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*Original Research Article*

# Efficacy of Vacuum-Assisted Closure Therapy versus Conventional Povidone Iodine Dressing in the Management of Diabetic Foot Ulcers: A Randomized Control Trial

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## ABSTRACT

**Objective:** To equate the effectiveness of vacuum-assisted closure therapy (VACT) with conventional povidone iodine dressing (CTPID) in the management of diabetic foot ulcer (DFU).
**Methods:** It was a 14-day study in which a total of 60 patients were divided into two equal groups (n = 30) using computer-generated random numbers. Group A and group B received VACT and CTPID treatment for DFU, respectively. A sub atmospheric pressure of 100–125 mmHg was applied to the wound in VACT group and povidone iodine-soaked gauze was used for dressing in CTPID group. The wounds were assessed on day 0, 5 and 14 of the treatment for the mean area of ulcer. Culture sensitivity test for bacterial growth was performed on day 0 and 14 to determine the infection status by disc diffusion method.
**Result:** At the end of the study (day 14),mean surface area of the ulcer treated with VACT and CTPID was reduced from 11.21cm$^2$ to 8.6cm$^2$ and 12.24cm$^2$ to 11.30 cm$^2$, respectively ($p$ = 0.029). Two patients of group A and eight patients of group B showed positive growth for gram-positive cocci such as *Staphylococcus aureus*, and gram-negative organisms such as *E.coli*, *Proteus*, *Klebsiella*, *Pseudomonas* and *Enterococcus* on day 14 of repeat culture ($p$ = 0.038).
**Interpretation:** VACT was found to be more effective in treating DFU with respect to healing rate and time when compared to the conventional povidone iodine dressing.

***Keywords:*** Vacuum-assisted closure therapy; povidone iodine; diabetic foot ulcer

## INTRODUCTION

Insulin controls the blood glucose levels; any defect in its secretion or action or both causes diabetes mellitus (DM). Deficiency in insulin production results in chronic hyperglycemia, which in turn causes disproportion in fat, carbohydrate, and protein metabolism. [1] DM is a chronic metabolic condition. It is divided into two primary types-type 1 and type 2. It has been predicted that the number of adults suffering from DM will reach approximately 300 million by 2025. [2]

Foot ulcers are one of the main complications of DM. It is a contributing reason for diabetic patients to be hospitalized in India. Diabetic foot ulcer is a common complication of type 1 and type 2 DM. The World Health Organization (WHO) has defined DFU as 'the foot ulceration seen in diabetic patients with potential risk of ulceration, septicity, and/or damage of the deep tissues related to neurological anomalies, various degrees of exterior vascular disease, and/or metabolic complication due to diabetes in the lower

limb. [3] A range from 4% to 10%of patients identified with diabetes is predisposed to DFU, of which approximately 15% are susceptible to amputation. [4] In recent years, progress in diabetic therapies has abridged the amputation rates.

The management of foot ulcer depends on the severity and vascularization of the wounded limbs. DFU requires appropriate wound care and antibiotic treatment for healing. [5] Conventionally, gauze moistened with saline or other topical solutions was used; however, it was difficult to uphold a moist wound environment essential for wound healing. [6] A good clinical treatment of foot ulcer would involve debridement, revascularization, off-loading, moist wound care, and treatment of infection with antibiotics. [7] Numerous topical routines and devices are available to treat diabetic foot ulcer. The present study compares the effectiveness of vacuum-assisted closure therapy (VACT) with conventional povidone iodine dressing (CTPID) in curing DFU with respect to area of the ulcer and time. VACT or negative-pressure wound therapy (NPWT) is a newer, noninvasive mechanical device, which uses an ideal sub atmospheric pressure. It effectively removes exudates from the tissues and aids in reducing edema. [8] It also improves the blood flow in the wounded area and reduces bacterial colonization. Povidone iodine solution contains antimicrobial properties, which reduces the bacterial load. However, its use has been restricted due to its toxicity, delayed healing process, and systemic absorption. [9, 10]

## METHODOLOGY

Patients were enrolled after obtaining a written consent form and detailed history with relative investigation. They were divided into two equal groups (n = 30) using computer-generated random numbers. Group A received VACT and group B received CTPID. Patients aged more than 18years with type1/type 2 DM and Wagner grade 2 class foot ulcers were included in the study. Patients suffering from osteomyelitis, collagen/ ischemia/ peripheral vascular diseases, malignancy, and having immunocompromised status were the excluded. Ethical clearance was obtained from institutional ethics committee.

