Cutoff Value of The Ankle Brachial Pressure Index for Vacuum-Assisted Closure Application in Diabetic Foot Ulcers

Original Article

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ABSTRACT

Background: Diabetes Mellitus (DM) is a chronic disease and has been considered a major health concern globally. It results in significant clinical, economic, social, and quality of life (QoL) issues for patients. Diabetic foot ulcer (DFU) represents a significant and debilitating complication of DM, affecting 15% of patients. Negative pressure wound therapy (NPWT) is a non-invasive treatment that facilitates fluid removal from wounds, improves the wound bed for closure, decreases oedema, and encourages the formation of granulation tissue by applying controlled negative pressure using a vacuum-assisted closure (VAC) device. This study aimed to determine the ankle-brachial pressure index (ABPI) cutoff value that indicates a benefit from VAC application for DFUs.

Patients and Methods: A descriptive, single-center, observational, prospective study was performed on diabetic patients. The study included 56 diabetic patients. All patients underwent three VAC application sessions, and debridement was performed when needed. The ABPI was measured prior to the first session, and ulcer dimensions were measured both before and after each session.

Results: This study revealed that the ABPI significantly predicts improvements in the dimensions of DFUs following vacuum-assisted closure application. The area under the curve was significantly elevated relative to the diagonal reference line (P= 0.028). At a cutoff point of 0.615, the ABPI demonstrated a sensitivity of 71.4% and a specificity of 100.0% (area under curve= 0.762).

Conclusion: Measuring the ABI allows for the prediction of DFUs, which may improve following the application of VAC.

Key Words: ABPI, Diabetic foot ulcers, Peripheral arterial disease, Vacuum-assisted closure, Vascular Doppler.

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INTRODUCTION

DM is a chronic disease considered a global public health problem, resulting in considerable clinical, economic, social, and quality of life challenges for patients[1]. DFU represents a significant and debilitating adverse event of DM, affecting 15% of patients[2].

Evaluation of foot perfusion is an essential step in the management of cases with DFU. The ABPI is a simple, rapid, non-invasive modality[3]. Efficient DFU management includes clinical awareness, maintenance of proper blood glucose values, regular foot examinations, provision of properly fitting therapeutic footwear, off-loading techniques, local wound care, and the recognition and management of osteomyelitis and ischemia[4].

Numerous studies have investigated multiple adjuvant therapies to reduce healing times for DFUs and lower amputation rates. These therapies include NPWT (VAC), non-surgical debridement agents, oxygen, energy-based, and systemic medications[5]. Cellular or tissue-based products (CTPs) are associated with an increased mean number of ulcer-free months and a decreased average number of amputations in comparison with standard of care (SOC) only[6].

NPWT is a non-invasive treatment that facilitates fluid removal from wounds, optimizes the wound bed for closure, diminishes edema, and enhances the formation and perfusion of granulation tissue through the application of controlled negative pressure via a VAC device[7]. NPWT is indicated in traumatic, acute wounds, sub-acute wounds, chronic open wounds, pressure ulcers, flaps, and meshed grafts[8].

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Therefore, the current study aimed to determine the cutoff value of ABPI at which DFUs benefit from VAC applications.

PATIENTS AND METHODS:

The study was registered at clinicaltrials.gov (ClinicalTrials.gov Identifier: NCT06000371) and received approval from the Institutional Review Board (under code number MS.20.03.1083)[9].

This single-center prospective observational study was conducted in the Department of Vascular Surgery at a tertiary teaching hospital in Mansoura, Egypt, between March 2020 and May 2021. The study included 56 diabetic patients, compromising one group.

The inclusion criteria consisted of patients aged 40 years or older with DFUs classified as grade I or grade II in wound and infection classes of the WIFI classification (Figure 1). Cases of immunodeficiency, varicose veins, chronic venous insufficiency, and foot ulcers belonging to grade III (Figure 1) were excluded.

Figure 1: Foot ulcers according to wound category of the WIFI classification.

We recruited participants from patients attending our outpatient clinic. We communicated with our patients via phone calls. Patients were monitored following each VAC session (4-6 days) across three sessions (up to 3 weeks). Recruitment of patients continued until the target sample size was achieved over 11 months. All participants in the study provided written consent.

