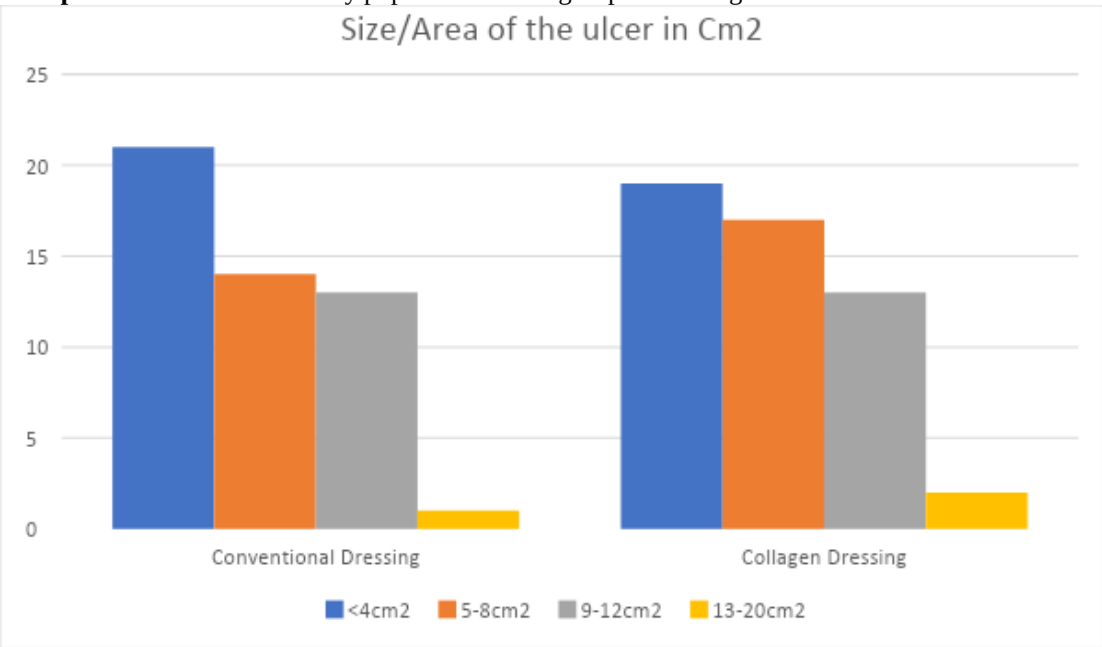


Table 5:- Distribution of study population in two groups according toAppearance of Healthy Granulation tissue (in days).

Appearance of healthy granulation tissue (days)	Conventional dressing (%)	Collagen dressing (%)	Total (%)
≤7	8	21	29
8-14	19	25	44
15-21	20	5	25
>21	2	0	2
Total	49	51	100
Mean			
	p=0.001		

Comparison by appearance of healthy granulation tissue:
Appearance of healthy granulation tissue was observed to be significantly earlier among patients of collagen dressing group as compared to other group (p<0.01).

Graph 5:- Distribution of study population in two groups according toAppearance of Healthy Granulation tissue (in days).

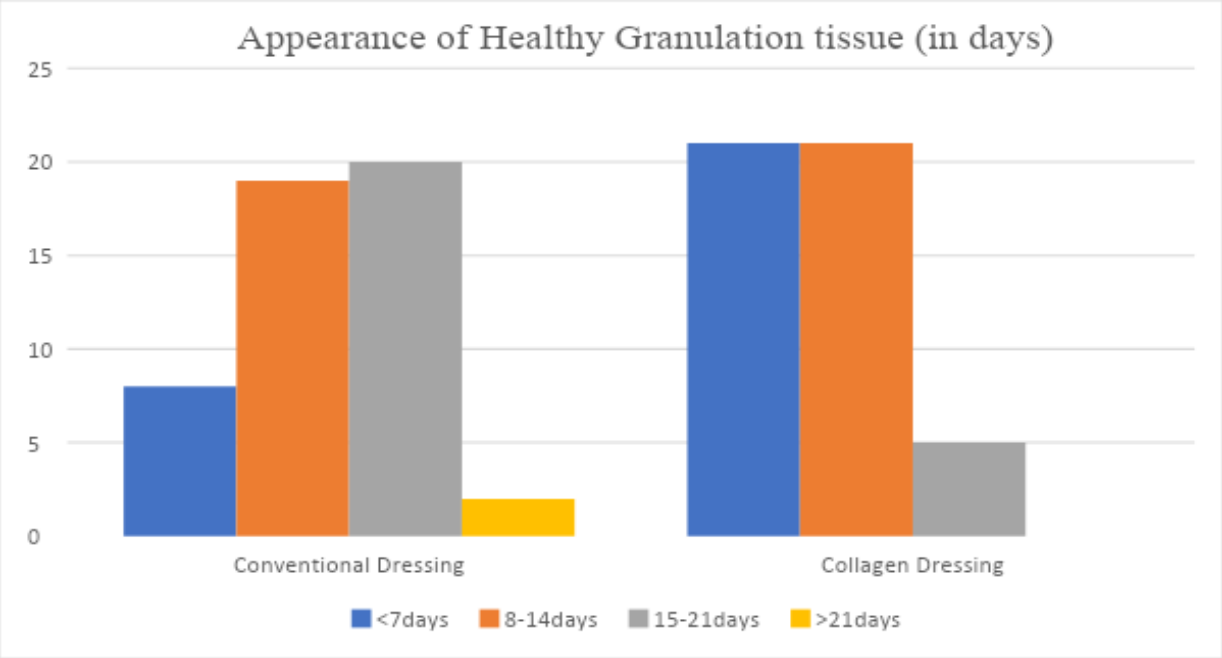


Table 6:- Distribution of study population in two groups according toRequirement of Skin Grafting.

