ISSN- O: 2458 - 868X, ISSN–P: 2458 – 8687
Index Copernicus Value: 49. 23
PubMed - National Library of Medicine - ID: 101731606

International Journal of Medical Science and Innovative Research (IJMSIR)
IJMSIR : A Medical Publication Hub
Available Online at: www.ijmsir.com
Volume – 4, Issue – 2, March - 2019, Page No. : 230 - 236

A Prospective Comparative Study of the Effect of Collagen Granules and Conventional Dressing on Healings of Chronic Wounds

Shyam Bhutra[1], Piyush Jain[2]

[1]Senior Professor and Unit Head, Department of General Surgery Jawaharlal Nehru Medical Collage & Hospital, Ajmer

[2]Resident Doctor, Department of General Surgery Jawaharlal Nehru Medical Collage & Hospital, Ajmer

Corresponding Author: Piyush Jain**,** Resident Doctor, Department of General Surgery Jawaharlal Nehru Medical Collage & Hospital, Ajmer

Type of Publication: Original Research Paper

Conflicts of Interest: Nil

Abstract

Background -Collagen protein that gives the skin its tensile strength plays a key role in each phase of wound healing. It attracts cells, such as fibroblast and keratinocytes to the wound, which encourage angiogenesis and reepithelialization.

Mehtod and Metriology-50 patients admitted in various surgical wards of J.L.N. Hospital Ajmer with Chronic wound. 25 patients would be randomly divided into test group and 25 in control group. TEST group out of these would be treated with collagen granules dressings (study group) and control groups treated with conventional dressing.

Results- After 6 weeks 1(4%) patient show partial healing in study group, 5(20%) patients show near complete healing, 19(76%) patients show complete healing occurred. While in conventional group wounds of 3(12%) patients show partial healing phase, 9 (36%) near complete healing and 12(48%) complete healing.

Conclusion- In our study we found that collagen dressing was better than conventional dressing in respect of time, hospital stay, patient satisfaction, low serum albumin and low hemoglobin patients.

Keywords- Wound Healing, Collagen Granules, Ulcer.

Introduction

A wound is a break in the continuity of any bodily tissue due to violence, where violence is understood to encompass any action by an external agent. While a chronic wound defined as one that has been in existence for more than three weeks or that has failed to proceed through an orderly and timely process to produce anatomical and functional integrity or proceed through the repair process without establishing a sustained and functioning results.

In recent years, several new treatment strategies have been developed to stimulate wound healing in the diabetic foot wounds. These are topical growth factors, extra cellular matrix products, bioengineered human skin, hyperbaric oxygen therapy, granulocytes macrophage colony stimulating factors and collagen granules. New topical dressings are emerging that may improve wound care. Such dressings are designed to modulate levels of biological molecules, such as growth factors, that may promote wound healing.

Collagen dressings were natural, non-immunogenic, non-pyrogenic, hypo-allergenic, and pain-free[1]. The use of collagen dressing has been found to inhibit the action of

metalloproteinase. While acting as a mechanical support these reduce edema 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.[2] Collagen formed molecular diversity in the body's protein scaffold.[3] Collagen dressings create the most physiological interface between the wound surface and environment and are impermeable to bacteria.[4] Collagen granule dressing had better advantage over conventional dressing in terms of collagen formation with greater reduction in inflammatory cells during healing days resulting in decreased days of healing, where as conventional dressing had minimal collagen formation, high grade of inflammation during the healing days with maximum exudates formation resulting in increased days of healing.[5] This study was conducted to compare the efficacy of collagen granule dressing with that of conventional dressing in the management of deep wounds includes diabetic wounds, venous wounds, chronic cellulites wounds, trophic wounds and pressure sores.

Material & Methods

This study was a prospective study and conducted in 50 patients admitted in various surgical wards of J.L.N. Hospital Ajmer with Chronic wound from 2017 to 2018. 25 patients were divided into test group and 25 in control group. Test group out of these treated with collagen granules dressings and control groups treated with conventional dressing.

Patients were then randomly divided into each group by computer generated randomization table. After explaining the procedure and motto of the study, written informed consent was taken prior to enrolment in the study.

A) Inclusion Criteria

• Patients of above 18 years with chronic wound.

• Wound area size > 2 cm2.

B) Exclusion Criteria

• Known hypersensitivity to any component of drug.

• An active systemic infection.

• An active neoplastic disease.

• Immune suppression treatment in last three months.

• Any serious pre-existing cardiovascular pulmonary or immunological disease. Pregnant women, lactating mother.

• Critically ill patients.

• Patient refusal.

