Original Article

Effectiveness of Vacuum-assisted Closure (VAC) Therapy in the Healing of Chronic Diabetic Foot Ulcers

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Abstract

Introduction: This is the first prospective study done locally to determine the effectiveness of vacuum-assisted closure (VAC) therapy in the healing of chronic diabetic foot ulcers. Materials and Methods: An electronic vacuum pump was used to apply controlled negative pressure evenly across the wound surface. Changes in wound dimension, presence of wound granulation and infection status of diabetic foot ulcers in 11 consecutive patients with diabetes were followed over the course of VAC therapy. Results: Healing was achieved in all wounds. Nine wounds were closed by split-skin grafting and 2 by secondary closure. The average length of treatment with VAC therapy was 23.3 days. Ten wounds showed reduction in wound size. All wounds were satisfactorily granulated and cleared of bacterial infection at the end of VAC therapy. Conclusions: 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 necrotising 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 good time. This reduced cost of VAC therapy, as therapy was not prolonged to attain greater reduction in wound area. VAC therapy also provides a sterile, more controlled resting environment to large, exudating wound surfaces. Large diabetic foot ulcers were thus made more manageable.

Ann Acad Med Singapore 2010;39:353-8

Key words: Diabetic foot wound, Negative pressure dressing, Wound healing

Introduction

Diabetes mellitus is a common problem in Singapore, with an incidence of 8.2% in the local population aged between 18 and 69 in 2004.[1] Ten per cent to 25% of diabetics developed foot ulcerations.[2] The lifetime incidence of developing a diabetic foot ulcer is as high as 25%.[3]

Diabetic foot ulcers were typically chronic wounds which were difficult to heal. This was due to a range of pathogenic abnormalities in diabetics, which included ischaemia and intrinsic defects in angiogenesis and impaired immunity against infection.[2]

The sequence of minor trauma, cutaneous ulceration and failure to achieve wound healing potentially led to amputations of the lower extremity. Diabetic foot ulcers were found to precede 84% of all non-traumatic amputations in diabetics.[2] An amputation incurred heavy financial cost, adversely affected a person's quality of life and caused a higher risk of mortality.

Several techniques have been developed to induce healing in chronic diabetic foot wounds. These included new generation dressings, namely silver dressings,[4] anodyne therapy,[5] ultrasonic debridement[6] and extracorporeal shockwave therapy.[7] This is a prospective study evaluating the effectiveness of vacuum-assisted closure (VAC) therapy (negative pressure wound therapy) in the healing of chronic diabetic foot ulcers in 11 patients.

Materials and Methods

Study Population

Eleven consecutive patients with diabetes and diabetic foot ulcers were enrolled into this study, conducted by the National University Hospital (NUH) Multi-Disciplinary Team for Diabetic Foot Problems (established in May 2003). These patients were seen in the Department of Orthopaedic Surgery of NUH, from January 2008 to February 2009. Characteristics of the study cohort are shown in Table 1.

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Indications

In this study, the indications for VAC therapy included ray amputation wounds (3 patients) (Fig. 1A), wounds post-debridement for necrotising fasciitis[2] (Fig. 1B), wounds post-drainage for abscess with exposed tendon or fascia,[4] heel ulcer with exposed calcaneum and tendo-achilles[1] and sole ulcer with exposed fascia[1] (Table 1). Three ulcers were ray amputation wounds, 4 ulcers were located on the dorsum foot, 1 ulcer was on the sole foot, 1 ulcer was on the heel, 1 ulcer was on the shin and 1 ulcer was on the thigh (Table 1). Each ulcer was classified as a Grade 2 ulcer (ulcer exposing bone, tendon or joint) or Grade 3 ulcer (ulcer with osteomyelitis or abscess), according to Wagner's Classification[8] (Table 1).

Study Protocol

Documentation in the study protocol included the patients' profile, diabetic history, presence of complications and co-morbidities, as well as history of smoking. Description of ulcer included cause of ulcer, location of ulcer in foot and wound measurements. Wound description included presence and amount of exudates, and presence of granulation tissue. Wound investigations performed prior to VAC application included infection markers, namely leukocyte count, C-reactive protein and erythrocyte sedimentation rate. A swab culture and sensitivity from the wound was sent before application of VAC therapy and weekly during treatment with VAC therapy. The date VAC therapy was initiated and stopped, pressure settings and dates of VAC dressing changes were recorded.