Radical debridement was performed before the VACT treatment. The wounds were cleaned and the foam was cut in such a way that it fitted the wound cavity. The drain was placed in a curl manner and the foam was covered with plastic drapes approximately 3–5 cm around the wound tissue. The drain was connected to a vacuum unit with a standard negative pressure being maintained at 100–125mmHg. Dressing was repeated every 48–72 h and carefully assessed if slough had surfaced so that additional debridement can be performed before the new dressing. The treatment process was continued for 14 days at a standard sub atmospheric pressure.

Group B patients' wounds were cleaned with povidone iodine and dressed with gauze soaked in povidone iodine solution.

Wounds were assessed after each dressing by observing various parameters such as size, surrounding skin, site, shape, edge, margin, floor, base, discharge, slough, and ulcer area. On day 0, 5, and 14, wound culture and sensitivity was done on day 0, and day 14. It was performed by disc diffusion method and results were observed and recorded and recorded during treatment.

In order to calculate and compare different areas of an ulcer, a digital image of an ulcer was obtained and processed. The standard square (1 $cm^2$) of the graph and the area of an ulcer is printed black. The black areas were calculated in pixels and the area of an ulcer and standard square are compared to calculate the ulcer area. All statistical analysis was carried out using SPSS version 22.

## RESULTS

The mean age of VACT and CTPID group were 35.7 and 36.4 years, respectively. In group A, 14 men and 16

women were treated with VACT, whereas group B had 18 men and 12 women treated with CTPID. The age ($p$ = 0.184) and the sex ($p$ = 0.301) of the patients were not statistically significant ($p$<0.005).

The mean area of ulcers on day 0 in CTPID group was 12.24cm$^2$ and 11.21cm$^2$ in VACT group. After the application of the respective treatment, the areas of ulcers were measured on day 5 and 14 to check the effectiveness of the two treatments. On day 5, the mean surface area of ulcers was found to be 11.91cm$^2$ in CTPID group and 9.89cm$^2$ in VACT group. At the end of day 14, the mean surface area of ulcers was 11.30cm$^2$ and 8.6cm$^2$ for CTPID and VACT group, respectively (Table 1). Both the treatments showed decrease in the area of ulcers, but patients treated with VACT showed greater decrease in mean area of the ulcer. This decline in the surface area of an ulcer was found to be statistically significant ($p$ = 0.029).

The percentage decrease in the area of the ulcer was 7.38% in CTPID group and 23.26% in VACT group at the end of day 14 when compared to 2.7% in CTPID group and 11.2% in VACT group on day 5.

Culture sensitivity was performed on day 0 and 14. Common micro-organisms isolated from various samples were gram-positive cocci such as *Staphylococcus aureus*, and gram-negative organisms such as *E.coli*, *Proteus*, *Klebsiella*, *Pseudomonas*, and *Enterococcus.*

On day 0, 50% and 60% growth of organisms was seen in the patients belonging to CTPID and VACT group, respectively ($p$ = 0.436). When this was compared with the results obtained on day 14, CTPID group showed 26.7% and VACT showed 6.7% growth ($p$ = 0.038; Table 2).

