



VACUUM ASSISTED CLOSURE THERAPY IN MANAGEMENT OF CHRONIC NON-HEALING ULCER IN TERTIARY CARE CENTRE -A RANDOMIZED CONTROLLED STUDY

General Surgery

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ABSTRACT

Background: Chronic non healing Ulcers pose a significant and challenging health as well as economic problem, as it needs long term surgical and nursing care whether it is a Burn wound, Diabetic ulcer or pressure ulcer. Ulcers are also susceptible to complications like infection and thus sepsis and limb loss. Vacuum-assisted closure (VAC) is an alternative method of wound management, which uses the negative pressure to prepare the wound for spontaneous healing or by lesser reconstructive options. All this improves the possibility of primary closure of wounds and reduce the need for plastic procedures. **Aim:** To study about wound healing using Vacuum Assisted closure therapy in management of non-healing ulcer in tertiary care centre. **Methods:** 50 patients who are admitted with chronic foot ulcers in General surgery department, Kanyakumari medical college are included during the study period from July 2022-march 2023. The patients are randomized in to two group with 25 patient on conventional therapy and 25 patients as study group with V.A.C. The results were tabulated and analysed. **Results:** Out of 25 non healing ulcer patients, in more than 92 percent patients (23patients) granulation tissue was achieved by VAC dressing at the end of 5th Week. All 23 cases were discharged, 2 cases were followed by split skin graft and only one case was amputated. No mortality. However in the control group only 19 patients were healed, 4 cases went for amputation and there were two mortality. The V.A.C impact on Microbial flora is very significant and duration of hospital stay is also significant. **Conclusion:** VAC therapy appears to be an effective and feasible alternative method in the management of chronic non-healing ulcers.

KEYWORDS

non healing foot ulcer, Vacuum Assisted closure therapy, chronic ulcer.

INTRODUCTION

Delayed wound healing particularly in chronic non-healing ulcers and in elderly with co morbidities is a major concern. It leads to the pain, morbidity, prolonged treatment, and require major reconstructive surgery which imposes enormous social and financial burden. Vacuum-assisted closure (VAC) can be used as an alternative to the conventional methods of wound management. Use of negative pressure optimizes the wound for spontaneous healing or by lesser reconstructive options. (1) The vacuum-assisted closure is a non-pharmacologic/ non-surgical means for modulating wound healing; it was first proposed by Argenta and Morykwas in 1997. (2) The application of vacuum reduces oedema, infection and increases local blood flow which promote healing. (3) 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.

Protocols for the use of V.A.C. therapy require tailoring specifically to the requirements of each individual patient. The protocol depends on the objective of the treatment. When the objective is to fill a wound cavity with granulation tissue then, the regular dressing changes shall be at two-day intervals. To achieve the objective is to hold a skin graft in place then the dressing is left in situ at a lower pressure of approximately 75mm Hg for five days. When ulcers requiring a flap reconstruction are subjected to V.A.C therapy, the wound size will be sufficiently reduced and good granulation tissue is formed, thereby producing a healthy wound bed that can be closed with a skin graft instead of a complicated flap reconstruction.

It is noted, to reduce the complication of pain associated with changing the dressings at 48-hourly intervals can be handled by the application of saline or lignocaine to the points of adhesion between the wound and dressing. When it is found out that the foam and adhesive layer is not effective in absorbing the exudates, the V.A.C therapy is to be discontinued, otherwise, it will finally end in a macerated and engorged wound. V.A.C therapy can be continued till the objectives of wound therapy have been reached or if infection or a lack of progress is noted.

