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VAC (Vacuum assisted closure) in the management of chronic non-healing wounds: Institutional study

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Abstract

Background: The management of chronic non-healing wounds has always been a cause of concern for the patients and treating team as well. There had been a marked increase in patients presenting with chronic non-healing wounds of varied etiology. The conventional methods of treatment have been in use traditionally include different medicated dressing application since the long-time yet desired results are not achievable always and some other applications like collagen are mostly not affordable to the poor local population. Vacuum-assisted closure using negative pressure being considered as a suitable alternative management for treating chronic non-healing wounds and the results are comparatively better in relatively lesser time than the conventional techniques.

Objective: To assess the impact of (VAC) in the management of non-healing Ulcers
To compare the advantage of VAC over conventional dressings in ulcer management

Methods: Prospective controlled study of 60 patients aged between 40 and 60 were randomly divided into two groups (Wagner grade 2-5) VAC dressing was kept for over 2-5 weeks. Ulcers were treated until the wound closed spontaneously, surgically or until completion of the 50 days, whichever was earlier.

Results: By the seventh week, discharge disappeared in 94 % in VAC and only 56 % in conventional dressing group. Granulation tissue appeared in 100 % of patients in the VAC group and only 63 % in the conventional dressing group. The patients treated with VAC dressing in our study showed comparable wound reduction capabilities with an average wound size reduction of 58 % in comparison to conventional dressing group which had an average wound size reduction of 26 %. Majority of wounds in the VAC group got closed in 7 weeks. Patient satisfaction was very good in the VAC group compared to those patients managed with conventional dressing group.

Conclusion: The application of VAC is feasible, reliable and affordable with a better outcome in the management of chronic non-healing ulcers.

Keywords: VAC, chronic non-healing ulcers, granulation tissue, wound healing

1. Introduction

Vacuum-Assisted Closure (VAC) helps in wound management, preparing wounds for future surgery if planned, reduction in surgical site infections and accelerate wound healing reduce hospital stay and complications [1]. NPWT works by draining fluid from wounds gradually through air and watertight dressing which is transparent with a tube connected to a transparent canister. Negative-pressure wound therapy (VAC) is a technique to achieve better-wound healing in patients with non-healing wounds especially of the lower limb (diabetic ulcers) that fail to heal on their own (primary healing) [2] Non-healing of ulcers is not only a significant health problem, for the patient himself but also add to the social and financial burden to the family. A chronic wound is one which requires a prolonged time to heal, recurs after initial healing or does not heal. (Kranke *et al.* 2003). The prevalence of chronic wounds increases with age with as with advancing age there is a gradual decline in the sensory nerves function which plays an important role in tissue repair [3]. In diabetic patients, lower limb ulcers progress into chronic non-healing ulcers in 10–25 % of cases, and management of a diabetic foot ulcer is often a challenging problem. Healing of these ulcers often takes a long time and may need one or more debridement. The treatment of such ulcers, therefore, needs time with a prolonged hospital stay, intensive wound management, rehabilitation and high recurring hospitalization costs [4]. The optimal topical therapy for non-healing lower limb ulcers remains poorly defined though saline-moistened antibiotic gauze has been the standard method however, it has been difficult to continuously maintain a moist wound environment with these dressings. Subsequently, various dressing techniques like growth factors, hydrocolloid wound gels, enzymatic debridement compounds, hyperbaric oxygen therapy, cultured skin substitutes, and other wound therapies have been advocated. All of these therapies are expensive and time-consuming also and there is

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little scientific evidence to support their efficacy [5].

Results of VAC indicate that this therapy is less costly and more effective than traditional dressings. Despite advances in the management of ulcers, healing of difficult chronic wound continues to be a challenge. NPWT is a technique that uses foam dressing (VAC) that is put inside the wound cavity and applying negative pressure of 120–130 mmHg [6]. Over the years several advanced wound care products have been developed, all to achieve wound bed optimization for eventual wound closure. Negative pressure wound therapy (NPWT) using the vacuum-assisted closure (VAC) has shown good results in the management of non-healing ulcers. VAC therapy has gained increasing popularity for the treatment of chronic and complex wounds. The VAC has been shown to accelerate wound healing by reducing local tissue oedema, promoting granulation tissue formation, increasing local blood flow, and decreasing bacterial burden in both animal and clinical studies [7]. This prospective case-control study to evaluate the role of VAC in comparison to conventional dressings in the healing of non-healing ulcers in lower socio-economic group patients.