The patients underwent history taking, such as foot ulcer, amputation, manifestations of claudication, neurological deficit, vascular surgeries, and associated comorbidities. The ulcer characteristics regarding site, shape, and boundaries were also evaluated.

The symptoms and signs of infection, such as redness, hotness, edema, or pain, were examined.

A comprehensive neurologic and vascular examination was conducted on all included feet.

Duplex U/S on the arteries was performed for all cases, with an *X*-Ray indicated for cases with higher suspicions of infection, and CT angiography was utilized when duplex results were not conclusive (Figure 2).

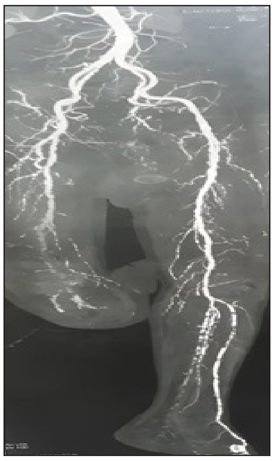

Figure 2: Computed tomography angiography showing highly calcified arterial systems of both lower limbs, mainly in the infragenicular portion.

Procedure description

The procedure was done as an outpatient practice. Before VAC (Smith& Nephew Renesys EZ plus NPWT device Hull HU3 2BN, England) application, ABPI was measured and recorded with Bistos hi dop vascular Doppler with 8-MHZ probe (Bistos Co., Ltd. Gyeonggi-do, Korea) and sphygmomanometer (ALPK2, 300v velcro cuff, Japan) following the procedures outlined by the ACC and the AHA guidelines[10]. Ulcer preparation was performed through debridement of devitalized tissue, maintaining appropriate haemostasis, and performing wound irrigation by using NaCl 0.9% (Figure 3).

Figure 3: Debridement of devitalized tissues with proper hemostasis.

The ulcer's dimensions, including length, width, and depth, were measured and recorded with a metal ruler. Gentle filling of the ulcer by foam was conducted, maintaining the foam's position just beyond the ulcer's margin. The drain was placed between foam layers. The drape was sized and trimmed to cover the whole ulcer, with about four cm of intact skin around it. The drape should not be stretched. Adhesive plaster was utilized at the margins to keep sealing and negative suction (Figure 4).

Figure 4: VAC application.

The dressing drain was connected to the canister tube. The suction pressure was set at 120mmHg (Intermittent mode). For cases who developed bleeding in spite of proper haemostasis, the pressure was decreased to 10 mmHg. The power button was activated to initiate the operation. Each patient participated in three consecutive VAC sessions, lasting 4 to 6 days for each session. The patient received information regarding the disconnection procedures and the maximum allowable disconnection duration of 2 hours daily. The patient or his relative received information regarding the causes of the alarm, such as low pressure, full canister, line blockade, and low battery, along with management strategies for these issues. A single vascular surgeon measured the length, width, and depth using a metal ruler after each VAC session every 4 to 6 days over three consecutive sessions without interruption.

Data analysis

The data was fed into the computer and analyzed using IBM SPSS Corp.'s (2021) release, for Windows, version 25.0 (Armonk, New York). Quantitative data was expressed using numbers and percentages. Following the assessment of normality via the Kolmogorov-Smirnov test, quantitative data were described using the median, interquartile range, and the mean and standard deviation for data with normal distribution. The significance of the results obtained was evaluated at the 0.05 significance level. ROC curve was utilized to assess the diagnostic performance or the capability for differentiation between diseased and non-diseased subjects.

RESULTS:

Figure (5) depicts patient flow during the study. The study commenced with 56 patients meeting the inclusion criteria. Fifty patients were monitored until the conclusion of the study. Two patients died, one patient was lost to follow-up, and three cases were excluded from statistical analysis due to elevated ABPI values exceeding the normal value of ABPI.

