

Vacuum-assisted Closure in Chronic Nonhealing Ulcers: A Randomized Control Study

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Abstract

Introduction: Vacuum-assisted closure (VAC) is a relatively new technology with applications in a variety of difficult to manage acute and chronic wounds. It involves the application of open cell foam to a suitable wound, adding a seal of adhesive drape and then the application of subatmospheric pressure to the wound in a controlled way.

Materials and Methods: A randomized control study was conducted at a tertiary care center in Madurai between the June 2013 and May 2014. Cases were those who underwent VAC and controls were those, who underwent conventional dressing total 25 cases and 25 controls, were selected from the same wards at different time periods.

Results: The study conducted among 50 participants divided into two groups cases and controls. The result showed that male and female distribution was almost equal in control and cases. 72% and 56% of the control and cases population, respectively, were males, whereas 44% of the cases were females grade of the ulcer distribution was almost equal in cases and control. Turning unsterile after VAC. However, 90% unsterile turns sterile after VAC. VAC dressing produces more split skin grafts before discharge and less rate of amputation, So, VAC dressing has better results in patients.

Conclusion: VAC dressing decreases hospital stay and improves pus culture sterility VAC dressing improves outcome by decreasing the number of amputations and increasing the number of patients undergoing skin grafting. Furthermore, VAC dressing has better result in patients with normal Doppler and has good result in patients with nonactive osteomyelitis.

Key words: Conventional dressing, Ulcer care, Vacuum-assisted closure

INTRODUCTION

Among the most common causes for admission, in general, surgical ward is chronic nonhealing ulcer of which diabetes is the most common etiology. In most of the cases, hospital stay of many weeks is required for management of the above. In many cases, they ultimately go for amputation. Wounds do not only lead to hospitalization of the patient but also lead to consequences like amputation of the limb and at times, even death. Vacuum-assisted closure (VAC) is a relatively new technology with applications in a variety of difficult to manage acute and chronic wounds.¹ It involves

the application of open cell foam to a suitable wound, adding a seal of adhesive drape and then the application of subatmospheric pressure to the wound in a controlled way.²

The application of negative pressure wound therapy (NPWT) to promote wound healing was first described in Russian medical literature for patients having infected breast wounds. These original reports actually described the application of a topical suction-cup-type apparatus to the surface of the wound to create negative pressures of around 80 mm Hg.^{2,3} Subsequent reports have described the successful management of enterocutaneous fistulae and open abdominal wounds using flat drains that delivered negative pressure under compliant plastic films.³⁻⁶ In these reports, surgical gauze was being used to create an interface between the surface of the wound and the vacuum source.

The purpose of this type of wound management is to decrease wound healing time and to facilitate wound care in situations that otherwise might be considered

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difficult or nonhealing; Of late, the NPWT has become a very commonly used method because of its lack of complications and effectiveness in complex situations. Still, in our hospital, the majority of dressings are conventional. The aim of the study is to show the advantage of VAC over conventional dressing in our hospital.

MATERIALS AND METHODS

A randomized control study was conducted at the Government Rajaji Hospital, Madurai, which is a tertiary care center between the June 2013 and May 2014. Patients are selected from general surgery wards. Patients were randomly allocated into two groups: Cases, and controls. Cases were those who underwent VAC and controls were those, who underwent conventional dressing total 25 cases and 25 controls, were selected from the same wards at different time periods. Patients included in the study are classified according to the grade of the ulcer (Wagner classification). All grades are included except grade 0 and 5, age between 13 and 70 years, diabetic ulcers, traumatic ulcers. We excluded those with fistulas to organs or body cavities, necrotic tissue in Eschar, osteomyelitis (untreated) exposed blood vessels and Gangrenous foot.

Method of Study⁷

During the period of study, cases and controls selected from the general surgery wards. After debridement of the wound, VAC dressing is applied after the bleeding gets stopped. Pre-VAC and post-VAC C and S are taken. Dressing is given for 72 h and intermittent suction is given for 10 min in an hour, daily for 12 h with a negative pressure ranging from 100 to 125 mm of mercury. Rest of the time drain of the VAC dressing connected to the Romo-VAC suction drain. Doppler study to assess the vascularity of the limb before the procedure and X-ray taken to rule out osteomyelitis. Control group patients are given with conventional dressings. The outcome variables that were assessed were the difference in the rate of healing, hospital stay, and us C and S before and after VAC.

Materials Used for Study

- Transparent, sterile material (OP-SITE)
- Transparent adhesive plaster
- Sponge (presterilized)
- Suction drain with suction apparatus.

Sequence of Procedure

1. Wound preparation
2. Placement of foam and drain
3. Sealing with drapes.

Procedure

The patient selected for VAC therapy undergoes wound debridement and homeostasis is achieved. Pre-VAC culture and X-ray to rule out active osteomyelitis is taken. A piece of presterilized foam (about one cm in thickness) is cut to the size of the wound and is placed on it. Then, a perforated drainage tube (Romo-VAC suction drain tube is used here) 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 (opposite). The tube is connected to a common suction apparatus with a pressure gradient. Suction is applied with a negative pressure of 100-125 mm of Hg for 10 min hourly for 12 consecutive hours. Rest of the time this drainage tube is connected to the Romo-VAC suction apparatus. Dressing changed after 72 h and post-VAC culture is taken. There cycles of dressings and vacuum are applied statistical assessment is done using outcome variables.

