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A Comparative Study of Cost Effective Vacuum Assisted Closure(VAC) Therapy and Conventional Dressing on Wound Healing in patients with Diabetic Foot Ulcer

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Abstract
Aims and objectives: *To compare the efficacy and safety of Cost Effective VAC therapy and conventional dressing in patients with diabetic foot ulcer.*
Materials and methods: *A prospective parallel randomized controlled trial was carried out in 60 patients with diabetic ulcer admitted in the Department of General Surgery, Govt Rajaji Hospital Madurai between August 2019 and August 2020*
Observation and Results: *Time to healing was significantly less in the study group as compared to the control group (mean time to healing of 22.52 days vs 33.85 days respectively, p=<0.0001). The reduction in ulcer area was significantly more in the VAC therapy groups with a mean reduction of 14.29 cm^2 vs 4.78cm^2 compared to the control group (p=<0.0001). The median rate of granulation tissue fonnation was 2.4cm^2/day and 1.7cm^2/day in the study and control group respectively (p=0.0306). Visual Analog Score (VAS) was found to be significantly less in the VAC therapy group*
Conclusion: *The present randomized controlled trial comparing VAC therapy with conventional dressing for DFU shows that VAC therapy is effective in reducing the time to complete wound healing and improving granulation cover with no increase in the complications such as bleeding and infection.*
Keywords: Debridement, Granulation, ulcer, vacuum, visual analog score.

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I. Introduction

Diabetic foot ulcers constitute one of the most important complications of diabetes mellitus, with a staggering 25% lifetime risk[1,2]. The morbidity and prolonged need for hospital stay greatly affects the quality of life of those affected by it. The importance to these becomes even more significant considering that India houses the largest number of diabetics in the world[3]. If not treated promptly, progression of infection and sepsis may necessitate a limb amputation to prevent mortality[4].

Treating diabetic foot is a challenging task since it requires multimodal approach including control of infection by appropriate antibiotics, serial and aggressive debridement, strict blood sugar control and effective pressure off-loading. Healing of the diabetic foot ulcers takes significantly longer duration even with strict glycaemic control and effective treatment for infection due to the larger raw area which requires considerable time for the granulation tissue coverage. Numerous studies have shown Negative Pressure Wound Therapy (NPWT) to be efficacious in wound healing of different types of wounds which include chronic wounds, bums wounds, diabetic foot ulcers, venous ulcers, orthopaedic trauma, flaps and grafts, open abdominal wounds and sternal wounds[5,11]. The efficacy and safety of NPWT in the management of DFU has been witnessed in numerous prospective and multi-centred randomised control. trials[12].Though the International Diabetes Federation (IDF) in its 'Clinical Practice Recommendation on the Diabetic Foot -2017' states Negative Pressure Wound Therapy (NPWT) as 'revolutionary' in the management of DFU[17], it states NPWT as an 'adjunctive' therapy and recommends its use, if 4 weeks of standard wound therapy fails to produce any improvement[17]. Majority of the studies have been performed in Western populations. Though these studies have significant implication on the use of NPWT in DFUs; the Indian population differs from the western population in various aspects. Theage of onset of the complications of diabetes one of which is DFUs; are comparatively much earlier in Indians due to the differences in genetics, lifestyle, culture, socio-economic status and health education. Also, general factors as BMI and albumin, and wound characteristics as size of DFU, bacteriology etc which affect wound healing are comparatively different in an Indian population. Hence this study was carried out to compare the efficacy, safety and complications of VAC therapy in DFU compared to the conventional dressings in Indian population.

II. Aims And Objectives

To compare the efficacy and safety of Cost-Effective VAC therapy and conventional dressing in patients with diabetic foot ulcers.

Primary objective

To compare the time taken for complete wound healing following VAC therapy and conventional dressing in patients with diabetic foot ulcers.

Secondary objectives

1. To compare granulation tissue formation between VAC therapy and conventional dressing among patients with diabetic foot ulcer using visual score**.**

2. To assess the complications of VAC therapy and conventional dressing in patients with diabetic foot ulcer patients: Bleeding, Pain and Infection.

