

## A COMPARATIVE STUDY BETWEEN HYDROFIBER DRESSING & POVIDONE DRESSING IN DIABETIC FOOT ULCERS

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### ABSTRACT

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#### BACKGROUND

Diabetic Foot Ulcer (DFU) is the most common complication of Diabetes Mellitus (DM). It occurs in 15% of all patients with DM. Major increase in mortality among diabetic patients, observed over the past 20 years is considered to be due to the development of macro and micro vascular complications, including failure of the wound healing process. Non-healing chronic diabetic ulcers are often treated with extracellular matrix replacement therapy. so far, it is a common trend in diabetic foot care domain to use advanced moist wound therapy. At present, there are various categories of moist dressings available such as povidone dressings, adhesive backing film, silicone coated foam, hydrogels, hydrocolloids etc.

#### AIMS & OBJECTIVES

- 1) To study efficacy of hydrofiber dressings and wound healing in diabetic foot ulcers.
- 2) To compare the safety, final outcome and patient compliance in hydrofiber and povidone dressing.

#### MATERIALS & METHODS

This prospective, observational study is carried in our department from September 2014 to September 2015. All the patients with age of 30 years and above were admitted in AJIMS satisfying the inclusion and exclusion criteria were taken into the study. The patients were followed until the ulcer is treated.

#### STATISTICAL ANALYSIS

Data are presented as Mean and Standard Deviation (SD). Fischer's exact test and Chi-Square Test were used as appropriate. GraphPad Prism Version 6.0h was used to analyze data and to prepare graphs. A 'P' value below the level of 0.05 was taken as statistically significant.

#### RESULTS

Among the patients who were studied, hydrofiber dressings helped in the better & faster healing of DFU.

#### CONCLUSION

In comparison with povidone gauze dressings to hydrofiber dressings in diabetic foot ulcers, the latter is more efficacious in controlling the infection, minimal usage of antibiotics, faster healing rate and patient compliance during dressings.

#### KEYWORDS

Hydrofiber dressing, Povidone dressing, Diabetic Foot Ulcer.

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**INTRODUCTION: Diabetic Foot Infection (DFI)** is a leading cause for hospital admission in India which is due to multiple precursors mainly neuropathy, peripheral vascular disease and impaired wound healing.<sup>1,2</sup> It has been reported that about 25% diabetics develop severe foot problems at some point in their lifetime and often end with amputation.<sup>3</sup>

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The risk of lower limb amputation is 15-46 times higher in diabetics than that in non-diabetics.<sup>4</sup> The impaired circulation in diabetic foot limits the access of phagocytes favouring the development of infection. DFI are often polymicrobial like *Escherichia coli*, *Proteus* species (spp), *Pseudomonas* spp., *Staphylococcus aureus* and *Enterococcus* spp. are the most frequently involved micro-organisms.<sup>5,6,7</sup> Non-healing or chronic wounds are a significant health care problem today, the quest for better wound healing agents is perhaps one of the oldest challenges for medical practice. One such agent is hydrofiber dressing.

Antiseptics, such as iodine-based preparations, are commonly used on wounds, although there is no evidence to support a beneficial effect. Typically, they are applied to locally infected wounds, usually in combination with systemic antibiotics. Povidone-iodine has long been used as a skin antiseptic, but its antimicrobial effect on wounds is doubtful. Disadvantages of povidone dressing are it causes maceration of the surrounding skin, removal of healthy granulation tissue while changing the dressing.

In vitro studies with hydrofiber dressing have demonstrated microbicidal activity against wide range of pathogens upto a period of 14 days. Hydrofiber dressing absorbs and retains exudate, the harmful components such as bacteria contained within exudate, directly into its fibres. Ionic silver starts killing a broad spectrum of pathogens. Hydrofiber dressing in its gelled state conforms to the wound surface, thereby reducing dead space. Hydrofiber dressing in its gelled state does not damage tender, granulating wound tissue or healthy tissue surrounding exuding wounds during dressing changes and reduces pain & trauma during dressing removal. Vertical wicking locks exudate in hydrofiber dressing which may reduce the risk of maceration of peri-wound skin. Hydrofiber dressing absorbs wound fluid and creates a soft gel, which maintains a moist wound environment that aids autolytic debridement and supports body's healing process.

