E-ISSN: 2616-3470
P-ISSN: 2616-3462

www.surgeryscience.com
2021; 4(4): 175-179
Received: 02-12-2020
Accepted: 25-12-2020

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A comparative study of the efficacy of topical hydrogel dressings and conventional dressings in chronic wounds

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DOI: https://doi.org/10.33545/surgery.2020.v4.i4c.790

Abstract
Aim: To compare the efficacy of topical Hydrogel wound dressings to that of a control group using conventional wound dressings in the healing of chronic ulcers in terms of the number of ulcers left unhealed in either group, the amount of non-viable tissue, the rate of granulation tissue formation as a percentage of ulcer surface area, and the duration of hospital stay.
Methods and materials: A prospective, parallel group, comparative trial was used for the study. Patients with chronic wounds were admitted to KGH Vishakapatnam, General Surgery Department. Based on their willingness to undergo topical hydrogel treatment, the entire sample population was separated into two equal and comparable groups of 40 patients. Those who refused were subjected to standard wound dressings and formed the control group. These groups were subsequently divided into two equal groups of 20 patients each, based on whether the patients had diabetes or not. As a result, the entire study population was separated into four groups. The patients were chosen using the purposive sampling method. Patients were followed up on, and their ulcer condition was determined using a visual score.
Results: The reduction of slough occurs as early as the third week in the test group compared to the control group. In the test group, the frequency of patients with 75-100 percent wound filled with granulation tissue was higher as early as the third week than in the control group, where it required more than four weeks. The number of patients who underwent secondary suturing, skin grafts, and flaps was much higher in the test group than in the control group, and this occurred as early as the third week.
Conclusion: Hydrogel is an excellent topical applicant for reducing slough, enhancing granulation tissue development, and reepithelization, as well as shortening the hospital stay of these patients. In comparison to standard treatment with local antiseptics, this allows for better wound bed preparation for healing, suturing, skin transplant and flap.

Keywords: Hydrogel; chronic wounds; rate of granulation tissue; hospital stay

Introduction
In this millennium, when humanity has succeeded in deciphering the human genetic code, the topic of chronic wound management remains an enigma. Chronic wounds, particularly non-healing wounds, are among the most common surgical problems encountered by surgeons. Doctors have been experimenting with various strategies to cure these types of wounds since the dawn of time [1-5].
The characteristic of a chronic wound is that, regardless of treatment, it refuses to heal, particularly pressure ulcers or bed sores. Although a significant majority of professionals still believe that wounds should be kept dry, this belief is progressively losing ground. We now know that wounds that are treated with dressings that allow moist wound healing re-epithelialize or produce granulation tissue more faster. We understand that occluding wounds does not result in infection. Even though several wound care modalities have emerged to assist surgeons, such as the use of compression bandages to treat venous ulcers, the problem of chronic wounds persists [6-9]. A wound care revolution is currently in the making. Many techniques have been tried over the centuries to heal chronic leg ulcers. Although wound dressing have been used for at least two millennia, there exists no ideal dressing. Surgical dressing of both open and closed wounds is based mainly on tradition, training and the surgeons own philosophy. During the last two decades a wide variety of innovative dressings have been introduced [10, 11].
Recent studies have shown that application of a topical hydrogel in a controlled manner to the wound site has got an important role in assisting wound healing. The present study was conducted to assess the efficacy of topical hydrogel wound dressings as compared to

conventional wound dressings in improving the healing process in chronic wounds and to prove that topical hydrogel dressings can be used as a much better treatment option in the management of chronic wounds.

Material and methods

Study design

Prospective randomized comparative study.

Source of data

All patients with chronic wounds of various aetiology admitted to Andhra Medical College/KGH between August 2019 and August 2020 who m *et al.* [1] of the inclusion criteria listed here after ethical committee permission.

Inclusion criteria

- Patients with age between 20 - 60 years
- All types of chronic wounds irrespective of etiology
- Wound size <10% TBSA
- Patients giving consent for topical hydrogel wound dressings

Exclusion criteria

- Wounds with necrotic tissue
- Untreated underlying osteomyelitis
- Fistulas to organs or body cavities
- Exposed arteries or veins
- Malignancy within wounds
- Dry gangrene

Sample size

Total of 80 patients, who fulfilled the above inclusion criteria from Andhra Medical College/KGH, will be included in the study.

Method of collection of data

The whole sample population was be divided into two equal and comparable groups of 40 patients, based on the willingness for undergoing topical hydrogel dressing. Those who were not willing were subjected to conventional wound dressings and formed the control group. These groups were further split into two equal groups of 20 Patients each, based on those who have diabetes and those without diabetes. Thus the whole study population was divided into four groups. Selection of patients was done by purposive sampling method. Care was taken so that all the groups had a comparable distribution of patients with regards to age as well as etiology of the ulcer.

