



## A STUDY ON COMPARISON OF VACUUM ASSISTED CLOSURE VERSUS NORMAL SALINE DRESSING IN THE HEALING OF DIABETIC WOUNDS

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**ABSTRACT** **Background:** The purpose of this study was to evaluate the clinical efficacy of Vacuum assisted closure compared with conventional normal saline dressing in healing of the diabetic wounds in the form of the rate of granulation tissue formation, duration and cost effectiveness.

**Methods:** This is a prospective interventional comparative study. In this study 30 randomly selected patients were assigned to the study group (VAC-Vacuum assisted closure dressings) and 30 patients to the control group using normal saline dressings all patients were studied and clinical findings were recorded, necessary investigations ordered and appropriate treatment given. All cases were followed up to discharge and subsequently for a follow up on 1st week. All the data were analyzed using the Chi-square test and The Student's T test and the results were tabulated. A "p" value of <0.05 was considered statistically significant.

**Results:** The efficacy of the dressings was compared as the percent of ulcer surface area covered by granulation tissue. The Split Skin Graft uptake was much better in the Vacuum assisted closure dressing group 84.789% ± 4.391 than the normal saline Dressing group 68.75% ± 5.718 which was statistically significant. The mean hospital stay was also significantly lesser in the study group than the control group.

**Conclusions:** The application of Vacuum assisted closure dressing increased the rate of formation of granulation tissue and had better graft uptake than the patients who underwent a conventional normal saline dressing for their diabetic wounds

**KEYWORDS :** Vacuum Assisted Closure(VAC). Normal Saline Dressings, Diabetic Wounds, Negative pressure wound therapy (NPWT),

### INTRODUCTION

The diabetic foot is defined as group of syndromes consisting of neuropathy, ischemia and infection leading to tissue loss resulting in morbidity and possible amputation. Infection in diabetic foot is the worst complication possessing a great burden to the society and to the patient. Over 150 million people worldwide afflicted by diabetes mellitus live in the developing countries. The lifetime risk for ulcers in people with diabetes has been estimated to be 15%.<sup>1</sup>

India is the diabetic capital of the world with 41 million Indians having diabetes. Every fifth diabetic in the world is an Indian.<sup>2</sup> This will increase to about 79.4 million by the year 2030.<sup>3</sup> The prevalence of diabetes is increasing and a leading cause of morbidity and mortality. There were one million deaths due to Diabetes mellitus in 2015.<sup>4</sup> More than 80% of diabetic death occur in low and middle income countries.<sup>5</sup> The annual incidence of foot ulcers with diabetes mellitus is about 2%, with a lifetime risk of 15% to 20%. And every 30 seconds a lower limb is lost due to diabetes. It is the single biggest risk factor for non-traumatic foot amputations.

Many techniques have been tried over the centuries to heal diabetic foot ulcers. There is no ideal wound dressings to manage chronic diabetic foot ulcers. The traditional moist dressings were initially supplemented with hydrocolloid dressings, gels, foams, and other advanced wound therapies like hyperbaric oxygen, topical growth factors, electrical stimulation and various offloading therapies.

Recent studies have shown that application of a vacuum-assisted closure (VAC) therapy by a sub atmospheric pressure in a controlled manner to the wound site has got importance in wound healing. The present study was conducted to assess the efficacy of vacuum-assisted closure (VAC) Therapy dressings as compared to conventional normal saline dressings to improve the healing process in diabetic foot wounds and to prove that vacuum-assisted closure wound dressings is a better treatment option in the management of these wounds.

### OBJECTIVES OF THE STUDY

To compare the efficacy of vacuum assisted closure (VAC) therapy with control group using normal saline dressings in diabetic wound healing in terms of

- The rate of granulation tissue formation from the ulcer bed.
- The rate of reduction in mean ulcer surface area.
- Skin graft take up.
- Cost effectiveness.
- To assess the bacterial load on the ulcer.