2. Materials and methods

Prospective randomized control study conducted in the Department of General Surgery at KIMS catering to surrounding rural population predominantly. This study was conducted for one year between March 2018 and February 2019. 60 patients were treated for non-healing lower limb ulcers Wagner grade 2 or 3. Ulcers were graded by the Wagner system of grading. The study population was made up of 30 male subjects and 30 female subjects with a mean age of 50 years (range, 40–60 years) (Tables 1). The study population was randomized into group A (patients managed with VAC) and group B (with conventional dressings), with an equal number of patients in each group (n = 30). VAC and the conventional dressing was done for a period ranging from 2–7 weeks. Treatment continued till the wound closed spontaneously, or surgically whichever was earlier. After discharge patients were followed up regularly for recurrence once in fifteen days for 6 months. Treatment considered a success if wound healed completely. Control group received conventional dressing consisting of placing saline-soaked gauze over the wound bed after thorough cleaning and layers of sterile gauze placed on the dressing and secured with bandages. Patients were assessed till wound healing is complete, defined as 100% granulation and fit for split skin grafting was achieved. The parameter for the primary outcome is considered was time taken for complete wound healing, and the secondary outcome was granulation tissue formation using the visual analogue score and complications like pain and infection. Only healthy granulation tissue was considered for scoring assessment. No granulation was given a score of 1, <25% granulation cover Score 2, score 3 was given for 25%–74% of granulation tissue and wounds with 75%–100% granulation tissue cover was given a score of 4. The pain was assessed using a similar score, which was done once in two days and a mean value was calculated for each week and analysed. Wound infection was assessed by wound culture sensitivity which was done weekly.

2.1. Preparation of wound was done in all patients in study

Step 1: wound bed

Wound culture swab did before wound irrigation with normal saline. Followed by minor surgical debridement and haemostasis achieved.

Step 2: Placement of foam

Sterile, foam dressing placed into the wound cavity for an even

distribution of negative pressure over the wound bed to aid in wound healing. This foam is lighter, easily collapsible and hydrophobic with a pore size of 400 to 600 mm. It is used when the stimulation of granulation tissue and wound contraction is required. Suction tube embedded in the foam (Picture 1.), then connected to a controlled vacuum pump with a gauge meter for control of pressure. Pressure range normally used was between 120 to 130 mmHg. Sealing of the wound then done by placing an adhesive dressing. Both wound and tube covered separately. The application of negative pressure (controlled pressure) is applied uniformly to all over the tissues on the inner surface of the wound (McCallon 2000) [12]. The foam dressing should compress to the negative pressure applied. The ideal pressure setting is 125 to 130 mmHg, but painful chronic leg ulcers are usually managed with lower therapeutic pressures of around 75 mmHg. Higher pressures of 150 mmHg plus are used for large cavity wounds such as acute traumatic wounds, as they produce copious amounts of exudates (Collier 2003) collected in the transparent canister. The dressing was changed every alternate day or earlier if the wound was infected. Statistical analysis in our study was done by a statistician. All the data were entered in SPSS 14 and analyzed. Variables were analyzed and correlations were made by using the mean, average, and Pearson's chi-square/Fisher's exact test. Two groups were compared using Student's t-test. Results were expressed as n (%). p values of <0.05 were considered to be statistically significant.

2.2. Inclusion criteria

- Wounds treated with VAC in our study included:
- Diabetic foot ulcers.
- Traumatic ulcers.
- Pressure sores.
- Fasciotomy wounds.

2.3. Exclusion criteria

- Following patients were excluded from the study
- Comorbidities like CKD
- Cases with septicemia.
- Bone involvement like osteomyelitis and obvious gangrene
- Peripheral Vascular Diseases.
- Patients not willing for inpatient treatment

3. Results

60 patients were randomly grouped in to two with 30 patients each in the VAC group or conventional dressing group. Homogeneity was maintained in terms of age, gender and nature of ulcer dimensions, for both VAC and conventional group. Patients with diabetes were monitored for glycemic control and routine co morbid consultations were obtained in all the patients regularly. All diabetic patients were on insulin for control of their blood sugars as advised by the diabetic consultants with regular follow up for glycemic control. Overall, lower doses of insulin were required to control hyperglycemia in the VAC group as compared to the conventional dressing group. Blood sugars were controlled within 1 week in the VAC group as compared to 2–3 weeks in a conventional dressing group. In our study, the final point was taken as a completely granulated wound, free of discharge or a wound ready for skin grafting or spontaneous healing by secondary intention. Age distribution of patients in the VAC group was between 40 and 60 years with a mean age of 50. While in conventional dressing group age, the range was between 42 and 60 years with an average of 51 years. Mean age of patients was slightly more in the conventional dressing group as compared to the Vacuum-assisted closure