The selected patients underwent screening for a period of one two weeks, to stabilize the wound and institute appropriate medical and surgical line of treatment like diabetic control, control of infection by initiating appropriate antibiotic based on culture sensitivity report, surgical debridement, correction of anemia and correction of other medical illness.

All patients underwent detailed clinical examination and relevant investigations. After the initial screening the eligible patients who required bed side debridement were divided randomly into test group and control groups-

1. Test group: Received hydrogel with colloidal silver along with bed side surgical debridement whenever required, for wounds / ulcers which had slough in the floor and till granulation tissue appeared.
2. Control group: Received bed side surgical debridement with Povidine Iodine dressings.

The test medication hydrogel with colloidal silver was applied to the test group once daily using an artery forceps. Enough medication was applied over the entire surface of the slough and only superficial slough was removed using bed side surgical debridement whenever required.

Treatment of control group was done with bed side surgical debridement whenever required and conventional dressing with topical Povidine Iodine once daily.

Wounds were treated once daily until complete debridement or up to seven weeks. The amount of nonviable tissue, degree of wound granulation. And overall wound response was evaluated weekly using a visual score.

The visual scores are as follows

a. The score for the percentage of wound covered by slough and nonviable (necrotic) tissue are

1. = 76-100% wound covered with nonviable tissue.
2. = 51-75% wound covered with nonviable tissue.
3. = 26-50% wound covered with nonviable tissue.
4. = 11-25% wound covered with nonviable tissue.
5. = 0-10% wound covered with nonviable tissue.
6. = No necrotic tissue

b. The score for the percentage of wound covered by granulation tissue are

1. = No granulation present
2. = < 25% of wound covered by granulation tissue
3. = 25-74% of wound covered by granulation tissue
4. = 75-100% of wound covered by granulation tissue

The reduction of wound size and area measured in cm^2.

The final parameters and wound characteristics of the two randomized groups were analyzed and compared.

Observation and Results

Age distribution

Most of the patients fell in the age group between 40 years to 60 years. The mean ± SD for test group is (53.87 ± 6.52) and control is (53.76 ± 6.69), so age distribution is statistically similar between the two group with $P > 0.05$.

Table 1: Age distribution

Age in years	Test group		Control group	
	No. of cases	Percentage	No. of cases	Percentage
20 – 30	7	17.5	6	15%
31 – 40	19	18	6	15%
41 – 50	10	25%	12	30%
51 – 60	14	35%	15	37%
Total	40	100%	40	100%

$P > 0.05$ Insignificant

Sex distribution

The male and female ratio of the test group is 65%: 35% and the control group is 70%: 30%. Hence sex distribution is statistically similar between the two groups with P > 0.05.

Table 2: Sex distribution

Sex distribution	Test group (n = 40)		Control group (n = 40)	
	No. of cases	Percentage	No. of cases	Percentage
Male	26	65%	28	70%
Female	14	35%	12	30%
Total	40	100%	40	100%
Inference	In my study the male female ratio is 13:7 with predominant of male ratio.			

Size of the ulcers

The mean size of the ulcer was 9.68 to 10.74 cm. The mean ± SD of the size of ulcer in test group (9.68 ± 5.73) and in control group (10.74 ± 6.34) is statistically similar between the two groups with P > 0.05.

Table 3: Size of the ulcers

Size of the ulcer (cm)	Test group		Control group	
	No. of Cases	Percentage	No. of Cases	Percentage
≤ 5	11	27.5%	10	25%
5 – 10	12	30%	12	30%
10 – 20	14	35%	15	37.5%
≥ 20	2	4%	4	7.5%
Total	40	100%	40	100%
Inference	Size of the ulcers is statistically similar between the two groups.			

Etiology of patients

All the patients included in the study were suffering from chronic ulcers of varied etiology.

The underlying etiologies of the ulcers were largely comparable in both groups. The etiology wise distribution of the ulcers in both groups is shown in the table and figure below. The main etiology in both groups was diabetes mellitus followed by post infective raw areas.

Table 4: Etiology of patients

	Test group		Control group	
	No.	Percentage	No.	Percentage
Diabetic ulcer	21	52.5%	22	55%
Ischemic ulcer	5	12.5%	4	10%
Venous ulcer	3	7.5%	4	10%
Traumatic ulcer	3	7.5%	2	5%
Bed sore	3	7.5%	2	5%
Pira	5	12.5%	6	15%
Total	40	100%	40	17.5%
Inference	The main etiology in both groups was diabetes Mellitus followed by post infective raw areas			

Presence of necrotic tissue or slough

The number of patients with no necrotic tissue are significantly higher in the test group at 3rd week follow up (P< 0.001), at 4th week (P < 0.001), at 5th week (P<0.001), at 6th week (P<0.001) and at the 7th week (P <0.01) when compared to control group as per the Chi-square / Fisher Exact test.

