Original Research Article

A study of vacuum assisted closure in chronic non-healing diabetic ulcers

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Abstract

Background: Diabetes is the most common etiology in those admitted with chronic non-healing ulcers under general surgery. In most cases, the hospital stay for many weeks is required for its management. Amputation becomes the endpoint in most such cases. A large number of people are affected by acute or chronic wounds.

Aim of the study: To study the advantage of vacuum-assisted closure over conventional dressing in the management of chronic non-healing ulcers.

Materials and methods: 50 Case were selected from the General Surgery wards of Govt. Royapettah Hospital, KMC. Cases, and controls were selected from the same wards at different time periods. A total of 25 cases and 25 controls, were randomized by the admission. During the period of study, cases and controls were selected from the general surgery wards. After debridement of the wound, VAC dressing was applied after the bleeding gets stopped. Pre VAC and post-VAC C and S were taken. The dressing was given for 72 hours and intermittent suction is given for ten minutes in an hour, daily for 12 hours with a negative pressure ranging from 100 to 125 mm of mercury. Rest of the time drain of the VAC dressing was connected to the Romo vac suction drain. Doppler study was done to assess the vascularity of the limb before the procedure and X-rays were taken to rule out osteomyelitis. Control group patients were given with conventional dressings. Controlled wound wherein vacuum was created through the perforated plastic tubing with a suction machine and the whole apparatus was developed into what was now referred to as vacuum-assisted closure (VAC). The purpose of the above dressing was done in those wounds which are other considered difficult or non-healing. Of late, the Negative Pressure Wound Therapy (NPWT) had become a very commonly used method it was more effective in complex situations and was less complicated.

Results: Grade of the Ulcer distribution was almost equal in cases and control. The chi-square test showed 'P' value was more than 0.05 which was statistically not significant. The chi-square test showed the study was not significant as the 'p' value was more than 0.05. So VAC dressing had an almost similar effect on normal Doppler study in the case and control Group. But VAC dressing showed better results in patients with normal Doppler study. Chi-square test showed significant statistical association as the p-value was less than 0.001. Patients with sterile pre-VAC culture were not turning unsterile after VAC. But 90% unsterile turns sterile after VAC.

Conclusion: VAC dressing reduced Hospital stay. VAC dressing improved pus culture sterility.
VAC dressing improved outcome by decreasing the number of amputations and increases the number of patients undergoing skin grafting.

Key words

Diabetes, Foot ulcer, VAC dressing, Lower limp amputation.

Introduction

Vacuum-Assisted Closure is a universally accepted method of wound healing. It has proved its efficacy for wound dressing, faster wound healing and reduces hospital stay. Yet in our hospital, conventional dressings are the norm [1]. The raw material requirements are a piece of foam, some perforated plastic tubing along with a suction machine. The foam, placed over the wound, is covered with a dressing that causes occlusion creating the vacuum and that in turn is connected to a suction machine, making it a closed environment [2]. Now, this controlled wound wherein vacuum can be created through the perforated plastic tubing with a suction machine and the whole apparatus was developed into what is now referred to as vacuum-assisted closure (VAC) [3, 4]. The purpose of the above dressing is done in those wounds which are other considered difficult or non-healing. Of late, the Negative Pressure Wound Therapy (NPWT) has become a very commonly used method it is more effective in complex situations and is less complicated [5]. The body's response to any form of injury is term wound healing. Wound healing has various phases and is presented as separate events, though these events do occur in conjunction with one another and there is a significant degree of temporal overlap [6]. Extreme importance is on the underlying process and the outcome status with surgical applications. Each and every tissue in the human body undergoes a process of repair when it sustains injury amongst which is the bone that has a unique ability to heal without scar formation [7]. This is the first phase of wound healing which begins instantaneously after injury. Bleeding is the first response when the body faces an injury. The hemostatic response to the trauma or injury is the hemostasis in order to reduce the bleeding. Hemostasis is said to be begun once the platelet plug is formed, along with the clotting factors activated by collagen and basement membrane which are exposed by the injury [8]. After any injury, catecholamines, thromboxane, and prostaglandins (PGF2) mediate transient vasoconstriction. Platelet degranulation occurs thereby emptying the granules into the extracellular space, which contain alpha granules and dense granules, most important of which are platelet-derived growth factor (PDGF) and transforming growth factor-beta a (TGF beta). PDGF and TGF beta then initiate t h e inflammatory response by bringing about chemotaxis and also the inflammatory cell proliferation [9]. At the site of injury, the formation of the platelet plug is aided by the transient vasoconstriction. This is further followed by vasodilatation, substances aiding wound repair are transported easily. Endothelial cells of the vessels play a vital role in altering the permeability of the wound [10].

