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ORIGINAL RESEARCH

A Comparative Study of the Efficacy of Topical HydrogelDressings and Conventional Dressings Inchronic Wounds

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ABSTRACT

Background:This study compared the efficacy of topical Hydrogel wound dressings with that of a control group using conventional wound dressings in the healing of chronic ulcers. The primary outcomes measured were the number of ulcers not healed in either group, the amount of non-viable tissue, the rate of granulation tissue formation as percentage of ulcer surface area, and the length of time spent in hospital.

Materials and Methods: A prospective, parallel group, comparative trial design was used in this study. Patients with chronic wounds were admitted to the general surgery department of the Government Medical College in Suryapet. After determining whether or not the participants were willing to receive topical hydrogel dressing, the entire sample population was separated into two equal and comparable groups of 120 patients. Those who refused to participate were exposed to traditional wound dressings, and this group served as the control group. They were then divided into two equal groups of 60 patients each, one for those with diabetes and one for those who did not, based on whether they had diabetes.

Results: As a result, the entire study population was separated into four categories. The purposive sample strategy was used to choose the patients for the study. Patients were followed up on, and the state of their ulcers was determined using a visual score.When compared to the control group, the test group shows significant reduction in slough as early as the third week. The frequency of patients with 75-100 percent wound filled with granulation tissue was higher in the test group as early as the third week compared to the control group, which took more than four weeks to achieve the same result. The number of patients who underwent secondary suturing, skin grafts, and flaps is much higher in the test group than in the control group, and this difference can be seen as early as the third week.

Conclusion: Hydrogel is an excellent topical applicant for the reduction of slough, the promotion of granulation tissue development, and the reepitheilization of wounds, as well as the decrease of hospitalisation time for patients with wounds. When compared to standard treatment with local antiseptics, this results in speedier wound bed preparation for healing, suturing, skin transplant and flap placement and healing.

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

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INTRODUCTION

The peculiarity of a chronic wound is that, whatever management you give, they refuse to heal, especially the pressure ulcers or bed sore. Although it is still maintained by a significant percentage of professionals, the belief that wounds should be kept dry is losing momentum all the time. We now understand that dressings that allow for moist wound healing promote

wound re- epithelialization and the development of granulation tissue considerably more quickly. Obviously, we understand that occluding wounds does not result in infection. Despite the fact that numerous wound care techniques have been developed to assist surgeons, such as the use of compression bandages to treat venous ulcers, the problem of chronic wounds continues to exist today.[1-3]

We are currently witnessing the beginning of a revolution in wound care. Over the years, a variety of methods for treating persistent leg ulcers have been attempted. Despite the fact that wound dressings have been in use for at least two millennia, there is no perfect bandage for every situation. The surgical dressing of both open and closed wounds is mostly determined by tradition, training, and the surgeon's personal philosophy. During the previous two decades, a diverse range of cutting-edge dressings has been developed.[4-8]

Recent studies have demonstrated that the controlled administration of a topical hydrogel to the wound site can have a significant impact on the speed of wound healing and healing outcomes.[9,10] The current study was designed to evaluate the efficacy of topical hydrogel wound dressings in improving the healing process in chronic wounds when compared to conventional wound dressings, as well as to demonstrate that topical hydrogel wound dressings are a superior treatment option for the management of chronic wounds when compared to conventional wound dressings.

Objectives of the Present Study

To compare the efficacy of topical hydrogel wound dressings with that of a control group using conventional wound dressings, in healing of chronic ulcers in terms of:

- Number of ulcers unhealed in either group.
- Amount of Non-Viable tissue.
- Rate of granulation tissue formation as percentage of ulcer surface area.
- Period of hospital stay.

MATERIALS & METHODS

Study Design: Prospective randomized comparative study.

Source of data: All patients with chronic wounds, of varying etiology, admitted in Govt medical college hospital Suryapet, from Septmber 2021 to January 2022 satisfying all the inclusion criteria mentioned below after the clearance from the ethical committee was obtained.

