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"A Comparative Study of Collagen Dressing Versus Conventional Dressing in Chronic Non Healing Ulcers"

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ABSTRACT

BACKGROUND

Foot ulcer is a major disease-causing disability to many patients around the world. Treatment of foot ulcer remains a major healthcare issue; and especially diabetic foot ulcer accounts for 15% of incidence which is the commonest cause of lower extremity amputation accounts for. Effective treatment of ulceration is necessary to reduce the number of amputations as emphasized by St. Vincent's declaration. Therefore, evaluation of the effect of the collagen dressing on various types of foot ulcers is undertaken.

The aim of the study was to compare the effectiveness of of collagen dressing in healing of these ulcers in comparison with the conventional wound dressings.

MATERIALS AND METHODS

- *The study was conducted in Aarupadai veedu medical college,puducherry following the ethical committee's approval and after obtaining informed consent from the patients. Patients admitted in the department of general surgery with the diagnosis of chronic non healing ulcers were taken into this study*
- *The study was conducted on total hundred patients with chronic ulcer , whoreported at Aarupadai veedu hospital,pondicherry Patients with chronic ulcers attending the Surgery Department were invited to participate in the study and written informed consent was taken. All patients underwent a standard clinical and laboratory evaluation. Briefly, information about age, known DM duration, smoking habits, arterial blood pressure, and anthropometric measurements was collected. In all patients, wound size was noted before treatment initiation. A collagen or conventional dressings were applied to wound, and all patients were followed as per standard post-application treatment protocol. Patients underwent dressing changes every 3 to 4 days until wound healing or for maximum period of 12 weeks. Changes in wound size were recorded when the dressing was removedHealing time, duration of antibiotic therapy, follow up period were noted. All patients were also followed up for adverse events. All the data were captured in the pre-printed pro-forma and compared*

RESULTS

Collagen dressing increases the rate of wound healing as compared to moistened gauze. It also reduces the requirement of skin cover. Further, it also reduces the follow up period and antibiotic use significantly as compared to conventional dressing.

CONCLUSION

Because of a simple method of application, better tolerance, non-allergic, safe and enhances wound healing; hence, collagen can be recommended as a temporary biological dressing material. Collagen dressing is safe and effective in the treatment of foot ulcer and significantly reduces healing time, duration of antibiotic therapy and follow up time.

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I. Introduction

In this millennium where man has succeeded in deciphering human genetic code, the issue of management of chronic wound still continues an enigmatic challenge. Diabetic ulcers, particularly non healing types, are one of the most common surgical issues. From time immemorial doctors are trying different methods to treat these kind of ulcers.

The difficulty in a chronic ulcer, is its refusal to heal, whatever management given, especially diabetic ulcer. Healing of an ulcer is a complex biological process, which needs interactions among different cell types along with growth of new blood vessels into the wound (neovascularization/angiogenesis), to promote adequate delivery of nutrients and regulatory factors required for tissue remodeling and regeneration. Collagen dressings have other advantages over conventional dressings in terms of ease of application and being natural, non-immunogenic, non-pyrogenic, hypo-allergenic, and pain-free.

The present study is conducted to compare the effectiveness of collagen dressing with that of conventional normal saline dressings , in the management of chronic ulcers.

II. Materials And Methods

METHODOLOGY

The study was carried out in the Department of General Surgery, AVMC, Pondicherry from September 2017 to September 2019. Institute Human Ethics Committee(IEC) approval was obtained for the study. The nature, methodology and risks involved in the study were explained to the patient and informed consent was obtained. All the information collected was kept confidential and patient was given full freedom to withdraw at any point during the study.

INCLUSION CRITERIA

1. Patients with chronic ulcers including diabetes and burns
2. Patients who are willing to give informed consent
3. Patient above 18 years age.

EXCLUSION CRITERIA

1. Patient who are critically ill.
2. Patient with any evidence of underlying bone osteomyelitis.
3. Malignancy.
4. Patient refusal

SUBJECTS AND METHODS

- Study subject : Patient with diagnosis of chronic non healing ulcers
- Type of study : prospective hospital based comparative study
- Place : Aarupadai veedu medical college
- Number of groups : 2
- Study population : 100
- Sample method : randomised sampling
- Study Population **:** Patients with chronic ulcers including diabetes and burns attending surgery OPD

The study was estimated to include 100 patients who present with chronic non healing ulcers to aarupadai veedu hospital with each grouped into 50, one group treated with collagen dressing and other group treated with conventional normal saline dressing

Primary source data was collected from a specially designed case recording proforma (CRF) pertaining to the selected patients, after explaining the options of treatment to each of the patient in the language understood by them and taking their consent .

- Patients were subjected to a detailed history elicitation followed by thorough clinical examination.

METHODS

- The study was conducted in Aarupadai veedu medical college,puducherry following the ethical committee's approval and after obtaining informed consent from the patients. Patients admitted in the department of general surgery with the diagnosis of chronic non healing ulcers were taken into this study The study was conducted on total hundred patients with chronic ulcer , who reported at Aarupadai veedu hospital,pondicherry
- Patients with chronic ulcers attending the Surgery Department were invited to participate in the study and written informed consent was taken.All patients underwent a standard clinical and laboratory evaluation. Briefly, information about age, known DM duration, smoking habits, arterial blood pressure, and anthropometric measurements was collected. In all patients, wound size was noted before treatment initiation.
- A collagen or conventional dressings were applied to wound, and all patients were followed as per standard post-application treatment protocol.
- Patients underwent dressing changes every 3 to 4 days until wound healing or for maximum period of 12 weeks. Changes in wound size were recorded when the dressing was removed
- Healing time, duration of antibiotic therapy, follow up period were noted. All patients were also followed up for adverse events. All the data were captured in the pre-printed pro-forma and compared

