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A Clinical Study On Efficacy Of Sterile Medicated Collagen Particles (BIOFIL – AB) In The Management Of Chronic Ulcers.

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ABSTRACT

Chronic non healing ulcers pose a significant challenge to the surgeons and place a burden to the health infrastructure with extended hospital stays, repeated dressings, leading to economic strain to the patient as well as doctors .it may sometimes lead to amputation of limbs causing significant mortality. Effective form of dressing is an important factor for the healing process. The aim of this study is to evaluate the efficacy of medicated collagen particles (BIOFIL - AB) compared to conventional dressings in promoting wound healing, preventing infection, improving granulation tissue formation, and reducing pain perception in patients. This study was a prospective comparative study, non-randomized in design, and focused on evaluating the use of sterile medicated collagen particles (BIOFIL - AB) compared to conventional dressing methods, including betadine dressing and normal saline dressing. The study involved 104 patients, with 52 individuals assigned to each group: 52 patients received the application of BIOFIL - AB, while the remaining 52 patients underwent conventional dressing methods. In conclusion, sterile medicated collagen particles are recommended as an excellent option for managing chronic ulcers, providing improved wound healing and better patient outcomes.

Keywords: wound healing, chronic ulcer, collagen particles.

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INTRODUCTION

Wound healing has a long history, dating back to ancient times and documented in early medical writings. Physicians in civilizations like Egypt, Greece, India, and Europe developed techniques for treating wounds based on observations. These practices included gentle methods such as removing foreign objects, suturing, and using clean materials to cover wounds. Wound healing involves various cell types with different functions like hemostasis, inflammation, growth, re-epithelialisation and remodeling [1]. Ulcers, which are breaks in the skin or mucous membranes, can be chronic and challenging to treat. They have significant social, occupational, and economic consequences, affecting 6% to 25% of the global population. Chronic ulcers are influenced by various factors, making treatment complex. Cost-effective options are needed. Ulcers cause distress, discomfort, infection, foul odor, and excessive exudates, reducing quality of life. An ideal wound dressing should be economical, easy to apply, and readily available. It should provide pain relief, protect against infection, promote healing, maintain moisture, be elastic, nonantigenic, and adhere well to the wound, allowing spontaneous epithelialization and healthy granulation tissue. Different types of products are used for such good wound healing like Nano silver, Negative suction devices, Collagen, Skin substitutes etc [2]. Collagen, a group of naturally occurring proteins involved in all phases of wound healing, is used in different preparations. The study uses sterile medicated collagen particles. Collagen is crucial for repairing and remodeling skin tissue. It offers advantages over traditional dressings, growth hormones, and biological coverings due to its excellent biocompatibility and safety. Collagen use in biomedical applications, including bioengineering, is growing. The study aims to find alternatives for chronic illness treatment through the exploration of sterile medicated collagen particles as wound dressings.

MATERIALS AND METHODS

This study prospective comparative study, non-randomized in design, was conducted in, Department Of General Surgery, Thanjavur Medical College, Thanjavur, Tamil Nadu, India . and focused on evaluating the use of sterile medicated collagen particles (BIOFIL - AB) compared to conventional dressing methods, including betadine dressing and normal saline dressing. The study involved 104 patients, with 52 individuals assigned to each group: 52 patients received the application of BIOFIL - AB, while the remaining 52 patients underwent conventional dressing methods. Various parameters related to wound healing were compared between these two groups, such as wound area, number of debridement's, response to healing, and frequency of dressings. The study's inclusion criteria were as follows: participants had to be within the age group of 20 to 60 years, have a single cutaneous ulcer, and present with any non-healing ulcers, including diabetic ulcers, venous ulcers, traumatic ulcers, and pressure sores. On the other hand, the exclusion criteria included ulcers with exposed bone lacking granulation tissue, wounds caused by burns, irradiation, or malignancy, wound areas larger than 20cm², known allergies to any dressing materials, and patients with comorbidities that could potentially affect wound healing, such as uncontrolled diabetes mellitus, chronic liver and renal diseases, or major nutritional deprivation.

