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General Surgery

A COMPARATIVE STUDY OF ULCER HEALING WITH SILVER FIX FOAM DRESSING AND REGULAR BETADINE DRESSING

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ABSTRACT **BACKGROUND** An ulcer is not a serious health problem for the patient but a major health concern due to discomfort, pain, loss of workdays, and treatment cost. Several treatment modalities are available in treating ulcers based on their aetiology. In most ulcer management, povidone-iodine has been used for a very long duration with good results. On the other hand, silver, an antibacterial and anti-inflammatory agent, is a newer treatment modality. **Aims and Objectives** In this study, we wanted to evaluate and compare the healing of an ulcer in patients treated with silver fix foam and betadine with regard to the progress of healing and duration, and rate of healing in both methods. **MATERIALS AND METHODS** This was a comparative study conducted after obtaining approval from the ethical committee of Rangaraya Medical College and Government General Hospital, Kakinada, in the Department of General Surgery, over two years from June 2018 to May 2020 among patients suffering from non-healing ulcer who attended the general surgery outpatient department of Government General Hospital, Kakinada. **RESULTS** The advantage of silver foam dressings is that they can be changed every 4th or 5th day when compared to betadine, which requires daily or alternate day dressings. **CONCLUSION** Silver foam dressings show better control of infection and rate of healing when compared to povidone-iodine in the management of all patients with ulcers.

KEYWORDS : Ulcer Healing, Silver Fix Foam Dressing, Betadine Dressing

INTRODUCTION

A wound is defined as a break in the continuity of the skin or epithelium and loss of underlying tissues often, which may be associated with disruption of structure and function. Injuries mainly occur due to an external force such as physical trauma or direct exposure to chemicals or surgical and microbial infections. Injuries usually affect the quality of life, and repair of damaged tissues is essential in life's survival.[1]

Healing is the body's response to injury in an attempt to restore normal structure and function. It is an important biological process that includes a series of cellular and biochemical events that help repair damaged tissue and restore the tensile strength of the injured tissue. The wound care approach is to promote healing in the shortest time possible with minimal pain, discomfort, and minimal scarring.[2]

An acute or chronic wound problem ranges from simple interruption to daily routine activities to severe life-threatening sepsis and organ dysfunction. About nearly 6 million people suffer from chronic wounds worldwide. The prevalence of chronic wounds in India is about 4.5 per 1000, whereas acute wounds is about 10.5 per 1000.[3] About 10 % of the population develops a chronic wound in their lifetime, with morbidity and mortality of 2.5 %.[4] Many new approaches and novel agents that promote wound healing have met with experimental research, and different pharmacological methods have been screened, but the potential of most remains unexplained.[5]

Management of ulcers is a multi-dimensional approach that includes regular debridement followed by different dressing materials like povidone-iodine, hydrogels, foams, ionic silver, or skin replacement, which helps in the autolytic breakdown and provides an antibacterial environment. Silver has vast antiseptic and anti-inflammatory properties along with broad-spectrum antibiotic effects [6] since Greeks and ancient Americans used silver coins to disinfect the stored liquids, mainly water.[7] As nanotechnology makes it possible to expand silver particles' surface area to the nanoscale, it helps in raising the contact period with the wound to protect it from bacteria or fungi, therefore increasing the bactericidal and fungicidal effects.

This study evaluates the effectiveness of povidone-iodine vs. silver fix foam pad dressings in terms of the time of healing, infection control, and formation of granulation tissue.

Aims and Objectives

1. To study the healing of an ulcer in the patients treated with silver fix foam and betadine.
2. To study the progress of healing and duration, rate of healing in both methods and do comparison between them.

MATERIAL AND METHODS

This is a comparative study conducted after obtaining approval from the ethical committee of Rangaraya Medical College and Government General Hospital, Kakinada, in the Department of General Surgery, for two years from June 2018 to May 2020 among patients suffering from non-healing ulcer who attended the general surgery outpatient department of Government General Hospital, Kakinada. Data were collected after taking consent using a case record form which included all particulars history, clinical findings, and cultural sensitivity of discharge from ulcers.

Size of Sample

The sample size of 80 (40 in each group) was calculated at 5 % absolute precision and 95 % confidence limit.

Inclusion Criteria

1. Age between 15 and 50 years
2. Patients with chronic non-healing ulcers such as diabetic ulcers, traumatic ulcers etc.

Exclusion Criteria

1. Age less than 15 years or more than 50 years.
2. Tubercular ulcers, venous ulcers, malignant ulcers, ulcers with underlying bone infections.
3. Patients who were allergic to iodine or silver.

Study Procedure

GROUP 1: Patients with non-healing ulcers were treated with silver fix foam pad dressings.
GROUP 2: Patients with non-healing ulcers were treated with regular betadine dressings.