Inclusion criteria:

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

Exclusion criteria:

1. Wounds with necrotic tissue
2. Untreated underlying osteomyelitis
3. Fistulas to organs or body cavities
4. Exposed arteries or veins
5. Malignancy within wounds
6. Dry gangrene

Sample Size:
Total of 120 patients, who fulfilled the above inclusion criteria fromGovt Medical College, Suryapet, 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 60 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 twoequal groups of 25 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 asetiology 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 ofother 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 when ever required, for wounds / ulcers which hadslough 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 testgroup 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: 50

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.

RESULTS

Table 1: Age in years

Age in years	Test group		Control group	
	No. Of cases	Percentage	No. Of cases	Percentage
20 – 30	9	18.3%	10	16.66%
31 – 40	13	21.66%	10	16.66%
41 – 50	15	25%	18	30%
51 – 60	15	35%	22	36.67%
Total	60	100%	60	100%
Mean ± S.D	53.67 ± 6.41		53.21± 4.21	
Inference:	Age distribution is statistically similar between the two groups.			

P > 0.05 Insignificant.

Sex Distribution

The male and female ratio of the test group is 36 %: 24% and the control groupis 39 %: 21%. Hence sex distribution is statistically similar between the two groups with P > 0.05.

Table 2: Sex distribution

Sex distribution	Test group (n = 60)		Control group (n = 60)	
	No. Of cases	Percentage	No. Of cases	Percentage
Male	36	60.0%	39	65%
Female	24	40.0 %	21	35%
Total	60	100%	60	100%
Inference	In my study, the male-female ratio is 6:4 with a 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 sizeof 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. ofCases	Percentage	No. ofCases	Percentage
≤ 5	13	25%	16	26.67%
5 – 10	21	35%	18	30%
10 – 20	20	33.35%	22	35%
≥ 20	4	10.0%	5	8.33%
TOTAL	60	100%	60	100%
MEAN ± S.D	9.49 ± 5.13		10.86 ± 6.12	
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. The main etiology in both groups was diabetes mellitus followed by postinfective raw areas.

Table 4: Etiology of the patients

	Test group		**Control group**	
	No.	**Percentage**	**No.**	**Percentage**
Diabetic ulcer	28	60%	28	46.67%
Ischemic ulcer	7	12%	6	10%
Venous ulcer	5	8%	7	11.6%
Traumatic ulcer	3	3%	4	6.6%
Bed sore	5	8%	3	5%
Pira	12	16%	12	20%
Total	60	100%	60	100%
Inference	The main etiology in both groups was diabetesmellitus followed by postinfective 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.

Visual score.[11]

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

Visual score[11]

1. = no granulation present
2. = < 25% of wound filled
3. = 25-74% of wound filled
4. = 75-100% of wound filled

Wound Surface Area

The number of patients with No wound surface (Nil) are significantly higher in Test group at 3rd week follow up (P< 0.05), at 4th week (P <0.05), at 5th week (P < 0.05), at 6th week (P<0.001) and at the 7th week (P<0.001) when compared to controlgroup as per the Chi-square / Fisher Exact test.

Period of Hospital Stay

The mean hospital stay in test group was 44.14 ± 3.83 (SD) days and that in control group was 48.32 ± 2.96 (SD) days.

Table 5: Period of Hospital Stay

Week and no of days	**Test group (n=60)**		**Control group (n=60)**	
1st week 1 - 7	No.	Percentage	No.	Percentage
2nd week 8-14	2	3.33%	-	-
3rd week 15-21	16	20%	6	10%
4th week 22-28	-	-	-	-

5th week 29-35	13	21.66%	3	5%
6th week36-42	18	30 %	10	16.66%
7th week43-49	7	11.6%	29	48.34%
8th week>49	4	6%	12	20%
	60	100%	60	100%
Mean ±SD	44.14 ±3.83		48.32 ± 2.96	