Patients Examination

Each selected patients was examined in detail by complete physical examination, complete history regarding age, sex, socio-economic status, rural urban, duration of ulcer, history of any chronic illness and treatment undertaken for illness and ulcer. This was followed by appropriate investigation like routine complete blood count, blood sugar, serum albumin, wound swabs taken from wound discharge for culture and sensitivity, x-ray of part.

Method of Application

The target wound was assessed before and after cleaning and / or debridement for local infection and for wound condition. The wound area was determined by means of planimetry (the greatest width x the greatest length, measured in centimeters).

Collagen Dressing

The wound was debrided and cleaned to leave the wound moist to facilitate the action of collagen granules was lightly sprinkled just enough to completely cover the surface of the wound bed then it was covered with gauge and bandage and tape and no other chemical was used. Changed dressing collagen daily until infection was resolved. Once the infection was reduced frequency was extended to once in 2-3 days for 6 weeks or until wound

closure, whichever occurred first until wound closure was achieved.

Conventional Dressings

Dressing with antiseptic solution like povidone iodine, saline, eusol etc. In control group, isotonic sodium chloride solution and betadine moistened gauge was applied as primary dressing over wound area covered with gauge and bandage and tapes.

Evaluation of Response

The 2 longest perpendicular dimensions of the wounds were recorded at baseline weekly on 1, 2, 3, 4 and 6.

At the end of 6 weeks, patients were divided into 4 groups as: 6

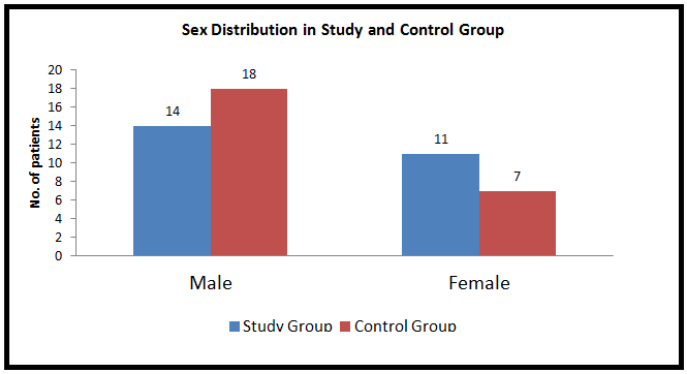
1. Complete Healing Stage: Complete healing of wounds.

2. Partial Healing Stage: 50% or greater reduction in product of the 2 longest perpendicular diameters from baseline.

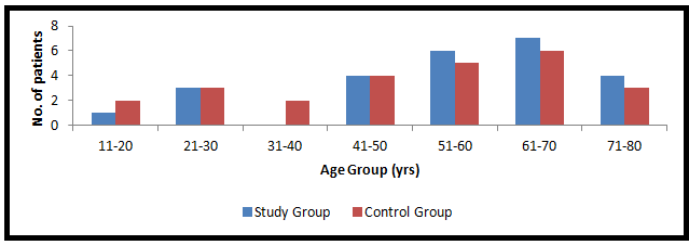
3. Non-complete Healing Stage: Less than 50% reduction in the product of the 2 longest perpendicular diameters from baseline.

4. Non-Healing Stage: No reduction in wound area or increase in wound area over baseline.

Results



In our study maximum number of patients 64% were males.



According to age distribution maximum number of patients was between 41-70 years of age group 32/50(64%).

Table 1: Duration of wound

Duration (months)	No. of Patient	% of Patient
0-1	1	2.00
1-2	16	32.00
2-3	23	46.00
3-4	9	18.00
4-5	-	0.00
5-6	1	2.00
Total	**50**	**100.00**

In the present study maximum 23 (46%) patients had duration of wounds between 2-3 months.

Table 2: Type of wounds

Type of wound	No. of Patient	% of Patient
Diabetic	18	36.00
Arterial	2	4.00
Venous	8	16.00
Trauma	6	12.00
Burn	1	2.00
Miscellaneous	15	30.00
Total	**50**	**100.00**

Present study included different type of wounds out of these maximum chronic wounds occur in diabetic patients (18/50, 36%). Because they had high sugar level and more prone to injury due to diabetic neuropathy.

Table 3:Healing Response in Study and Control Group after 1st Week

Stage of Healing	Study Group		Control Group	
	Collagen granules			
	No. of Patients	% of Patients	No. of Patients	% of Patients
Complete healing	00	00.00	00	00.00
Near complete healing	02	08.00	00	00.00
Partial healing	19	76.00	14	56.00
Delayed healing	4	16.00	11	44.00
Total	**25**	**100.00**	**25**	**100.00**

Healing response after 1st week there was no complete healing in study group as well as control group.In near complete healing stage there were 08% in study group and no response in control group.Majority of patients (76%) were showing partial healing within study group while in the control group (56%) was showing partial healing response after one week. Patients were in no healing stage in control group 11 (44%) while in the study group only 16% were showing no healing response.