All patients were started with strict antibiotic therapy as per the culture report followed by daily debridement along with dressing in the betadine group and debridement and dressing every 4 days in the silver foam treated group. Endpoint parameters included rapidity of healing, complete healing of small ulcers, the appearance of bacteria-free healthy granulation tissue, and presence of slough and progress of healing and duration rate of healing in both methods.

Statistical Analysis

Data was entered in MS-Excel and analysed in SPSS V21. Descriptive statistics were represented with percentages. A chi-square test was applied to find significance. $P < 0.05$ was considered statistically significant.

RESULTS

In the present study, the majority of non-healing ulcers were found in the 31-40 yrs age group (37.5 %) followed by 41-50 yrs (32.5 %), 21-30 yrs age group (10 %) and < 20 yrs age group (5 %) in group-A treated with silver fix foam dressing, whereas 41 - 50 yrs age group (40 %), followed by 31 - 40 yrs age group (37.5 %) and 21 - 30 yrs age group (22.5 %) in group-B treated with betadine dressings.

In the present study, there is predominant involvement of males (61 %) whereas females are 39 %**.** In this study, 62.5 % of males and 37.5 % of females were included in the silver fix foam group whereas in the betadine group, 60 % of males and 40 % of females were involved.

In the present study, the majority were diabetic ulcers (56.25 %) followed by traumatic ulcers (31.25 %) and trophic ulcers (12.5 %).

Table 1

Age	AG Fix Foam		Betadine		P-value
	Count	%	Count	%	
< 20	2	5.0%	0	0.0%	0.501
21 - 30	10	25.0%	9	22.5%	
31 - 40	15	37.5%	15	37.5%	
41 - 50	13	32.5%	16	40.0%	
Total	40	100.0%	40	100.0%	
Age Distribution					
Sex		Frequency		Percent (%)	
Female		31		38.8	
Male		49		61.2	
Total		80		100.0	
Sex Distribution					

Table 2

Ulcer Type	AG Fix Foam		Betadine		P-value
	Count	%	Count	%	
Diabetic ulcer	25	62.5	20	50.0	0.46
Traumatic ulcer	10	25.0	15	37.5	
Trophic ulcer	5	12.5	5	12.5	
Total	40	100.0	40	100.0	
Ulcer Types in Both Groups					
Purulent Discharge	AG Fix Foam		Betadine		P-value
	Count	%	Count	%	
Absent	8	20.0	9	22.5	0.50
Present	32	80.0	31	77.5	
Total	40	100.0	40	100.0	
Discharge in Both Groups					

Table 3

4 Weeks	AG Fix Foam		Betadine		P-value
	Count	%	Count	%	
Healed	15	37.5%	7	17.5%	0.045*
Non-healed	25	62.5%	33	82.5%	
Total	40	100.0%	40	100.0%	
Healing Comparison at 4 Weeks					
5 Weeks	AG Fix Foam		Betadine		P-value
	Count	%	Count	%	
Healed	26	65.0%	13	32.5%	0.004*
Non-healed	14	35.0%	27	67.5%	
Total	40	100.0%	40	100.0%	
Healing Comparison at 5 Weeks					
6 Weeks	AG Fix Foam		Betadine		P-value
	Count	%	Count	%	
Healed	37	92.5%	21	52.5%	0.001*
Non-healed	3	7.5%	19	47.5%	
Total	40	100.0%	40	100.0%	
Healing Comparison at 6 Weeks					
7 Weeks	AG Fix Foam		Betadine		P-value
	Count	%	Count	%	
Healed	39	97.5%	29	72.5%	0.001*
Non-healed	1	2.5%	11	27.5%	
Total	40	100.0%	40	100.0%	
Healing Comparison at 7 Weeks					
8 Weeks	AG Fix Foam		Betadine		P-value
	Count	%	Count	%	
Healed	40	100.0%	35	87.5%	0.02*
Non-healed	0	0.0%	5	12.5%	
Total	40	100.0%	40	100.0%	
Healing Comparison at 8 Weeks					

In the present study, there was predominant involvement of diabetic ulcers in both groups with silver fix foam (62.5 %) and betadine group (50 %)

In the present study, purulent discharge was present in 78.8 % of cases and absent in 21.2 % of cases.

In the present study, the majority of cases showed purulent discharge with 80 % in the silver group and 77.5 % in the betadine group.

In the present study, at the end of 4 weeks, silver fix foam group showed better healing with 37.5 % (P-0.045) when compared to the betadine group (17.5 %).

In the present study, at the end of 5 weeks, the silver fix foam group showed better healing with 65 % (P- 0.004) when compared to the betadine group (32.5 %).

In the present study, at the end of 6 weeks, the silver fix foam group showed better healing with 92.5 % (P-0.001) when compared to the betadine group (52.5 %).

