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COMPARATIVE STUDY OF NEGATIVE PRESSURE WOUND THERAPY WITH MOIST GAUZE DRESSING IN THE TREATMENT OF DIABETIC WOUNDS

Dr. Shubham Sharma, Dr. Shyam Bhutra,[2] Dr. Bhagchand khorwal[3], Dr. Saksham Rakesh[4]

[1]Resident, Department of General Surgery, JLN Medical College, Ajmer. Email:
[2]Senior Professor, Department of Surgery, JLN Medical College, Ajmer. Email: [3] Assistant
[3]Professor, Department of Surgery, JLN Medical College, Ajmer. Email:
[4]Resident, Department of Surgery, JLN Medical College, Ajmer. Email:

Corresponding author: Dr. Shubham Sharma, Resident, Department of General Surgery, JLN Medical College, Ajmer. Email: coolestsilky14@gmail.com

ABSTRACT

Introduction: Foot infections are common in patients with diabetes and are associated with high morbidity and risk of lower extremity amputation. Negative-pressure wound therapy (NPWT) is an innovative technique in managing complex wounds. **Aim:** to assess the efficacy of topical negative pressure moist wound dressings as compared to conventional moist wound dressings in improving the healing process in diabetic foot ulcers. **Methods:** prospective interventional study on 30 randomly selected cases in vacuum group (TOPICAL NEGATIVE PRESSURE) and 30 patients in control group (MOIST GAUZE DRESSINGS) during the period of 2 years (July 2020– september 2022) at department of surgery JLN Hospital Ajmer. The cases in this study were patients admitted in general surgical wards, plastic surgery ward and patients with surgery reference for diabetic foot care from other departments like medicine, orthopedics in JLN HOSPITAL, AJMER. **Results:** 63.33% presented as ulcer in moist gauze group and in vacuum group 93.33%. 70% had no growth in moist gauze group and in vacuum group 66.67% and pseudomonas in 10% in both groups. Mean graft uptake was 68± 13.01% in moist group and 71±12.59% in vacuum group (p=0.020*). 33.33% were healed in moist gauze group whereas 66.67% were healed in vacuum group (p=0.029*). Association of both groups with granulation tissue development on each follow up was found to be statistically significant. **Conclusion:** topical negative pressure increased the rate of formation of granulation tissue, less infection rate and had better graft uptake than the patients who underwent a conventional dressing for their ulcers.

Keywords: TOPICAL NEGATIVE PRESSURE, **diabetic wounds, moist gauze.**

INTRODUCTION:

Diabetes mellitus is one of the most common metabolic disease with high prevalence, having causing a heavy medical burden. World over, people of Indian descent have one of the highest risk of type 2 diabetes mellitus.[1]

The prevalence of diabetes in adults is about 2.4% in rural and 4.0-11.6% in urban dwellers. By the year 2030, it is estimated that 366 million persons in the world will have diabetes. The

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worldwide prevalence of diabetes was estimated to be 2.8 percent in 2000 and was expected to grow to 4.4 percent in 2030. [2]
Foot infections are common in patients with diabetes and are associated with high morbidity and risk of lower extremity amputation. Diabetic foot ulcers are the most common cause of chronic wounds throughout the world.

The lifetime risk of a person with diabetes developing a foot ulcer could be as high as 25 percent, and it is believed that every 30 seconds a lower limb is lost somewhere in the world because of diabetes. Diabetic foot ulcers are the single biggest risk factor for non-traumatic foot amputations. DFUs are the most common preventable precursors of more than 85% of non-traumatic lower extremity amputations in Europe and USA and almost similar figures are trending in India. After amputation of lower limb, the incidence of a new ulcer and/or contra lateral amputation at 2-5 years is 50% and 2-5 year survival is only 40 - 50% for amputees and prognosis further worsens as level of amputation goes up. The peculiar characteristic of such ulcers is the refusal to heal despite the best wound care management.[3]

Many techniques have been tried over the centuries to heal chronic leg ulcers. Although there is no ideal wound dressing in the management of chronic wounds, diabetic foot ulcers has seen many new developments. Saline-moistened gauze has been the standard however, it has been difficult to continuously maintain a moist wound environment with these dressings. Recent studies have shown that application of a sub atmospheric pressure in a controlled manner to the wound site has an important role in assisting wound healing.