PARAMETERS STUDIED

- Ulcer Healing Time
- Reduction in size of ulcer
- Duration of hospitalization
- Duration of Antibiotic therapy required

- Any Adverse events reported with collagen/conventional dressings

III. Results And Analysis

- This study includes 100 samples, 100 patients who were attending general surgery OPD over a period of two years. Patients with chronic ulcers including diabetes and burns were included in this study

Each divided into two groups

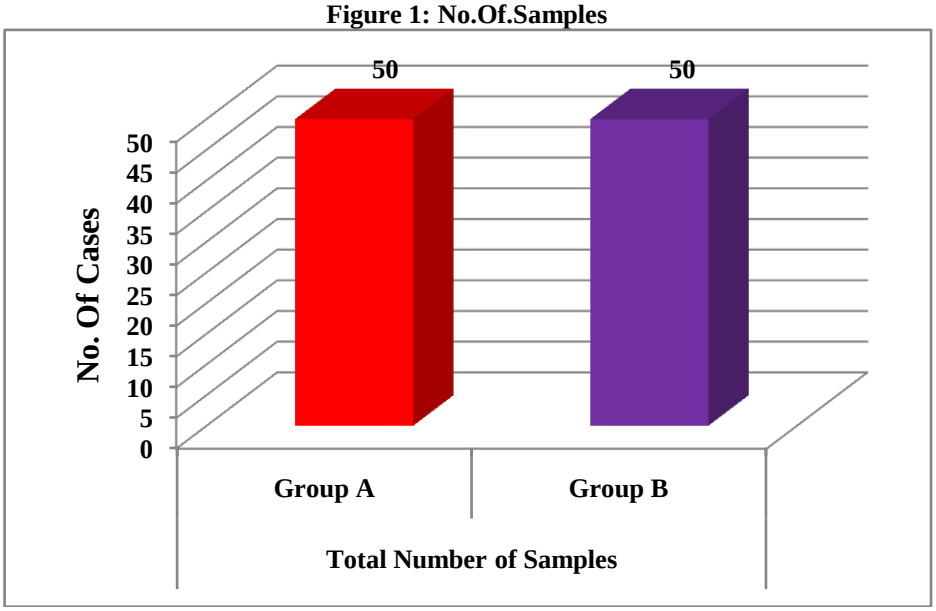
Each group contains 50 samples.

GROUP A –Collagen dressing & Group B–coventional dressing.

Table-1 No.of Samples

Total Number of Samples	
Group A	**Group B**
50	50

Figure 1: No.Of.Samples



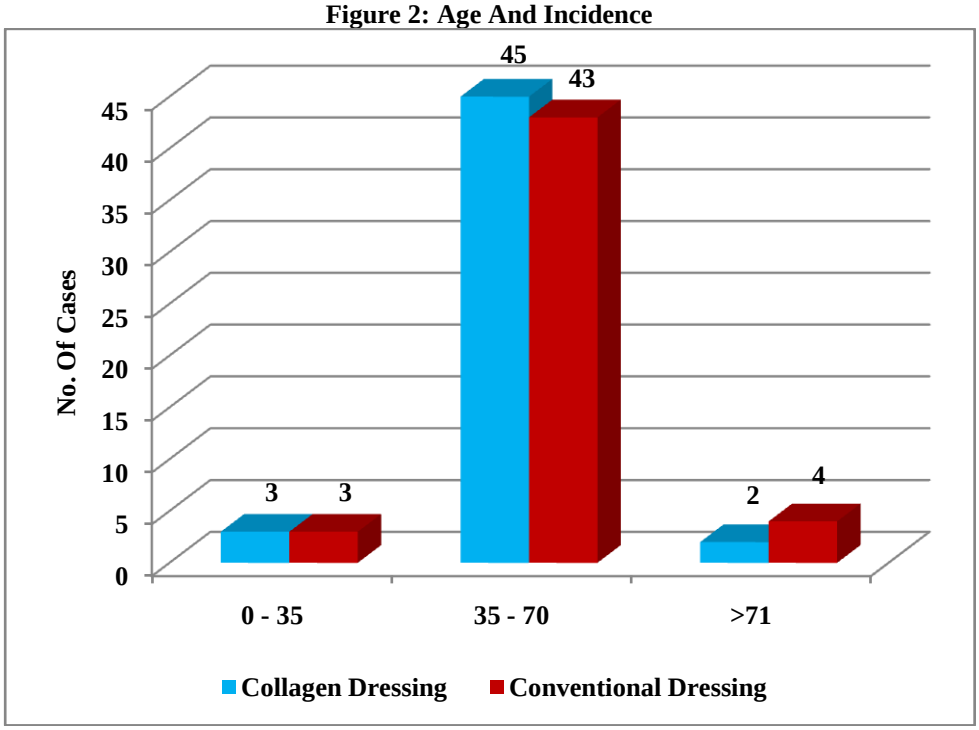
AGE AND INCIDENCE

Table-2 Age And Incidence

Age in Years	Collagen Dressing	Conventional Dressing	P Value
0 - 35	3 (6%)	3 (6%)	**<0.001 (S)**
35 - 70	45 (90%)	43 (86%)	**<0.001 (S)**
>71	2 (4%)	4 (8%)	**<0.001 (S)**
Average	**52.36**	**52.8**	

There is increased incidence of ulcer in age group 35-70. In my study youngest patient was 34 yrs and oldest patient was 77 yrs old.

Figure 2: Age And Incidence



DISTRIBUTION OF CASES BY SEX

Table-3a Sex Distribution

Total Number of Samples	
Male	Female
71	29

In the Present Study, 71 patients were male, and 29 patients were female, In my study, incidence of ulcers are more common in males.