Skin grafting	Conventional dressing(%)	Collagen dressing(%)	Total(%)
Required	11	3	21
Not required	38	48	79
Total	49	51	100

Comparison of requirement of skin grafting:
The requirement of skin grafting was observed to be minimum in group with collagen dressing as compared to other group and the observed difference was statistically highly significant ($p<0.01$).

Graph 6:- Distribution of study population in two groups according toRequirement of Skin Grafting.

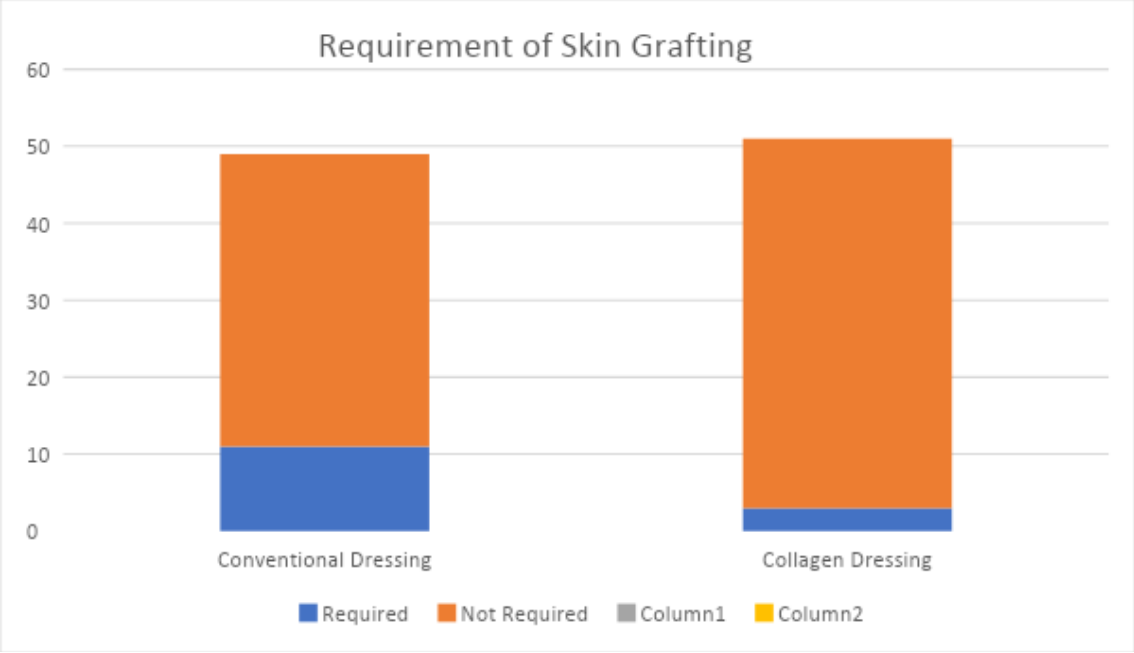
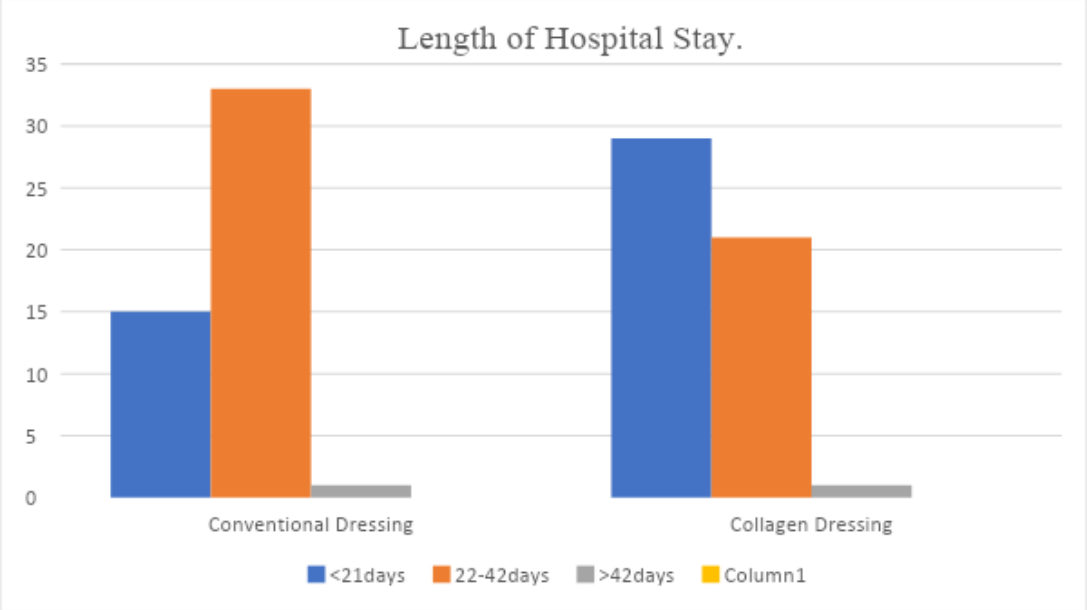