Negative-pressure wound therapy (NPWT) is an innovative technique in managing complex wounds. It was first described by Charikar[4] as an experimental technique for treating subcutaneous fistulas. However, it was the clinical work by Argenta and Moryk was a decade later that allowed NPWT to gain recognition as a useful clinical tool for managing complex and difficult wounds.[5]

The treatment of diabetic foot wounds requires a multidisciplinary approach. Treatment of peripheral vascular disease (PVD), infection and pathological plantar pressure play a significant role in the overall management of these lesions. Topical treatment of wounds using advanced wound dressings has unfortunately, not yet produced consistent results. Recently, outcomes that are more promising has been obtained in the treatment of neuropathic wounds due to the introduction of bioengineered tissue in clinical practice and to the availability of negative pressure social therapy.

Aim:
To assess the efficacy of topical negative pressure moist wound dressings as compared to conventional moist wound dressings in improving the healing process in diabetic foot ulcers.

Methods:
Prospective intervantional study on 30 randomly selected cases in vacuum group (TOPICAL NEGATIVE PRESSURE) and 30 patients in control group (MOIST GAUZE DRESSINGS) during the period of 2 years (July 2020– september 2022) at department of surgery JLN Hospital Ajmer. The cases in this study were patients admitted in general surgical wards, plastic surgery

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ward and patients with surgery reference for diabetic foot care from other departments like medicine, orthopedics in JLN HOSPITAL, AJMER.

All cases of diabetic wounds / foot presented to the hospital during the study period, with wound size more than 5 cm were included in study. Cases of osteomyelitis, patients with recognized active Charcot disease or ulcers resulting from electrical, chemical, or radiation burns and those with collagen vascular disease, ulcer malignancy and untreated osteomyelitis, concomitant medications such as corticosteroids, immunosuppressive medications, or chemotherapy; recombinant or autologous growth factor products; skin and dermal substitutes within 30 days of study start; or use of any enzymatic debridement treatments were excluded from study.

All patients were undergo evaluation with clinical findings recorded and necessary investigations carried out and appropriate treatment given. Diabetic status was monitored and controlled throughout the course of treatment. All cases were followed up to discharge and subsequently after1st and 2nd week.

Wounds were debrided upon admission with an aim to achieve complete skin cover and save the limb. Regular dressings were done once in 2 day basis (more frequent dressing depending on wound status) for the study and control groups respectively. Moist gauze dressings was applied to 30 patients (control group) and vacuum dressing for remaining 30 patients(study group).

Dressing can be done either by using VAC (vacuum assisted closure) dressings if available. Otherwise another method is to cut the sponge in the shape of wound and autoclaved. Then small central hole is made in the sponge and a betadine soaked dried gauze piece is placed over wound bed, stuck it to wound area by chlorhexidine gluconate (tegaderm) first then dynaplast adhesive plaster to create tight air seal. Distal end of Ryles tube is connected to vacuum suction apparatus, intermittent every 10minutes/30 minutes/1 hourly/2 hourly at pressure ranging from 150-200mmHg. New Ryles tube was kept over the wound bed for each successive dressing. Negative pressure was created with the help of either mobile vacuum suction apparatus available with adjustable vacuum pressure or fixed centralized vacuum suction apparatus, or by romo-vac drain or by syringes. Wound debrided, surrounding area was shaved and Ryles tube placed in wound bed. Small central hole was made in the centre of the sponge and a betadine soaked dried gauze piece placed over wound bed, stuck it to wound area by tegaderm first then dynaplast adhesive plaster to create tight air seal. Distal end of Ryles tube was connected to vacuum suction apparatus, intermittently every 10minutes/30 minutes/1 hourly/2 hourly at pressure ranging from 150-200mmHg depending upon the stage of healing of wound. The main demerit of using sponge was ingrowth of granulation tissue into the sponge and bleeding. Wound healing is monitored by measuring size of the wound by the paper and rate and changes in granulation tissue by photographs serially. Skin grafting done once the wound is clean and free of microbial growth usually at the end of first week.

Statistical analysis

All the data collected was entered into excel spread sheet. Descriptive statistics like proportions and percentages were employed for describing the qualitative data and whenever quantitative data was encountered, they were expressed using mean and standard deviation. For comparing the diagnostic accuracy of the tests, the results were obtained after obtaining the distribution into

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medcalc's diagnostic test evaluation calculator. The results consisted of sensitivity, specificity, predictive values and diagnostic accuracy. In order to find out the agreement in diagnosis between two modalities kappa statistics were employed. A *p* value of less than 0.05 was taken as statistically significant result.

Results:

In moist gauze group, maximum 23.33% were in 36-45 years whereas maximum 26.67% were in 46-55 and 56 – 65 years in vacuum group. The mean age in moist gauze group was 52.33±17.09 years whereas 52.43±15.29 years in vacuum group. Moist gauze group and vacuum group both had male preponderance as 80% and 73.33% respectively.