Diabetic ulcer treated with silver fix foam dressing showed early reduction of the slough, the appearance of granulation tissue and early healing.

In the present study, at the end of 7 weeks, the silver fix foam group showed better healing with 97.5 % (P-0.001) when compared to the betadine group with 72.5 %.

Trophic ulcers treated with silver fix foam dressings showed early reduction of the slough and early appearance of granulation tissue.

In the present study, at the end of 8 weeks, the silver fix foam group showed 100 % healing (P-0.02) when compared to the betadine group 87.5 %.

In the present study, there was a significant reduction in the slough by the end of 2 weeks in the silver fix foam group.

In the present study, there was a significant appearance of granulation tissue by the end of 2 weeks in the silver fix foam group.

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Table 4

Presence of Slough					
Presence of Slough	Betadine		AG fix foam		P-value
	Count	%	Count	%	
1 day (Baseline)	38	95.0%	39	97.5%	0.556
1 week	35	87.5%	30	75.0%	0.152
2 week	31	77.5%	22	55.0%	0.033*
3 week	27	67.5%	10	25.0%	0.001*
4 week	19	47.5%	2	5.0%	0.001*

5 week	10	25.0%	0	0.0%	0.001*
6 week	0	0.0%	0	0.0%	-
Presence of Slough					
Granulation tissue					
Appearance of Granulation Tissue	Betadine		AG fix foam		P-value
	Count	%	Count	%	
1 day	2	5.0%	1	2.5%	0.556
1 week	5	12.5%	10	25.0%	0.156
2 weeks	9	22.5%	18	45.0%	0.03*
3 weeks	13	32.5%	30	75.0%	0.001*
4 weeks	21	52.5%	38	95.0%	0.001*
5 weeks	30	75.0%	40	100.0%	0.001*
6 weeks	40	100.0%	40	100.0%	-
The appearance of Granulation Tissue					

In the present study, there was a significant reduction in the slough by the end of 2 weeks in the silver fix foam group.

In the present study, there was a significant appearance of granulation tissue by the end of 2 weeks in the silver fix foam group.

In the present study, there was a significant improvement in healing every week in the silver fix foam group when compared to betadine.

Table 5

AG fix foam					P-value
Time	Healed		Non-healed		
	Count	%	Count	%	
4 weeks	15	37.5	25	62.5	0.001*
5 weeks	26	65	14	35	
6 weeks	37	92.5	3	10	
7 weeks	39	97.5	1	2.5	
8 weeks	40	100	0	0	
Healing in AG Fix Foam Group					
Betadine					P-value
Time	Healed		Non-healed		
	Count	%	Count	%	
4 weeks	7	17.5	33	82.5	0.001*
5 weeks	13	32.5	27	67.5	
6 weeks	21	52.5	19	47.5	
7 weeks	29	72.5	11	27.5	
8 weeks	35	87.5	5	12.5	
9 weeks	39	97.5	1	2.5	
10 weeks	40	100	0	0	
Healing in Betadine Group					
Time	AG fix foam		Betadine		P-value
	Count	%	Count	%	
4 weeks	15	37.5	7	17.5	0.045*
5 weeks	26	65	13	32.5	0.004*
6 weeks	37	92.5	21	52.5	0.001*
7 weeks	39	97.5	29	72.5	0.001*
8 weeks	40	100	35	87.5	0.02*
9 weeks	0	0	39	97.5	-
10 weeks	0	0	40	100	-
Healing Comparison in Both Groups					
(*-Significance)					

In the present study, there was a significant improvement in healing every week in the silver fix foam group when compared to betadine.

DISCUSSION

A comparative study was conducted on the effectiveness of ulcer healing on treatment with regular betadine dressings and silver fix foam pad dressings for a period of 2 yrs. from June 2018 to May 2020 on patients attending General surgery OPD in GGH, Kakinada.

The primary treatment for ulcers is surgical debridement and the use of variable materials for biodegradable therapy. Choosing proper dressing material is a major decision for the disinfection and removal of necrotic debris from ulcers. These are aimed at modifying the micro condition of the wound and promoting its healing. For this purpose, a prospective clinical trial was conducted. Very few studies were available that compared the outcomes between povidone-iodine and silver foam dressing; hence our study enlightens the comparative analysis.

A total of 80 patients were selected who fulfilled the inclusion criteria of the study proposed and approved by the ethical committee of Rangaraya medical college, Kakinada.

Out of the 80 patients selected, they were divided into 2 groups of 40 each by random sampling by double-blinding. Amongst the age incidence, 41-50 age group was predominantly seen accounting for about 17 in group 1 and 23 in group 2 followed by age group of 31-40 yrs about 13 in group 1 and 8 in group 2 and, age group of 21-30 yrs. about 6 in group 1 and 7 in group 2, age group of < 20 yrs. about 4 in group 1 and 2 in group 2 respectively.

