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Original Article

Efficacy of Vacuum Assisted Closure Therapy In Healing Diabetic Foot

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ABSTRACT

Objective: To determine the efficacy of vacuum assisted closure therapy compared to conventional therapy in treatment of diabetic foot.

***Study design*:** Prospective comparative study.

Place and Duration of Study: Pak Emirates Military Hospital and Combined Military Hospital, Rawalpindi Pakistan, from November 2019 to December 2020.

Methodology: All patients with type II diabetes mellitus aged 45 years and above having Wagner's classification I or II for diabetic foot were consecutively enrolled into two groups (Group A: vacuum assisted closure technique; Group B: conventional wound management technique). Patients were assessed till 4 weeks. The outcomes were assessed as pain, ulcer size, Wagner's grade, Granulation score, complete healing, time duration since healing, and debridement requirement.

Results: Of total 60 patients, the median age was 58(54-64) years. There were 21(35%) males and 39(65%) females. The median duration of diabetes was 13(12-15) years. Pain was found significantly lower in group A than that of group B, i.e., 3(0-3) vs. 7 (6-7), *p*-value <0.001. Similarly, ulcer size was significantly lower in group A as compared to group B, i.e., 12(10-12) vs. 13(13-14), *p*-value <0.001. However, no significant association of Wagner's grade (*p*-value 0.108), granulation score (*p*-value 0.776), complete healing (*p*-value 0.573), time duration since healing (*p*-value 0.633), and debridement requirement (*p*-value 0.273) was found with respect to group.

Conclusion: The efficacy of vacuum assisted closure was found higher in treatment of diabetic foot compared to conventional therapy.

Keywords: Diabetes, Foot, Negative Pressure Wound Therapy, Vacuum Assisted Closure.

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INTRODUCTION

Diabetes mellitus is a complex pathology that affects multiple physiological aspects of the human body.[1] One of the most frequent complications seen are foot ulcers. Current literature estimates that one in every four diabetic patients develops foot ulcers during their lifetime.[2-3]

Peripheral neuropathy, secondary to diabetes and non-uniform pressure distribution on the feet leads to development of these ulcers on the feet. The impaired immunity and poor blood supply, which is caused by the diabetes, makes healing and wound management more complex. These wounds typically take extensive time to heal and require dressings in sterile environments, to protect from secondary infection. Failure to do so has seen cases of complications which may end with foot amputation.[4-6]

Vacuum assisted closure, also known as negative pressure wound therapy is a technique that aims contract the margins of the wound to reduce its size and also increase local vascularity. It is thought to be an effective technique which attempts to solve the problem of multiple dressing changes, while also maintaining a sterile environment.[7]

While multiple studies have attempted to evaluate this method[8-9], it is mostly seen in comparison to conventional dressing, such as in Cheema et al[10], which focused on general wound healing but not on diabetic ulcers specifically.

We believe there is a scarcity of local data evaluating the efficacy of vacuum assisted closure for treatment of diabetic ulcers, and that this data is necessary. If this method shows promise, it can then be encouraged in other institutions as standard practice to improve patient outcomes. Therefore, this study was designed to evaluate the clinical efficacy of vacuum assisted closure in treatment of diabetic foot.

METHODOLOGY

This multicenter prospective comparative study was conducted at Combined Military Hospital, and Pak Emirates Military Hospital, Rawalpindi, Pakistan

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from November 2019 to December 2020.Ethical approval was obtained from the ethical committee of the institute. Moreover, signed informed consent was also obtained from all study participants after explaining the pros and cons of the study.

Inclusion Criteria: Type II diabetes mellitus patients with age 45 years and above having Wagner's classification I or II for diabetic foot ulcer were included.

Exclusion Criteria: Patients with following characteristics were excluded; (i) having foot ulcer other than diabetes (ii) osteomyelitis of the underlying bone, (iii) coagulopathy (iv) patients on corticosteroid or immunosuppressive medications (iv) patients receiving chemotherapy, (v) Charcot's joint, (vi) bleeding disorders and fistula to organ / body cavities, (viii) diabetic foot ulcer of both feet.

Non-probability consecutive sampling technique was applied. Open Epi sample size calculator was used for the estimation of sample size taking confidence interval 95%, power 80%, ratio 1:1, complete wound healing at 4 weeks in group A 67% while complete wound healing in group B 28%11. The estimated same size came out to be 60, i.e., 30 in each group.

All patients were enrolled into two groups. In group A, vacuum assisted closure technique was applied whereas in group (B) conventional Wound management technique like wound dressing was applied. Initial treatment included wound debridement, antibiotics therapy, and glycemic control.