Table 1. Sociodemographic profile

Age (years)	MOIST GAUZE Group		VACUUM Group	
	Frequency	Percent	Frequency	Percent
15-25	1	3.33	2	6.67
26-35	4	13.33	1	3.33
36-45	7	23.33	6	20.00
46 – 55	5	16.67	8	26.67
56 – 65	5	16.67	8	26.67
66 – 75	5	16.67	3	10.00
>75	3	10.00	2	6.67
MEAN±SD	52.33±17.09		52.43±15.29	
Sex				
Male	24	80.00	22	73.33
Female	6	20.00	8	26.67

63.33% presented as ulcer in moist gauze group whereas in vacuum group 93.33 % presented as ulcer. Mean graft size of wound was **17.59 ± 5.25** cm^2 in moist group and **17.89 ± 6.15** cm^2 in vacuum group. Association of both groups with wound size was found to be statistically insignificant.

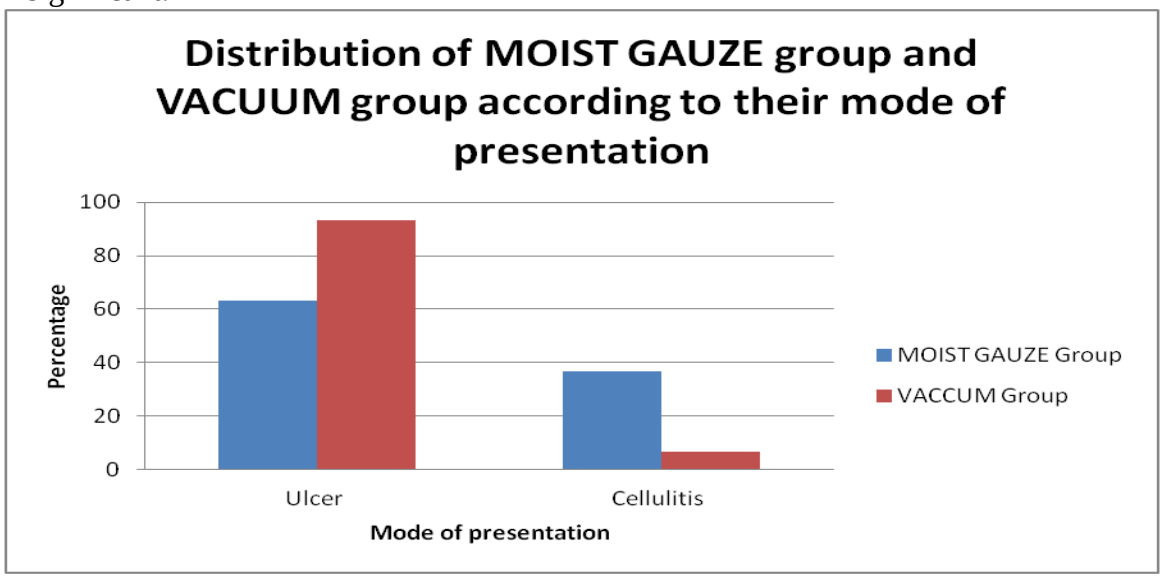

Fig1: According to their mode of presentation

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70% had no growth followed by pseudomonas (10%), multiple organisms (10%) while 3.33% had klebsiella in moist gauze group. In vacuum group, 66.67% had no growth on culture followed by pseudomonas (10%), multiple organisms (10%) whILE 6.67% had klebsiella and staphylococcus aureus.