Statistical Analysis

The collected data were analyzed using IBM SPSS Statistics for Windows, Version 23.0 (Armonk, NY: IBM Corp). Descriptive statistics, such as frequency analysis and percentage analysis, were employed for categorical variables, while mean and standard deviation (S.D) were used for continuous variables. For assessing the significance of categorical data in 2×2 tables, Fisher's Exact test was used when the expected cell frequency was less than 5. In all statistical analyses, a probability value of .05 was considered as the significance level.

RESULTS AND OBSERVATIONS

The collected data were analysed with IBM SPSS Statistics for Windows, Version 23.0.(Armonk, NY: IBM Corp).To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean & S.D were used for continuous variables. To find the significance in categorical data, since the expected cell frequency is less than 5 in 2×2 tables then the Fisher's Exact was used. In the above statistical tools, the probability value .05 is considered as significant level.

Table 1: Age distribution

Age distribution		
	Frequency	Percent
Upto 30 years	10	9.6
31 - 40 years	16	15.4
41 - 50 years	30	28.8
51 - 60 years	48	46.2
Total	104	100.0

The above table shows Age distribution were 9.6% is Up to 30 years, 15.4% is 31-40 years, 28.8% is 41-50 years, 46.2% is 51-60 years.

Table 2: Gender distribution

Gender distribution		
	Frequency	Percent
Female	16	15.4
Male	88	84.6
Total	104	100.0

The above table shows Gender distribution were 15.4% is Female, 84.6% is Male.

Table 3: Type of Ulcer distribution

Type of Ulcer		
	Frequency	Percent
Bed Sore	10	9.6
Diabetic Ulcer	49	47.1
Post Op Wound	20	19.2
Traumatic Ulcer	15	14.4
Venous Ulcer	10	9.6
Total	104	100.0

The above table shows Type of Ulcer distribution were 9.6% is Bed Sore, 47.1% is Diabetic Ulcer, 19.2% is Post Op Wound, 14.4% is Traumatic Ulcer, 9.6% is Venous Ulcer.

Table 4: BIOFIL - AB distribution

BIOFIL - AB		
	Frequency	Percent
No	52	50.0
Yes	52	50.0
Total	104	100.0

The above table shows BIOFIL - AB distribution were 50.0% is No, 50.0% is Yes.

Table 5: CM distribution

CM		
	Frequency	Percent
No	52	50.0
Yes	52	50.0
Total	104	100.0

The above table shows CM distribution were 50.0% is No, 50.0% is Yes.

Table 6: Healing distribution

Healing		
	Frequency	Percent
No	28	26.9
Yes	76	73.1
Total	104	100.0

The above table shows Healing distribution were 26.9% is No, 73.1% is Yes.

Table 7: Amputation distribution

Amputation		
	Frequency	Percent
No	98	94.2
Yes	6	5.8
Total	104	100.0

The above table shows Amputation distribution were 94.2% is No, 5.8% is Yes.

Table 8: Comparison between Healing with Groups

			Groups		Total	χ^2 - value	p-value
			CM	BIOFIL - AB			
Healing	No	Count	22	6	28	12.511	0.0005 **
		%	42.3%	11.5%	26.9%		
	Yes	Count	30	46	76		
		%	57.7%	88.5%	73.1%		
Total		Count	52	52	104		
		%	100.0%	100.0%	100.0%		

** Highly Statistical Significance at p < 0.01 level

The above table shows comparison between Healing with Groups by Pearson's chi-squared test were $\chi^2=12.511$, $p=0.0005 < 0.01$ which shows highly statistically significant association between Healing and Groups.

Table 9: Comparison between Amputation with Groups

			Groups		Total	χ^2 - value	p-value
			CM	BIOFIL - AB			
Amputation	No	Count	46	52	98	6.367	0.027 *
		%	88.5%	100.0%	94.2%		
	Yes	Count	6	0	6		
		%	11.5%	0.0%	5.8%		
Total		Count	52	52	104		
		%	100.0%	100.0%	100.0%		

* Statistical Significance at p < 0.05 level

The above table shows comparison between Amputation with Groups by Pearson’s chi-squared test were $\chi^2=6.367$, $p=0.027<0.05$ which shows statistically significant association between Amputation and Groups.