**Table 1: Summary of mean surface area of ulcer on day 0, 5 and 14**

| | Group | N | Mean | Std. deviation | Std. error mean | *t*-value | *p*-value |
|---|---|---|---|---|---|---|---|
| Area of ulcer on day 0 | CTPID | 30 | 12.24 | 4.666 | 0.852 | 0.815 | 0.419 |
| | VACT | 30 | 11.21 | 5.115 | 0.934 | | |
| Area of ulcer on day 5 | CTPID | 30 | 11.91 | 4.726 | 0.863 | 1.610 | 0.113 |
| | VACT | 30 | 9.89 | 4.958 | 0.905 | | |
| Area of ulcer on day 14 | CTPID | 30 | 11.33 | 4.593 | 0.839 | 2.239 | 0.029 |
| | VACT | 30 | 8.60 | 4.861 | 0.888 | | |

**Table 2: Infection status of an ulcer (culture) on day 0 and 14**

| Culture | | Group | | Total |
|---|---|---|---|---|
| | | CTPID | VACT | |
| Day 0 | No growth | 15 | 12 | 27 |
| | | 50.0% | 40.0% | 45.0% |
| | Growth present | 15 | 18 | 33 |
| | | 50.0% | 60.0% | 55.0% |
| Total | | 30 | 30 | 60 |
| | | 100.0% | 100.0% | 100.0% |
| | | Value | df | *p*-value |
| Pearson Chi-square | | 0.606 | 1 | 0.436 |
| Day 14 | No growth | 22 | 28 | 50 |
| | | 73.3% | 93.3% | 83.3% |
| | Growth present | 8 | 2 | 10 |
| | | 26.7% | 6.7% | 16.7% |
| Total | | 30 | 30 | 60 |
| | | 100.0% | 100.0% | 100.0% |
| | | value | df | *p*-value |
| Pearson Chi-square | | 4.320 | 1 | 0.038 |

## DISCUSSION

The foot, being a multifaceted structure, provides a foundation for the entire body. It is important to prevent DFU, as well as limit the chances of amputation. [11] DFU is an outcome of factors such as failure of sensation due to exterior neuropathy in which the patient's feet become numb and a wound is disregarded. [12] The process of wound healing is complex and involves specific responses from the cell types. These cells port growth factors, which are locally secreted and play a vital role in wound healing. [13] Recent advancement in treating DFU has improved wound healing and limited amputation.

VACT or negative pressure wound therapy (NPWT) is a pioneering technique of treating trauma wounds. It uses sub atmospheric pressure of 100–125mmHg, which is generally accepted in clinical practice. [14] The relevance of NPWT in healing DFU has proved effective in our study. At the end of day 14, a reduction in the mean area of the ulcer was observed (8.6cm$^2$ and 11.30 cm$^2$in group A and group B, respectively). At the end of day 14, 23.26% of the ulcer area was decreased and only 6.7% of the patients showed positive

culture sensitivity growth of organisms when treated with VACT. Similar conclusions were observed from the past studies. [15-17]

Povidone-iodine is a polyvinylpyrrolidone and elemental iodine complex. Iodine has been effectively used as a broad-spectrum antimicrobial agent for more than 170 years. However, its use has been limited due to its cytotoxicity. [18] Iodine dressings involve the slow release of iodine into the wounds. These dressings are only for a relatively short period and require frequent changes. A constant moist wound environment needs to be maintained for quick healing. [19, 20] Previous studies have reported that long-term use of povidone iodine is associated with mild hyperthyroidism, therefore medical supervision in patients with thyroid disease or iodine sensitivity is required. [21]

Research suggests that negative pressure causes an increase in vascular diameter, volume, and velocity of the blood flow. [14] The mechanism of VACT is not thoroughly clear; however, evidence put forward that interstitial pressure gets decreased due to edema reduction, which positively influences lymphatic drainage, oxygen, and also the nutrient availability. By providing a moist environment, VACT promotes formation and development of the blood vessels (angiogenesis), tissue granulation, and stimulates cell proliferation by causing mechanical stress in the wound bed. The treatment should be continued until healthy granulation has formed over the surface of the ulcer. [22]

Therefore, it is crucial to prevent DFU to decrease the rate of limb amputation, as it has a negative impact on quality of life. Regular examination, awareness, precautions, and appropriate treatment of minor injuries can considerably decrease the incidence of DFU. [23,24]

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