In patients with vacuum assisted closure, i.e., group A, all wounds were washed thoroughly with normal saline and debridement done if needed. Wounds of the patients was covered with a polyurethane foam and a multi hole drain placed over it. It was then sealed with airtight dressing. Drain attached to a negative pressure system that provided intermittent negative pressure of -80mmhg with 45 min ON and 15 min OFF cycle. Patients underwent change of dressing after 48-72 hours. Negative pressure was provided for 2 days average period for the sake of better management.

A saline soaked gauze piece was put over the wound bed after cleaning the wound in patients who were treated conventionally, i.e., group B. The dressing was placed on two layers of sterile gauze and secured with roller bandages. The dressing was changed regularly, and the treating surgeon conducted an examination of the wound every forty-eight hours for improvement or any adverse wound parameters.

Patients were assessed till 4 weeks. The outcome variables like wound granulation, bleeding, and pain were assessed. The granulation scoreswere categorized into 1-4 based on wound covering. The granulation score "1" was labeled in patients whom no granulation was observed, patients with less than twenty-five percent wound coverage by granulation tissue was labelled as "2", patients with granulation score in between twenty-five and seventy-four were labeled as "3", and patients with granulation score in between seventy-five to hundred were labeled as "4". All those patients who had hundred percent granulation score were also labeled as complete wound healing. The time duration since complete healing was also observed in all patients with granulation score 4. To assess the intensity of pain in both groups,visual Analog Scale was used.

All patients were given the same systemic antibiotics during the postoperative period. Vacuum assisted closure therapy was discontinued when aim of therapy had been met; or if there was no improvement in wound after 3-4 applications of therapy; or in case of any complication.

SPSS version 24 will be used for the purpose of data analysis. Descriptive analyses were explored using median and interquartile range for quantitative variables like age, duration of diabetes, ulcer size, and time since complete healing whereasfrequencies and percentages was calculated for qualitative variables like gender, diabetes treatment, hypertension, and outcome. Chi-square test and Mann-Whitney U test was applied for inferential statistics. The *p*-value ≤0.05 considered as significant.

RESULTS

Of 60 patients, the median age of the patients was 58(54-64) years. There were 21(35%) males and 39(65%) females. The median duration of diabetes was 13(12-15) years. Majority of the patients were on insulin, i.e., 42(70%) followed by insulin and oral medication both 12(20%) whereas 6(10%) patients were on oral medication. Left side was involved in 42(70%) whereas right side in 18(30%) patients. Most of the patients were hypertensive, i.e., 50(83.3%). The comparison of baseline characteristics with respect to group showed insignificant difference between groups (*p*-value >0.05) (Table-I).

Table-I: Comparison of baseline Characteristics with respect to group (n=60)

Characteristics	Groups		*p*-value
	Group A (n=30)	Group B (n=30)	
Age, years	57(54-62)	58(54-65)	0.259¥
Gender			
Male	8(26.7)	13(43.3)	0.176ß
Female	22(73.3)	17(56.7)	
Duration of diabetes, years	13(12-15)	3(12-14)	0.155¥
Medication			
Oral	4(13.3)	2(6.7)	0.683ß
Insulin	20(66.7)	22(73.3)	
Both	6(20.0)	6(20.0)	
Extremity Involved			
Right	8(26.7)	10(33.3)	0.573ß
Left	22(73.3)	20(66.7)	
Ulcer size at baseline, cm	15(15-16)	15(14-16)	0.291¥
HTN			
Yes	24(80.0)	26(86.7)	0.488ß
No	6(20.0)	4(13.3)	

Group A: Vacuum assisted closure, Group B: Conventional group, ¥Mann-Whitney U test applied, ßchi-square test applied

The outcome of the patients showed that overall, 38(63.3%) patients were presented with Wagner grade I whereas 22(36.7%) with Wagner's grade II. The granulation score showed that 2 score was observed in 14(23.3%) patients, granulation score 3 in 28(46.7%), whereas granulation score 4 in 18(30%) patients. Of 18 patients with granulation score 4, i.e., who had complete healing, the median time duration in complete healing was 24(21-25). Debridement was observed in 0(33.3%) patients. The median pain score was 6(2-7). The median ulcer size at baseline was 15 (14-15) whereas ulcer size at 4 weeks was 13(11-13). Table-II.