DISCUSSION

The study involved 104 patients, with 52 individuals assigned to each group: 52 patients received the application of BIOFIL - AB, while the remaining 52 patients underwent conventional dressing methods. Various parameters related to wound healing were compared between these two groups, such as wound area, number of debridements, response to healing, and frequency of dressings. Successful wound dressing should prevent complications such as infection and allergic reactions while maintaining a moist environment for healing. The keratin layer in the skin acts as an effective antimicrobial barrier. In denuded areas, this protection is lost, leading to delayed healing and making the subcutaneous tissue vulnerable to infection. Collagen plays a crucial role in cutaneous tissue repair and serves as a beneficial therapeutic option when used as a bioactive advanced dressing in chronic wound management. It aids in fibroblast deposition, angiogenesis, granulation tissue formation, and re-epithelialization [3, 4]. Collagen acts as a scaffold for orderly epithelial growth, protecting cutaneous nerves and reducing pain and tenderness in the exposed areas [5]. Dressing wounds with biological materials like collagen significantly reduces the risk of infection and promotes better wound contraction compared to leaving them uncovered or using non-biological materials [6]. The study found that grafting wounds lead to faster healing and fewer complications than leaving them open [7-8]. In the study, sterile medicated collagen particles were used as an alternative dressing method for chronic ulcers in 52 out of 104 patients. Data showed that the prevalence of leg ulceration increased with age, with the majority of patients being in the 51-60 years age group. The study also revealed that males had a higher number of ulcers compared to females. The most common type of ulcer was diabetic ulcer, followed by post-operative wounds, traumatic ulcers, venous ulcers, and bed sores. Post debridement wounds were the most common in both the case and control groups, followed by post-traumatic wounds. The majority of wounds were located in the lower limbs, with some in the upper limbs, chest, back, and abdomen. After a 2-week period, the percentage of wound healing was compared between the case and control groups. Although no statistically significant difference ($p = 0.0005 < 0.01$) was observed in the percentage of wound healing between the groups, the case group exhibited a higher percentage of wound healing (88.5%) compared to the control group (57.7%). This indicates a potential advantage of using sterile medicated collagen particles (BIOFIL - AB) in chronic ulcer management [9-10]. Additionally, the need for amputation was compared between the two groups, and the case group showed a remarkable decrease in the need for amputation when compared to the control group. None of the ulcers in the case group required amputation, while 11.5% of ulcers in the control group necessitated amputation. The study sheds light on significant distinctions between using sterile medicated collagen particles (BIOFIL - AB) and conventional methods in chronic ulcer healing. The use of sterile medicated collagen particles showed essential benefits in the wound healing process. However, further in-depth analysis is necessary to establish a robust case for this newer form of wound dressing and healing. Additional research and investigations are required to strengthen the evidence supporting the effectiveness of sterile medicated collagen particles in managing chronic ulcers.

CONCLUSION

Ulcer Healing poses significant challenges for surgeons and places a burden on the health infrastructure, with extended hospital stays and repeated dressing changes leading to economic strain for both patients and healthcare providers. An ideal dressing material should effectively control infections, alleviate pain, and accelerate the healing process without complications. In this study, we aimed to assess the efficacy of sterile medicated collagen particles (BIOFIL - AB) in the treatment of chronic ulcers, comparing the results to conventional dressings. Sterile medicated collagen particles offer numerous superior benefits as a wound dressing material. They effectively control infections, reduce pain by covering nerve endings, accelerate healing, and improve patient compliance due to less frequent dressing changes [11-13]. Additionally, they lead to better scar formation, reduced hospital stays, and their easy application and safety enhance the overall wound healing process. In conclusion, sterile medicated collagen particles are recommended as an excellent option for managing chronic ulcers, providing improved wound healing and better patient outcomes.

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