Figure 3a: Sex Distribution

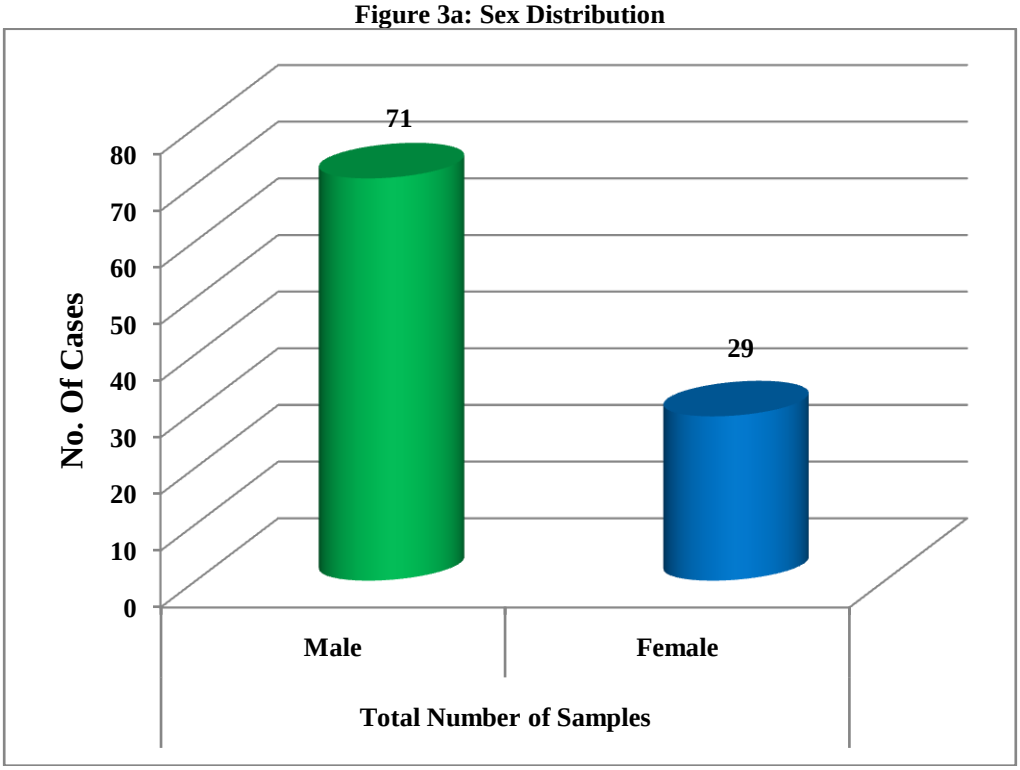


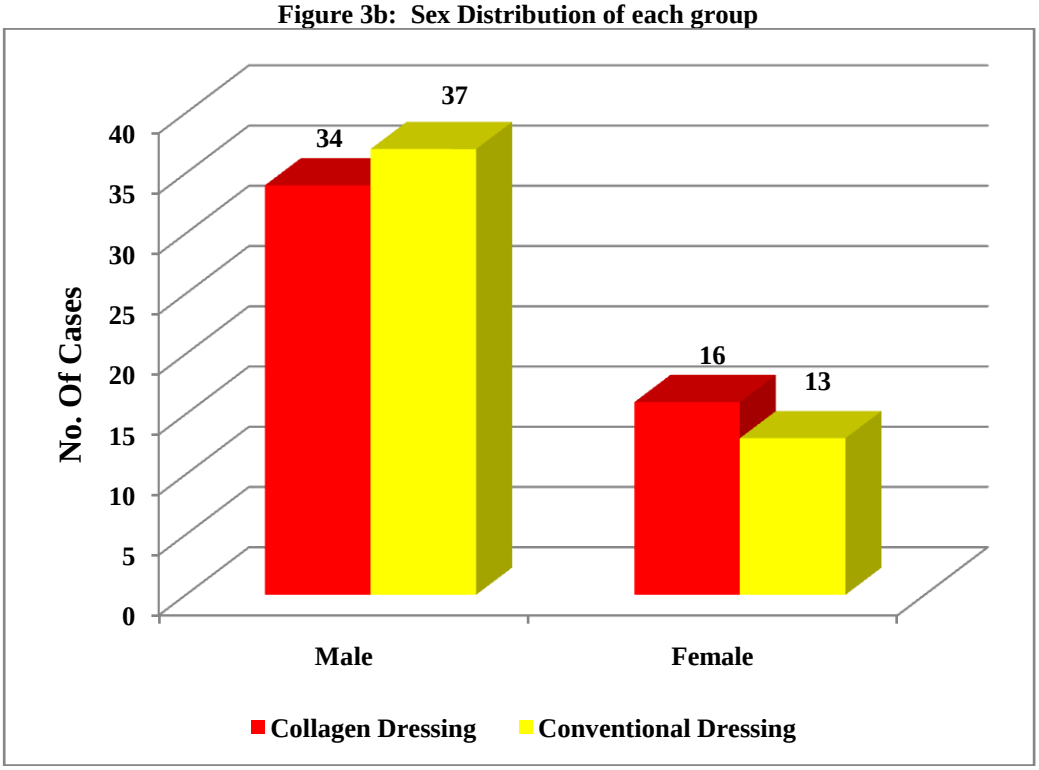
Table-3b Sex Distribution of each group

Type of Dressing	Male	Female
Collagen Dressing	34 (68%)	16 (32%)
Conventional Dressing	37 (74%)	13 (26%)

In the Present Study, 71 patients were male, among them 34 underwent collagen dressing and 37 underwent conventional dressing

29 patients were females, among them 16 underwent collagen dressing and 13 underwent conventional dressing.