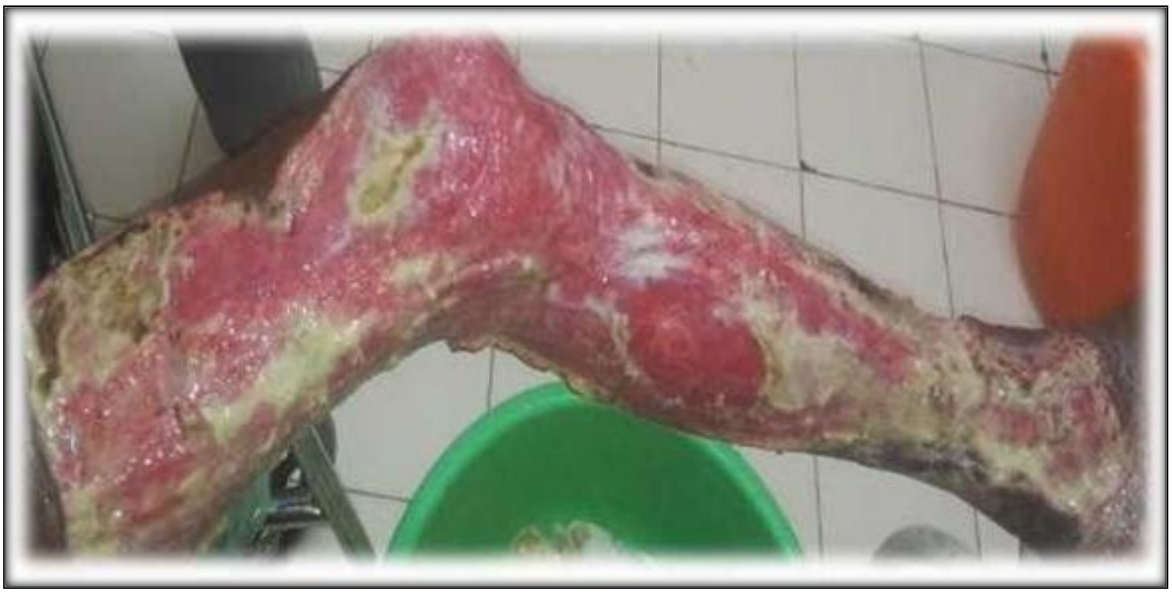

Figure 1: images: hydrogel dressings- test group

Patient 1: Day 7 Pira-Post Debridement Ulcer Over Thigh and leg.

Patient 1: Day 14 –ULCER SHOWING HEALTHY GRANULATION TISSUE

Patient 1: Diabetic Ulcer –Day1 Ulcer Covered with Slough and Minimal Granulation Tissue

Patient 1: Diabetic Ulcer –Day 14 Ulcer Covered with Slough, Edema And Pale Granulation Tissue

DISCUSSION

The whole sample population was be divided into two equal and comparable groups of 60 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 60 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 4^{th}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 theuse 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 AL12 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 weekwhereas in control group the presence of granulation tissue in 1st week was 52%, afterusing 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 whichshowed 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 ephithilized in test group by usinghydrogel dressing was from 68% to 20% in the 3rd week whereas in control group the wound surface area ephithilized by using conventional dressing was from 92% to 8%.At the end of 7th week the wounds ephithilized was 96% by using hydrogel dressing whereas 44% by using conventional dressing. So in our study the wound surface area ephithilized was better by using hydrogel dressing than the conventional dressing. Similar study was done by KAYA AZ, ET AL13 which showed almost similar results where 84% of the wounds ephithilized by hydrogel dressing and 54% of wounds by conventional dressing.

In our study the mean hospital stay in test group was 53.67 ± 6.41 (SD) days andthat in control group was was 53.21± 4.21 (SD) days. In similar study done by KAYAAZ,ET AL13 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 53.67 ± 6.41, 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 groupbecause 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. Althougha sample size of 120 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 comparedto conventional dressings.

CONCLUSION

The study was conducted in order to gain a better understanding of the complexity of chronic wound management, which has emerged as a major issue in recent years. The purpose of this study was to improve the wound / ulcer by removing necrotic tissue and debris, removing senescent cells from the wound bed, providing moisture, and preparing the wound for a healthy bed of granulation tissue in order to promote rapid healing. The agents used in this study were hydrogel and colloidal silver. As a result, we can deduce that:

1. The use of hydrogel in conjunction with colloidal silver has proven to be quite successful in reducing slough, increasing granulation tissue development, and reepithelialization.
2. When compared to traditional treatment with local antiseptics, the combination of hydrogel and colloidal silver demonstrated to be much more efficient in wound bed preparation.
3. It was also discovered that the use of hydrogel dressings resulted in a significantly shorter overall hospital stay.

The use of hydrogel dressings in the therapy of chronic wounds can therefore be considered to be a preferable choice.

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