Method of Application of VAC Therapy

The materials used in the application of VAC therapy are shown in Figure 2. The method of application entailed placing a sterile, polyurethane foam dressing, into the wound defect after it had been trimmed to shape (Fig. 3A). Adhesive drape was used to cover the foam and an additional 3 to 5 cm of surrounding intact skin (Fig. 3B). A slit measuring 1 to 2 cm long was created in the drape – it acted as the diameter of the circular hole which was cut in the drape. The non-collapsible tube was placed directly over the hole in the drape (Fig. 3C) and connected to the electronic vacuum pump. Finally, negative pressure was applied to the wound via the therapy unit, causing the dressing to collapse into the wound (Fig. 3D).

Table 1. Patient Demographics, Wound Diagnosis and Infection Markers

No.	Age (y)	Gender	Race	Endocrine control HbA1c (%)	Wound diagnosis	Wagner grade	Infection markers			Wound swab before VAC
							WBC	CRP	ESR	
1	44	Male	Chinese	14.3	Ray amputation of R big toe	3	14.23	200	126	*Streptococcus milleri*
2	66	Female	Chinese	6.8	Necrotising fasciitis, L thigh	3	37.82	310	150	*Pseudomonas aeruginosa*; MRSA
3	53	Male	Chinese	5.4	Necrotising fasciitis, L foot dorsum	3	4.49	24	94	*Candida*
4	62	Female	Chinese	15.0	Cellulitis and abscess, L foot dorsum (exposed tendon)	3	16.71	243	106	*Streptococcus agalactiae*; *Bacteroides fragilis*
5	45	Male	Chinese	15.7	Ray amputation of R 4th toe	3	9.5	108	116	*Streptococcus agalactiae*; *Staphylococcus aureus*
6	46	Male	Chinese	5.0	Cellulitis and abscess, L foot sole (exposed fascia)	3	12.19	149	145	*Bacteroides fragilis*
7	59	Male	Malay	11.4	Cellulitis and abscess, L shin (exposed bone)	3	14.73	269	92	*Staphylococcus aureus*
8	50	Female	Chinese	14.5	Cellulits and abscess, L foot sole (exposed fascia)	3	15.55	102	131	*Bacteroides fragilis*
9	46	Female	Chinese	15.3	L heel ulcer (exposed fascia, calcaneum and tendo-achilles)	2	9.00	5	141	*Streptococcus agalactiae, Bacteroides fragilis; Candida albicans*
10	56	Male	Indian	6.9	L sole ulcer (exposed fascia)	2	17.48	232	132	*Pseudomonas aeruginosa;* MRSA; *Peptostreptococcus*
11	59	Male	Chinese	9.5	Ray amputation of right 4th and 5th toes	2	9.13	81	132	*Bacteroides fragilis; Morganella morganii*; *Staphylococcus aureus*; *Peptostreptococcus*

CRP: C-reactive protein; ESR: erythrocyte sedimentation rate; L: left; MRSA: methicillin-resistant *Staphylococcus aureus*; R: right; VAC: vacuum-assisted closure; WBC: white blood cell

VAC Dressings

Prior to application of VAC therapy, radical debridement was performed on all wounds in the operating theatre. Debridement entailed the excision of all necrotic and infected tissue until healthy, bleeding tissue was reached.[2] After debridement, the wound was thoroughly cleansed and irrigated by jet lavage. A standard negative pressure of -125 mmHg was applied to the wound, either continuously or intermittently (5 minutes "on", 2 minutes "off"). However, when patient felt pain or too much bleeding was seen in the wound despite haemostasis, a lower negative pressure of about -75 to -100 mmHg was used post-debridement.