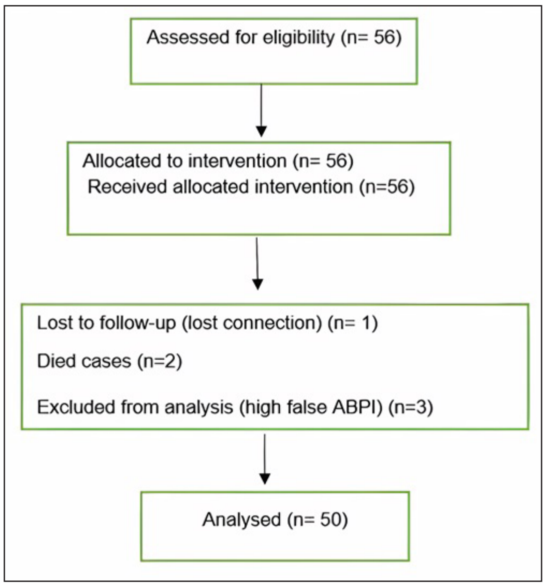

Figure 5: Flow chart showing study design.

Table (1) illustrates the characteristic data of the studied cases. The mean age was 59.42. The male-to-female ratio was 66% to 34%, and the prevalence of smokers among the studied cases was 42%.

Table 1: Characteristics of the studied cases:

	Total number= 50	%
Age/years		
mean±SD	59.42±10.82	
Median (IQR)	59(51.25-69.25)	
Gender		
Male	33	66
Female	17	34
Smoking		
Smoker	21	42
Non-smoker	29	58
Hypertension		
Hypertensive	36	72
Normotensive	14	28
Cardiac disease		
Cardiac patient	22	44
Non-cardiac	28	56
Vascular intervention		
Thrombectomy	10	20
Angioplasty	11	22
Bypass	7	14
no surgery	22	44
length		
mean±SD	8.064±2.44	
Median (IQR)	7.75(6.9-9.0)	

	Total number= 50	%
width		
mean±SD	5.31±1.88	
Median (IQR)	5.15(4.5-6.3)	
depth		
mean±SD	0.758±0.736	
Median (IQR)	0.40(0.3-1.0)	

Furthermore, 72% of the cases examined were identified as hypertensive. Of the cases, 56% underwent vascular interventions at varying ratios.

The follow-up of ulcer length, width, and depth demonstrated significant improvement following each VAC session throughout the study. Length demonstrated the most remarkable improvement after the third session (8.1%), with a total percent reduction after three sessions collectively (18.9%), indicating significant improvement (*P*< 0.001). The most significant improvement in width was observed following the third session, with an increase of 11.1%. The total decrease in ulcer width following three sessions was 28.1%, demonstrating a statistically significant improvement (*P*< 0.001). Ulcer depth exhibited the most significant reduction of 42% following the third session. The total percent reduction in ulcer depth after three sessions was 66.7%, indicating a significant improvement (*P*< 0.001).

Figure (6) displays the ROC curve plotted for the different cut off values of the ABPI. The AUC was 0.762(95% CI: 0.476–1), (Table 2). The AUC was significantly elevated relative to the diagonal reference line (*P*= 0.028).

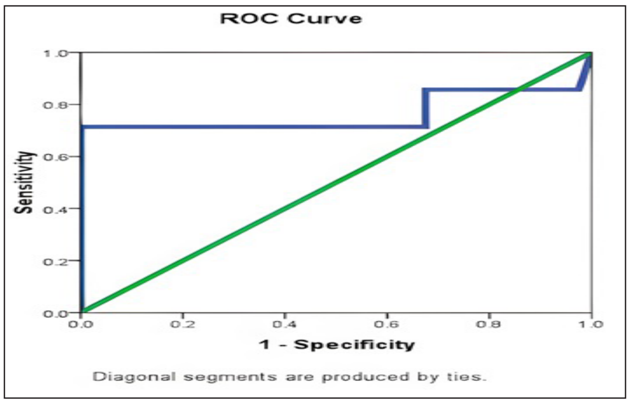

Figure 6: ROC curve of ABPI in predicting improvement of ulcer dimensions.

Table (3) depicts the different cut off values of the ABPI, demonstrating the sensitivity in relation to different values of 1- specificity. The test result variable(s): ABPI before has at least one tie between the positive and negative actual state groups.