III. Materials And Methods

This study; designed as a prospective parallel randomized controlled trial was carried out in the Department of General Surgery, Govt Rajaji Hospital Madurai between August 2019 and August 2020 after being approved by the Institute Ethical Committee (IE).

With a power of 80%, a error of 5%, and expected difference of 20 days in the time taken for complete granulation cover[18], the sample size was calculated to be 54 with 27 in each group. With the expected drop out rate of 10%, the sample size of 30 in each group was taken for the trial.

Inclusion Criteria

All diabetic patients >18 years of age admitted in Rajaji Hospital General Surgery wards with a diabetic foot ulcer (DFU).

Exclusion Criteria

1. Coagulopathy
2. Venous disease
3. DFU patients with underlying osteomyelitis
4. DFU patients with Charcot's joint
5. DFU classified under Wagner-Meggit classification as grade III,IV and V
6. Peripheral vascular disease.
7. DFU involving both foot.

Randomization of patients

Stratified Block randomization was carried out with randomly selected block sizes of 4 and 6. Further after randomization of patients in two groups, the patients in the respective groups were stratified into two groups of ulcer size <10 cm in and of ulcer size >10cm in the longest dimension, considering size of ulcer as a known confounding variable.

Study Procedure

All patients with a DFU in Rajaji Hospital General Surgery wards were enrolled into the study after fulfilling exclusion criteria and after informed written consent. The nature, methodology and risks involved in the study were explained to the patient and informed consent was obtained. All the information collected was kept confidential and patient was given full freedom to withdraw at any point during the study. All provisions of the Declaration of Helsinki were followed in this study.

Initial treatment including necessary surgical debridement of the wound, appropriate antibiotic based on culture sensitivity and glycemic control was done. The wound was defined fit to be included in the study when the DFU was deemed "clean" by the treating surgeon and the wound culture shown no growth or skin flora, all patients were also checked for strict glycemic control defined as having AC (ante-cibum) and PC (post-cibum) values of less than 120mg/dL and 180 mg/dL respectively before including in the trail. After satisfying the said criteria, the enrolled patients were then randomized into two groups to receive either conventional dressings or Vacuum Assisted Closure (VAC) therapy. The patients in the study group received VAC therapy while those in the control group received conventional dressing. Further patients in the two groups were stratified in to groups of patients with DFUs of <10cm and >10cm in the longest dimension. Wagner's grade of the DFU, duration of diabetes (in years), whether the patient was on Insulin/OHAs/both prior to study, HbAlc, baseline albumin, hemoglobin, BMI and comorbidities were recorded in both the groups before starting the intervention. Assessment of nutrition was done by monitoring albumin and hemoglobin levels every week.

Culture sensitivity was sent at the start of the study and then every week.

In the study group, the wound bed was filled with a saline soaked gauze piece after it was thoroughly cleaned. VAC was applied by placing sterile pads in two layers with a 16Fr Ryle's tube placed between the two layers and then the wound was sealed by a sterile transparent polyurethane sheet. The tube was connected to a wall mounted suction device and the pressure was set at -125mm Fig. Mode of Negative Pressure Wound Therapy (NPWT) was continuous. This dressing was changedevery 48 hrs. At any point of time during the study if the treating surgeon notices any adverse wound parameters, the VAC therapy was immediately discontinued.

In the control group conventional dressing was given. This consisted of placing a saline soaked gauze piece over the wound bed after cleaning the wound. Two layers of sterile gauze piece was placed on the dressing and secured with roller bandages. The dressing was changed daily and assessment of the wound was done every 48 hours by the treating surgeon for improvement or any adverse wound parameters. The outcome parameters were recorded in a specified proforma. Photographic documentation was also done at the start of the study and then followed weekly. Patients were assessed till satisfactory wound healing was achieved which is defined when the wound is completely filled with granulation tissue and is fit for split-skin grafting (SSG).