Table 4:Healing Response in Study and Control Group after 2nd Weeks

Stage of Healing	Study Group		Control Group	
	Collagen granules			
	No. of Patients	% of Patients	No. of Patients	% of Patients
Complete healing	02	08.00	00	0.00
Near complete healing	02	08.00	1	4.00
Partial healing	20	80.00	19	76.00
Delayed healing	1	4.00	5	20.00
Total	**25**	**100.00**	**25**	**100.00**

Complete healing in 2 (08%) patients after two weeks treatment within study group. Two patients (08%) in study group and 1 patient (04%) in control group showing near complete healing response. Nineteen patients (76%) were in partial healing stage in the control group in comparison to study group 20 patients (80%) after two week treatment. In study group only 1 patient (4%) wound was showing the no healing signs while in control group 5 patients (20%) wound in non healing stage after two weeks treatment.

Table 5: Healing Response in Study and Control Group after 3rd Weeks

Stage of Healing	Study Group		Control Group	
	Collagen granules			
	No. of Patients	% of Patients	No. of Patients	% of Patients
Complete healing	04	16.00	01	4.00
Near complete healing	14	56.00	06	24.00
Partial healing	07	28.00	18	72.00
Delayed healing	00	00	03	12.00
Total	**25**	**100.00**	**25**	**100.00**

Healing response after three week treatment wound showing complete healing response were 4 (16%) within study group and only 1 (04%) in control group. There were 14 wounds (56%) in study group and 6 wounds (24%) in control group showing near complete healing.Eighteen (72%) are still in partial healing stage in control group in comparison to study group 7 (28%) group.There was no patient in study group which did not show healing. While in control group 3 patients (12%) were in non healing stage.

Table 6: Healing Response in Study and Control Group after 4th Week

Stage of Healing	Study Group		Control Group	
	Collagen granules			
	No. of Patients	% of Patients	No. of Patients	% of Patients
Complete healing	18	72.00	10	40.00
Near complete	3	12.00	6	24.00

healing				
Partial healing	4	16.00	8	32.00
Delayed healing	0	0	1	04.00
Total	**25**	**100.00**	**25**	**100.00**

Four weeks treatment 18 patients (72%) within study group and 10 patients (40%) in control group were showing complete healing response.There were 3 patients (12%) in study group and 6 patients (24%) in control group showing near complete healing.Eight (32%) are still in partial healing stage in control group in comparison to study group 04 (16%) group.There was no patient in study group which did not show healing. While in control group 1 patient (4%) was in non healing stage.

Table 7:Healing Response in Study and Control Group after 6th Week

Stage of Healing	**Study Group**		**Control Group**	
	Collagen granules			
	No. of Patients	**% of Patients**	**No. of Patients**	**% of Patients**
Complete healing	19	76.00	12	48.00
Near complete healing	5	20.00	9	36.00
Partial healing	1	4.00	3	12.00
Delayed healing	0	0	1	4.00
Total	**25**	**100.00**	**25**	**100.00**

After 6 weeks follow-up 19 patients (76%) in Study group showing complete healing response and only 12 patients (48%) in control group showing complete healing response.In Study group 5 patients (20%) in near complete healing stage as compared to the control group 9 patients (36%) in near complete healing stage.Three (12%) are still in partial healing stage in control group in comparison to study group 01 (4%) group.There was no patient in study group which did not show healing. While in control group 1 patient (4%) was in non healing stage.

Discussion

Chronic wounds are a troublesome clinical problem. These wounds are associated with pain and suffering and take months to heal. It leads to loss of working hours, hospitalization and great inconvenience both to the patient and family.

For these wounds a variety of clinical measures have been used and despite treating the underlying etiology which may be post operative, post traumatic, arterial disease, venous disease wound and a host of other conditions they do not heal.

To accelerate healing various treatment modalities have been used from time to time. We used collagen granules dressing in our study.

Our study was done in the Department of Surgery, JLN Medical College & Hospital, and Ajmer. It was a prospective and comparative study from 2017 to 2018.

The main aim of this study was to examine the effect of collagen granules and to compare result with conventional dressing.

We randomly selected 50 patients with chronic non-healing wounds for our study. We excluded those patients who were having neoplastic disease, pre-existing cardiovascular pulmonary or immunological disease.

We did collagen granules dressing in 25 patients and conventional dressing in 25 patients and followed standard treatment protocol of associated disease and debridement was done if needed.

In our study majority of patients (64%) were male. This could be due to the fact that males are outdoor workers and more prone to traumatic injuries.