Success is defined as a reduction in surface area at the conclusion of follow-up. The optimal cutoff point is identified, resulting in maximal sensitivity and specificity. Due to the absence of multiple factors for regression analysis, we used the ROC curve to detect the optimal cut-off value for diagnosis.

Table 2: Validity of ABPI before treatment in predicting ulcer dimensions improvement:

	AUC (95% CI)	*P* value	Cut off point	Sensitivity%	Specificity%
ABPI Before	0.762 (0.476-1.0)	0.028*	0.615	71.4	100.0

Table 3: Coordinates of the Curve:

Positive if less than or equal to	Sensitivity	1 – Specificity
-0.5000	0.000	0.000
0.5250	0.143	0.000
0.5650	0.286	0.000
0.5950	0.571	0.000
0.6150	0.714	0.000
0.6450	0.714	0.025
0.6800	0.714	0.075
0.6950	0.714	0.100
0.7100	0.714	0.150
0.7350	0.714	0.175
0.7750	0.714	0.200
0.8050	0.714	0.325
0.8300	0.714	0.375
0.8600	0.714	0.425
0.8750	0.714	0.450

Positive if less than or equal to	Sensitivity	1 – Specificity
0.8850	0.714	0.475
0.8950	0.714	0.500
0.9100	0.714	0.600
0.9300	0.714	0.625
0.9600	0.714	0.675
0.9900	0.857	0.675
1.0500	0.857	0.900
1.1500	0.857	0.975
2.2000	1.000	1.000

DISCUSSION

Management of DFUs represents nearly 1/3 of the total cost of diabetic care. In spite of high healthcare costs, approximately one-third of the overall expenses are associated with diabetes care. Despite elevated healthcare expenditures, around 20% of patients experience DFUs after one year. DFUs frequently occur post-wound healing, exhibiting a recurrence rate of approximately 40% among patients within one year. Despite the existence of well-established guidelines for the management of DFUs, the treatment of these ulcers remains a significant challenge[11].

Several studies investigated various novel therapies to promote wound healing in patients with DFUs. DFU treatment necessitates a comprehensive approach encompassing lifestyle modification, addressing underlying causes, antibiotic coverage, and proper wound care[5].

The VAC system, or NPWT, involves the continuous or intermittent application of sub-atmospheric pressure to a wound's surface[12]. In addition, it has been shown to increase the rate of granulation tissue formation by up to 40% to 103%, reduce local edema, and significantly decrease wound bacterial counts[13].

This study established the cutoff value of ABPI, which indicates the benefit of VAC applications for DFUs.

Our study demonstrated significant improvements in ulcer length, width, and depth during the follow-up period. The comparison of dimensions before and after VAC applications reveals significant percent changes in length, width, and depth, recorded at -18.9%, -28.1%, and -66.7%, respectively (*P*-value <0.001). Eginton, Brown, *et al.,* reported a significant reduction in ulcer depth following VAC application, with a percent change of -49% and (*P* value <0.05). In contrast, the changes in length and width were non-significant, with a percent change of -4.3 % and -12.9%, respectively[14]. Our study did not include randomized controls; therefore, the reduction in wound dimensions following VAC therapy cannot be compared to those treated with conventional dressings.

Consistent with the current results, NPWT promotes wound contraction through macro-deformation resulting from centripetal forces at the wound-foam interface[15]. Similarly, in a study by James (2019), wound contraction was more pronounced in ulcers exceeding 10cm in diameter, which were deeper and consequently exhibited a more favorable response to the macro-deformation effect of NPWT[13].

The present study demonstrated that ABPI can significantly predict the improvement in the dimensions of DFUs after VAC application. The AUC was significantly elevated relative to the diagonal reference line (*P*= 0.028). At a cutoff point of 0.615, ABPI demonstrated 71.4% sensitivity and 100.0% specificity (AUC= 0.762), confirming its efficacy in detecting the benefits of VAC application for DFU.

A small sample size has been considered the main limitation. However, it was larger than the two comparable studies reported. Although most related studies included a control group, we decided to include all patients as an experimental group. Due to the lack of funds, we used a manual method to measure ulcer dimensions.