Although VAC dressings can be left in place for up to 120 hours, frequent change of dressing was done to allow more regular wound inspection and cleansing to avoid infection. For a chronic diabetic foot ulcer, VAC change of dressing was performed every 48 to 76 hours in the ward for the patient by a trained Medical Officer or nurse. As before, a negative pressure of -75 to -125 mmHg was applied to the wound, either continuously or intermittently. If the wound was found tolerant enough, a higher negative pressure of -150 mmHg could be used instead.

In wounds with necrotising fasciitis, change of dressing was performed frequently at every 24 to 48 hours. This was due to large wound size and copious discharge of exudates from the wound's surface. It was necessary to inspect such wounds early to ensure that no accumulation of new infection had occurred.

At each dressing change, the wound was carefully assessed to determine if the wound was healthy, clean and granulating. If infection or slough had surfaced in the wound, additional surgical debridement had to be performed in the operating theatre, before a new VAC dressing could be applied.

Once it was decided that VAC therapy could be stopped, the patient was subjected to secondary closure or surgical intervention by split-skin grafting. A final debridement and cleansing of the wound was performed in the operating theatre before the surgical procedure.

Wound Measurement

Before the start of VAC therapy, after initial debridement, the wound was photographed with a ruler placed beside the wound. A double layer of polyethylene sheets was held firmly in place over the wound, and an outline of the wound was traced using a permanent marker. The layer in direct contact with the wound was discarded. The tracing made on the top layer of polyethylene was fixed against a graphic grid (2 x 2 mm), and its area was quantitated to measure the area of the wound to the nearest 4 mm^2.

At subsequent VAC dressing changes, the wound was likewise photographed, and its area was quantitated using the double polyethylene sheet technique. Before surgical intervention at the end of VAC therapy, the final appearance of the wound was again noted and recorded.

Statistical Analysis

A *t*-test was used to compare between areas of wounds before and after treatment with VAC therapy. A *P* value of 0.05 was used to determine statistical significance.

Results

The age of patients in this study ranged from 44 to 66 years (average, 53.3) (Table 1). There were 7 males and 4 females (Table 1). As for ethnic distribution, there were 9 Chinese, 1 Malay and 1 Indian (Table 1). Only 4 patients

Table 2. Vacuum-assisted Closure (VAC) Therapy Settings and Changes of Dressings

No.	Settings for VAC therapy		Frequency of VAC dressing change (h)	Length of treatment (days)	No. of VAC dressings used
	Negative pressure (mmHg)	Mode of application			
1	-125	Continuous	72-96	39	13
2	-125	Intermittent	24	37	37
3	-100	Continuous	48-72	11	5
4	-125	Continuous	48	13	6
5	-125	Continuous	48-72	15	7
6	-125	Continuous	72	24	8
7	-125	Continuous	48-72	18	9
8	-125	Continuous	48-72	26	13
9	-75/-150	Intermittent	48-72	21	10
10	-75	Intermittent	48-72	37	18
11	-75	Intermittent	48-72	15	7

Fig. 1A.

Fig. 1B.

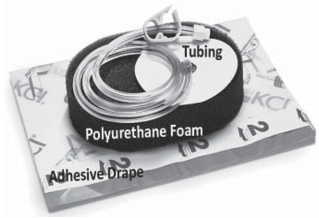

Fig. 2.

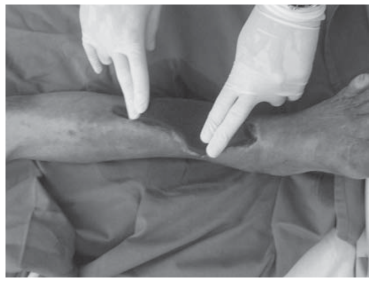

Fig. 3A.

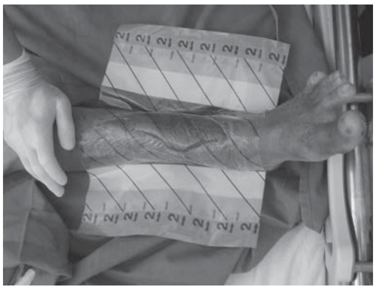

Fig. 3B.

Fig. 3C.

Fig. 3D.

