

ORIGINAL RESEARCH

Role of vacuum assisted closure therapy in diabetic foot ulcer at tertiary care centre in southern Bihar

¹Dr. Om Prakash Yadav, ²Dr. Pravin Kumar, ³Dr. Indrajeet Rajan

^{1,3}PG III, ²Assistant Professor, Department of General Surgery, NMCH, Jamuhar, India

Corresponding author

Dr. Om Prakash Yadav

PG III, Department of General Surgery, NMCH, Jamuhar, India

Email: Om.prakash10d@gmail.com

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ABSTRACT

Diabetes mellitus is one of the most common endocrine disorders and is rapidly increasing in prevalence worldwide. About 15-20 % diabetes patients develop diabetic ulcers especially in the foot. Vacuum pressure therapy for diabetic ulcer is shown to be beneficial in variety of wounds. It is used as an adjunct or alternate to surgery for wide range of wounds with an aim to decrease morbidity, cost, duration of hospitalization and increase patient comfort. **Materials and Method:** This study was conducted over 60 patients who were randomly allotted to 2 groups after initial wound debridement. Group A received vacuum therapy for wounds while Group B received Conventional dressing. Results were compared with time of granulation tissue formation. **Results:** There was statistically significant difference between two groups in time of granulation tissue formation and mean time of healing. Group A had better rate of granulation tissue formation and Mean time to achieve >75% granulation tissue cover was significantly less in Group A. **Conclusion:** Vacuum assisted closure therapy is more effective than conventional dressing for wound healing in diabetic foot ulcers.

Key words- Wound healing; Vacuum therapy; Diabetic foot ulcer; Negative Pressure wound therapy

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INTRODUCTION

Diabetes mellitus is one of the most common endocrine disorders and is rapidly increasing in prevalence worldwide. About 15-20 % diabetes patients develop diabetic ulcers especially in the foot. Disease involves foot bones, muscles, arches, ligaments, tissue e planes and skin ^[1] Neuropathy, ischaemia and infection are most dangerous triad of diabetic foot. If diabetic foot ulcer is not treated promptly chances of amputation are higher.^[1]

The treatment of diabetic foot requires a cross-disciplinary and systematic approach that comprises blood glucose control, surgical debridement, decompression treatment and supportive treatment.^[1]

Controlling wound infection and promoting tissue repair are vital for preventing amputation or reducing the level of amputation.^[2,3] Wound coverage is done with secondary suturing, split skin grafting, flap reconstruction.

The concept of negative pressure wound therapy (NPWT) was first established and applied in clinical practice by a German physician, Fleischmann, in 1993 and has, ever since, been recognized for its remarkable effect in improving wound drainage,

enhancing perfusion, and promoting the growth of granulation tissue.^[4] It is used as an adjunct or alternate to surgery for wide range of wounds with an aim to decrease morbidity, cost, duration of hospitalization and increase patient comfort.

AIMS AND OBJECTIVES**Aim**

To study effect of Vacuum assisted closure therapy in diabetic foot ulcer.

Objectives

1. To assess the Time taken for wound healing in either group.
2. To determine time taken to form granulation tissue in either group.
3. To compare complications in either group.

MATERIALS AND METHODS

This study was conducted in department of General surgery, Narayan medical college and hospital, Jamuhar, Sasaram. It was Prospective comparative study, conducted on 60 patients with diabetic foot ulcer for duration of 12 months. Informed and written

consent was taken from participants and they were allowed to withdraw from study at any point of time. They were randomly divided into two groups
 Group A- 30 patient received Vacuum Pressure therapy and dressing changed every third day.
 Group B – 30 patients received daily antiseptic dressing of wound.

INCLUSION CRITERIA

- All adult patients of diabetic foot ulcer in surgery department in NMCH, Sasaram.
- Wound size- <100cm²
- Patients who give consent for participation.
- Age >18 years

EXCLUSION CRITERIA

- Patient with venous ulcer
- Osteomyelitis
- Patient with septicaemia
- Patient with CVS disorder/ coagulopathy

The patients were subjected to detailed history taking, general survey, systemic examination, and relevant investigations. Patients initially underwent wound debridement and then allotted Randomly to either group with antibiotics coverage and glycaemic control.