**MATERIAL & METHODS:** A Prospective, Randomised study was conducted in our department with the aim to evaluate the pattern of healing in diabetic foot ulcer patients with different dressings. We included the patients of type 1 & type 2 DM patients having foot lesions with their consent. Prior approval from Institutional Ethical Committee was obtained. The total number of diabetic foot ulcer patients enrolled in the prospective study was 100 cases (September 2014 to September 2015). We excluded the patients with foot lesions due to other causes like arterial diseases, traumatic foot ulcers, immune compromised patients & diabetic patients with malignancy and patients with ketoacidosis. Thirty patients were excluded for not satisfying the inclusion criteria. Each group contained 35 patients, which were either managed by hydrofiber dressings or by povidone dressings.

A detailed history and examination was recorded on a predesigned proforma with sketching of foot ulcers on transparent sheets with different colours. All the foot lesions were classified as per Wagner's classification and university of Texas diabetic wound classification. Wound swab samples were obtained by rubbing the swab stick in the deepest accessible area of the lesion while ensuring aseptic techniques. The samples were sent for bacteriological assessment to determine the presence of infective

organisms. X-rays of the affected limb & colour Doppler examination were done during first visit. The detailed demographic profile & other details like complete blood count, fasting and post-prandial blood sugar levels, glycosylated haemoglobin, renal and liver function tests, urine routine, serum electrolytes, lipid profile pertaining to disease & treatment were recorded on a predesigned case record form.

The materials used are either Hydrofiber dressing with silver ions (H group) or with Povidone based gauze dressing (P group). The dressing techniques included as follows, all wounds were cleaned with sterile saline prior to assessment and dressing application. The sterile hydrofiber dressing with silver ions was left in place for upto 5 days. The method of use of the sterile, povidone gauze dressing was similar except for keeping the wound moist before use on dry wounds and to change the dressing daily.

Data are presented as Mean and Standard Deviation (SD). Fischer's exact test and Chi-Square Test were used as appropriate. GraphPad Prism Version 6.0h was used to analyze data and to prepare graphs. A 'P' value below the level of 0.05 was taken as statistically significant.

**RESULTS:** The mean age of presentation was  $54.6 \pm 10.6$  years (H group,  $n=35$ ) and  $56.6 \pm 12.6$  years (P group,  $n=35$ ) and the mean duration of diabetes was  $8.20 \pm 10.06$  years (H group) and  $9.06 \pm 11.06$  years (P group), (Table 1). The most common presenting complaint is a non-healing ulcer. The necessary investigations required in both the groups were comparable (Table 2). As per Wagner's classification, the maximum lesions were grade 3-deep ulcer with abscess or osteomyelitis, however comparable distribution of ulcer grading between the groups. (Fig. 1)

After treating both the study groups with their respective dressings, hydrofiber dressing showed better healing of the foot ulcer with higher percentage of patients when compared to povidone dressing. (Fig. 2)

The growth of microorganisms on ulcer/wound was also reduced in hydrofiber dressings ( $P < 0.001$ , table 3). Requirement of higher level of antibiotics was not necessary in H group ( $P < 0.001$ , vs P group, table 4). Lesser number of patients required amputation in H group, though management methods did not differ much between the groups ( $P > 0.05$ , Table 5/Fig. 3). Patient compliance was much better in hydrofiber dressings. The healing was assessed with healthy granulation and minimal slough in H group. The rate of wound healing in the patients managed with hydrofiber dressings was better when compared with povidone dressings (Fig. 4).

	No. of Patients (Povidone)	No. of Patients (Hydrofiber)	Percent	Statistical Significance
<b>Age (years):</b>				
31-40	4	4	11%	P= 0.98 Chi-Square Test
41-50	4	4	11%	
51-60	10	11	31%	
61-70	12	10	31%	
71-80	5	6	16%	
<b>Sex:</b>				P= 0.71 Fischer Exact Test
Male	31	32	90%	
Female	4	3	10%	
<b>Types of DM:</b>				P=0.74 Chi-Square Test
Type 1	5	6	16%	
Type 2	30	29	84%	
<b>Family h/o diabetes</b>				P=1.0 Fischer Exact Test
Present	15	14	41%	
Absent	20	21	59%	

**Table 1: Sociodemographic characteristics of patients (n=70)**

Investigations	Povidone dressing	Hydrofiber Dressing	Statistical Significance
X-ray foot	35	35	-
Colour Doppler	30	30	P=0.84 Chi-Square Test
a) Normal study	23	21	
b) Stenosed vessels	7	9	