Table 5: Presence of necrotic tissue or slough

Study period	Test group (n=40) visual score of slough covering the ulcer						Control group (n=40) visual Score of slough covering the ulcer					
	1	2	3	4	5	6	1	2	3	4	5	6
Baseline	20(50%)	12(30%)	8(20%)	1(2%)	-	-	26(56%)	11(22%)	8(20%)			
1st week	10(25%)	12(30%)	8(20%)	7(17.5%)	6(15%)	1(2.5%)	22(55%)	12(30%)	6(15%)	5(12.5%)	4(10%)	
2nd week	1(2.5%)	10(25%)	7(17.5%)	3(7.5%)	12(30%)	14(35%)	5(12.5%)	18(45%)	7(17.5%)	5(12.5%)	3(7.5%)	8(20%)
3rd week	-	2(5%)	4(10%)	12(30%)	0	25(62.5%)	2(5%)	12(24.0%)	10(25%)	5(12.5%)	6(15%)	12(30%)
4th week			2(5%)	5(12.5%)	6(15%)	32(80%)		1(2.5%)	12(30%)	10(25%)	6(15%)	17(42.5%)
5th week				3(6%)	4(10%)	33(82.5%)			5(12.5%)	12(30%)	11(27.5%)	21(52.5%)
6th week					2(5%)	36(90.0%)				8(20.0%)	12(30.0%)	28(70%)
7th week						38(95%)					10(25%)	35(87.5%)
Inference	Number of patients with No Necrotic tissue are significantly higher in Test group at 3rd week follow up (P < 0.001), at 4th week (P < 0.001), at 5th week (P < 0.001), at 6th week (P < 0.001) and at the 7th week (P <0.01) when compared to control group as per the chi-square / FisherExact test											

Figures in brackets are percentages Visual score.

1. = 76-100% wound covered with nonviable tissue
2. = 51-75% wound covered with nonviable tissue
3. = 26-50% wound covered with nonviable tissue
4. = 11-25% wound covered with nonviable tissue
5. = 0-100% wound covered with nonviable tissue
6. = no necrotic tissue

Period of hospital stay

The mean hospital stay in test group was 42.8 ± 3.58(SD) days and that in control group was 46.6 ± 1.72 (SD) days.

Table 6: Period of hospital stay

Week and no. of days	Test group (n=40)		Control group (n=40)	
1st week 1 - 7	No.	Percentage	No.	Percentage
2nd week 8-14	2	5%	-	-
3rd week 15-21	10	25%	3	7.5%
4th week 22-28	-	-	-	-
5th week 29-35	9	22.5%	2	5%
6th week 36-42	12	30%	5	12.5%
7th week 43-49	4	10%	20	50%
8th week >49	3	7.5%	10	25%
	40	100%	40	100%

Images: Hydrogel dressings- test group

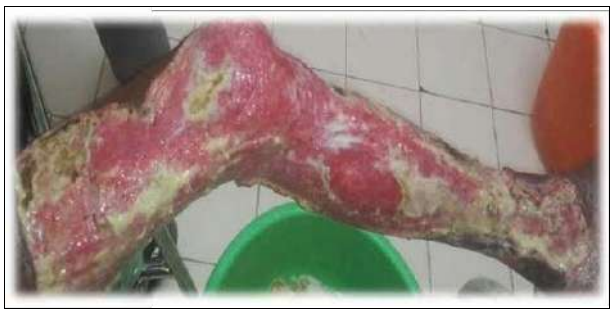

Fig 1: Day 7 pira-post debridement ulcer over thigh and leg

Fig 2: Day 14 –ulcer showing healthy granulation tissue

Fig 3: Traumatic ulcer –before image showing granulation tissue on day 1, after image showing epithelized wound on day 14

Fig 4: Ischaemic ulcer –before image showing slough on day 1, after image showing healthy granulation tissue on day 7

Discussion

The whole sample population was be divided into two equal and comparable groups of 40 patients, based on the willingness for undergoing topical hydrogel dressing. Those who were not willing were subjected to conventional wound dressings and formed the control group. These groups were further split into two equal groups of 20 Patients each, based on those who have diabetes and those without diabetes. Thus the whole study population was divided into four groups. Selection of patients was done by purposive sampling method. Both the test and control groups were matched regarding their age, sex, etiology and size of ulcer size. In addition, there was no significant difference between the two groups with respect to baseline ulcer size and amount of nonviable tissue / slough.