MECHANISM OF ACTION

- By the enhancement of capillary blood flow, the vascularity of the

wound bed is increased, resulting in increased neo-angiogenesis with profuse granulation tissue formation

- The number of active fibroblasts and macrophages is increased along with epithelial cell migration
- The bioburden a, bacterial toxins, toxic metabolic products and the harmful fluid collections impairing the healing process are decreased
- Decompressed excess interstitial fluid with subsequent decreased microvascular occlusion, inelasticity, and peri-wound induration.
- Provision of an optimum normothermic wound environment that augments epithelization and synthesis of growth factors and as the number of dressing changes is reduced it decreases the damage to delicate new tissue
- The mechanical approximation of wound edges promotes primary healing
- Due to the stretching of tissues viscoelastic flow is promoted with distraction histogenesis and resulting persistent stimulation of the cytoskeleton that causes subsequently enhanced mitosis
- Decreased shear forces at the graft site during the stage of inosculation via uniform wound bed immobilization
- Decreased seroma/hematoma of grafts and flaps
- Bacterial clearance demonstrated by the decreased organism counts by day 5 of therapy.

Chen and colleagues (4) showed that even though VEGF was not present in the wound fluid, the vascular endothelial cell growth factor (VEGF) pathway was stimulated by the V.A.C therapy by the shear stress. The studies by Morykwas M (1) have shown, shear stress may have an independent effect on wound-healing pathways by up-regulation of a variety of kinases involved in wound-healing pathways in response to deformation. Stimulation of shear stress events in wounds ends upon enhanced wound healing.

In his book on vacuum therapy, published in 2006, Willy cites five mechanisms by which V.A.C therapy helps in the process of wound healing:

- Retraction of wound surface
- Stimulation of granulation tissue formation,
- continuous wound cleansing after adequate primary surgical debridement,

- continuous removal of exudate
- reduction of interstitial oedema.

MATERIALS AND METHODOLOGY

Total 50 Patients of both sexes with chronic non healing foot ulcers admitted in the Department of General Surgery, Kanyakumari Government Medical College, Tamilnadu, are grouped in to two of each 25 case arm with odd or even linear series method. The control group was treated with the conventional dressing using wound healing growth factors and the study group with the V.A.C therapy. Both groups were subjected to same optimization of wounds procedure.

It is prospective Randomized control interventional study carried out from July 2022 to March 2023 with appropriate ethical clearance and consent.

Inclusion Criteria:

- Patient of both sexes from 18 years and above
- Ulcers of Wagner's grade II-III
- Patients with crush injuries, burns, flap injuries, animal bites and frost bites.
- Venous or arterial ulcers

Exclusion Criteria

- Patients with malignant wounds
- Wounds with exposed arteries or veins.
- Patients on anticoagulants or with actively bleeding wounds.
- Patients on corticosteroids, immunosuppressive agents, or chemotherapeutic agents and patients with poorly controlled medical problems

PROCEDURE :

Patient selected for VAC therapy undergoes wound debridement and haemostasis is achieved. Pre VAC culture and X-ray to rule out active osteomyelitis is taken. A piece of pre sterilized foam (about one cm in thickness) is cut to the size of the wound and is placed on it. Then a perforated drainage tube is put on it. Again a piece of foam is placed on the underlying foam and tube. The whole foam with tube is covered with a sterile transparent dressing (opside). The tube is connected to a Vacuum Pump. Suction is applied with a negative pressure of 100 to 125 mm of Hg for 10 minutes hourly for 12 consecutive hours. Rest of the time this drainage tube is connected to the collecting bag in the vacuum pump. Dressing changed after 72 hours and post VAC culture is taken. There cycles of dressings and vacuum are applied statistical assessment is done using outcome variables. Wound cultures were taken every week and antibiotics changed as per culture and sensitivity reports. The progress of the wounds was monitored and tabulated.



Figure 1: Procedure and outcome of VAC therapy

The data were analysed using computer software, statistical package for social sciences (SPSS) version 12. P value less than 0.005 were considered as significant.

RESULTS:

Among the 25 patients in the study arm, 14 patients (56%) were male and 11 (44%) patients were female. The age distribution was evenly distributed with 26.6% each in the categories 46-50 years, 51-60 years and 61-70 years respectively in both the group. There is no significant difference in the demographic pattern of Age and sex in two group.