Primary Outcome measure

The time needed for satisfactory wound healing was calculated by the number of days from the start of the study till the wound was fit for grafting.

Secondary Outcome measures

Granulation tissue formation: This was assessed using a visual score[19] as mentioned , Granulation tissue score was noted every week and the mean value was taken for statistical analysis.

Definition	Score
No granulation present	1
<25% of wound covered by granulation tissue	2
25-74% of wound covered by granulation tissue	3
75-100% of wound covered by granulation tissue	4

IV. Observation And Results

Baseline Characteristics		**Group A**	**Group B**	**P –value**
Age in years (Mean)		55.85(35-95)	52.89(28-70)	0.3596[a]
Gender	Male	16 (59.26%)	15 (55.56%)	0.783[b]
	Female	11 (40.74%)	12 (44.44%)	
Diagnosis	Right DFU	16(59.26%)	13(48.15%)	0.413[b]
	Left DFU	11(40.74%)	14(51.85%)	
Duration of DM		7.29 years	6.24 years	0.462[a]
Treatment of DM before study	New onset	1(3.7%)	0(0%)	0.779[b]
	On OHA	20(74%)	20(74%)	
	On insulin	5(18.52%)	6(22.22%)	
	On insulin &OHA	1(3.7%)	1(3.7%)	
Co-morbidities	None	22(81.48%)	20(74.07%)	0.067[b]
	CAD	0 (0%)	2(7.41%)	
	HTN	5(18.52%)	1(3.7%)	
	HTN& CAD	0 (0%)	3(11.11%)	
	BA	0(0%)	1(3.7%)	
BMI (kg/m^2)		22.99	23.26	0.7780[a]
Haemoglobin (g/dL)		10.28	10.18	0.8163[a]
Albumin (g/dL)		2.77	2.72	0.5287[a]
HbAlC		8.74	8.54	0.6525[a]
Wagner-Meggit Grade	Grade 1	8(29.63%)	2(7.41%)	0.036[b]
	Grade 2	19(70.37%)	25(92.59%)	
Number of patients with ulcer size	>10cm	11(40.74%)	10(37.04%)	0.780[b]
	<10cm	16(59.26%)	17(62.96%)	
Ulcer area (cm)		70.97	80.44	0.5675[a]

Group A- Negative Pressure Wound Therapy group; Group B- Conventional Dressing group

Table 1- Time to wound healing

Time to wound healing			Group A	Group B	P -value
Time to wound healing in days	Mean		22.52	33.85	<0.0001[c]
	Median		21	34	
	Min		13	18	
	Max		36	55	
Time to wound healing in days	>10cm size ulcers	Mean	29.36	38.5	0.0042[c]
		Median	30	39.5	
		Min	19	27	
		Max	36	50	
	<10cm size ulcers	Mean	17.81	31.11	<0.0001[c]
		Median	17.5	30	
		Min	13	18	
		Max	25	55	

Table 2- Time to healing (days) with respect to Wagner grade

Wagner Grade		Group A	Group B	P value
1	Mean	15.75	30	0.0361°
	Median	15.5	30	
	Min	13	21	
	Max	19	39	
2	Mean	25.37	34.16	0.0012°
	Median	27	34	
	Min	15	18	
	Max	36	55	

Table 3. Reduction is ulcer area (cm^2)

Reduction in ulcer area (cm^2)			Group A	Group B	P value
Reduction in ulcer area (cm^2)	Mean		14.29	4.78	<0.000 l[c]
	Median		10.34	3.5	
	Min		0.28	0.00	
	Max		36.85	25	
Reduction in ulcer area (cm^2) based on ulcer size	>10cm size ulcers	Mean	23.93	7.04	0.0005[c]
		Median	25	6.845	
		Min	10	0	
		Max	36.85	25	
	<10cm size ulcers	Mean	7.66	3.46	0.0018[c]
		Median	7.73	3	
		Min	0.28	0	
		Max	13.25	16.7	

Table 4 Mean time taken (in days) for granulation tissue cover of Visual score 3 and 4.

