# ORIGINAL ARTICLE Comparison of Hydrogel and Papaya Dressings in the Treatment of Diabetic Foot Ulcers

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## ABSTRACT

Diabetes mellitus is the most common metabolic problem all over the world. Over 150 million people worldwide, are affected with this problem.<sup>1, 2</sup> In Pakistan, the prevalence of diabetic patients are between 7.6% to 11%.<sup>3</sup>.

**Objective and Methodology:** The aim of this study is to compare the relative efficacy of hydrogel and papaya dressings for diabetic foot ulcers. Patients from the General Surgery Department at Mayo Hospital in Lahore were 114 in total. Patients were randomized into: group H, who received hydrogel dressings, and group P, who received papaya dressings. Both dressings were done in ward for 20 days, every 48 hours and if wound healing occurred earlier and slough decreased then dressings were stopped and patient was discharged. The wound was assessed by photographic wound assessment tool (PWAT).

**Results:** In Group P, mean age of patients was 52.98±8.90 and in Group H, mean age of patients was 50.98±9.62. In Group P, 34(59.6%) patients were male and 23(40.4%) were female. While in Group H 29(50.9%) patients were male and 28(49.1%) were female patients. We used Wound Assessment tool "PWAT" to compare the efficacy of these two treatment regimes. As per final "PWAT" score hydrogel dressing is more effective as compared to Papaya dressing for diabetic wound healing. i.e. Group P (Papaya dressing): 5.09±1.65 vs. Group H (hydrogel Dressing): 6.02±1.78, p-value=0.005

**Conclusion:** Depending upon the outcomes of this research, it can be concluded that hydrogel dressing is more useful than papaya dressing for treating diabetic wound. Although papaya dressing also have a beneficial effect on diabetic wound but still its efficacy is less as compared to hydrogel dressing

Keywords: Papaya, Hydrogel, Dressing, Diabetic Foot, Wounds, Ulcer.

# INTRODUCTION

Diabetes mellitus is the most common metabolic problem all over the world. Over 150 million people worldwide, are affected with this problem.<sup>1, 2</sup> In Pakistan, the prevalence of diabetic patients are between 7.6% to 11%.<sup>3</sup>The most common complication of these patients are diabetic foot ulcers. Diabetic foot ulcers are a major complication of long-standing diabetes, especially if it is poorly controlled. It enhances the morbidity and mortality of diabetic patients with the complications of this disease. More than 15% of these patients have an increased risk of diabetic foot ulcers in their lifetime.<sup>4</sup>

Diabetic foot ulcers have a very big influence on the economic burden of a country, due to its non- healing nature.<sup>5,6</sup> Complete debridement of dead and dying tissue is very important to get healthy margins, which help in rapid healing of that ulcers. There are lots of different type of dressings, being used in the management of diabetic foot patients. These dressings are vacuum suction dressings, platelet rich plasma dressings, saline soaked dressing, povidone iodine soaked dressings, honey dressings, medicated dressings, hydrogel and papaya dressings.<sup>7</sup>

Green papaya has two very important enzymes named papain and chymopapain, which have the ability to liquify the dead tissue. Extracts of papaya have a very strong activity against the different bacteria found in the diabetic foot patients. The papaya has its efficacy in preventing the growth and killing the bacteria and fungi.<sup>8</sup> Hydrogel dressings are made up of a combination of different polymers with 96% of water. They let the oxygen and water vapours to pass through it and permeability of fluid and bacteria depends upon the type of dressing used with it.<sup>9</sup>

Hydrogels hydrate the wound and thus help in the moisturizing the wound. It also facilitates the natural autolysis of the dead tissue. Autolysis is the automatic breakdown of devitalised tissue, and this process is enhanced in the presence of moisture.<sup>13</sup> In people with diabetes, autolysis is often impaired as the result of inhibition of leucocyte activity: thus, dressings that provide a moist environment can facilitate autolysis. A variety of hydrogel dressings are currently available and their properties

have been reported in a large number of clinical trials and case studies. Their ability to donate water and absorb fluid varies according to their formulation.<sup>9</sup>

Saline dressing reduced necrotic tissue by  $15.54\pm4.86$  and papaya dressing by  $19.93\pm5.29$ . Papaya dressing had  $95.09\pm2.45$ mean granulation tissue formation and saline  $85.9\pm0.70$ . Papaya dressing healed 78% of wounds and standard saline dressing 72% at follow-up.<sup>10</sup> In another study, 83.0% of patients were male. These individuals were debrided (67.2%) or amputated (33.8%). 89.0% of patients used papaya after debridement. 6(7%) patients required further debridement, and 4(4%) required amputation.<sup>11</sup>

In another investigation, hydrogel and saline had comparable mean slough at all intervals (p>0.050). The mean Slough decrease on day five ( $6.93\pm6.14\%$  vs.  $4.37\pm2.96\%$ ; p=0.045), day ten ( $15.22\pm7.40\%$  vs9.10 $\pm7.00\%$ ; p=0.002), and day fifteen ( $21.57\pm8.71\%$  vs 15.90 $\pm8.11\%$ ; p=0.012) was considerably higher than group B.<sup>12</sup>

Due to a deficiency of local research and conflicting worldwide literature, this study compares hydrogel and papaya dressing for diabetic wounds. This study will improve future patient management.