All patients with DFUs must undergo an ABPI assessment prior to the application of VAC. Future studies, including larger sample sizes, control groups, and more objective methods for measuring ulcer dimensions, should be conducted soon.

CONCLUSION

Measuring ABPI allows for the prediction of DFUs, which can be beneficial after VAC application.

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CONFLICT OF INTEREST

There are no conflicts of interest.

REFERENCES

1. Bonoto BC., de Araújo VE., Godói IP., de Lemos LLP., Godman B., Bennie M., *et al.* (2017). Efficacy of mobile apps to support the care of patients with diabetes mellitus: a systematic review and meta-analysis of randomized controlled trials. JMIR mHealth and uHealth; 5(3):e4.

2. Yazdanpanah L., Nasiri M., Adarvishi S. (2015). Literature review on the management of diabetic foot ulcer. World journal of diabetes; 6(1):37.

3. Hajibandeh S., Hajibandeh S., Shah S., Child E., Antoniou GA., Torella F. (2017). Prognostic significance of ankle brachial pressure index: a systematic review and meta-analysis. Vascular; 25(2):208-24.

4. Mavrogenis AF., Megaloikonomos PD., Antoniadou T., Igoumenou VG., Panagopoulos GN., Dimopoulos L., *et al.* (2018). Current concepts for the evaluation and management of diabetic foot ulcers. EFORT open reviews; 3(9):513-25.

5. Everett E., Mathioudakis N. (2018). Update on the management of diabetic foot ulcers. Annals of the New York Academy of Sciences; 1411(1):153.

6. Serena TE., Yaakov RA., Mostow EN. (2016). Use of Cellular and Tissue-based Products in the Treatment of Diabetic Foot Ulcers. The Journal of Foot and Ankle Surgery (Asia-Pacific); 3(2):92-6.

7. Lone AM., Zaroo MI., Laway BA., Pala NA., Bashir SA., Rasool A. (2014). Vacuum-assisted closure versus conventional dressings in the management of diabetic foot ulcers: a prospective case–control study. Diabetic foot & ankle; 5(1):23345.

8. Yadav S., Rawal G., Baxi M. (2017). Vacuum-assisted closure technique: a short review. The Pan African Medical Journal; 28:246.

9. Mathew G., Agha R., Albrecht J., Goel P., Mukherjee I., Pai P., *et al.* (2021). STROCSS 2021: Strengthening the reporting of cohort, cross-sectional, and case-control studies in surgery. International Journal of Surgery Open; 37:100430.

10. Aboyans V., Criqui MH., Abraham P., Allison MA., Creager MA., Diehm C., *et al.* (2012). Measurement and interpretation of the ankle-brachial index: a scientific statement from the American Heart Association. Circulation; 126(24):2890-909.

11. Lavery LA., Davis KE., Berriman SJ., Braun L., Nichols A., Kim PJ., *et al.* (2016). WHS guidelines update: diabetic foot ulcer treatment guidelines. Wound repair and regeneration: official publication of the Wound Healing Society [and] the European Tissue Repair Society; 24(1):112-26.

12. Thurston B., Dawson J. (2019). Ankle Brachial Pressure Index: An update for the vascular specialist and general practitioner. Vascular; 27(5):560-70.

13. James SM., Sureshkumar S., Elamurugan TP., Debasis N., Vijayakumar C., Palanivel C. (2019). Comparison of vacuum-assisted closure therapy and conventional dressing on wound healing in patients with diabetic foot ulcer: a randomized controlled trial. Nigerian Journal of Surgery: official publication of the Nigerian Surgical Research Society; 25(1):14.

14. Eginton MT., Brown KR., Seabrook GR., Towne JB., Cambria RA. (2003). A prospective randomized evaluation of negative-pressure wound dressings for diabetic foot wounds. Annals of vascular surgery; 17(6):645-9.

15. Singh B., Sharma D., Jaswal K. (2017). Comparison of negative pressure wound therapy versus conventional dressings in managing chronic diabetic foot ulcers in a tertiary care hospital in North India. Int J Sci Res; 6(8).