Fig. 1A. Wound, post-ray amputation.
Fig. 1B. Wound, post-debridement for necrotising fasciitis.
Fig. 2. Materials used in the application of VAC therapy are a polyurethane foam, adhesive drape and non-collapsible tube.
Fig. 3A. Sterile, polyurethane foam is trimmed to shape and placed into wound.
Fig. 3B. Adhesive drape placed over foam.
Fig. 3C. Opening created in adhesive drape and opening of non-collapsible tube is placed over it.
Fig. 3D. Tube is connected at the opposite end to an electronic vacuum pump and negative pressure is applied, causing VAC dressing to collapse into wound.

had good endocrine control, with HbA1c levels of 4% to 7% (Table 1). Complications of diabetes seen in patients were neuropathy (4 patients), vasculopathy,[1] retinopathy[2] and nephropathy.[2] The comorbidities which affected patients were hypertension,[9] dyslipidaemia,[7] ischaemic heart disease[3] and cataract.[2] The duration of diabetes in patients ranged from 2 to 20 years, with an average of 10.2 years.

Ulcers in our study had an average chronicity of 34.7 (range, 7 to 98) days. All 11 wounds were infected at the start of VAC therapy (Table 1). They were cleared of bacterial infection by the end of VAC therapy.

A pressure of -125 mmHg was applied in 7 wounds and a pressure of -75 mmHg in 4 wounds (Table 2). A pressure of -150 mmHg was used in 1 wound (Table 2). Negative pressure was applied continuously in 7 patients and intermittently in 4 patients (Table 2). The frequency of VAC dressing change was every 48 to 72 hours for 9 wounds, every 24 hours for 1 wound and every 72 to 96 hours for 1 wound (Table 2). Wounds were administered VAC therapy for an average of 23.3 ± 10.3 days (range, 11 to 37) (Table 2). An average of 14 VAC dressings (range, 7 to 37) was used per patient in the study (Table 2).

No additional surgical debridement was performed in 7 patients during the course of VAC therapy (Table 3). There were 2 patients who required an additional surgical debridement, 1 patient who required 2 additional surgical debridements and 1 patient who required 3 additional surgical debridements (Table 3).

Initial wound area ranged from 6.9 to 124.0 cm^2, the average area being 54.6 cm^2 (Table 3). After VAC therapy, the wound area ranged from 3.4 to 104.0 cm^2, the average area being 44.5 cm^2 (Table 3). From Table 3, all wounds had decreased in size, except for wound 10, which increased in size due to 2 radical debridement performed during VAC therapy. The actual reduction in wound area attained by VAC therapy varied from 3.5 to 35.5 cm^2, with an average reduction of 10.1 cm^2 (Table 3). The percentage reduction in wound area ranged from 9.6% to 65.1%, with an average reduction of 24.9% (Table 3). This reduction was not statistically significant ($P > 0.05$).

Eight wounds were reduced in area and closed with a split-skin graft (Table 3). One wound increased in area, but was successfully closed with a split-skin graft. Two wounds showed excellent reduction in area and were subjected to successful secondary closure (Table 3).

Discussion

Whilst VAC therapy has been shown by several workers to facilitate the healing of chronic diabetic foot ulcers,[9-13] this is the first study conducted in Singapore to evaluate its

Table 3. Change in Wound Area and Final Outcome

No.	No. of surgical debridement performed	Wound area (cm^2)		Change in wound area		Final outcome
		Initiation	Cessation	Actual (cm^2)	Percentage (%)	
1	0	21.5	7.5	-14.0	-65.1	Secondary closure
2	3	124.0	88.5	-35.5	-28.6	Split-skin graft
3	0	116.0	104.0	-12.0	-10.3	Split-skin graft
4	1	76.8	69.0	-7.8	-10.2	Split-skin graft
5	0	6.9	3.4	-3.5	-51.0	Secondary closure
6	1	52.0	47.0	-5.0	-9.6	Split-skin graft
7	0	56.5	39.5	-17.0	-30.1	Split-skin graft
8	0	47.0	27.5	-19.5	-41.5	Split-skin graft
9	0	17.1	10.3	-6.8	-39.8	Split-skin graft
10	2	50.3	67.7	+17.4	+34.6	Split-skin graft
11	0	32.2	25.3	-6.9	-21.4	Split-skin graft
Av.		**54.6**	**44.5**	**-10.1**	**-24.9**	

effectiveness in the treatment of chronic diabetic foot ulcers.