# MATERIALS AND METHODS

The goal of this study is to examine the relative efficacy of hydrogel and papaya dressings for diabetic foot ulcers. From the date of the approved study summary, researchers in the Surgical Department at Mayo Hospital in Lahore gathered data for a comparative study.

Nonprobability consecutive sampling was employed for this study's data collection. A Sample size of 114(57 in each group) is calculated by 95% confidence level and 80% power of test and taking expected mean reduction in slough/necrotic tissue 19.93 $\pm$ 2.2 <sup>(9)</sup> in papaya dressing and 21.5 $\pm$ 3.7<sup>(12)</sup> in hydrogel dressing in patients with diabetic wounds.

In the inclusion criteria, the criteria for selecting the sample are Patients with diabetic wounds (as defined operationally) and Post-operative wound dehiscence Wagner's grades II and III are included. Patients can be of either sex. However, patients with Wagner's grade IV (severely infected) ulcers, those with diabetes and peripheral vascular disease (such as renal artery stenosis, burger's disease, Raynaud's syndrome, peripheral artery disease, or disseminated intravascular coagulopathy) often develop diabetic foot, patients with advanced liver illness, kidney disease, or haematological disease, all of which impair the body's ability to heal wounds; immunocompromised patients taking steroids or undergoing chemotherapy or radiation and patients with burns were excluded.

Total 114 patients who were having the diabetic foot and satisfying the inclusion criteria were added in the study from General Surgery Department, Mayo Hospital, Lahore. Informed consent was taken from each patient. Patients will be segregated into two groups by lottery method, Group H, which included the patients with hydrogel dressing and group P, which included the patients with papaya dressing. Name of the patient was written on a slip and put in a box. Then the patient was assigned to that specific group.

In Group H, patients were treated with hydrogel dressing and in Group P, patients were treated with Papaya dressing. Measurement of ulcer will be done by using sterile gauze and graph paper. Area of ulcer will be calculated in Sq.cm. Measurement in reduction and granulation tissue size was measured in sq.cm. In hydrogel dressing, we will be soaked gauze pieces with hydrogel and will do dressing every 48 hours. Then will continuously check patient's wound and its healing by granulation tissue appearance. In papaya dressing, early management with proper antibiotics, debridement of dead and necrotic tissue or amputation, good glycaemic control will be included and then wound was managed with papaya dressings. The outer layer and seeds of the papaya were discarded and the rest of the fruit was made like a paste.

Patients and attendants both were guided for the dressing. Both dressings were done in ward for 20 days, every 48 hours and if wound healing occurred earlier and slough decreased then dressings were stopped and patient was discharged. The wound was assessed by photographic wound assessment tool (PWAT). Images were taken by digital camera. While taking the photographs, special attention was given on the brightness and picture quality with good resolution. Photographs were taken after receiving the patient's written permission with the understanding that the patient's identity will not be revealed at any cost.

After taking the picture of the wound, wound will be rated according to the PWAT score, and will be explained this clearly defines the wound characteristics. If a wound has many characteristics, wound is then rated according to the most predominate feature on the photograph. Scores are added together to make a total sum. Total scores range from 0 to 32, where a decreasing total score indicate healing.

The collected data was entered and analysed in "SPSS" version-23.0. Variable with quantitative nature like age was presented as Mean $\pm$ S.D. Variables in qualitative nature like gender was presented as frequencies and percentages. Comparison of two groups' hydrogel and papaya was done with the help of independent sample t-test. The level of significance was set as  $\leq 0.05$ .

#### RESULTS

Histogram shows age distribution of all patients included in this study. In Group P mean age of patients was  $52.98\pm8.90$  and in Group H was  $50.98\pm9.62$ . In Group P the age of patients rages in between 30- 70 years while in Group H it was 26 and 65 years respectively. In this study 63 (55.3%) patients were male and 51 (44.7%) were female patients. In Group P, 34 (59.6%) patients were male and 23(40.4%) were female. While in Group H 29(50.9%) patients were male and 28(49.1%) were female patients. Mean PWAT score in Group P and in Group H patients was  $5.09\pm1.65$  and  $6.02\pm1.78$ . Patients in Group P had significantly higher PWAST score as that of Group P patients. i.e.

p-value=0.005. Box plot shows PWAST score in both treatment groups. Patients in Group P had higher PWAST score as that of Group H patients.