In Group-A, Patients wound were cleaned and saline soaked gauze were placed over wound after placing a suction catheter no. 14. Sterile padding was done and then Dressing was covered with sterile adhesive sheet to create airtight seal. Catheter Tube was connected to a wall mount suction device with continuous negative

pressure of -125 mm hg. Dressing was changed after 48h. Dressing was examined every day and changed if any blood soakage or any other complications seen.

In Group B – Patients received conventional antiseptic dressing. Wound was cleaned and saline soaked gauze placed over wound and sterile padding done over wound. Daily dressing was done.

Initially broad-spectrum antibiotics were given to either group, then given according to culture report. Sample was taken every week from floor of wound.

Wound was assessed till formation of granulation tissue over wound or wound fit for split skin grafting or secondary suturing or up to maximum of 3 weeks. During the study period if any complication developed then participant was dropped from study and further management done.

At End of study period, patients were categorized as:

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 Category 1- (Significantly effective)- Formation of more than or equal to 75% granulation tissue cover over wound.

Category 2- (effective)- Formation of 50 - 75% granulation tissue covers over wound.

Category 3- (Partially effective)- formation of 25-50% granulation tissue

Category 4- (ineffective)- formation of less than 25% granulation tissue cover over wound and or Culture positive after 3 weeks.

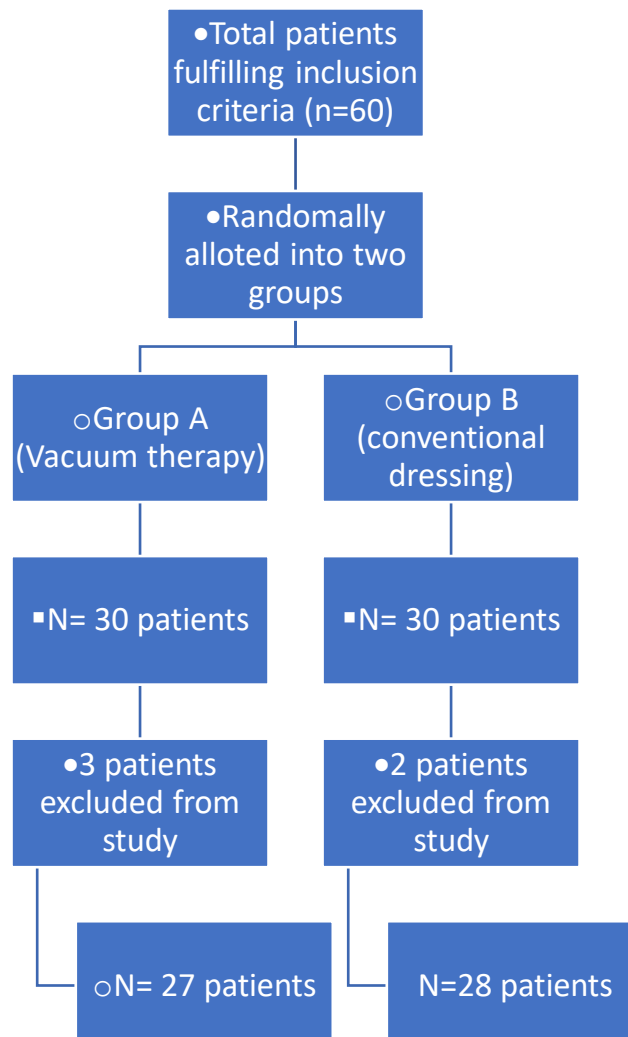
All the collected data were statistically analyzed using appropriate statistical tests. A p value less than 0.05 was considered significant.



Figure 1- Wall mount suction device

RESULTS

Study was conducted on 60 patients who were randomly distributed into two groups. Group A patient received VAC dressing while Group B patients received conventional dressing. 5 patients left the study (3 in group A and 2 in group B). Results of this study are based on 55 patients (27 in group A and 28 in Group B).