Table-II: Comparison of Outcome of the patients with respect to group (n=60)

Outcome of the patients	Groups		
	Group A (n=30)	Group B (n=30)	*p*-value
Pain (Vacuum assisted closure score)	3(0-3)	7(6-7)	<0.001
Ulcer size at end of therapy, cm	12(10-12)	13(13-14)	<0.001
Time duration since healing (n=18)	22(21-25)	24(21-25)	0.633

Group A: Vacuum assisted closure, Group B: Conventional group, Mann-Whitney U test applied

Pain was found significantly lower in group A than that of group B, i.e., 3(0-3) vs. 7(6-7), *p*-value <0.001. Similarly, ulcer size was significantly lower in group A as compared to group B, i.e., 12(10-12) vs. 13(13-14), *p*-value <0.001. However, no significant association of Wagner's grade (*p*-value 0.108), granulation score (*p*-value 0.776), complete healing (*p*-value 0.573), time duration since healing (*p*-value 0.633), and debridement requirement (*p*-value 0.273) was found with respect to group (Table-III)

Table-III: Comparison of outcome of the patients with respect to group (n=60)

Outcome of the patients	Groups		
	Group A (n=30)	Group B (n=30)	*p*-value
Wagner's grade			
I	16(53.3)	22 (73.3)	0.108
II	14(46.7)	8 (26.7)	
Granulation score			
2	6(20.0)	8(26.7)	0.776
3	14(46.7)	14(46.7)	
4	10(33.3)	8(26.7)	
Complete healing			
Yes	10(33.3)	8(26.7)	0.573
No	20(66.7)	22(73.3)	
Debridement requirement			
Yes	8(26.7)	12(40.0)	0.273
No	22(73.3)	18(60.0)	

Group A: Vacuum assisted closure, Group B: Conventional group, chi-square test applied

DISCUSSION

In the current study, vacuum assisted closure therapy was evaluated in treatment of patients with diabetic foot ulcers. For this purpose, patients with type II diabetes mellitus patients with age 45 years and above having Wagner's classification I or II for diabetic foot ulcer were consecutively enrolled. All patients were divided into two groups, i.e., vacuum-assisted closure and conventional group. The findings of this study have shown that pain was considerably higher among patients who received conventional therapy as compared to the patients who received vacuum-assisted closure therapy. Similar to the current study findings, a study conducted by James et al also showed similar findings in which pain score was significantly lower in patients who received vacuum assisted closure therapy than conventional therapy.[12] It is reported that negative pressure during vacuum assisted closure induce some pain in initial days. However, as the number of dressing requirement in these patients are low as compared to conventional and more importantly due to the higher

efficacy as reported in the current and pervious studies[12-14], overall, the pain intensity founds low in patients who received vacuum assisted closure therapy than that of those who received conventional therapy.

According to the current study findings, ulcer size was considerably higher among patients who received conventional therapy as compared to the patients who received vacuum assisted closure therapy. This finding also found similar with a previous study conducted in combined military hospital in Rawalpindi by Sajid et al in 2015 who reported less ulcer size in vacuum assisted closure as compared to those who received advanced moist wound therapy.[15] Similarly, other published studies from United States, India, and Nigeria and a systematic review also showed similar findings.[11-17]

However, the findings of the current study have showed non-statistical significance difference of complete healing in between group. It is noted that complete healing was slightly higher in vacuum assisted closure group as compared to the conventional group. Similarly, in the current study, of 18 patients in whom complete healing was observed, shorter time duration was observed in patients who received vacuum assisted closure as compared to the patients who received conventional therapy, though the finding was statistically non-significant. In contrast to the current study findings, complete healing was found a statistically higher in patients who received vacuum assisted closure therapy as compared to those who received conventional therapy.12 Other studies from also showed significantly shorter duration of complete healing in vacuum assisted closure group.[18-20]

The findings of the current study have revealed that non-significant association of Wagner's grade, granulation score, and debridement requirement was found with respect to group. Similar findings were reported in a previous study conducted in our hospital.[15]

There were certain issues involved while conducting this study. Firstly, as this study was conducted during coronavirus-19 (COVID-19) outbreak period, the included number of patients was very limited. Though, to accomplish the minimal required patients in both groups, two centers were involved for the purpose of data collection and the study duration period was also increased, still, the current study faced difficulty in acquiring the data from high number of patients. The current study also faced difficulty while follow-up during this outbreak. All patients with confirmed COVID-19 polymerase chain reaction (PCR) negative or with no sign and symptoms of COVID-19 were included. In addition to this, strict measures regarding the standard operating procedures as instructed by Government of Pakistan and hospital protocol was followed while recruiting the patients in the study. Due to the above mentioned issues, the follow-up period in this study was limited to 4 weeks only.

CONCLUSION

The outcome of vacuum-assisted closure therapy in patients treated with diabetic foot was found to be better compared to conventional therapy. Lower pain severity and ulcer size were discovered as the substantially improved outcome variables, in particular.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

KK& IAS: Study design, drafting the manuscript, data interpretation, critical review, approval of the final version to be published.