Figure 3b: Sex Distribution of each group



DISTRIBUTION OF CASES BY AETIOLOGY

Table-4a Distribution of patients based on aetiology

Total Number of Aetiology			
Diabetic Ulcer	**Traumatic Ulcer**	**Venous Ulcer**	**Burns**
55 (55%)	39 (39%)	4 (4%)	2 (2%)

In our study of total 100 patients, 55 patients had ulcer due to diabetes, 39 patients had ulcer due to trauma, 4 patients had venous ulcer,2 patients had burns ulcer

In our study diabetic ulcers are higher, which clearly indicates most common ulcers are due to diabetes.

Figure 4a: Distribution of patients based on aetiology

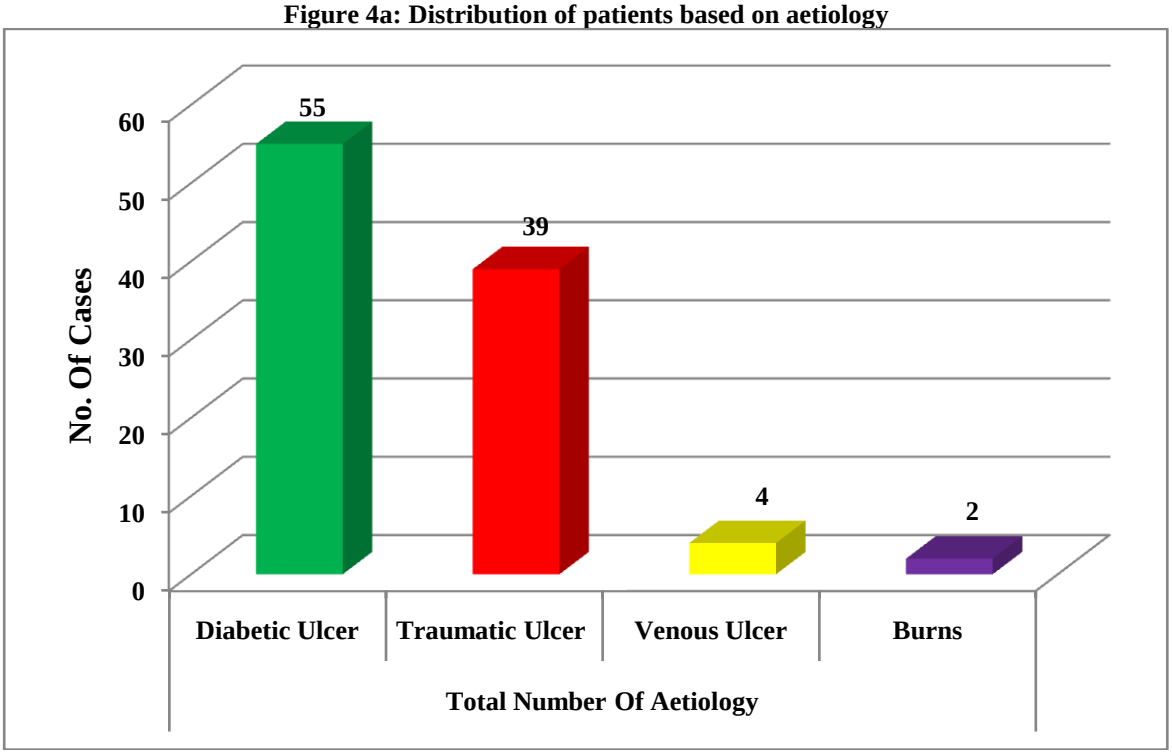
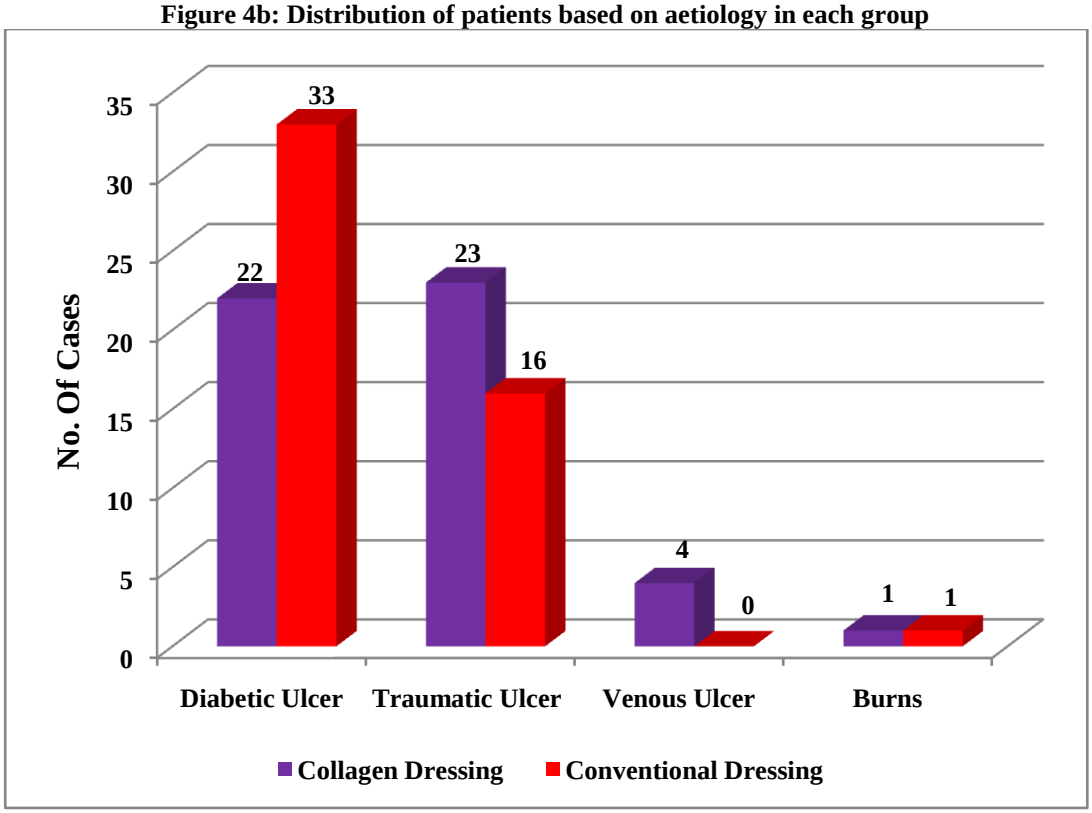