### METHODS

This study was conducted among the patients admitted in the ward with diabetic foot wound for the period from January 2015 to December 2015. This is a prospective interventional comparative study. In this study 30 randomly selected patients were assigned to the study group (VAC dressings) and 30 patients to the control group using normal saline dressings.

All patients clinical findings were recorded as per the Performa case sheet and necessary investigations ordered and appropriate treatment was given. All cases were followed up to discharge and subsequently for one week thereafter.

### INCLUSION CRITERIA:

Patients admitted with diabetic foot wounds below the knee during the study period

1. Age 30- 80 years
2. Ulcer area ranging between 10 sq.cm and 100 sq.cm
3. Diabetes mellitus made by American diabetes association criteria.

### EXCLUSION CRITERIA:

1. Patients with age <30 or >80 yrs.
2. Patients with evidence of an obvious septicaemia / osteomyelitis
3. Patients with wounds resulting from venous insufficiency / malignancy
4. Patients with corticosteroids / immune suppressive drugs /

- chemotherapy
- 5. Patients with other serious co morbid illness –cardio vascular / pulmonary / immunological diseases
- 6. Patients with ischemic ulcer
- 7. Wounds sites other than lower limb

**Sample size**

60 cases were studied during this scheduled period. They were divided into Group A and Group B

The patients were allocated randomly into 2 groups Study group(A)Received vacuum assisted closure dressing ,Control group(B) Received daily dressing changes with saline-moistened gauze.

Wounds of the subjects included in this study underwent initial sharp debridement to remove necrotic tissue and slough as much as possible.

After the debridement, foam-based dressing was done over the wounds of the study group under aseptic conditions. The dressing was covered with an adhesive airtight seal. A drain tube embedded in the foam was connected to a fluid collection canister contained within a portable vacuum/suction machine or wall mound suction. Negative pressure was applied with a range of 50mmHg-125mmHg continuously for 48 hrs, then intermittently (5 min on and 2 min off),then dressing changed once in two to three days

Subsequently the control group received daily saline-moistened gauze dressing.

Weekly cultures were taken from the ulcers. Broad spectrum antibiotic regimens were administered to all the patients initially and later changed according to the culture sensitivity. Ulcer was treated until the wound ready for skin cover or spontaneous closure.

The amount of granulation tissue as percent of the ulcer floor

covered was assessed at the end of 7<sup>th</sup> ,14<sup>th</sup> , 21<sup>st</sup> and 28<sup>th</sup> day. Once the ulcer showed evidence of healing / good granulation tissue skin grafting was done.

Upon discharge the patient was advised regarding diabetic diet to be followed, diabetic medication insulin/OHA's, foot care and followed for 1 week immediate post discharge. The mean rate of granulation tissue formation, graft survival and hospital stay were calculated and compared for both groups.

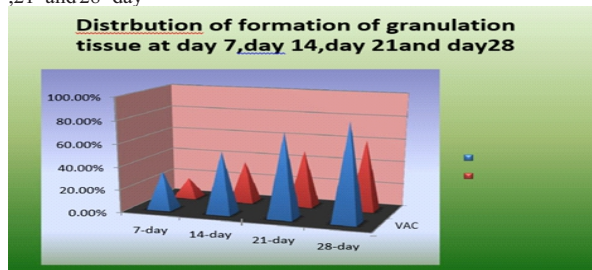
**RESULTS**

In our study 14(46.6%) of the patients in Group I were suffering from diabetes for > 5 <= 10years as compared to 13 (43.3%) of the patients in Group II. The mean duration of suffering from Diabetes was 94 months in Group I when compared to 107.2 months in Group II.

The discharge from the ulcers on admission was analyzed to determine the most common organism causing the infection. -Staphylococcus aureus was the most common organism to be found on culture.

In this above study, wound cultures taken from base of the wound after 14 days of the dressing. In VAC study group there was significant reduction of bacterial count and negative culture on compared with control saline group and p value <0.001 its statistically significant.