VAC therapy had the ability to provide an occlusive environment in which wound healing could take place under moist, clean and sterile conditions. This environment increased the rate of granulation in the wound,[14] besides reducing pain caused by the wound.[15] Such a sterile, occlusive environment is not given by conventional dressings.

Thus, VAC therapy was particularly useful for the treatment of large diabetic foot ulcers. Wounds in our study had an average surface area of 54.6 cm^2 (Table 3). This was 2 to 3 times larger than the average wound area of 20.7 cm^2 in the study by Armstrong and Lavery.[12] Two patients in our study with necrotising fasciitis in the lower limb presented with especially large wounds after radical debridement, with areas of 124 and 116 cm^2 (Table 3). Use of VAC therapy in large wounds obviated the need for a daily change of dressing, hence removing the trouble of a daily change of dressing, which was painful, difficult to perform and could lead to increased fluid loss.

VAC therapy has been shown to produce a greater reduction in wound dimension than conventional dressings. Eginton et al reported a 49% and 59% reduction in the wound depth and volume, respectively, of 6 VAC-treated diabetic foot ulcers.[11] This was significantly greater than the 7.7% reduction in wound depth and 0.1% reduction in wound volume achieved when the same wounds were treated with moist gauze dressings.[11] However, when the wound area before and after VAC therapy was compared, Eginton et al found no significant reduction in the area.[11] The greater reduction in wound dimension had been attributed to the three-dimensional stress which VAC exerted across the whole area of the wound, also known as macro-strain, that drew wound edges inwards in a centripetal fashion, thus shrinking the wound.[16] In our study, no randomised controls were included. We were therefore unable to compare reduction in wound area after VAC therapy to controls treated by conventional dressings. Nevertheless, reduction in wound area was observed in 10 of 11 wounds. This decrease in size was, however, not statistically significant.

Besides reducing wound size, VAC therapy encouraged wound healing by stimulating the formation of granulation tissue. Morykwas et al[17] demonstrated that wounds treated with negative pressure achieved more granulation using either continuous or intermittent pressure than those treated using conventional dressing (n = 10).

A freshly granulating wound surface indicates good wound healing, as the formation of granulation tissue is part of the proliferative stage of wound healing.[18] The time from VAC therapy initiation to the achievement of a continuous and fresh bed of granulation in the wound was taken as the time needed for wound bed preparation for surgical intervention. In our study, this was achieved in all 11 cases, prior to closure via split-skin grafting or secondary closure.

An additional benefit observed was the ability of VAC therapy to alleviate bacterial infection in a wound. In the study performed by Morykwas et al,[17] VAC therapy achieved a clinically significant reduction in bacterial load of chronic wounds inflicted on a swine model by the fifth day (n = 5). A similar reduction, however, took 11 days in control wounds which were untreated (n = 5).[17] In our study, wound culture and sensitivity were found to be positive for micro-organisms for all 11 wounds at the start of VAC therapy.

All 11 wounds showed clearance of bacterial infection at the end of VAC therapy, when surgical intervention was undertaken.

In our study, the length of time taken to complete VAC therapy ranged from 11 to 39 days, with an average of 23.3 days. This was much shorter than the average time taken by Armstrong et al of 32.9 days[9] and Clare et al of 57.4 days.[10]

In Singapore, VAC therapy costs $100 per day. For in-patients, the cost of hospitalisation adds on to the cost of VAC therapy. In order to make VAC therapy more affordable for patients, surgical treatment was performed once the wound had been adequately prepared with sufficient formation of granulation tissue and wound culture shown to be negative for bacteria, instead of waiting for further reduction in wound area through prolonged application of VAC therapy.

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 include ray amputation wounds, wounds post-debridement for necrotising 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 good time. This reduced the cost of VAC therapy, as therapy was not prolonged to attain greater reduction in the wound area. VAC therapy also provides a sterile, more controlled resting environment to large, exudating wound surfaces. Large diabetic foot ulcers were thus made more manageable.

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