Table-4b Distribution of patients based on aetiology in each group

Type Of Aetiology	Collagen Dressing	Conventional Dressing	P Value
Diabetic Ulcer	22 (44%)	33 (66%)	**<0.001 (S)**
Traumatic Ulcer	23 (46%)	16 (32%)	**<0.001 (S)**
Venous Ulcer	04 (08%)	00 (00%)	**<0.001 (S)**
Burns	01 (02%)	01 (02%)	**<0.001 (S)**

Figure 4b: Distribution of patients based on aetiology in each group



COMPARISON OF REDUCTION IN SIZE OF ULCER IN EACH GROUP

Table-5a Comparison of initial size of ulcer

Comparison Of Initial size of ulcer						
Size of Ulzer CM2	**Collagen Dressing**	**Mean**	**SD**	**Conventional Dressing**	**Mean**	**SD**
15 - 25	10 (20%)	**11**	**10.8**	03 (06%)	**10**	**11.3**
25 - 35	27 (54%)			27 (54%)		
35 - 45	12 (24%)			16 (32%)		
>45	01 (02%)			04 (08%)		
Average	30.33 CM.Sq			33.75 CM.Sq		

In this study, initial wound size of collagen dressing averages 30.33 cm.sq,and initial wound size of conventional dressing averages 33.75 cm.sq.

Figure 5a: Comparison of initial size of ulcer

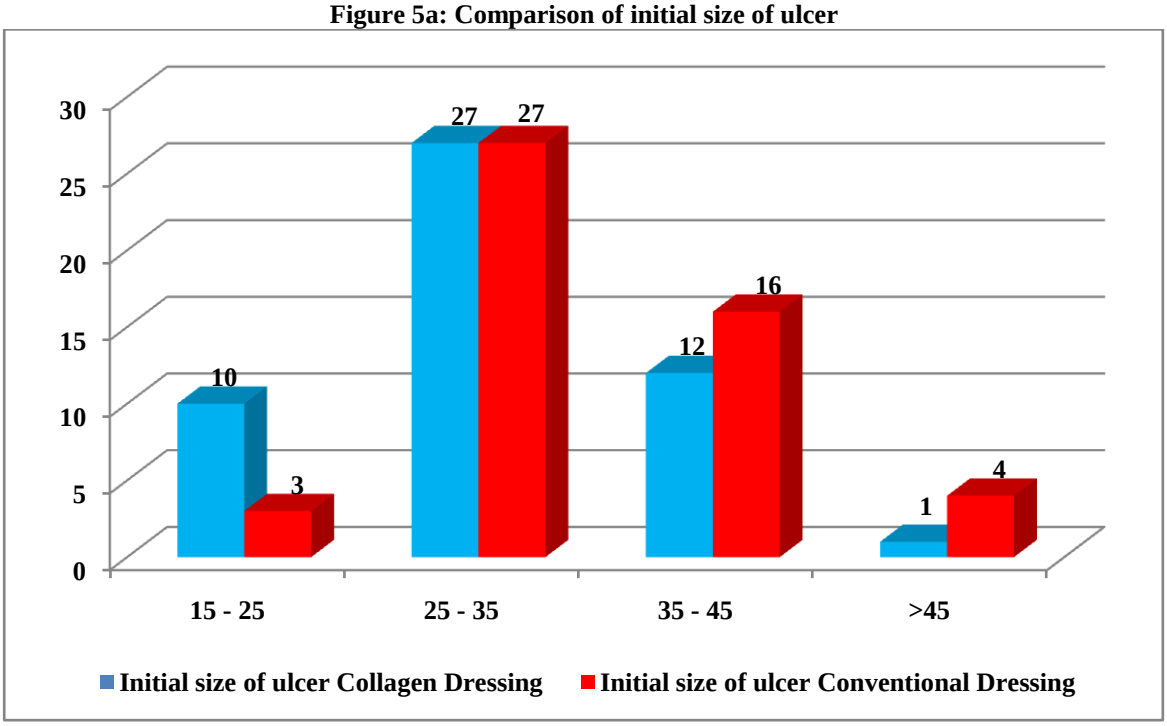
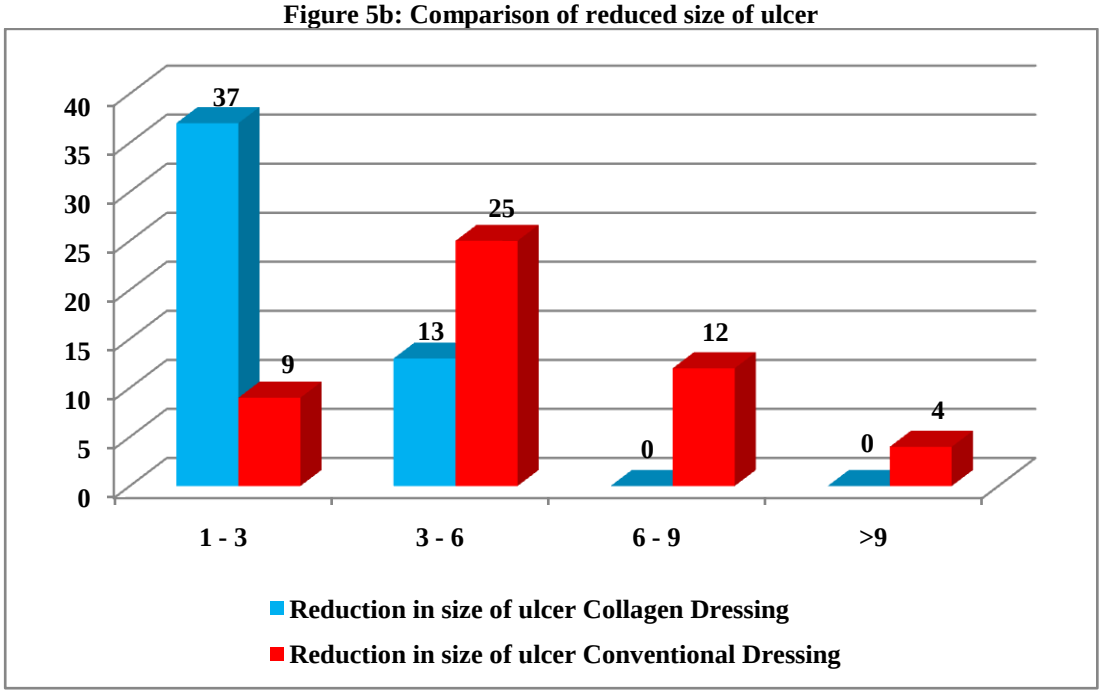