group. (Table1) Out of the total, 60 patients studied each group received an equal number of patients. Majority of patients in the VAC group were females (52%) and the majority of the patients in the conventional dressing group were males. (56%) Granulation tissue appeared in 73 % of patients in the VAC

group by the end of week 2 which further reached 100 % by the end of week7. While in conventional dressing group, only 46 % of patients showed granulation tissue by the end of week 2 which further reached to 63 % by the end of week 7.

Table 1: Age and Gender distribution

| Group | n | Male | Female | Age | Mean |
|-----------------------------|----|------|--------|--------|------|
| VAC group | 30 | 18 | 12 | 40-60 | 50 |
| Conventional dressing group | 30 | 16 | 14 | 42 -60 | 51 |

Table 2: Frequency of diminished wound discharge

| Group | Week 2 | | Week 7 | |
|--------------|----------------|------------|----------------|------------|
| | No of patients | Percentage | No of patients | Percentage |
| VAC | 18 | 60 | 29 | 96% |
| Conventional | 9 | 30 | 17 | 56% |

Granulation tissue formation was assessed by the single observer reference to gross appearance of ulcer. Cultures were taken from the wound at the time of start of treatment, in both groups. Wound size decreased in 28 (92 %) patients in NPWT group as compared to 19 (63 %) patients in conventional dressing group. In 2 weeks' time, wound discharge disappeared in 60 % of wounds in VAC group which further reached to 96 % in week 7

on continuation of NPWT. In conventional dressing group, at the end of 2 weeks wound discharge disappeared in 30 % which reached to 56 % in week 7 on continuation of dressings. (Table 2)Above was statistically significant correlation with *p* value of less than 0.05. The range of wound size in our study was from 11 to 21.4 cm².



Fig 1: Wound with VAC application



Fig 2: Post VAC (Fit for SSG)

Average wound dimension in the VAC group was 16 cm² and in conventional dressing group it was 13.5 cm². The patients treated with VAC dressing in our study showed comparable wound reduction in terms of average wound size reduction of 55 % in comparison to conventional dressing group which had an average wound size reduction of only 28 %. One patient had to undergo amputation in the VAC group as compared to as high as three patients in the conventional dressing group. Eighteen patients in total were managed by split-thickness skin graft (STSG). In seven wound healed spontaneously with VAC treatment. Majority of the patients in the VAC group were finally managed with split tissue skin grafting once the wound bed showed healthy granulation tissue with VAC. (Picture 2) Average wound size in the VAC group was 16 cm² and an average wound size in conventional dressing group was 13.5 cm². The patients treated with VAC dressing in our study showed comparable wound reduction capabilities with an average wound size reduction of 55 % in comparison to conventional dressing group which had an average wound size reduction of 28 %. One patient had to undergo amputation in the VAC group as compared to three patients in the conventional

dressing group. Eighteen patients in total were closed by split-thickness skin graft (STSG). Seven patients got closed spontaneously during VAC treatment. Majority of the patients in the VAC group by split tissue skin grafting. STSG was done in routine theatre after ulcer was covered by granulation tissue and was devoid of discharge. (Picture 2)

6. Discussion

A prospective case-control study conducted Karpaga Vinayaga Institute of Medical Sciences, General surgery department for a period of one year from March 2018 to Feb 2019. The ability of regular NPWT in promoting wound bed granulation and healing has been documented in several studies [8]. Application of NPWT over the ulcer allows improved vascularity, reduces oedema, angiogenesis, reduces the bacterial burden and leads to the formation of granulation tissue over the wound. The optimization wound bed is essential in preventing complications and accelerates eventual wound healing either spontaneously or split skin grafts [9].