Visual Score	Group A	Group B	P value
3	14.52 days	15.04 days	0.561 l[a]
4	23.33 days	32.15 days	<0.0001[a]

Table 5.Rate of granulation tissue formation (cm^2 /day)

Rate of granulation tissue formation (cm^2 /day)			Group A	Group B	P value
Rate of granulation tissue formation cm^2 /day			2.91	2.16	0.0306[c]
	Size	Mean	2.12	1.50	
		Median	2.025	1.43	

Rate of granulation	of ulcer <10cm				0.035 l[c]
		Min	0.79	0.77	
		Max	5.2	3.89	
Tissue Formation cm^2/day based on ulcer size	Size of ulcer >10cm	Mean	4.05	3.29	0.3598[c]
		Median	4.2	2.766	
		Min	2.37	1.54	
		Max	7.29	5.5	

Table 6. Assessment of Pain: Visual Analog Score (VAS)

Time		Visual Analog Score		P value
		Group A	Group B	
Week 1	Mean	8.22	8.46	0.271[c]
	Median	8.5	8.5	
	Min	7	7	
	Max	9	10	
Week 3	Mean	3.18	4.42	0.004[c]
	Median	3	4	
	Min	2	2	
	Max	6	7	

Table 7-Assessment of Bleeding

Time	Number of change in dressings due to bleeding	Number of patients		P value
		Group A	Group B	
Week	0	13	11	0.656[c]
	1	8	10	
	2	6	5	
	3	0	1	
Week 3	0	25	25	0.579[c]
	1	1	2	
	2	-	-	
	3	-	-	

Table 8

Bleeding causing soakage	Number of patients		P value
	Group A	Group B	
Yes	14	16	0.584[b]
No	13	11	

Bacteriology

Table 9

Organism	Number of patients		Total number of patients (% of 54)
	Group A	Group B	
No Growth	12	11	23(42.6%)
CONS	5	4	9(16.7%)
Staphylococcus aureus	16	19	35(64.8%)
Streptococcus spp	6	5	11(20.4%)

Pseudomonas aeruginosa	5	6	11(20.4%)
Escherichia coli	1	13	14(25.9%)
Klebsiella spp	1	2	3(5.6%)7%
Proteus mirabilis	2	5	7(12.9%)
Acinetobacter baumannii	2	5	7(12.9%)
MRSA	1	1	2(3.7%)
Morganella morgagnii	1	1	2(3.7%)
Enterococcus faecalis	2	4	6(11.1%)
Citrobacter spp	1	1	2(3.7%)
Bacteroides spp	1	0	1

Table 10

Nature of growth	**Number of patients**		**P Value**
	Group A	**Group B**	
Polymicrobial	8	22	<0.00 l[b]
Monomicrobial	19	5	
No Growth	12	11	0.783[b]
CONS	5	4	0.715[b]
No Growth/CONS	16	12	0.276[b]
Escherichia coli	1	13	<0.0001[b]
Gram +	22	21	0.735[b]
Gram -	10	23	0.0003[b]
Aerobes	5	6	0.735[b]
Facultative Anaerobes	26	27	0.315[b]
Anaerobes	1	0	0.315[b]

Table 11a & 11b Minor Amputations

Table 11a

Number of Amputations	**Number of patients**		**P value**
	Group A	**Group B**	
0	24	22	0.541[b]
1	3	4	
3	0	1	

Table 11b

Amputations	**Number of patients**		**P value**
	Group A	**Group B**	
Yes	24	22	0.444[b]
No	3	5	

Table 12a & 12b. Debridement

Table 12a

Number of debridement	**Number of patients**		**P Value**
	Group A	**Group B**	
0	5	3	0.147[c]
1	5	6	
2	11	7	
3	6	4	

4	0	5	
5	0	2	

Table 12b

Debridement (Pearson Chi^2)	**Number of patients**		**P value**
	Group A	**Group B**	
No	5	3	**0.444^b**
Yes	**22**	**24**	