UG & SS: Data acquisition, data analysis, approval of the final version to be published.

TMK & SN & IM: Critical review, concept, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

REFERENCES

1. Adnan M, Aasim M. Prevalence of type 2 diabetes mellitus in adult population of Pakistan: a meta-analysis of prospective cross-sectional surveys. Ann Glob Health 2020; 86(1): 7.
2. Ardila IC, Espinosa CM, Vernot PP, Hernández YC, Vaca-González JJ. Clinical-surgical treatment of diabetic foot ulcers in a colombian hospital. Obes Med 2020:100308.
3. Mavrogenis AF, Megaloikonomos PD, Antoniadou T, Igoumenou VG, Panagopoulos GN, Dimopoulos L, et al. Current concepts for the evaluation and management of diabetic foot ulcers. EFORT Open Rev 2018; 3(9): 513-25.
4. Selvarajah D, Kar D, Khunti K, Davies MJ, Scott AR, Walker J, et al. Diabetic peripheral neuropathy: advances in diagnosis and strategies for screening and early intervention. Lancet Diabetes Endocrinol 2019; 7(12): 938-48.
5. Beckman JA, Duncan MS, Damrauer SM, Wells QS, Barnett JV, Wasserman DH, et al. Microvascular Disease, Peripheral Artery Disease, and Amputation. Circulation. 2019; 140(6): 449-58.
6. Perez-Favila A, Martinez-Fierro ML, Rodriguez-Lazalde JG, Cid-Baez MA, Zamudio-Osuna MJ, Martinez-Blanco MDR, et al. Current Therapeutic Strategies in Diabetic Foot Ulcers. Medicina 2019; 55(11): 714.

7. Brem H, Sheehan P, Rosenberg HJ, Schneider JS, Boulton AJ. Evidence-based protocol for diabetic foot ulcers.Plast Reconstr Surg 2006; 117(Suppl.7): S193–211.
8. Hussein AE, Ahmed Hamdy AS, Abd El-Hafez A, El-Aziz A. Outcomes of vac versus conventional dressing in management of diabetic foot ulcer. Al-Azhar Med J 2020; 49(4): 1619-28.
9. Liu Z, Dumville JC, Hinchliffe RJ, Cullum N, Game F, Stubbs N, et al. Negative pressure wound therapy for treating foot wounds in people with diabetes mellitus. Cochrane Database Syst Rev 2018; 10(10): CD010318.
10. Cheema SA, Nasir H, Dogar SR, Ahmad UT. Comparison of Vacuum Assisted Closure Technique Versus Conventional Dressing for Management of Wounds in Term of Duration of Wound Healing. Annals Punjab Med Coll 2020; 14(1): 1-4.
11. Lone AM, Zaroo MI, Laway BA, Pala NA, Bashir SA, Rasool A. Vacuum-assisted closure versus conventional dressings in the management of diabetic foot ulcers: a prospective case–control study. Diab foot ankle. 2014; 5(1): 23345.
12. James SM, Sureshkumar S, Elamurugan TP, Debasis 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(1): 14.
13. 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(1): 79-84.
14. Nather A, Chionh SB, Han AY, Chan PP, Nambiar A. Effectiveness of vacuum-assisted closure (VAC) therapy in the healing of chronic diabetic foot ulcers. Ann Acad Med Singapore 2010; 39(5): 353-8.
15. Sajid MT, Mustafa Q, Shaheen N, Hussain SM, Shukr I, Ahmed M. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers. J Coll Physicians Surg Pak 2015; 25(11): 789-93.
16. McCallon SK, Knight CA, Valiulus JP, Cunningham MW, McCulloch JM, Farinas LP. Vacuum-assisted closure versus saline-moistened gauze in the healing of postoperative diabetic foot wounds. Ostomy/wound Manag 2000; 46(8): 28-32.
17. 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 Rep 2011; 3(1): 17-22.
18. McCallon SK, Knight CA, Valiulus JP, Cunningham MW, McCulloch JM, Farinas LP, et al. Vacuum-assisted closure versus saline-moistened gauze in the healing of postoperative diabetic foot wounds. Ostomy Wound Manag 2000; 46(8): 28-32.
19. Blume PA, Walters J, Payne W, Ayala J, Lantis J. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: A multicenter randomized controlled trial. Diab Care 2008; 31(4): 631-6.
20. 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(8): 948-53.
21. Vaidhya N, Panchal A, Anchalia MM. A new cost-effective method of NPWT in diabetic foot wound. Indian J Surg 2015; 77(Suppl 2): 525-9.

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