NPWT therapy had the appearance of granulation tissue comparatively earlier in our study, compared to the patients in

control group managed with conventional dressings. Complete granulation and wound healing were achieved much earlier and in a relatively higher percentage of patients in the NPWT group in comparison to the conventional dressing group. Our study results found to be comparable with two randomized controlled relatively large trials carried out by Armstrong *et al.* and Blume *et al.* in different centers^[10]. Their study reported an average time of 42 and 56 days, respectively, for 76–100 % wound granulation using NPWT dressings for an average wound sizes of 22.3 and 13.5 cm², respectively. We also noted by second-week discharge from the wound reduced to 60 % in NPWT study group which further accelerated to 96 % in week 7 on the continuation of NPWT in comparison to conventional dressing group. Wound discharge disappeared only in 30 % at 2 weeks and reached to 54 % in week 7 on the continuation of dressings (p-value of 0.04, statistically significant). We found the rate of reduction of wound discharge was much earlier in NPWT group as compared to a conventional group, which was statistically significant (p<0.04), similar to the outcome of the study by Prabhdeep SN, *et al.*^[11]

The ulcer size in our study range was from 12 to 21.6 cm² with average wound size in NPWT group was 15.5 cm² and average ulcer size in conventional dressing group was 13.5 cm² which was comparable to study by McCallon^[12]. In our study, wound size reduced in 27 (90%) patients in VAC group as compared to 19 (63 %) patients in conventional dressing group, in comparison to the study conducted by Mullner *et al.* A prospective trial of 45 patients with soft tissue injuries including sacral pressure ulcers. They reported that in (84 %), of cases the application of the NPWT technique following surgical debridement caused decline of the dimensions accelerating healing and the elimination of infection. The patients managed with VAC dressing in our study showed comparable results in average reduction of wound size of 56 % in comparison to conventional dressing group which had wound size reduction of 29 %. These results are favorably comparable to crossover randomized controlled trial by Eginton *et al.*^[13] who could achieve an average 59 % reduction in wound dimensions patients on NPWT.

Similar study conducted by McCallon *et al.* observed an average reduction of 28.4 % (± 24.3) in ulcer size in the VAC group as compared to 9.5 % (± 16.9) wound dimensions in the control group (treated only using saline-moistened gauze dressings). Mark *et al.* had also documented that the wound dimensions and depth diminished markedly in VAC dressings as compared to wet gauze dressings. M. Singh *et al.* reported excellent results with manually operated vacuum devices and Romovac and described them be an equally effective wound management. The dimensions in our study range was from 12 to 21.6 cm² with average size in NPWT group was 15.5 cm² and average wound size in conventional dressing group was 13.5 cm² which was comparable to study by McCallon. In our study, the reduction in wound dimensions 27 (90 %) patients in VAC group as compared to 19 (63 %) patients in conventional dressing group, similar to the study conducted by Mullner *et al.*—A prospective trial of 45 patients with combined soft tissue injuries with sacral pressure ulcers, following rigid stabilization of lower limbs bone injuries. They reported that in (84 %), of cases the application NPWT in wound management following surgical debridement reduced the dimensions, helps in accelerating the healing and elimination of infection. The study group with VAC dressing showed favorably comparable results with an average reduction of ulcer size of 56 % to conventional dressing group which had reduction in wound size of 29 %. Our results are comparable to

the crossover study conducted by Eginton *et al.* who documented an average 59 % wound size reduction in patients on NPWT. Another study conducted by McCallon *et al.* observed an average decrease of 28.4 % (± 24.3) in wound size in the VAC group as compared to 9.5 % (± 16.9) average decrease in wound size in the study group managed only with saline gauze dressings. Mark *et al.* had also in their study on NPWT observed that the reduction in size of the ulcer and volume is visibly better as compared to moist gauze dressings. Study conducted by M. Singh *et al.* registered significant results with mechanical vacuum devices. Singh *et al.* applied NPWT using Romovac proved it to be a practical and effective method of which should benefit huge population where the sophisticated equipment is not available^[14].

The majority of ulcers in VAC group 25 (83.3 %) were completely healed in seven weeks comparison to only 20 (66 %) in the non-VAC dressing group in 7 weeks. SSG was needed in 80 % once the wound was clear of discharge and had healthy granulation coverage of wounds^[15].

Conclusion

The application of VAC is found to be an effective way of treatment for chronic non-healing ulcers as it improves wound conditioning and accelerates wound healing. It further promotes wound area reduction, improves wound bed granulation, and clears bacterial infection crucial for wound healing. Though many studies on VAC reveal good results and early healing of ulcers than standard methods, further studies with larger sample sizes assessing the use of VAC therapy on different types of wounds are required. Proper training in the application of vacuum-assisted closure and competent use, VAC is an economical, feasible and effective alternative for the management of chronic non-healing ulcers thereby preventing amputations.

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