Figure 4. Materials used for NPWT in the study

Figure 5. Wall-mount based VAC device with pressure set at 126 mm Hg

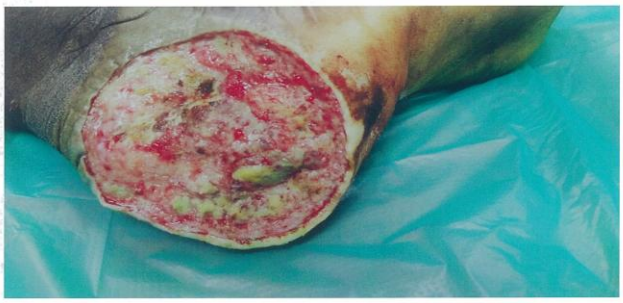

Figure 6. Diabetic foot ulcer at the start of NPWT

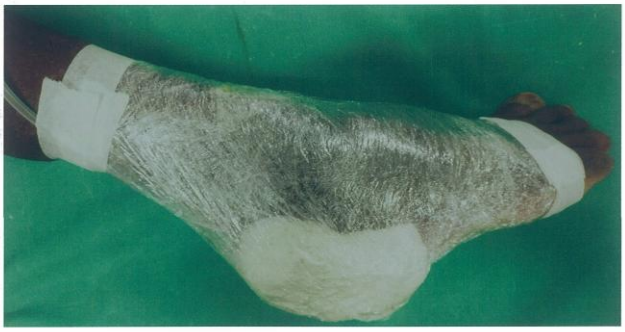

Figure 7. VAC therapy for the DFU in fig. 6

V. Discussion

This study was done to demonstrate the efficacy and safety of NPWT in the treatment of DFU as compared to conventional Saline dressings, essentially comparing the time to healing (defined as the time taken to make the wound fit for grafting), granulation cover and complications attributed to NPWT. Analysis was done for a total of 54 patients with 27 patients in the study group where in patients received NPWT therapy; and 27 patients in the control group, where conventional dressing was given.

Analysis of outcome variables

Time to wound healing

The time to wound healing was significantly better in the VAC therapy group as compared to conventional dressing. Similar results were obtained when comparison was done between the two groups stratifying the patients based on ulcer size (i.e. <10 cm and >10cm). while the time to complete healing in VAC group was significantly better in both DFU of <10 cm and >10cm compared to the conventional dressing group, its efficacy was more evident in the DFUs <10cm (p <0.0001), than the DFUs >10cm (p= 0.0042). This can be attributed to the fact that time to healing is directly proportional to the size of the ulcer.

Reduction in ulcer area

Reduction in ulcer area in our study was significantly better in the study group with a mean reduction of 10.34cm^2 (20.1% reduction) as compared to 3.5cm^2 (5.9% reduction) (p value <0.0001). Reduction in ulcer area was found to be more significant in ulcers >10cm compared to those <10cm (p value 0.005 vs 0.0018). NPWT enhances wound contraction by macro-deformation due to the centripetal forces acting at the wound-foam interface[16]. The extent of macro-deformation is dependent on the deformability of the wound tissue[8]. Thus in-our study too, wound contraction was more significant for ulcers >10cm which were more deep and hence responded better to the macro-deformation effect of NPWT

Granulation tissue formation

In our study granulation formation in the two groups was analysed by comparing the time to achieve Visual Score of 3 and 4; and the rate of granulation tissue formation. Though the time to achieve scores of 3 and 4 were comparatively less in VAC, this was significant only for Visual score 4 (23.33 days vs 32.15 days, p <0.0001). The possible reason as to why values were not significant in terms of Visual score 3 could be the wide range of 25-75% granulation used in score of 3.In the present study, we also found that the mean rate of granulation tissue formation was 2.91cm and 2.16cm in the study and control groups respectively and this was found to be statistically significant (p of 0.0306).