Table-5b: Comparison of reduced size of ulcer

Comparison Of Reduced size of ulcer						
Size of Ulzer CM2	**Collagen Dressing**	**Mean**	**SD**	**Conventional Dressing**	**Mean**	**SD**
1 - 3	37 (74%)	**6.5**	**17.5**	9 (18%)	**10.5**	**8.96**
3 - 6	13 (26%)			25 (50%)		
6 - 9	00 (00%)			12 (24%)		
>9	00 (00%)			04 (08%)		
Average	2.26 CM.Sq			5.3 CM.Sq		

In this study, reduced wound size of collagen dressing averages 2.26 cm.sq, and reduced wound size of conventional dressing averages 5.3 cm.sq.

Figure 5b: Comparison of reduced size of ulcer



Initial size of ulcer			Reduction in size of ulcer		
Size of Ulzer CM2	**Collagen Dressing**	**Conventional Dressing**	**Size of Ulzer CM2**	**Collagen Dressing**	**Conventional Dressing**
15 - 25	10 (20%)	03 (06%)	**1 - 3**	37 (74%)	9 (18%)
25 - 35	27 (54%)	27 (54%)	**3 - 6**	13 (26%)	25 (50%)
35 - 45	12 (24%)	16 (32%)	**6 - 9**	00 (00%)	12 (24%)
>45	01 (02%)	04 (08%)	**>9**	00 (00%)	04 (08%)
Average	30.33 CM.Sq	33.75 CM.Sq	**Average**	2.26 CM.Sq	5.3 CM.Sq

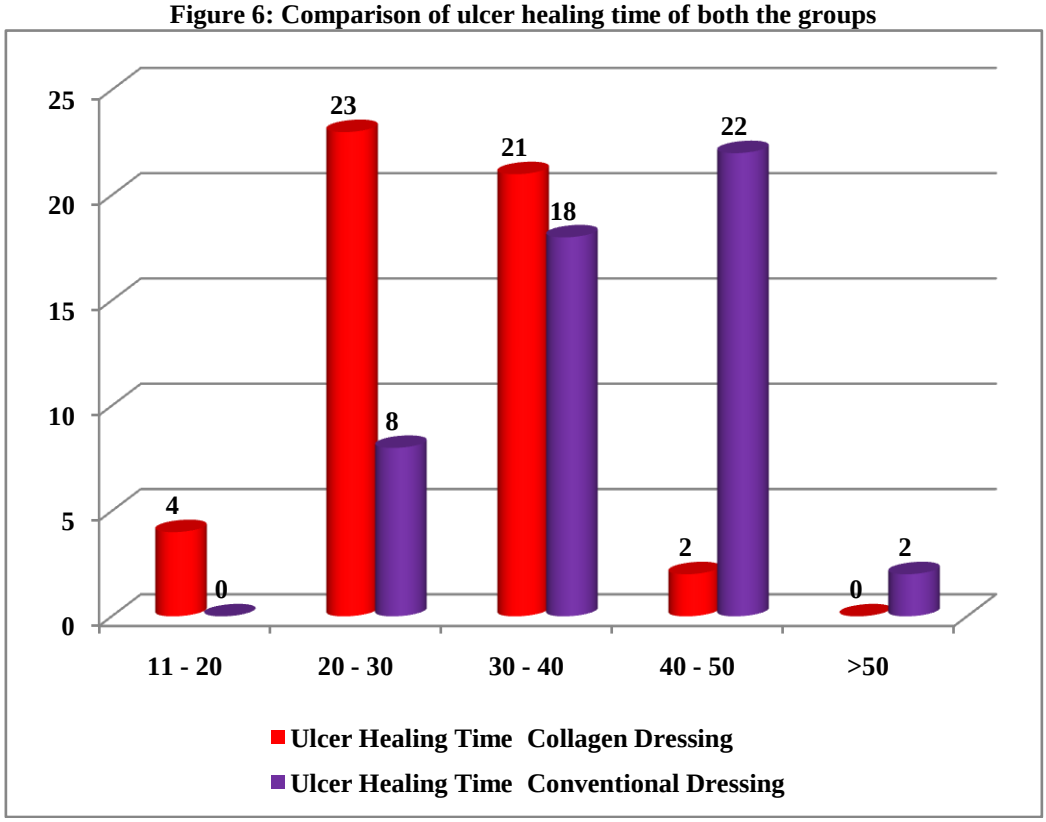
In our study average size of ulcer in collagen dressing was reduced from 30.33 cm.sq to 2.26 cm sq,where as average size of ulcer in conventional dressing was reduced from 33.75 cm.sq to 5.3 cm sq
From our study, it is understood that collagen dressing decrease the wound size better compared to conventional dressing