In the present study, patients from both groups were found almost comparable in terms of age, sex, and surface area of ulcers. Out of them, maximum patients were in the age group of 41- 50 years, 42 % in the silver fix foam treated group and 57 % in the povidone-iodine group. Male preponderance was seen in both groups with 61 % of males and 39 % of females. Both the dressing groups were statistically similar (p-value= 0.42) for age.

Both groups were studied for the reduction of the slough, the appearance of granulation tissue, infection control, and rate and progress of healing with group-wise treatment with povidone-iodine and silver foam dressing.

The present study showed that at the end of 3rd week there was a 75 % decrease in slough by povidone-iodine which is better than the study conducted by Chandra Mouli Vyas where 30 % slough was reduced by the end of 3rd week but nearer to the study conducted by Kapur V & Marwaha AK, where they reported 90 % decrease in slough by 3rd week with povidone-iodine. Hence, time required for a decrease of slough is longer in our study with povidone-iodine.[8]

In present study group that was treated with nanosilver, there was 45 % of slough reduction in the 2nd week (P=0.033), 75 % by end of the 3rd week (P=0.001), 95 % by the end of the 4th week and 100 % by the end of 5th week which correlates with the study done by Singh S and Apte A[9] where the reduction in slough in nanosilver group was 2 weeks and 3 weeks in povidone-iodine group with a p-value < 0.0001, but the study done by Chandra Mouli Vyas reported the time taken for slough reduction as 3 weeks for 84 % and 4 weeks for 96 % reduction and 5 weeks for 100%. But the patients who were treated with betadine showed a reduction of the slough 22.5 % by the end of 2nd week, 32.5 % by the end of 3rd week, 52.5% by the end of 4th week, 75 % by the end of 5th week and 100 % by the end of 6th week. Reduction of the slough is earlier and better in patients treated with silver fix foam pad when compared to betadine dressings.

After day 1 and day 7, we got statistically similar results between both groups (p-value > 0.05). There was no difference in the appearance of granulation tissue in both groups at that stage.

A study done by Chandra Mouli Vyas et al showed the results as at the end of 2nd, 3rd, 4th, and 5th week, there was a faster appearance of healthy granulation tissue in the group treated with silver fix foam dressing such as 20%, 56%, 84%, and 96 %. This shows a statistically significant value (P=<0.001). In the present study, the appearance of granulation tissue in patients treated with Ag fix foam dressings was 45% (P=0.03), 75 % (P=0.001), 95 % (P=0.001) and 100 % (p=0.001) at the end of 2nd, 3rd, 4th and 5th weeks respectively whereas in patients treated with regular betadine dressings showed 22.5 %, 32.5 %, 52.5 %, 75 % and 100 % at the end of 2nd, 3rd, 4th, 5th and 6th week respectively. The results showed that the appearance of granulation tissue was earlier in patients treated with Ag fix foam dressings.

In a study conducted by Florence Jurczak, rates of complete healing at study completion were 23 % for Hydrofiber Ag dressing and 9 % for povidone-iodine gauze. A study conducted by Bhavkeeret Singh reported that the percentage reduction in size was more in the nanosilver group as compared to the betadine group.

The present study showed a statistically highly significant difference (P < 0.001) between the povidone-iodine and silver foam groups which

is similar to findings obtained from the study conducted by Chandra Mouli Vyas. 96 % granulation tissue formation at end of the 5th week and Ramanaiah NV and Saikrishna et al[10] found that appearance of granulation tissue was 94.81% in nanosilver group at the end of 5th week and the difference was also statistically significant (P<0.05).

A study done by K.C.Munter et al 2006 compared the[11] effect of silver foam dressings with local best practices. 619 patients with ulcers were studied for 4 weeks. Silver foam dressings decreased wound area by 50 % while local best practices reduced by 34 %. In addition, less slough, less time and more progressive healing of the wound were achieved with a silver foam dressing.

The present study showed significant improvement in the rate of healing in the silver fix foam group with healing at 4 weeks (37.5 %), 5 weeks (65 %), 6 weeks (92.5 %), 7 weeks (97.5 %) and 8 weeks (100 %) with significant P value (0.001) when compared to betadine group which showed healing at 4 weeks (17.5 %), 5 weeks (32.5 %),6 weeks (52.5 %), 7 weeks (72.5 %), 8 weeks (87.5 %), 9 weeks (97.5 %) and 10 weeks (100 %).

CONCLUSION

The advantage of silver foam dressings is that they can be changed every 4th or 5th day when compared to betadine, which requires daily or alternate day dressings.

Limited studies are found with this compound, and there is an essentiality for more elaborate studies to define the efficacy of silver dressings in ulcer management. Hence, the present study results proved that silver foam dressings showed better control of infection and rate of healing when compared to povidone-iodine in the management of all patients with ulcers.

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