**Age**

Mean age in Group A was 56.33 ± 1.23 years and in Group B it was 56.23 ± 1.42 years. Minimum age in study was 26 and maximum was 69.

Sex

In group A 20 patients were males and 7 were females. In group B 19 patients were males and 9 were females.

Hemoglobin

Mean age in Group A was 9.9 ± 0.22 and in Group B it was 9.83 ± 0.18 .

HbA1c and Ulcer Area

Mean HbA1c in group A was 8.08 ± 0.22 and in group B was 8.43 ± 0.15 . Mean ulcer area was 64.2 ± 2.53 in group A and in Group B it was 63.88 ± 2.66 .

Wound size

The median reduction in ulcer area was more in Group A (11.5 cm sq.) than Group B (4cm sq.) which was statistically significant ($p < 0.05$). Ulcers with larger area had more reduction in size in compared to smaller ulcers. Two patients in Group B showed no

change in wound size and 1 patient had increase in wound size.

Wound discharge

Wound discharge was present in all patients in first week which gradually decreased over time. Rate of disappearance was faster in group A. At the end of study period, none of the patients in group A had discharge while Group B had 3 patients.

Bleeding

Soakage due to bleeding was comparable between two groups in first week. However, number of patients with no bleeding at all was lower in Group A (12 vs 7) which was statistically significant ($p < 0.05$).

Pain

Pain was comparable between the two groups.

Bacterial load

Most common organism associated with diabetic foot ulcer was *Staphylococcus aureus*. It was seen that Group A had better clearance of bacterial load than Group B. At end of Study period, none were culture positive in group A compared to 2 in Group B.

Granulation tissue	Group A (n=27)	Group B (n=28)
Category 1 (Significantly effective) >75%	22	12
Category 2 (effective) 50-75%	5	8
Category 3- (Partially effective) 25-50%	0	5
Category 4- (ineffective) <25%	0	3

Granulation Tissue

At the end of study period, 20 out of 27 patients in Group A showed more than 75% granulation tissue cover (category 1) but in Group B it was only 12 out of 28. Seven patients in group A were in category 2 while Group B has 8 patients. In category 3, Group A had 0 patients while Group B had 5 patients. In category 4, Group B had 3 patients.