Table-6 Comparison of ulcer healing time of both the groups

Comparison Of Ulcer Healing Time							P Value
Duration in Days	**Collagen Dressing**	**Mean**	**SD**	**Conventional Dressing**	**Mean**	**SD**	
11 - 20	4 (08%)	**4**	**11.07**	0	**8**	**9.7**	**<0.001 (S)**
20 - 30	23 (46%)			8 (16%)			**<0.001 (S)**
30 - 40	21 (42%)			18 (36%)			**<0.001 (S)**
40 - 50	2 (04%)			22 (44%)			**<0.001 (S)**
>50	0			2 (04%)			**<0.001 (S)**
Average	28.14 Days			39.28 Days			

In this study, we have found that ulcer healing time is reduced with collagen dressing, comparing to conventional dressing.

Figure 6: Comparison of ulcer healing time of both the groups



Average healing period for patients who underwent collagen dressing was 28.14 days, which is relatively lower than average ulcer healing time of 39.28 days for conventional dressing. Thus wound healing time is reduced with collagen dressing

Table-7 Duration of hospitalisation in both the groups

Duration Of Hospitalisation			**P Value**
Duration in Days	**Collagen Dressing**	**Conventional Dressing**	
10 - 20	3	-	**<0.001 (S)**
20 - 30	23	1	
30 - 40	22	25	
40 -50	2	22	
50 -60	-	2	
Average	29.24 days	40.32 days	

In this study, duration of hospital stay was compared in both the groups of collagen and conventional dressing. In my study, the shorter duration of hospital stay was with the use of collagen dressing, it was 12 days, The longest duration of hospital stay recorded with collagen dressing was 42 days, whereas in conventional dressing, the shortest hospital stay was 28 days, which is higher compared to collagen dressing
Thus collagen dressing reduces the duration of hospitalisation

Figure 7: Duration of hospitalisation in both the groups

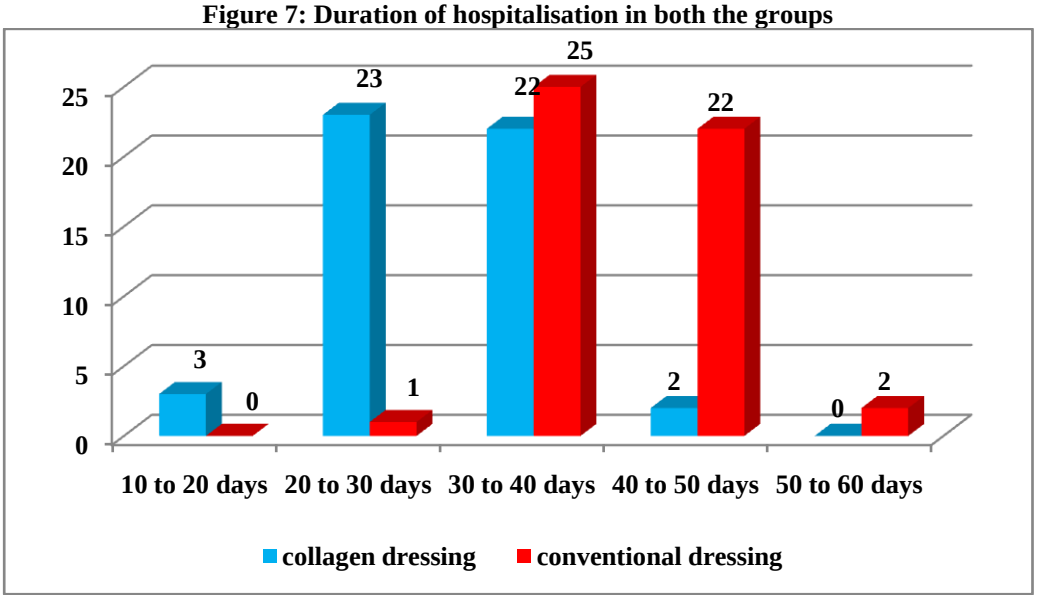
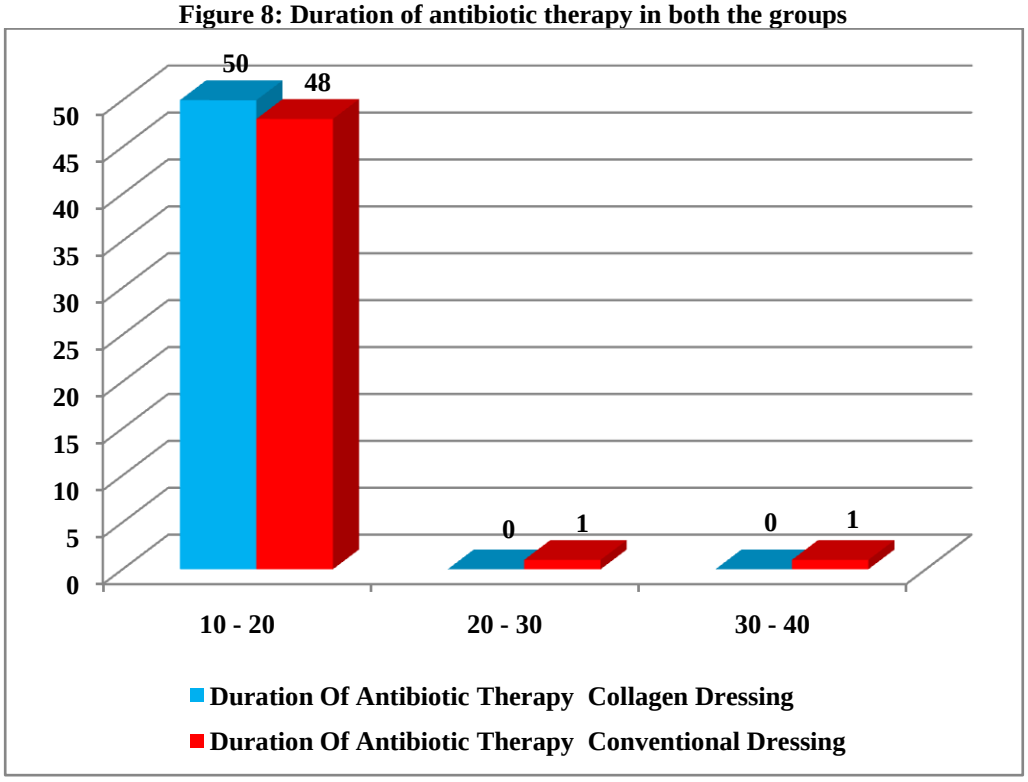