**Table 2: Investigations of patients**

Organisms (Culture & sensitivity)	Betadine Dressing	Hydrofiber Dressing	Total	Statistical Significance
Staphylococcus sp.	14	7	21	P=0.0008 Chi-Square Test
E. coli	8	4	12	
Proteus sp.	5	3	8	
Pseudomonas sp.	4	2	6	
Klebsiella sp.	3	1	4	
No organisms	1	18	19	
<b>Total</b>	<b>35</b>	<b>35</b>	<b>70</b>	

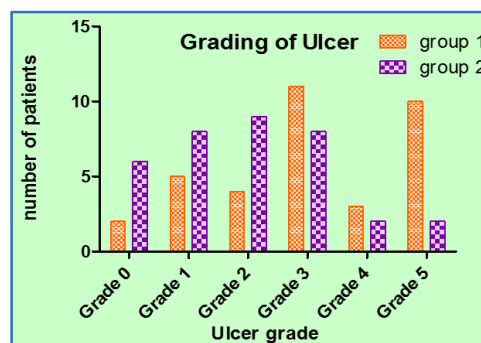
**Table 3: Distribution of the isolates between the two groups**

Level	Povidone Dressing (n=35)	Hydrofiber dressing (n=35)	Statistical Significance
1	5	10	P=0.0015
2	12	21	Chi-Square
3	18	4	Test

**Table 4: Usage of antibiotics**

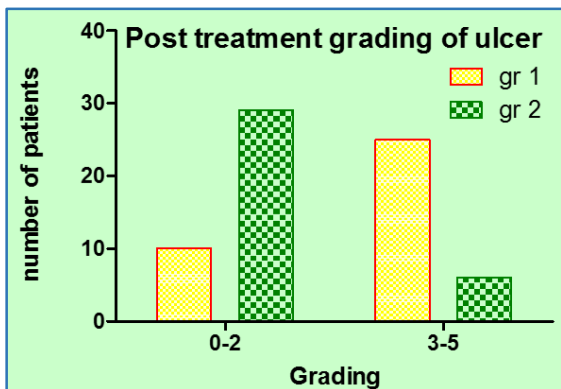
Characteristics	Povidone Dressing (n=35)	Hydrofiber Dressing (n=35)
Conservative antibiotics	35	35
Incision & drainage	06	08
Debridement and dressing	10	14
Amputation (total)	13	05
a) Transmetatarsal	02	0
b) Ray	03	02
c) Digital	05	03
d) Below knee	02	0
e) Above knee	01	0
Skin graft for chronic ulcer	06	08

**Table 5: Management**



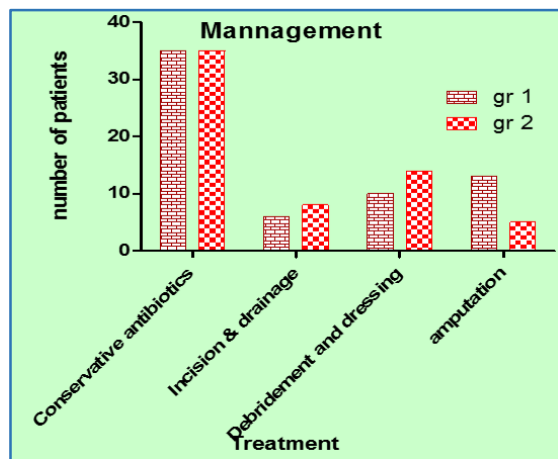
**Fig. 1: Pre-Treatment Grading of ulcer**

Group 1-Povidone dressing; Group 2-Hydrofiber dressing; chi-square; p=0.05.



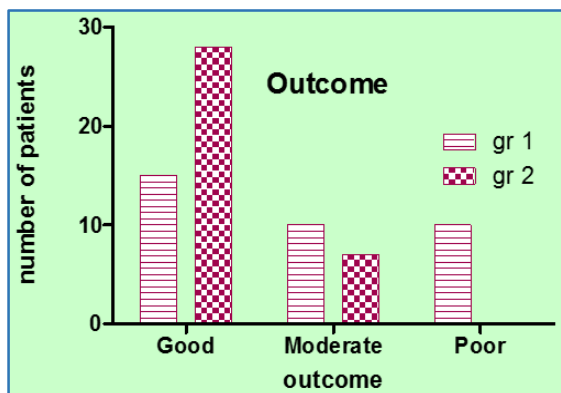
**Fig. 2: Post treatment ulcer grading**

Group 1-Povidone dressing; Group 2-Hydrofiber dressing; Fischer's exact test,  $p < 0.0001$ .