Table 1 : Gender And Age Distribution

	CONTROL group N= 25		STUDY Group N=25	
35 Years	0	0	0	0
35-45 yrs	3	3	2	2
45-50 yrs	3	3	3	2
51-60	2	2	4	3
61 and above	5	4	5	4
	13	12	14	11

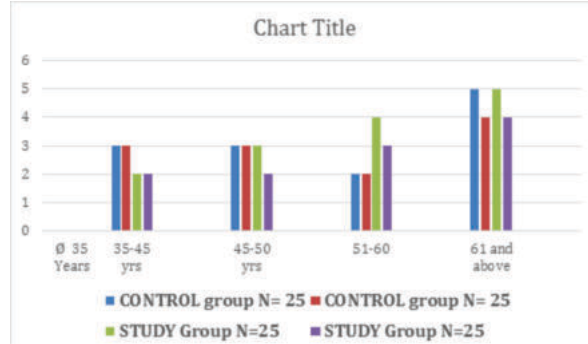


Fig: 2: Gender And Age Distribution

Among the included patients in both groups the male female ratio are almost equal with marginal increase in Male candidates. The mean age of both the group are compared and have no statistically significant difference. However the hospital stay for the treatment was statistically significant among the groups. The data shown in Tab 2:

Table 2: comparison Of Mean Age And Duration Of Hospital Stay (Days) Between Cases And Controls

Parameter	Group	Mean	+ SD	t value	p value
Age (years)	Control	57.2	8.1547	0.159	>0.05
	Cases	56.8	9.2331		
Duration of Hospital Stay (Days)	Control	31.5	9.3897	3.131	<0.01
	Cases	21.2	9.1287		

The patients were subjected to Vascular assessment with doppler. 74 percentage of the patients in both the groups shown normal flow pattern and 26 percentage of patients had vascular impairment in the form of monophasic flow. Chi-square test shows study is not significant as 'p' value is more than 0.05 and the values are tabulated in table 3.

Table 3: Vascular Impairments In The Patients

Doppler Finding	Group		Total	Chi Square:	P value
	Control	case			
Normal	19 76.00%	18 72.00%	37 74.00%	0.104	P> 0.05
Vascular Impairment	6 24.00%	7 28.00%	13 26.00%		
	25	25	50		

Etiology of ulcer:

Among the 25 patients in the study group 67% of the patients had the chronic non healing ulcer due to Type 2 Diabetes Mellitus, 26% patients due to vascular causes and 7 percent. There was no statically significant difference in the aetiology in both the groups. The data are tabulated in Table 4.

Table 4: Etiology Of The Ulcer

	Control group	Perce ntage	Study group	Perce ntage	Chi Square	P value
Diabetic	17	68	15	60	0.114	P> 0.05
Vascular impairment	6	24	7	28		
Trauma	2	8	2	8		
Miscellaneous	-	0	1	4		
Total	25	100	25	100		

Impact on the Microbial Patterns:

As reported by Morykwas MJ, Argenta LC, Shelton – Brown EI, et al, the effect of VAC therapy on the microbial culture was studied . It showed it show a significant impact on altering and reducing the microflora in the wound when vac therapy is applied . In the culture before VAC 80% of the patients shown poly microbial growth pattern and but after three settings of the VAC therapy , 92 percent of the patients shown no growth .

Table 5: Impact On VAC Therapy On Microbial Culture

Culture Sterility in cases	Group Pre VAC	Post VAC	Total	Chi-square	P - value
Sterile	5 20%	23 92%	28 56%	26.2961	< 0.001
Non sterile	20 80%	2 8%	22 44%		

Analysis Of Outcome Of VAC Therapy

Out of the 25 patients, 23 patients (92%) had good granulation and discharged on the mean average of 3 weeks . Among the 23 patients 4 patients underwent SSG .