Minor amputations and secondary debridement

Our study also compared the two groups with respect to minor amputations (digital amputations). Of the 54 patients, only 8 patients underwent a digital amputation of which 3 were in the VAC group and 5 were in the conventional dressing group, which was of no statistical significance (0.444). Of the 8 patients, 7 underwent one digital amputation and 1 underwent three digital amputations and the latter belonged to the control group. In our study all the wounds were well debrided at initial presentation and hence most of them did not require further secondary amputations.

Pain

Pain is one of the most common complications implicated due to NPWT. Pain in NPWT is thought to occur due to negative suction and during change of dressing and when granulation tissue which grow into the foam's pores, gets disrupted. In our study pain was assessed by Visual Analogue Score (VAS) and analysis done by comparing the scores in week 1 and week 3 of the study. Week 3 was chosen because the average time to healing was 22.52 days and 33.85 days in the study and control group respectively, which approximated to about 3 weeks. Pain was comparable with no difference in the two groups in the first week (p=0.271); with mean scores of 8.22 and 8.46 in the study and control groups. However, in week3, the mean score was 3.18 and 4.42 in the study and control groups respectively and this was significant (p=0.004). At first presentation, all wounds would be extensively infected and covered with slough and necrotic tissue which require extensive debridement leading to more pain. With time, as the wounds fill up with granulation, pain is expected to come down. Hence, in our study pain scores were better in the NPWT group than the control group in week 3.

Bleeding

Bleeding was another common complication attributed to NPWT, which was compared between the two groups. Bleeding was said to be present when there was blood stained soakage necessitating change in dressing after the application of first dressing. 14 patients in NPWT group and 16 patients in conventional

dressing group had bleeding. In week 1, 30 patients had bleeding; 18 patients had bleeding once of which 8 belonged to the study group and 10 belonged to the control group. Of the 12 patients who bled more than once in week 1, 6 belonged to the study group and 6 belonged to the control group. In week 3, only 3 patients had bleeding once of which 1 belonged to study group and 2 to control group. No patient reported bleeding more than once in either group in week 3. Though these results were figuratively in favour of NPWT, these were not statistically significant. The increased bleeding in week 1 in both groups was possibly due to aggressive debridement which the patients underwent.

Infection/Bacteriology

Monomicrobial growth was significantly more in the NPWT group (19 vs 5, p=<0.001). When comparison was done between the two groups based on gram stain, growth of Gram negative organism was significant less in the NPWT group (10 vs 23, p=0.0003). Several other studies have shown that NPWT reduces Gram negative non-fermentative bacterial growth[14,15]. Gram positive organisms were equally distributed in both groups (22 and 21 in study and control group respectively, p=0.7355). Anaerobic growth was demonstrated in only one patient who belonged to the study group. Singh et al[16] in a similar study showed that Staphylococcus aureus was the common organism grown (23.3%). Nather et al[15] in a prospective study showed that Staphylococcus aureus was cultured from wounds of all five patients. Though different Indian studies report Pseudomonas as the most common organism, staphylococcus was the most common in our study. Most DFUs in the developing countries present late and thus are deep infections; often polymicrobial, mostly showing Gram negative and anaerobic growth

VI. Conclusion

The present study showed that VAC therapy significantly decreases the time to complete wound healing when compared to conventional dressing. It was found that VAC therapy significantly improves total granulation cover over the wound and the study also showed significantly high rate of granulation tissue formation with VAC therapy. We found that pain score was significantly better at week 3 with VAC group compared to conventional dressing group and the study did not find any significant increase in the bleeding and infection in the VAC therapy group. The study showed significant reduction in the ulcer size in the VAC group compared to the conventional dressing group and the reduction was more pronounced in the ulcer DFU of >10cm size. We did not find any significant difference in the number of amputations or the number of debridement required between the two groups.

The present randomized controlled trial comparing VAC therapy with conventional dressing for DFU shows that VAC therapy is effective in reducing the time to complete wound healing and improving granulation cover with no increase in the complications such as bleeding and infection. Further RCTs with a larger number of patients is recommended to extrapolate the results of the present study.

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