Materials and methods

50 Case were selected from the General surgery wards of Govt. Royapettah Hospital, KMC

Cases, and controls were selected from the same wards at a different time period. Total of 25 cases and 25 controls, were randomized by the admission. During the period of study cases and controls were selected from the general surgery wards. After debridement of the wound, VAC dressing was applied after the bleeding gets stopped. Pre VAC and post-VAC C and S were taken. The dressing was given for 72 hours and intermittent suction was given for ten minutes in an hour, daily for 12 hours with a negative pressure ranging from 100 to 125 mm of mercury. Rest of the time drain of the VAC dressing was connected to the Romo vac suction drain. Doppler study was done to assess the vascularity of the limb before the procedure and X-rays were taken to rule out osteomyelitis. Control group patients were given with conventional dressings. Controlled wound wherein vacuum was created through the perforated plastic tubing with a suction machine and the whole apparatus was developed into what was now referred to as vacuum-assisted closure (VAC). The purpose of the above dressing was done in those wounds which are other considered difficult or non-healing. Of late, the Negative Pressure Wound Therapy (NPWT) had become a very commonly used method it was more effective in complex situations and was less complicated.

Inclusion criteria: Patients included in the study were classified according to the grade of the ulcer (Wagner classification), All grades were included except grades 0 and 5, Age between 13 and 70 years, Diabetic ulcers, Traumatic ulcers.

Exclusion criteria: Fistulas to organs or body cavities, Necrotic tissue in eschar, Osteomyelitis (Untreated), Exposed blood vessels, Gangrenous foot, Active bleeding and patients undergoing anticoagulant therapy, Malignancy, Patients below 13 years and above 70 years.

Procedure

The patient selected for VAC therapy underwent wound debridement and hemostasis was achieved. Pre VAC culture and X-ray was done to rule out active osteomyelitis. A piece of pre-sterilized foam (about one cm in thickness) was cut to the size of the wound and was 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 was placed on the underlying foam and tube. The whole foam with the tube was covered with a sterile transparent dressing (opposite). The tube was connected to a common suction apparatus with a pressure gradient. Suction was 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 was connected to the Romo vac suction apparatus. Dressing was changed after 72 hours and post VAC culture was taken. Their cycles of dressings and vacuum were applied statistical assessment was done using outcome variables.

Statistical analysis

Data were analyzed using computer software, statistical package for social sciences (SPSS) version 12. Data were expressed in its comparison between controls and cases, the chi squire (x^2) test was used as a nonparametric test. Student's test was used to compare mean values between two groups. For all statistical evaluations, a two-tailed probability of value, <0.05 was considered significant.

Results

Female and Male distribution were 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 (Chi-Square: 1.389; P> 0.05) as per **Table - 1**.

Grade of the Ulcer distribution was almost equal in cases and control. The chi-square test showed 'P' value was more than 0.05 which was statistically not significant (Chi-square: 0.603; P> 0.05) as per **Table - 2**. Chi-square test showed the study was not significant as the 'p' value was more than 0.05. So VAC dressing had

an almost similar effect on normal Doppler study in the case and control Group but VAC dressing showed better results in patients with normal Doppler study (Chi-Square: 0.104; P> 0.05) as per **Table - 3**.

Table – 1: Gender distribution and its association with group.

Gender	**Group**		**Total**
	Control	**Cases**	
Male	18 (72.00%)	14 (56.00%)	32 (64.00%)
Female	7 (28.00%)	11 (44.00%)	18 (36.00%)
Total	25	25	50

Table - 2: Grade of the ulcer.

Grade of Ulcer	**Group**		**Total**
	Control	**Cases**	
Grade 1	1 (4.00%)	2 (8.00%)	3(6.00%)
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%)
Total	25	25	50

Table - 3: Doppler findings in cases and control.