Statistical Analysis

Data were analyzed using computer software, statistical package for social sciences version 12. Data are expressed in its comparison between controls and cases; Chi-square (χ^2) test was used as nonparametric test. For all statistical evaluations, a 2-tailed $P < 0.05$ was considered significant.

RESULT

The study conducted among 50 participants divided into two groups: Cases and controls. The result showed that male and female distribution was almost equal in control and cases. 72% and 56% of the control and cases population, respectively, were males, whereas 44% of the cases were females. The gender difference between groups was not found to be statistically significant. Age distribution was almost equal in control and case groups. Chi-square test shows no statistical significance as $P > 0.05$. Duration of hospital stay in days was found to be statistically significant between groups. Control population stayed more days in hospital than cases. Majority (52%) of the cases left the hospital within 3 weeks time, whereas major chunk (88%) of control population stayed more than 3 weeks time (Table 1).

Grade of the ulcer distribution was almost equal in cases and control. Chi-square test shows $P > 0.05$, which is statistically not significant (Table 2). Chi-square test shows study is not significant as $P > 0.05$. Hence, VAC dressing has almost similar effect on normal Doppler study in case and control group. However, VAC dressing shows better results in patients with normal Doppler study (Table 2).

With regards to culture sensitivity, Chi-square test shows a significant statistical association as $P < 0.001$. Patients with

sterile pre-VAC culture are not turning unsterile after VAC. However, 90% unsterile turns sterile after VAC.

VAC dressing produces more split skin grafts before discharge and less rate of amputation. Chi-square test shows study is significant as $P < 0.001$. Hence, VAC dressing have better results in patients (Table 3).

DISCUSSION

The study conducted among 50 participants showed that age distribution was almost equal in control and case groups

Table 1: Distribution of age, gender, and hospital stay among study groups

Study variables	Group		Total (%)
	Control (%)	Cases (%)	
Gender			
Male	18 (72.00)	14 (56.00)	32 (64.00)
Female	7 (28.00)	11 (44.00)	18 (36.00)
Age (years)			
<40	1 (4.00)	2 (8.00)	3 (6.00)
40-49	4 (16.00)	5 (20.00)	9 (18.00)
50-59	11 (44.00)	8 (32.00)	19 (38.00)
Duration of hospital stay			
7-14	1 (4.00)	6 (24.00)	7 (14.00)
14-21	2 (8.00)	7 (28.00)	9 (18.00)
21-28	10 (40.00)	6 (24.00)	16 (32.00)
28-35	6 (24.00)	5 (20.00)	11 (22.00)
>35 days	6 (24.00)	1 (4.00)	7 (14.00)
Total	25	25	50

Table 2: Ulcer grading and Doppler report among study groups

Study variables	Group		Total (%)	Chi-square and P value
	Control (%)	Cases (%)		
Ulcer grading				
Grade 1	1 (4.00)	2 (8.00)	3 (6.00)	$\chi^2=0.603$; $P>0.05$
Grade 2	10 (40.00)	11 (44.00)	21 (42.00)	
Grade 3	10 (40.00)	8 (32.00)	18 (36.00)	
Grade 4	4 (16.00)	4 (16.00)	8 (16.00)	
Doppler findings				
Normal	19 (76.00)	18 (72.00)	37 (74.00)	$\chi^2=0.104$; $P>0.05$
Vascular impairment	6 (24.00)	7 (28.00)	13 (26.00)	
Total	25 (100)	25 (100)	100 (100)	

Table 3: Analysis of cases and control groups in outcome/plan

Outcome/plan	Group		Total	Chi-square and P value
	Control	Cases		
Discharge	19 (76.00)	11 (44.00)	30 (60.00)	$\chi^2=16.133$ $P<0.001$
Split skin graft	0	12 (48.00)	12 (24.00)	
Amputation	6 (24.00)	2 (8.00)	8 (16.00)	
Total	25	25	50	

duration of hospital stay in days was found to be statistically significant between groups. Control population stayed more days in hospital than cases a blinded, prospective, randomized controlled trial of topical negative pressure wound closure in India by Mody *et al.*⁸ also showed similar results faster healing rate and less hospital stay. On assessing the outcome of the study, it was found that 16% required amputation and also 60% of the study participant were discharged without any complications.

With regards to culture sensitivity report, it was found that Chi-square test shows a significant statistical association as $P < 0.001$. Patients with sterile pre-VAC culture are not turning unsterile after VAC.

Studies by Lone *et al.*⁹ and Morykwas *et al.*,² all showed the efficacy of VAC dressing over conventional dressing and its better outcome. More than this VAC dressing decreases hospital expenses, hospital waster, and nursing care required The bacteriological and cytological assessment of VAC on purulent wounds Davydov *et al.*¹⁰ has shown efficacy of VAC in turning pus C and S sterile.

CONCLUSION

VAC dressing decreases hospital stay and improves pus culture sterility VAC dressing improves outcome by decreasing the number of amputations and increasing the number of patients undergoing skin grafting. Furthermore, VAC dressing has better result in patients with Normal Doppler and has good result in patients with nonactive osteomyelitis NPWT aids in the recovery time and may reduce the need for more extensive operations.^{11,12} NPWT is a useful tool in transforming a wound to a point where more traditional dressings or simpler surgical methods for reconstruction can be used. Although a pragmatic addition at present, NPWT is a well-deserved addition to the armamentarium of wound healing and reconstruction.

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