

# A Comparative Study of the Efficacy of Topical Hydrogel Dressings and Conventional Saline Dressings in Diabetic Foot Ulcers

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## Abstract

**Aim:** To compare the efficacy of topical Hydrogel wound dressings with that of conventional wound dressings in healing of diabetic foot ulcers

**Methods :** A Prospective Comparative study was done from December 2018 to October 2020 among 100 patients with clinical diagnosis of diabetic foot ulcers. They were divided into two groups; Group A: 50 patients subjected to hydrogel application and Group B: 50 patients subjected to normal saline dressing. The day of appearance of granulation tissue was observed and Size of the ulcer was measured on; Day 0, Day 7 and Day 14. One sample t-test was used to compare the results.

**Results:** In the hydrogel dressing group, the mean age of the participants is 58.6 years. In the saline dressing group, the mean age of the participants is 53.3 years. In both the groups, there were equal number of males and females. Comparison of two groups were done based on percentage reduction: The percentage reduction in two groups is hydrogel dressing on Day 7: 4.95%, Saline Dressing on Day 7: 3.15%; hydrogel dressing on Day 14: 11.07% and Saline Dressing on Day 14: 7.27%. Independent sample t-test for comparison of size of ulcer shows that the two groups differ significantly in the results. Statistically p-value is <0.05. The size of the ulcer reduces considerably reduces in 14 days following application of hydrogel dressing and saline dressing. The percentage reduction in hydrogel dressing group is 11.07% in two weeks. The percentage reduction in saline dressing group is 7.27% in two weeks.

**Conclusion:** Hydrogel is an effective topical applicant in promoting granulation tissue formation and reepithelization and in decreasing hospital stay in comparing with normal saline dressing.

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## I. Introduction

Diabetes mellitus is a worldwide epidemic resulting in significant morbidity and mortality<sup>1</sup>. It starts as a disorder of glucose metabolism and ends up as a multisystem disease. The main underlying mechanism is the abnormal insulin production or impaired insulin utilisation or both. It affects the kidneys, eyes, heart, cardiovascular system, limbs, etc. One of the main manifestations of increased morbidity related to uncontrolled diabetes mellitus is diabetic foot. Diabetic foot is common throughout the globe with serious effects on quality of life, livelihood and has economic consequences for the families and the society as a whole<sup>2</sup>. The majority of diabetic foot ulcers is neuropathic in origin which suggests that it can be prevented if there are adequate measures in place. It is estimated that in the coming days, diabetic foot will cause serious problems to the developing countries<sup>3</sup>. This can be avoided by early screening and identification of people who are at high risk of developing diabetic foot ulcers, educate them and follow-up to avoid incidence. The lifestyle modifications are absolutely necessary. A lower limb is lost every 30 seconds due to diabetes worldwide<sup>5</sup>. Therefore, it is essential to prevent the long term complications of diabetic foot to avoid social, economic, personal and medical costs

## II. Materials And Method

**AIM AND OBJECTIVE:** To compare the efficacy of topical hydrogel wound dressings with that of conventional saline dressings in healing of diabetic foot ulcers.

### STUDY AREA :

GMKMCH ,Salem

Study population: 100 patients with diabetic foot ulcers admitted in GMKMCH, Salem.

### INCLUSION CRITERIA:

All the cases of diabetic foot ulcers

### EXCLUSION CRITERIA:

1. Those patients with non-diabetic foot ulcers

2. Patients with severe anemia
3. Patients with collagen vascular disorders.
4. Patients with immunocompromised states

**STUDY PERIOD:** December 2018 to October 2020

**SAMPLE SIZE:**

100

**STUDY DESIGN:**

A Prospective study is to be conducted on patients admitted in GMKMCH for diabetic foot ulcer management

#### **METHODS**

The material for the study is taken from the cases admitted to department of General Surgery in GMK Medical College & Hospital Salem, who are clinically diagnosed to have diabetic foot ulcers.

- a) A detailed history is taken and examination is done to diagnosed diabetic foot ulcers
- b) Other causes of ulcer was ruled out
- c) Clinical evaluation was done
- d) Laboratory investigations were done.They were divided into two groups.

Group A: 50 patients subjected to hydrogel application

Group B: 50 patients subjected to normal saline dressing.Patients were followed up till their discharge and at periodic intervals.