Figure-1: Age of patients

Table-1: Descriptive statistics for PWAT Score in Treatment Groups

	Group H	Group P
	Hydrogel Dressing	Papaya Dressing
Ν	57	57
Mean	6.02	5.09
SD	1.78	1.65
p-value	0.005	



Figure-2: Box Plot for PWAST Score in Treatment Groups

#### DISCUSSION

Diabetic Foot Ulcers behave differently depending on the condition, so, to date there is no ideal dressing for these wounds. It is an accepted fact that the idea behind the development of these dressing is to make a dressing, which will keep the wound moist all the time. Moist environment help the wound in autolytic debridement, enhances granulation, promote angiogenesis and causes speedy movement of epidermal cells over the wound.<sup>13, 14, 15</sup> The dressing should be able to absorb excess exudates in the wound. A variety of dressings are available and are studied to check their effectiveness. But to date, there is no single dressing ideal which has been recommended by the competent authority for the management of these wounds.<sup>13</sup>

Hydrogel dressings have been used since decades for the management of these wounds. These days, many types of hydrogel and non-hydrogel dressings are available, to use in different types of wound. Many different studies have shown the efficacy of papaya dressings in the management of these wounds.  $^{\rm 16-18}$ 

In this study, we compared of hydrogel dressing with papaya dressing in patients with diabetic wounds. We used Wound Assessment tool "PWAT" to compare the efficacy of these two treatment regimes. As per final "PWAT" score hydrogel dressing is more effective as compared to Papaya dressing for diabetic wound healing. i.e. Group P (Papaya dressing): 5.06±1.65 vs. Group H (Hydrogel Dressing): 6.02±1.78, p-value=0.005

Studies have not compared hydrogel dressing with papaya dressing in patients with diabetic wounds. However, both the modalities have been compared with other dressing types for treating diabetic wounds. Different studies have used different criteria for assessment of final outcomes in terms of wound healing.

Å 2013 Cochrane review and meta-analysis of three RCTs stated that hydrogel based dressings are more effective in the management of these patients as compared to the conventional dressings.<sup>19</sup>Most recently, in 2017, Jimenez et al. compared CCO to standard care plus hydrogel and also found no difference in the wound size at 6 and 12weeks.<sup>20</sup>

A recently published systematic review and meta-analysis on clinical efficacy and wellbeing of hydrogel dressing in the management of diabetic foot wound stated the better efficacy of hydrogel dressings as compared to the controls and that the difference was statistically significant (RR = 1.57, 95% Cl:1.13–2.17, P = 0.007).<sup>82</sup> The above mentioned studies have reported the efficacy of hydrogel for treating diabetic wound thus supporting the results of this study and advocating hydrogel dressing as better treatment option as compared to papaya dressing.

In literature no study was found who compared both these two treatment regimens together making this study unique as well as important to decide the ultimate treatment options for diabetic wounds in our clinical setup.

The advantageous effects of hydrogel are due to the moisturizing nature of these dressings in the management of diabetic foot ulcers. This provides a more physiological environment for the healing of wounds. The added advantage for these dressings is that they absorb wound exudates, auto debride the dead and dying tissue and promote granulation. It helps in reducing the amount of fluid collection in between the dressings and wound surface. Besides, it adheres with the wound tightly and evenly, which prevents the wound from harmful external environment and decreases soreness of the wound.<sup>21</sup>

A local study from Pakistan assessed the effectiveness of papaya dressings in the management of Diabetic foot ulcers. Results of this study showed that after the early surgical debridement and dressings 88.4% do not require any further intervention. In 3 patients (7%), further debridement was done and in 2 (4.7%) patients, amputations were done. Healing time ranged from18 to 29 days. Mean healing duration was 19.23 days with Standard Deviation (SD) of ± 3.624.<sup>22</sup>

An Indian study used papaya dressing for managing chronic ulcer in manner of cost and healing duration and further surgical treatment. The study stated that papaya dressings are associated with most economical management and results in early wound healing.<sup>23</sup>

Vasuki V compared papaya dressing with normal saline soaked dressing in management of diabetic foot ulcers. The favourable results of this study showed that papaya dressings are associated with auto debridement and keeping the wound moist. It helps in further decreasing the healing time and outcome in these pateints.<sup>10</sup>

The therapeutic potential of papaya has been studied from a pharmacological perspective in clinical trials. There are two enzymes in green papaya (papain and chymopapain) that have powerful liquefaction characteristics and can disintegrate dead and dying tissue. Gram-positive bacteria are inhibited by extracts of both ripe and unripe papaya fruit, as well as the seeds. Infected wounds caused by gram-negative bacteria respond well to high doses. The protein-like compound produces the antimicrobial, bacteriostatic, and fungicidal aglycone of gluco-tropaeolin benzyl lsothiocynate (BITC)..<sup>24</sup>

### CONCLUSION

Based on result of this study it can be concluded that hydrogel dressing is more effective than papaya dressing for treating diabetic wound. Although papaya dressing also have a beneficial effect on diabetic wound but still its efficacy is less as compared to hydrogel dressing

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