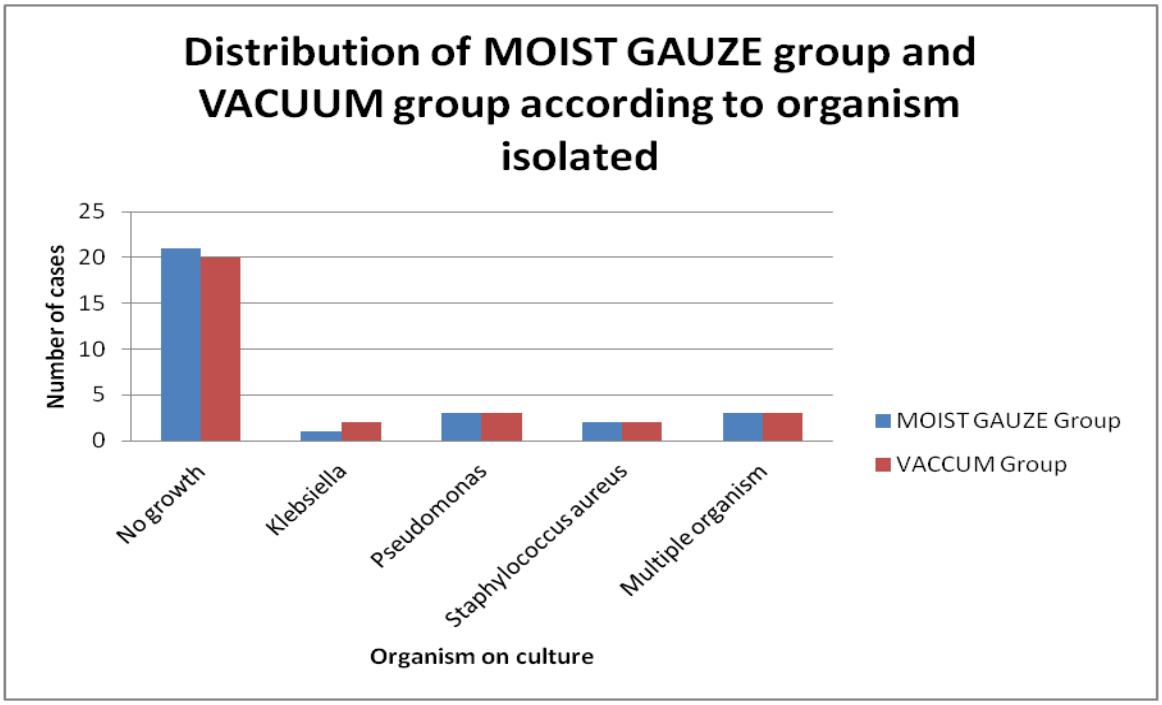

Fig. 2 shows distribution of groups according to organism isolated.

In moist gauze group, 53.33% had grafting and 6.67% had healing by secondary intention whereas in vacuum group, 70.00% had grafting and 10% had healing by secondary intention. In rest secondary suturing was done. The difference between two groups was insignificant.

Table 2. According to their end result

End Result	MOIST GAUZE Group		VACUUM Group		P value
	Frequency	Percent	Frequency	Percent	
Grafting	15	50.00	19	63.33	0.394
Secondary suturing	13	43.33	8	26.67	
Healing by secondary intention	2	6.67	3	10.00	
Days of hospital stay					
10 – 15	9	30.00	14	46.67	0.044*
16 – 20	10	33.33	6	20.00	
21 – 25	4	13.33	1	3.33	
>25	7	23.33	9	30.00	

In moist gauze group, 33.33% had 16-20 days of hospital stay while in vacuum group, 46.67% had 10- 15 days of hospital stay. The mean days of hospital stay was 20.96 ± 7.99 days in moist

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gauze group while 16.96±7.03 days in vacuum group, and the difference was statistically significant (p=0.044*).

In moist gauze group, 60.83 ± 7.82 % granulation tissue developed on 28th day. In vacuums group, 65.98± 8.82 % granulation tissue developed on 28th day. Association of both groups with granulation tissue development was found to be statistically significant. The mean graft uptake was 68± 13.01% in moist group and 71±12.59% in vacuum group.

Table 3. Granulation tissue

Granulation tissue (days)	MOIST GAUZE Group		VACUUM Group		P Value
	Mean	SD	Mean	SD	
7	21	5.34	26.33	11.88	0.029*
14	33.66	7.80	38.06	9.01	0.39*
21	48.66	8.60	54.46	12.50	0.041*
28	60.83	7.82	65.98	8.82	0.020*
Graft uptake (%)					
<40	3	18.75	0	0.00	0.020*
40 – 60	5	31.25	1	4.76	
61 – 80	7	43.75	17	80.95	
>80	1	6.25	3	14.29	

After 1 week 33.33% were healed followed by 30% uneventful suturing while 16.67% had pus formation and 20% had poor healing in moist gauze group. 66.67% were healed in vacuum group followed by uneventful suturing in 26.67% while 3.33% had pus formation and poor healing. Association of both groups with treatment outcome was statistically significant (p 0.029).