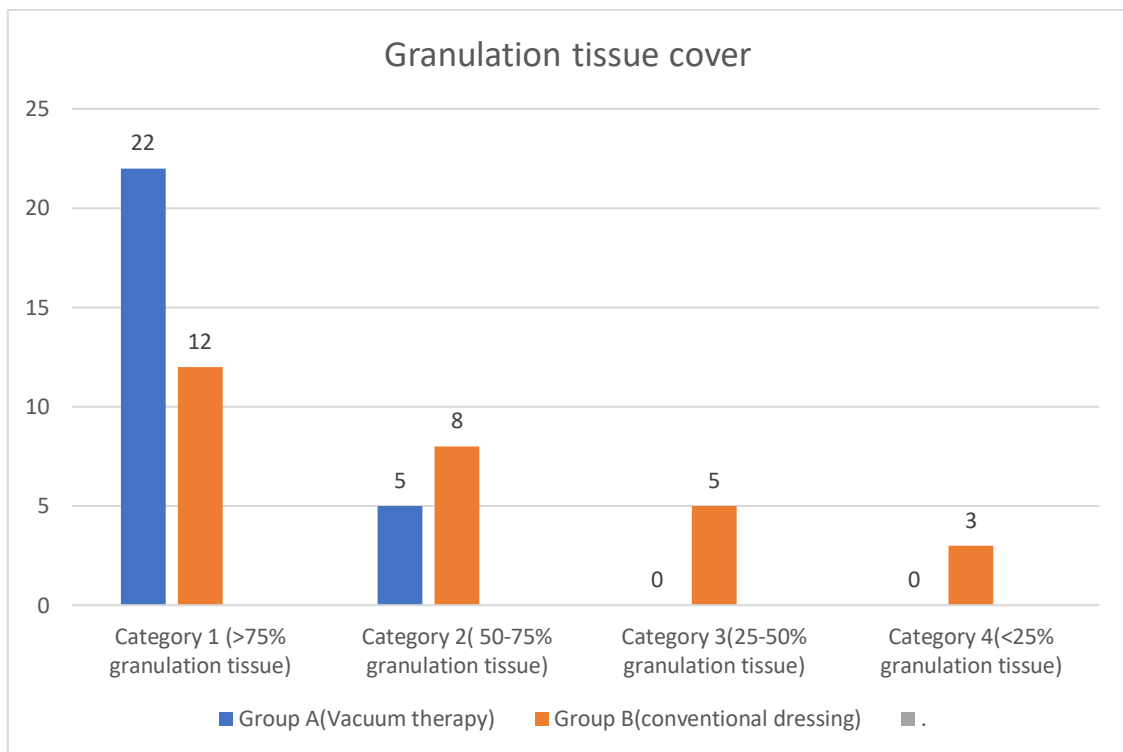


Figure 2- Before and After Vacuum Therapy for 2 week. Later split skin grafting was done



Figure 3 - vacuum therapy for 1 week. initially debridement with disarticulation was done. split skin grafting was done later

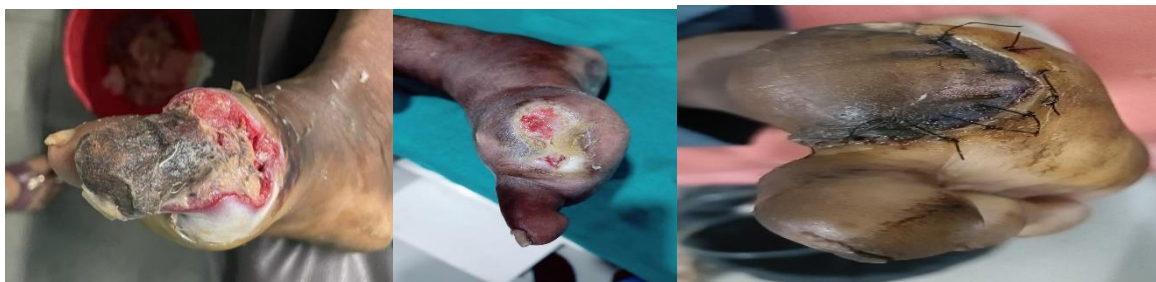


Figure 4- vacuum therapy for 10 days was done after initial wound debridement. wound size decreased, secondary suturing was done later.



Figure 5- vacuum therapy for 1 week. Later SSG was done.

DISCUSSION

It has been suggested that negative pressure dressings have a role in the healing of diabetic foot ulcers by modifying the chronic wound environment in a way that lowers the bacterial burden and chronic interstitial wound fluid while increasing vascularity and cytokine production.

Vaidhya et al. in a Indian study of sixty patients with DFU in 2015 showed a time to healing of 17.2 days in VAC therapy group as compared to 34.9 days in conventional dressing group.^[5] Our study showed similar results, there was faster healing of wound in Group A with NPWT compared to conventional dressing in group B.

Singh et al. In a study in 2017 showed mean time to complete wound closure of 41.2 days and 58.9 days in VAC therapy group and conventional group, respectively.^[6] In our study, The median reduction in

ulcer area was more in Group A (11.5 cm sq.) than Group B (4cm sq.) which was statistically significant ($p < 0.05$). Ulcers with larger area had more reduction in size in compared to smaller ulcers. This result was similar to Liu et al. who showed that NPWT significantly reduces DFUs compared to standard dressing in a systematic review and meta-analysis(2017).^[7]

In our study pain was similar in both groups. This can be attributed to use of Gauze for covering the wound which is both cost effective and easily available. Study conducted by Fracalvieri et al^[8]. and Dorafshar et al.^[9] Concluded that use of gauze based NPWT produces less pain.