- e) The day of appearance of granulation tissue was observed
- f) Size of the ulcer was measured from maximum width and maximum breadth and it is measured on

Day 0

Day 7

Day 14

### **III. Results**

The analysis revealed the following findings:In the hydrogel dressing group, the mean age of the participants is 58.6 years with a standard deviation of 8.14 years. It ranges between 42-75 years. The median age of the sample is 60 years. In the saline dressing group, the mean age of the participants is 53.3 years with a standard deviation of 8.4 years. It ranges between 32-75 years. The median age of the sample is 54 years. Independent samples t-test shows that the two groups do not differ significantly in age distribution. Hence, the two groups are comparable. This comparability is important to establish in comparative studies like this in order to avoid bias in patient selection and categorisation.In both the groups, there were equal number of males and females. In the hydrogel dressing group, there were 25 males (50%) and 25 females (50%) In the saline dressing group, there were 25 males (50%) and 25 females (50%)The gender distribution is comparable in both the groups. Since, there are equal numbers of males and females, the risk of age based confounding factor are minimal. The bias is also reduced. In order to establish the comparability of the two groups, the mean size of the ulcer between the two groups was found out. On Day 0, the mean size of the ulcer for hydrogel dressing is 186.74 cm<sup>2</sup> the mean size of the ulcer for saline dressing is 187.56 cm<sup>2</sup>.Though the size of the ulcer is slightly lesser in the hydrogel dressing group, yet the difference is not statistically significant, hence the two groups are comparable and there is no bias in the selection of cases.

Then these cases were followed up for two weeks and the ulcer was measured on Day 7 and Day 14.

On Day 7, the mean size of the ulcer for hydrogel dressing is 177.48 cm<sup>2</sup> the mean size of the ulcer for saline dressing is 181.64 cm<sup>2</sup>

On Day 14, the mean size of the ulcer for hydrogel dressing is 166.06 cm<sup>2</sup> , the mean size of the ulcer for saline dressing is 173.92 cm<sup>2</sup>

Comparison of two groups based on percentage reduction

The percentage reduction in two groups is;

hydrogel dressing on Day 7: 4.95%

Saline Dressing on Day 7: 3.15%

hydrogel dressing on Day 14: 11.07%

Saline Dressing on Day 14: 7.27%

Independent sample t-test for comparison of size of ulcer shows that the two groups differ significantly in the results. Statistically p-value is <0.05.

- a) The size of the ulcer reduces considerably reduces in 14 days following application of hydrogel dressing and saline dressing
- b) The percentage reduction in hydrogel dressing group is 11.07% in two weeks
- c) The percentage reduction in saline dressing group is 7.27% in two weeks
- d) There is around 3.5% more reduction in the size of the ulcer following application of hydrogel dressing in comparison to saline dressing

**Descriptive Statistics**

**Size of the ulcer**

The important outcome of the study is the appearance of granulation tissue and the reduction in the size of the ulcer.

The mean size of the ulcer for hydrogel dressing on

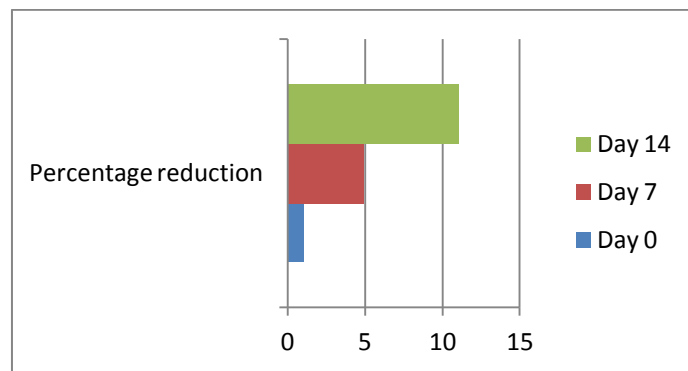
Day 0 is 186.74 cm<sup>2</sup>

Day 7 is 177.48 cm<sup>2</sup>

Day 14 is 166.06 cm<sup>2</sup>

DAY	hydrogel dressing (Mean size in cm <sup>2</sup> )	% reduction
Day0	186.74	-
Day7	177.48	4.95%
Day14	166.06	11.07%