In a similar study by KM Rai et al[6] with collagen particles, male patients were 78% and females were 22%. In the study of Yash Bhargav et al [7]was found that male patients were 73.33% and female patients were 26.67%. These results are similar to our study.

Maximum patients 11(22%) in this study were in the age group of 51-60 years and 13(26%) in age group of 61-70

years. This shows that around 48% patients were in the age group of 51-70 years in our study. The minimum age of patient was 12 years and maximum age was 80 years.

In the study by VK Shukla et al[8] 62% cases belonged to 40 and above age group while in another study of 50 patients by KM Rai et al[6] with collagen particles age range was 18-74 years. These data show that maximum patients are in the most productive group of society and these chronic wounds were cause of great expense to individual and community.

In this study we included wounds of more than 4 week duration. In a similar study by V.K. Shukla et al. (2004)[8] with placental extract, duration was more that 6 weeks. Also in study by K.M. Rai et al.[6] with collagen particles dressings duration was more than 30 days. Thus chronicity of wound was considered after 30 days in all studies.

After 1st week there was no complete healing in study group and control group. Near complete healing was there in 08% from study group and nil in control group. Majority of patients 19 (76%) were showing partial healing in study group while in the control group 14 (56%) were showing partial healing response. In study group, 4 (16%) patients wound showed the no healing signs while in control group 11 (44%) patients were in non healing stage after one week treatment.

In a study by Yash Bhargav et al[7] in year 1992 on diabetic ulcers, there were 17.75% patients in study group showing complete healing, 48% showing partial healing and 10% showing no healing after 1st week.

In our study there was complete healing in 2 (08%) patients after two weeks treatment within study group, no complete healing seen in control group, 2 patients (08%) within study group and 1 patient (04%) in control group showing near complete healing response while 19 patients (76%) were in partial healing stage in the control group in comparison to study group 20 patients (80%). In study group only 1 patient (4%) showed the no healing signs while in control group 5 patients (20%) were in non healing stage after two weeks treatment.

In a similar study done by Yash Bhargav[7] after 2 weeks treatment with collagen granules 30% patients showed complete healing and 42% showed near complete healing. In contrast in study done by VK Shukla [8]36% patients showed complete healing and 40% showed near complete healing after 2 weeks treatment.

After three week treatment wound showing complete healing response were 4 (16%) within study group and only 1 (04%) in control group. There were 14 wounds (56%) in study group and 6 wounds (24%) in control group showing near complete healing. Eighteen (72%) were still in partial healing stage in control group in comparison to study group 7 (28%). There was no patient in study group which did not show healing. While in control group 3 patients (12%) were in non healing stage.

After four weeks of treatment 18 patients (72%) within study group and 10 patients (40%) in control group were showing complete healing response. There were 3 patients (12%) in study group and 6 patients (24%) in control group showing near complete healing. Eight (32%) were still in partial healing stage in control group in comparison to study group 04 (16%) group. There was no patient in study group which did not show healing. While in control group 1 patient (4%) was in non healing stage.

After 6 weeks follow-up 19 patients (76%) in study group showing complete healing response and only 12 patients (48%) in control group showing complete healing response. In Study group 5 patients (20%) in near complete healing stage as compared to the control group where 9 patients (36%) in near complete healing stage.

Three (12%) were still in partial healing stage in control group in comparison to study group 01 (4%) group. There was no patient in study group which did not show healing. While in control group 1 patient (4%) was in non healing stage.

After treatment of 6 weeks in our study 76% patients showed complete healing and only 0% showed no healing in comparison to study done by VK Shukla whose 58% patients showed complete healing and 5% patients showed no healing. Results of healing in our study were slightly better than the results in study by VK Shukla et al[8].

Yash Bhargav's[7] study showed complete healing in 86.67% and near complete healing in 13.33% with collagen particles after twelve week treatment. These results were slightly better (86.6 vs 76%) probably because of 12 weeks treatment vs 6 weeks treatment in our study.

Conclusion

No doubt such kind of dressings are very costly , but if we consider the cost of hospitalization and if we can prevent amputation in diabetes and peripheral vascular disease, then these therapies seem to be very logical. At present time dressing with collagen granules are more effective in respect of time saving, less painful, less hospital stay time, decrease hospital charge, decrease morbidity. Almost patients were satisfied with collagen dressings in chronic wounds, but main disadvantage was the cost. Collagen dressings were also better in those patients who had low serum albumin and low hemoglobin. Over all comparison with conventional dressings collagens dressing were better and showed excellent result with patient's satisfaction. Thus we advocate the routine use of collagen granules in all cases where wounds do not heal after 4 weeks.

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