Table-8 Duration of antibiotic therapy in both the groups

Duration Of Antibiotic Therapy			P Value
Duration in Days	**Collagen Dressing**	**Conventional Dressing**	
10 - 20	50 (100%)	48 (96%)	**<0.001 (S)**
20 - 30	00 (00%)	01 (02%)	
30 - 40	00 (00%)	01 (02%)	
Average	8.22 Days	13.78 Days	

In this study, we have found that duration of antibiotic therapy required is reduced with collagen dressing. Patients who underwent collagen dressing, requirement of antibiotic therapy is less than 20 days with an average of 8 days Patients who underwent conventional dressing, requirement of antibiotic therapy is more than 20 days with an average of 13 days. Hence use of antibiotics can be limited for lesser period in collagen dressing

Figure 8: Duration of antibiotic therapy in both the groups



IV. Discussion

It is desire of every surgeon that after dressing the wound, it should heal without any complications. Successful wound dressing should keep the wound devoid of any adverse reactions such as infections and allergic reactions, as well keep it moist The antimicrobial barrier of skin is the keratin layer ulcer areas are lacking of keratin protection thus delaying wound healing.The in growth of epithelium needs a layer of collagen to act as the scaffold on which it grows and arranges itself. Ulcers are not able to provide this efficiently, leading to extensive scars and even keloids.The intact epithelium provides a protective layer over cutaneous nerves otherwise these areas expose the nerves and cause pain and tenderness.Wounds that are left uncovered are prone to infection and scarring with additional clinical problems.It has been well proven that the incidence of infection and degree of contraction are very much reduced when wounds are dressed with biologic materials rather than being dressed with non-biologic material during healing.It was noted that xenogenous collagen membrane had good adaptability in lining mucosa and skin i.e. it was supple and adapted to the all kinds of wound.

In our study of total 100 patients, 55 patients had ulcer due to diabetes, 39 patients had ulcer due to trauma, 4 patients had venous ulcer,2 patients had burns ulcer

In our study diabetic ulcers are higher, which clearly indicates most common ulcers are due to diabetes

Infection

Infection of the wound is one of the most common complications in burns and presence of dirt in abrasions as most of them are traumatic.Infection in turn leads to delayed healing of the wound. Reduction in the infection rate improves the quality of lifeIn our study collagen dressing decreases infection rate compared to conventional dressingOut of 100 samples, only 8 people who underwent conventional dressing suffered infection Whereas patients who underwent collagen dressings are devoid of infection, this proves collagen dressing prevents superadded infection, thereby promotes wound healing.Duration of antibiotic therapy needed in collagen dressing patient is relatively lower than conventional dressing patientsPatients who underwent collagen dressing, requirement of antibiotic therapy is less than 20 days with an average of 8 days Patients who underwent conventional dressing, requirement of antibiotic therapy is more than 20 days with an average of 13 days. Hence use of antibiotics can be limited for lesser period in collagen dressing

Size of ulcer

In our study, initial wound size before dressing is measured & recorded,

The reduced wound size at the end of 3rd week is also recorded, thus reduction in wound size is compared. Patients who underwent collagen dressing has significant reduction in size of ulcer, compared to conventional dressingIn this study, reduced wound size of collagen dressing averages 2.26 cm.sq, and reduced wound size of conventional dressing averages 5.3 cm.sq. From our study, it is understood that collagen dressing decrease the wound size significantly compared to conventional dressing The duration of hospital stay is also reduced with collagen dressing Average healing period for patients who underwent collagen dressing was 28.14 days, which is relatively lower than average ulcer healing time of 39.28 days for conventional dressing. Thus wound healing time is reduced with collagen dressing Patients were asked to give feedback during follow-up regarding the comfortability of the dressing and the resultant scar after healing of the wound. Collagen dressing was considered comfortable as it was only one time application unless there was infection unlike conventional dressing in which the patient had to be subjected to dressings at regular intervals subjecting them to painful stimuli over the raw nerve endings. The use of collagen dressing inhibits the action of these proteases without affecting the activity of the growth factors.

Thus, theoretically, collagen dressing is an advantageous alternative to the moistened gauze that is the routine standard of care. This study is analysed based on the following points

V. Summary And Conclussion

Based on our study on 100 patients in general surgery department of Aarupadai Veedu Medical College, it is found that collagen dressing is more effective than conventional dressing in a chronic non healing ulcer.

It also reduces the follow up period, duration of hospital stay. Duration of antibiotic therapy is significantly reduced in collagen dressing when compared to conventional dressing. Its because, its spongy network causes exudate absorption and blocking of possible extensions of the wound, thus prevents bacterial growth that would delay the healing process.

It also reduces the requirement of SSG. Better patient compliance as dressing need not be changed frequently compared to conventional dressing. Reduces hospital stay hence decreases the economic burden.

Because of a simple method of application, better tolerance, non-allergic, safe, and enhances wound healing; hence, collagen can be recommended as a temporary biological dressing material.

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