Percentage of granulation tissue formation on the wound on 7<sup>th</sup> , 14<sup>th</sup> ,21<sup>st</sup> and 28<sup>th</sup> day



On the 7th day the patients in the VAC study group had mean granulation tissue over the wound 33.5% in comparison with 17.3% of the patients in the control saline group. On day 14, the patients in the

VAC study group had 54.17% mean granulation tissue their ulcer floors when compared with 36.0% mean granulation tissues in the control saline group.

A similar result was seen on day 21 with 8 patients in the study group already having some form of surgical therapy for skin closure and of the remaining 22 patient's had 73.86% mean granulation tissue their ulcer. The control group had 49.1% mean granulation tissues.

By the 28th day of the study 18 patients had already undergone treatment for their diabetic foot like split skin grafting, secondary suturing. The control group still having 61.15% means granulation tissue on the ulcers.

In this above study there is significant difference between two groups and P value <0.001 and statistically significant

**(%) PERCENTAGE OF GRAFT (SSG) UPTAKE**



The mean graft up take in VAC Group was 84.78% ± 4.39 (standard deviation) and in SALINE Group was 68.75%± 5.098 (standard deviation).

**NUMBER OF DRESSING DURING HOSPITAL STAY-(VAC DRESSING ONCE IN 2-3 DAYS AND SALINE DRESSING -DAILY)**

TYPE OF DRESSING	NO. Patients	Mean	Std. Deviation	Std. Error mean	Significance
VAC	30	6.57	1.960	0.358	P=0.000<0.001
SALINE	30	28.87	7.500	1.369	

Table - 1

Above table shows number of dressing in VAC group mean dressing 6.57 and saline group mean dressing 28.87. It reflected the cost of dressing and P value <0.001 and statistically significant

In VAC Group 22 (73.3%) of the patients had a GOOD uneventful recovery, 08(26.7%) had a satisfactory recovery. Where as in SALINE Group 18 (60 %) had a GOOD recovery, 12(40.0%) had a satisfactory recovery.

**DISCUSSION**

The modern dressings are designed to promote and to maintain a moist wound environment in the different phase of the wound healing. The traditional dressing has several disadvantages compared with newer dressings.

The modern dressing not only provides moist environment and also reduces the contamination, minimises the trauma to delicate wound tissues and reduces the treatment cost for which the newer dressing designed to be left for several days over the wound.

This study is in agreement with multiple other studies that state that VAC therapy is superior to conventional dressings for the management of Chronic diabetic foot ulcers.<sup>6,7,8,9</sup>

The explanation of the success of the use of the VAC is found in the work of Argenta and Morykwas, that postulated that this new treatment technique removes excess interstitial liquid, increases angiogenesis, decreases bacterial colonization, and increases the formation of granulated tissues as a response to the stimulus of the mechanical forces created by the negative pressure transmitted through the sponge.

Our study compared with the existing similar study conducted by Joseph et al., and Peter A Blume et al. In our study the rate of granulation was faster in VAC therapy group observed on the 7th, 14th, 21st, and the 28th day, the ulcers in the study group showed evidence of granulation tissue on an earlier date than the control group.

On the 7th day the patients in the VAC study group had mean granulation tissue of about 33.5% in comparison with 17.3% of the patients in the control saline group. On day 14, the patients in the VAC study group had 54.17% mean granulation tissue on their ulcer floors when compared with 36.0% mean granulation tissues in the control saline group.

A similar result was seen on day 21 with 8 patients in the study group already having some form of surgical therapy for skin closure and of the remaining 22 patients had 73.86% mean granulation tissue over their ulcer. The control group had 49.1% mean granulation tissues.

By 28th day of the study 18 patients had already undergone treatment for their diabetic foot like split skin grafting or secondary suturing. The control group still having 61.15% mean granulation tissue on the ulcers needing further treatment.

A mean duration of hospital stay in the vacuum assisted closures study group was  $26.73 \pm 5.232$  days as compared to  $36.70 \pm 9.703$  in the saline control group. Thus indicating a shorter duration of hospital stay in VAC therapy when compared to the latter group.