Table 4. According to age (15-45 years and >45 years) after 1 week follow up

1 week Follow up	**MOIST GAUZE Group**		**VACUUM Group**		**P Value**
	15 – 45	**>45**	**15 – 45**	**>45**	
Healing	8	2	7	12	0.007*
Poor healing	1	5	0	1	
Pus formation	0	5	0	1	
Uneventful secondary suturing	3	6	2	7	

In moist gauze group, 8 cases in 15 – 45 year had healing while 6 cases had secondary suturing in >45year. In vacuum group, 7 cases in 15 – 45 year and 12 cases in >45year had healing. The difference between age group was significant (p=0.007*)

DISCUSSION

In control group, 23.33% were observed in 36-45 years whereas 3.33% in 15 -25 years age group. In test group, 26.67% were observed in 46-55 and 56-65 years whereas 6.67% were in 15 – 25 and >75 years age group. Mean age in control group was 52.33±17.09 years whereas 52.43±15.29 years in test group. Sridhar J et al. (2020)[6] found that the mean age of the participants was 50.4 (SD=11.1), 35% participants were in the age group of 51-60 years.

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In our study, both control group and test group had male preponderance with 80% and 73.33% respectively which was similar to study done by Sridhar J et al. (2020)[6] which observed 67% were males and 33% were females.

In our study, most common mode of presentation was ulcer in both groups. Sixty percent had 10-15 cm^2 wound size while 6.67% had >25 cm^2 in control group whereas in test group, 56.67% had 10-15 cm^2 wound size while 6.67% had >25 cm^2 wound size. Mean size of wound was 17.59 ± 5.25 cm^2 in control group and 17.89 ± 6.15 cm^2 in test group. These findings were in line with study by Tanveer Sajid et al. (2015)[7] in which wound size in control group was 15.07 ±2.92 cm^2 and in test group was 15.09 ±2.81 cm^2 (p = 0.95).

In our study, no microbe growth was seen in 2/3rd cases in both groups. Pseudomonas and multiple organisms' growth on culture was seen in 10% of the participants respectively. In control group, 53.33% had grafting whereas in test group, 70.00% had grafting and was found to be statistically significant on comparison between the groups (p>0.05).

In control group, 33.33% had 16-20 days of hospital stay whereas in test group, 46.67% had 10-15 days of hospitalization. The mean days of hospital stay was 20.96 ± 7.99 days in control group whereas 16.96±7.03 days in test group (p=0.044). Peter A Blume et al (2008)[8] reported that mean hospital stay in test group was 63.6 ± 36.57 days and 78.1 ± 39.29 days in control group.

In our study, wound in 33.33% participants were healed following grafting and 30% had uneventful suturing while 16.67% had pus formation and 20% had poor healing in control group. In test group, wound in 66.67% participants were healed following grafting and uneventful suturing was seen in 26.67% while 3.33% had pus formation. Association of both groups with treatment outcome was statistically significant (p<0.05). Sridhar J et al. (2020)[6] reported that 1.3% got treated by amputation, 1.3% were treated using a collagen sheet, 38.9% of the ulcer state was treated by secondary intention, 13.8% were treated with secondary suturing, and 44.4% were treated with skin grafting.

In our study, 60.83 ± 7.82 % granulation tissue developed on 28th day in control group. In test group, 65.98± 8.82 % granulation tissue developed on 28th day. Association of both groups with granulation tissue development was found to be statistically significant (p>0.05). Peter A Blume et al (2008)[8] found that the rate of granulation in test group was 95%. Ashraf f. Abadir et al. (2021)[9] in control group showed earlier full granulation tissue in 10% of patients after 2 weeks, 68% after 4 weeks and 100% after 8 weeks, compared to 0% of patients treated with SMWT after 2 weeks, 21% after 4 weeks and 83% after 8 weeks, with a significant difference after 4 weeks (*p*-value 0.003).

In our study, 43.75% had 61-80 % graft uptake and 6.25% had >80% graft uptake in control group whereas 80.95% had 61-80% graft uptake and 14.29% had >80% graft uptake in test group. The mean graft uptake was 68 ± 13.01% in control group and 71 ±12.59% in test group. Association of both groups with graft uptake was found to be statistically significant (p<0.05). Peter A Blume et al (2008)[8] found that graft uptake in test group was 43.2% and 28.9% in control group.

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In control group, 8 males had secondary suturing whereas 3 cases had healing in female. In test group, 14 male and 6 female cases had healing. In control group, 8 cases in 15-45 years had healing whereas 6 cases had secondary suturing in >45 years. In test group, 7 cases in 15-45 years and 12 cases in >45 years had healing (p=0.007*).

Conclusion:

It was found that the application of topical negative pressure increased the rate of formation of granulation tissue, less infection rate and had better graft uptake than the patients who underwent a conventional dressing for their ulcers. The patients in the study group had a shorter duration of hospital stay when compared to the control group. Thus, topical negative pressure moist foot dressing can be considered as a superior option in the management of diabetic foot ulcers. But further studies with larger population will be needed in the future before topical negative pressure dressing can be added to the wide spectrum of treatment modalities available in the management of diabetic foot.

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