The number of patients with no necrotic tissue is significantly higher in Test group at 3rd week follow up (P< 0.001), at 4th week (P <0.001), at 5th week (P <0.001), at 6th week (P < 0.01) and at the 7th week (P<0.01) when compared to control group. The loss of viable tissue is less in the test group compared to that of control group because the number of bedside surgical debridements required is less and done superficially to remove dead tissue only.

The number of patients with 75-100% wound filled by granulation tissue is significantly higher in Test group at 3rd week follow up (*P*<0.001), at 4th week (*P* <0.001), at 5th week (*P* <0.001), at 6th week (*P* <0.001) and at the 7th week (P< 0.05) when compared to control group.

The number of patients with no wound surface (nil) is significantly higher in Test group at 3rd week follow up (*P*<0.05), at 4th week (*P* <0.05), at 5 week (*P* <0.05), at 6thweek (*P* < 0.001) at the 7th week (*P* < 0.001) when compared to control group.

In our study, Presence of necrotic tissue in 1st week was 76% in test group, after using hydrogel dressing the fall of necrotic tissue was to 30% in 4th week whereas in control group the presence of necrotic tissue in 1st week was 54%, after using conventional dressing the fall of necrotic tissue was to 34%. So in our study the use of hydrogel dressing was more superior than the conventional dressing in response to fall in necrotic tissue. Similar study was done by Zoellner P, *et al.* [12] which showed fall in necrotic from 62% to 23% by using hydrogel dressing which is similar to our study.

The presence of granulation tissue in 1st week was 28% in test group, after using hydrogel dressing the granulation tissue increased to 52% in the 3rd week whereas in control group the presence of granulation tissue in 1st week was 52%, after using conventional dressing it was only 20%.So in our study the use of hydrogel dressing was more superior than the conventional dressing in response to presence of granulation tissue. Similar study was done by Zoellnerp, *et al.* [12] which showed increased in granulation tissue from25% to 37% by using hydrogel dressing which is almost similar to our study.

In our study, the wound surface area epithelized in test group by using hydrogel dressing was from 68% to 32% in the 3rd week whereas in control group the wound surface area epithelized by using conventional dressing was from 92% to 8%. At the end of 7th week the wounds epithelized was 96% by using hydrogel dressing whereas 44% by using conventional dressing. So in our study the wound surface area epithelized was better by using hydrogel dressing than the conventional dressing. Similar study was done by Kayaaz, *et al.* [13] which showed almost similar results where 84% of the wounds epithelized by hydrogel dressing and 54% of wounds by conventional dressing.

In our study the mean hospital stay in test group was 42.9 ± 3.58(SD) days and that in control group was 47.61 ± 1.72 (SD) days. In similar study done by Kayaaz, *et al.* [13] the mean hospital in hydrogel group was 48 days, as this study involves only pressure ulcers as there etiology whereas our study involves varied etiology and the mean age being 53.87 ± 6.52, healing was faster.

This study demonstrated that enzymatic hydrogel with colloidal silver debridement along with bedside surgical debridement had cumulative effect in reduction of slough, increase granulation

tissue and faster wound bed preparation.
The test group patients also experienced less pain than the control group because the need for the bed side surgical debridement is less than the control group.
The test group patients under went skin grafting, secondary suturing and flap as early as 3rd week than control group because of faster wound bed preparation. The wound also healed faster this is due to increased epithelization.

Limitations of the study
The most important limitation of the present study is its sample size. Although a sample size of 100 patients is sufficient for statistical analysis, a randomized controlled comparative study with a much larger population may help to further substantiate the findings or reveal variations which were not observed in the present study. The cost burden on the patient is also not analyzed in this study as this can be influenced by various factors other than the cost of dressings. The quantitative assessment of the post operative parameters like wound contraction, pain and residual raw ulcer area was also not included in the present study, which if included, might have given a much better analysis of the efficacy of hydrogel dressings as compared to conventional dressings.

Conclusion
The study was conducted to provide insight into the depth of chronic wound management, as it has become a major issue in recent years. The purpose of this study was to improve wounds and ulcers by removing necrotic tissue and debris, removing senescent cells from the wound bed, providing moisture with hydrogel and colloidal silver as agents, and preparing the wound for a healthy bed of granulation tissue to promote speedy healing. As a result, we conclude that,

1. The combination of hydrogel and colloidal silver has proven to be particularly successful in reducing slough, increasing granulation tissue development, and reepithelization.
2. In comparison to standard treatment with local antiseptics, the combination of hydrogel and colloidal silver demonstrated to be much more effective in wound bed preparation.
3. It was also discovered that employing hydrogel dressings resulted in a shorter overall hospital stay.
4. As a result, hydrogel dressing can be regarded as a superior choice in the treatment of chronic wounds.

Acknowledgment
The author is thankful to Department of General Surgery for providing all the facilities to carry out this work.

Conflict of Interest
None

Funding support
Nil

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