**Fig. 3: Management of ulcer**

Group 1-povidone dressing; Group 2-hydrofiber dressing.



**Fig. 4: Final Outcome**

Group 1-povidone dressing; Group H-hydrofiber dressing; chi-square;  $p = 0.0007$ .

**Sequential Photographs:**



**Wound Before**



**Hydrofiber Dressing**



**Healed Wound**

**DISCUSSION:** Foot ulcer infection is the most common and dangerous adversary in the diabetic foot. Therefore, it is also vital to identify symptoms of ulcer infection and address infection proactively. While the incidence of infection was somewhat lower than that reported elsewhere, infection was the most common adverse event, underscoring the strong need to address the microbial burden in the ulcer.

Important measures of such effects in future studies may include antibiotics prescribed, days to discontinue antibiotic usage, and the relative effects of topical and systemic antimicrobial agents.

In a recent study,<sup>8</sup> it took 20 weeks for 31% of Diabetic foot ulcers receiving good standard wound care to heal; the same percent healed during 8 weeks in the hydrofiber-dressing group.

Proportions healed or improved during 8 weeks (88% in hydrofiber group) compare favourably with 71-72% reported clinically improved in a 12-week trial managing Wagner grade I/II DFU's with iodine gauze based dressings.<sup>9</sup>

Smaller trials of various durations report similar results with other wound dressings.<sup>10-18</sup>

In larger trials, a collagen-oxidized regenerated cellulose dressing<sup>19</sup> took 10 weeks for a similar percentage of wounds to heal, dermal substitute 12 weeks<sup>20</sup> and a human skin equivalent approximately 5 weeks.<sup>21</sup> The results are also comparable to results reported for non-infected DFU's managed with hyaluron based autologous dermal and epidermal grafts.<sup>22</sup>

Clinically, these findings support the role of a hydrofiber dressing with ionic silver as an effective option to include with appropriate off-loading, accommodative footwear and debridement in a non-ischaemic DFU.

The significant greater depth reduction and overall wound bed improvement at final clinical evaluation were noted in the group using the ionic silver hydrofiber technology.

The microbial sequestration properties, so observed differences may result from the dressing fibers, ionic silver in the hydrofiber dressing or nature of the wound-dressing interface.

These suggest that once the burdens of exudate and its microbial contents are addressed, ulcer depth reduces as granulation tissue fills the wound, further increasing the tissue barrier against invading organisms.

Of note, a recent 12-week prospective North American study of hydrofiber dressing with silver ions compared with saline moistened gauze showed a greater reduction in the ulcer depth in hydrofiber dressing group, a finding supporting the depth reduction results in the study.

The more positive effects of the ionic silver Hydrofiber dressing on overall wound condition (more improvement/less deterioration) for the patients initially prescribed antibiotics might be expected from use of a dressing which absorbs and holds wound exudate and microorganisms within its fibres where bacteria are killed by the ionic silver, providing an effective topical antimicrobial barrier for up to 14 days.<sup>23</sup>

One hypothesis generated by this research is that the capacity to absorb, hold and kill bacteria in infected wound fluid in the Hydrofiber silver dressing may work in synergy with systemic antibiotics, which may not always reach organisms on the wound surface.

Results of this study suggest that subjects prescribed systemic antibiotics for their DFUs (i.e. with clinically infected ulcers or those at significant risk of infection) may benefit particularly from the hydrofiber dressings with ionic silver.

This hypothesis of topical and systemic antimicrobial synergy merits additional research.

Overall, while healing speed, was comparable in the two groups, the silver ion hydrofiber-dressed subjects in this study experienced significantly greater depth reduction. There was a trend toward more overall wound improvement/ less deterioration with silver ion hydrofiber-dressed subjects than with iodine gauze- dressed subjects, statistically significant in subjects prescribed antibiotics on enrolment for the study ulcer.

The study generates interesting hypothesis regarding potential synergy between topical silver and systemic antibiotics.

**CONCLUSION:** In comparison with povidone gauze dressings to hydrofiber dressings in diabetic foot ulcers, the latter is more efficacious in controlling the infection, minimal usage of antibiotics, faster healing rate and patient compliance during dressings.

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