Doppler Finding	**Group**		**Total**
	Control	**Cases**	
Normal	19 (76.00%)	18 (72.00%)	37 (74.00%)
Vascular Impairment	6 (24.00%)	7 (28.00%)	13 (26.00%)
Total	25	25	50

Table - 4: Analysis of cases and control groups in outcome/ plan.

Outcome/ Plan	**Group**		**Total**
	Control	**Cases**	
Discharge	19 (76.00%)	11 (44.00%)	30 (60.00%)
Split Skin Graft	--	12 (48.00%)	12 (24.00%)
Amputation	6 (24.00%)	2 (8.00%)	8 (16.00%)
Total	**25**	**25**	**50**

Table - 5: Analysis of culture sterility in pre-VAC and post- VAC state.

Culture Sterility in cases	**Group**		**Total**
	Pre VAC	**Post-VAC**	
Sterile	5 (20.00%)	23 (92.00%)	28 (56.00%)
Non-sterile	20 (80.00%)	2 (8.00%)	22 (44.00%)
Total	25	25	50

Chi-square test showed the study was significant as the p-value was less than 0.001. So VAC dressing had better results in patients, VAC dressing produces more split skin grafts before discharge and less rate of amputation (Chi-Square: 16.133; P> 0.001) as per **Table - 4**.

Chi-square test showed significant statistical association as the p-value was less than0.001. Patients with sterile pre-VAC culture were not turning unsterile after VAC but 90% unsterile turns sterile after VAC (Chi-square: 26.299; P <0.001, Very highly significant) as per **Table – 5**.

Discussion

The study conducted among 50 participants showed that age distribution was almost equal in control and case groups duration of hospital stay in days was found to be statistically significant between groups [11]. Control population stayed more days in hospital than cases a blinded, prospective, randomized controlled trial of topical negative pressure wound closure in India by Joseph E et al. 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 participants were discharged without any complications. With regards to the culture sensitivity report, it was found that the Chi-square test shows a significant statistical association as P < 0.001. Patients with sterile pre-VAC culture are not turning unsterile after VAC [12]. Kaplan M, et al. [10] have shown the efficacy of VAC in turning pus C and S sterile. Colonization of a wound, corresponding to a level of $>10^5$ colonies of bacteria per gram of tissue, has been recognized as a detrimental factor in the process of wound healing. VAC therapy enhances bacterial clearance, which may account for the wound-healing effects. Blood culture positivity was less with patients in Group A compared to Group B. However, blood culture negativity was documented earlier in Group A patients as compared to Group B patients. The majority of wounds in the VAC group (78.6%) decreased in size as compared to that in the conventional group (53.6%) [13]. Leininger BE, 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 increase in wound size in the control group (treated by saline-moistened gauze dressings) [14]. Miller PR, et al. also reported fewer numbers of secondary amputations in VAC treated patients as compared to those treated by gauze dressings. In our study, the endpoint taken was a completely granulated wound or a wound ready for skin grafting or spontaneous healing by secondary intention. Both of the groups received similar treatment for the closure of the wound, the most common mode of wound closure being a split-thickness skin graft. In 86.4% of patients, wounds were closed by a split-thickness skin graft in Group A as compared to 93.33% of patients in Group B [15]. The rest of the patient's wounds were closed spontaneously. Our observations are consistent with those of Molnar JA, et al. who also reported a split-thickness skin graft as the most common mode of wound closure. In Group A patients, overall lower doses of insulin were required to control hyperglycemia compared to Group B. Success rate in terms of complete granulation and readiness for closure by split-thickness skin grafting or secondary intention was more in Group A compared to Group B and the need for amputation was more in Group B [16].

Conclusion

VAC therapy was useful in the treatment of diabetic foot infection and ulcers, which after debridement, may present with exposed tendon, fascia and/or bone. These included ray amputation wounds, wounds post-debridement for necrotizing fasciitis, wounds post-drainage for abscess, a heel ulcer and a sole ulcer. It was able to prepare ulcers well for closure via split-skin grafting or secondary closure in a good time. This reduced the cost of VAC therapy, as therapy was not prolonged to attain a greater reduction in wound area. VAC therapy also provides a sterile, more controlled testing environment to large, exudating wound surfaces. Large diabetic foot ulcers were thus made more manageable.

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