Table 7:- Distribution of study population in two groups according toLength of Hospital Stay.

Hospital stay (days)	Conventional dressing(%)	Collagen dressing(%)	Total(%)
<21	15	29	44
22-42	33	21	54
>42	1	1	2
Total	49	51	100
Mean	25	20.66	

Number of days of hospital stay:
The observed difference between number of days of hospital stay of patients with collagen dressing was statistically significant as compared to other group ($p<0.001$).

Graph 7:- Distribution of study population in two groups according toLength of Hospital Stay.



Discussion:-

There is less data regarding collagen dressing in treatment of chronic wound. The study is a prospective comparative study which was conducted to compare the efficacy of collagen dressing with conventional dressing used in the treatment of chronic wound. In this study, observation of a total of 100 patients with chronic wound was done and of them, 51 patients were managed by collagen dressing and 49 patients were managed using conventional dressing, modality of treatment was decided by randomization.

Age:
In this study, most of the patients with chronic ulcers belonged to age group of 56 – 65 years. Test of significance (chi square test) observed no statistically significant difference in age composition of both groups and thus comparable with respect to age ($p>0.05$)

These findings were supported by findings of Rahman et al in which the authors concluded that chronic ulcers tend to increase with age. They reported chronic ulcers in maximum patients belonging to age range of 50 to 69 years.

Gender:
Chronic wounds may be seen in equal proportions amongst both genders. In this study, majority i.e., 81% of patients with chronic ulcers were males while rest 19% patients were females. The test of significance (chi square test) showed no statistically significant difference in gender composition of both groups ($p>0.05$).
Study by Panda et al showed about 76.2% patients with chronic ulcers were male and the rest 23.8% were females, which is similar to findings of our study.[20]

Etiology:
Chronic ulcers can be due to various etiologies, most common being diabetic ulcers, trauma, and pressure (bedsore). Both groups in present study were comparable in etiology of chronic wound ($p>0.05$).

Findings similar to our study were noted by Panda et al in which, 53.19% of patients had traumatic ulcer followed by Diabetic ulcer and vascular ulcer observed in 48.65% and 36.36% patients respectively.[20]

Size of ulcer:
The initial size of ulcer helps determine the prognosis of the ulcer and also the healing of ulcer. Size of the ulcer is measured in terms of area. Largest diameter of the ulcer was ≤9 cms. Test of significance (chi square test) showed no statistically significant difference in area of ulcer between participants of both groups ($p>0.05$)

Jegoda et al in another study assessed the efficacy of topical use of collagen in wound healing. The study included 60 patients divided in 2 groups. The authors noted 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. [21]

Appearance of granulation tissue:
The first sign of wound healing is appearance of granulation tissue. Appearance of healthy granulation tissue was observed to be significantly earlier among patients of collagen dressing group as compared to other group ($p<0.05$).

In a prospective study on 60 patients with chronic ulcers, Choudhary et al compared the efficacy of collagen dressing with that of conventional dressing in the management of chronic ulcers and their healing process. The granulation tissue appeared in around 2 weeks in most 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 and the findings are similar to our study.[22]

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 other conventional dressing.

A comparative study by Velappan et al on 60 patients of chronic ulcers titled collagen granule vs conventional dressing in case of chronic non healing ulcers, 76% of patients in conventional group required split skin graft and 26% of patients in the collagen group has required split skin graft[23]

Number of days of hospital stay:
In collagen dressing group, the average number of days in hospital was significantly less as compared to patients in other group. The observed difference between number of days of hospital stay of patients with collagen dressing was statistically significant as compared to other group ($p<0.005$).

According to Chaurasia S et al, 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, But, complete healing time for majority of patients of povidone iodine group was greater than 42 days., This difference was statistically significant and significantly reduced hospital stay in patients with collagen dressing.[24]

Conclusion and Summary:-

Based on the findings of present study it can be concluded that chronic ulcers are common amongst male patients in the age range of 56 to 65 years. Diabetic ulcers are most common etiology for development of chronic ulcers followed by trauma.

Collagen based dressing were observed to be superior from conventional dressings in terms of aspects of healing viz. appearance of healthy granulation tissue.
As healing was better in collagen-based dressing group, requirement of skin grafting was much lower as compared to other group.

Collagen based dressings showed early healing in all patients irrespective of etiology of chronic ulcers.

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