Percentage reduction in hydrogel dressing Group



Percentage reduction in hydrogel dressing group

The mean size of the ulcer for saline dressing on

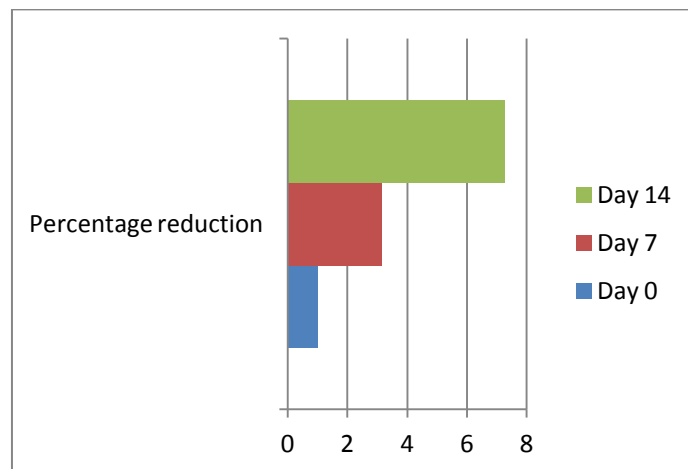
Day 0 is 187.56 cm<sup>2</sup>

Day 7 is 181.64 cm<sup>2</sup>

Day 14 is 173.92 cm<sup>2</sup>

DAY	Saline Dressing (Mean size in cm <sup>2</sup> )	% reduction
Day0	187.56	-
Day7	181.64	3.15%
Day14	173.92	7.27%

Percentage reduction in Saline Dressing Group



Percentage reduction in Saline Dressing Group

### Comparison of ulcer size between the two groups

In order to establish the comparability of the two groups, the mean size of the ulcer between the two groups was found out.

On Day 0, the mean size of the ulcer for hydrogel dressing is 186.74 cm<sup>2</sup>

On Day 0, the mean size of the ulcer for saline dressing is 187.56 cm<sup>2</sup>

Though the size of the ulcer is slightly lesser in the topical insulin group, yet the difference is not statistically significant, hence the two groups are comparable and there is no bias in the selection of cases.

Then these cases were followed up for two weeks and the ulcer was measured on Day 7 and Day 14.

On Day 7, the mean size of the ulcer for hydrogel dressing is 177.48 cm<sup>2</sup>

On Day 7, the mean size of the ulcer for saline dressing is 181.64 cm<sup>2</sup>

On Day 14, the mean size of the ulcer for hydrogel dressing is 166.06 cm<sup>2</sup>

On Day 14, the mean size of the ulcer for saline dressing is 173.92 cm<sup>2</sup>

Comparison of two groups based on percentage reduction

	Hydrogel dressing (Mean size in cm <sup>2</sup> )	% reduction	Saline Dressing (Mean size in cm <sup>2</sup> )	% reduction
Day0	186.74	-	187.56	-
Day7	177.48	4.95%	181.64	3.15%
Day14	166.06	11.07%	173.92	7.27%

### Independent sample t-test for comparison of size of ulcer

Independent sample t-test for comparison of size of ulcer shows that the two groups differ significantly in the results. Statistically p-value is <0.05.

From the findings of the study,

- ✓ The size of the ulcer reduces considerably reduces in 14 days following application of hydrogel and saline dressing
- ✓ The percentage reduction in hydrogel dressing group is 11.07% in two weeks
- ✓ The percentage reduction in saline dressing group is 7.27% in two weeks
- ✓ There is around 3.5% more reduction in the size of the ulcer following application of hydrogel dressing in comparison to saline dressing.

### IV. Discussion:

The whole sample population was divided into two equal and comparable groups of 50 patients. In the hydrogel dressing group, the mean age of the participants is 58.6 years. In the saline dressing group, the mean age of the participants is 53.3 years. In both the groups, there were equal number of males and females. Comparison of two groups based on percentage reduction: The percentage reduction in two groups is; hydrogel dressing on Day 7: 4.95%, Saline Dressing on Day 7: 3.15% ; hydrogel dressing on Day 14: 11.07% and Saline Dressing on Day 14: 7.27%. Independent sample t-test for comparison of size of ulcer shows that the two groups differ significantly in the results. Statistically p-value is <0.05. The size of the ulcer reduces considerably reduces in 14 days following application of hydrogel dressing and saline dressing. The percentage reduction in hydrogel dressing group is 11.07% in two weeks. The percentage reduction in saline dressing group is 7.27% in two weeks.

### V. Conclusion:

It is evident from the study that hydrogel is a effective topical applicant in promoting granulation tissue formation and reepitheilization and in decreasing hospital stay in comparing with normal saline dressing.

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