This above study revealed that application of Vacuum Assisted Closure dressing over the ulcer surface can reduce the ulcer size and depth and promote ulcer healing to a greater extent than conventional normal saline moist wound dressings.

In our study, the percentage of successful graft up take was  $84.78 \pm 4.39$  in the Vacuum Assisted Closure groups compared to  $68.75 \pm 5.09$  in the control saline group ( $p < 0.001$ ). Enhanced vascularity, reduced wound edema, reduced bacterial growth in the former group all favoured better up take of the graft.

This study is in agreement with multiple other studies

#### MECHANISM OF VAC THERAPY

##### 1) MOIST ENVIRONMENT

A moist wound bed facilitates re-epithelization, availability of matrix material, growth factor activity, and potential for wound healing and suggested that VAC therapy provides a moist-healing environment is favourable for the repair process.

##### 2) EDEMA REDUCTION

Localized edema results in increased interstitial pressure and occlude microvasculature and lymphatic drainage, that leads to decreased nutrients and oxygen delivery.

##### 3) INCREASED BLOOD FLOW

Morykwas et al<sup>34</sup>, reported the effect of TNP therapy on the blood flow in pigs. and. Worldwide, a negative pressure of 125 mmHg became the baseline setting for the treatment of all kind of wounds.

##### 4) ANGIOGENESIS AND GRANULATION TISSUE FORMATION

Chean et al<sup>36</sup> noted that VAC Therapy increased the capillary blood flow velocity, capillary caliber and blood volume, stimulated the endothelial proliferation and angiogenesis, endothelial spaces were narrowed, and the integrity of the capillary basement membrane were restored.

##### 5) Alterations in bioburden

The effect of VAC in this regard remains controversial with some studies suggesting a decrease in local bioburden while others that state no significant difference.<sup>10,11,12</sup> The effect of NPWT on bacterial load remains an area to further explore, particularly in terms of the variety of responses that may be elicited by different strains.

#### CONCLUSION

In our study it was found that the application of Vacuum assisted closure (VAC) dressing increased the rate of formation of granulation tissue and had better graft up take than the patients who underwent a conventional normal saline dressing for their diabetic foot ulcers. The patients in the study group had better patient compliance and had a shorter duration of hospital stay and less cost when compared to the control group. This vacuum assisted closure -wound dressing can be considered as a superior option in the management of diabetic foot ulcers, especially complex diabetic wounds like exposed bones and tendons and also reduced reconstructive surgery like flap cover to simple skin graft and the amputation rate. But further studies with larger population will be needed in the future before the application of the vacuum assisted closure dressing can be added to the wide

spectrum of treatment modalities available in the management of diabetic foot.



Figure :1 after VAC therapy



Figure :2 complete wound healing after VAC therapy

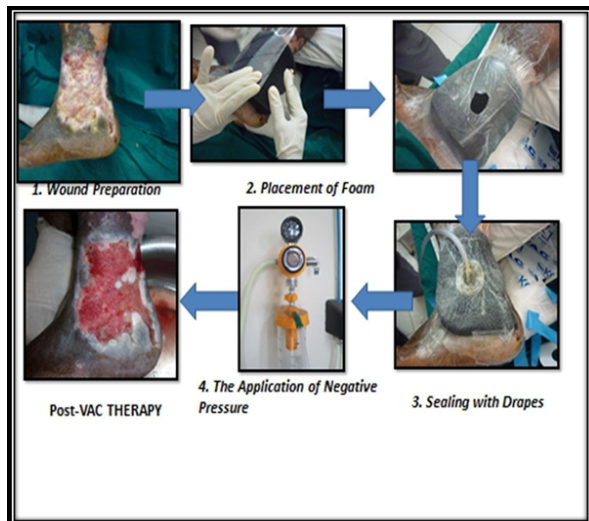


Figure 3; CLINICAL PHOTOGRAPHS APPLICATION OF VAC THERAPY

#### DECLARATIONS

No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee

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