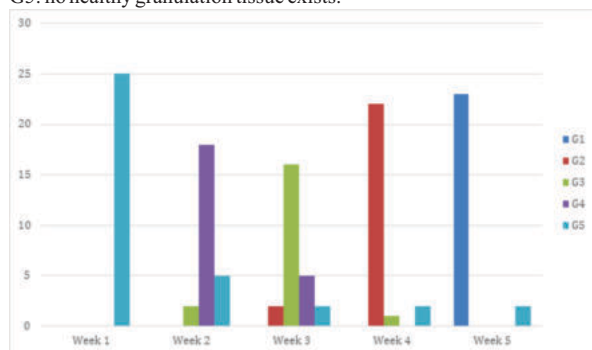
Two patient (8%) underwent amputation due to poor wound healing. However in the conventional therapy the duration of treatment is prolonged more than 5 weeks ,with only 76 percentage of the patients had good granulation tissue and 16 percentage of the patients had undergone amputation as the wound could not be healed.

Table 6: Outcome Of The Treatment

	Study Group	Control group	P value
Healed	23	19	< 0.005
Amputation	2	4	
Mortality	nil	2	
Hospital Stay	3 weeks	5 week	

COMPAIRISON ON THE PRESENCE OF GRANULATION TISSUE

G1: healthy granulation tissue occupies 90 % or more
G2: healthy granulation tissue occupies 50 %- 90%
G3: healthy granulation tissue occupies 10- 50 %
G4: healthy granulation tissue occupies less than 10 %
G5: no healthy granulation tissue exists.

**Fig 3: Presence Of Granulation Tissue In Each Week****DISCUSSION**

Vacuum-assisted closure (VAC) is a method of decreasing air pressure around a wound to assist the healing. It's also referred to as negative pressure wound therapy. VAC therapy can help healing in several ways, such as reducing swelling, stimulating the growth of new tissue, and preventing infections. (5-9)

In our study we found that there was 80% patients showed improvement in the second week. 15 patients progressed from G5 to G4 and 2 patients had still better granulation and progressed from G5 to G3. In week 3 we could see 73.3% of patients progressed from G5 to G3. In week 4, 86.6% of patients progressed from G5 to G2. Finally at the end of 5th week, we had 92% patients progressing well and attaining good granulation G1 stage among which 2 patients had excellent improvement of wound that they were followed up for Split Skin Graft. 2 patient (8%) didn't have any improvement in the progression of the wound and healthy granulation tissue was not formed in spite of effective treatment for 5 weeks. This patient was proceeded with limb

amputation after 5 weeks. However 4 patients in the conventional group ended with amputation .In the study group there was no mortality , however in the control group 2 patients succumbed to the disease.

Hence Vacuum Assisted Closure therapy can be used as an effective method of treatment as it shows promising results in this study.

Chronic non healing ulcers follows a multidisciplinary approach in its treatment. It depends on many factors like general condition of the patient, glycaemic control, co-morbidities of the patient and various other factors. Hence it is to be noted that appropriate use of sub-atmospheric pressure dressing therapy to achieve a rapid granular bed in diabetic foot wounds may have promise in treatment of this population at high risk for amputation (12)

There has been rapid adoption of vacuum Assisted Closure therapy to treat many acute and chronic wounds due to their promising results (10) Studies have shown that the pressure applied during VAC therapy also plays a major role in the healing of ulcers (11). Hence optimisation of the negative pressure also to be taken into account.

CONCLUSION

VAC therapy shows promising results and is an effective method of treatment for non-healing ulcer wounds and can be used as an alternative therapy in the management of chronic non healing ulcers. Negative pressure therapy stabilizes the wound environment, reduces wound oedema/bacterial load, improves tissue perfusion, and stimulates granulation tissue and angiogenesis. V.A.C is a cost effective adjunct or alternate to surgery in variety of wounds and helps in decrease morbidity, duration of hospitalization and increase patient comfort.

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