Application of negative pressure over wound bed allows the arterioles to dilate, so increasing the effectiveness of local circulation, promoting angiogenesis, which assists in the proliferation of

granulation tissue.^[10]James SM et al. in a study in 2019 showed that NPWT reduces the time to complete wound healing by hastening granulation tissue formation without any increase in the incidence of complication such as bleeding and infection.^[11]

Our study showed similar results, At the end of study period, 22 out of 27 patients in Group A showed more than 75% granulation tissue cover (category 1) but in Group B it was only 12 out of 28. Five (5) patients in group A were in category 2 while Group B has 8 patients.

It was also seen that Group A had better clearance of bacterial load than Group B. At end of Study period, none were culture positive in group A compared to 2 patients in Group B.

CONCLUSION

The treatment of diabetic foot requires a cross-disciplinary and systematic approach, within which vacuum therapy is an important adjunct treatment for diabetic foot wounds. Management and application of vacuum therapy may improve wound exudate drainage, enhance blood perfusion and promote wound healing.

Based on this study, we can conclude that Vacuum therapy has definitive role in management of diabetic foot ulcer. It helps in promoting granulation tissue development, shrinking the wound, rapidly removing the discharge from the site, and lowering the bacterial burden. It is proposed that NPWT is an affordable, easy to use, and patient-friendly approach to treating diabetic foot ulcers. It aids in the early closure of wounds, reducing complications, and so improving prognosis.

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REFERENCES

1. Bhat S. SRB's Manual of Surgery. Jaypee Brothers Medical Publishers; 2023; 144.
2. Everett E, Mathioudakis N. Update on management of diabetic foot ulcers. *Ann NY Acad Sci.* 2018 Jan;1411(1):153–65
3. Bakker K, Apelqvist J, Lipsky BA, Van Netten JJ. International Working Group on the Diabetic Foot. The 2015 IWGDF guidance documents on prevention and management of foot problems in diabetes: development of an evidence-based global consensus. *Diabetes Metab Res Rev.* 2016 Jan;32(Suppl 1):2–6.
4. Ji S, Liu X, Huang J, Bao J, Chen Z, Han C, Hao D, Hong J, Hu D, Jiang Y, Ju S. Consensus on the application of negative pressure wound therapy of diabetic foot wounds. *Burns & Trauma.* 2021;9:tkab018.
5. Vaidhya N, Panchal A, Anchalia MM. A new cost-effective method of NPWT in diabetic foot wound. *Indian J Surg* 2015;77:525-9.

6. Singh B, Sharma D, Jaswal KS. Comparison of negative pressure wound therapy v/s conventional dressings in the management of chronic diabetic foot ulcers in a tertiary care hospital in North India. *Int J Sci Res* 2017;6:948-53
7. Liu S, He CZ, Cai YT, Xing QP, Guo YZ, Chen ZL, et al. Evaluation of negative-pressure wound therapy for patients with diabetic foot ulcers: Systematic review and meta-analysis. *Ther Clin Risk Manag* 2017;13:533-44.
8. Dorafshar AH, Franczyk M, Gottlieb LJ, Wroblewski KE, Lohman RF. A prospective randomized trial comparing subatmospheric wound therapy with a sealed gauze dressing and the standard vacuum-assisted closure device. *Ann Plast Surg* 2012;69:79-84.
9. Fraccalvieri M, Ruka E, Bocchiotti MA, Zingarelli E, Bruschi S. Patient's pain feedback using negative pressure wound therapy with foam and gauze. *Int Wound J* 2011;8:492-9
10. Morykwas MJ, Argenta LC, Shelton-Brown EI, McGuirt W. Vacuum-assisted closure: A new method for wound control and treatment: Animal studies and basic foundation. *Ann Plast Surg* 1997;38:553-62
11. James SM, Sureshkumar S, Elamurugan TP, Debas N, Vijayakumar C, Palanivel C. Comparison of vacuum-assisted closure therapy and conventional dressing on wound healing in patients with diabetic foot ulcer: A randomized controlled trial. *Niger J Surg* 2019;25:14-20.
12. Nain PS, Uppal SK, Garg R, Bajaj K, Garg S. Role of negative pressure wound therapy in healing of diabetic foot ulcers. *J Surg Tech Case Report* 2011;3:17-22