

WOUND THERAPY IN DIABETIC FOOT ULCER: COMPARISON OF OUTCOMES BETWEEN CONVENTIONAL AND NEGATIVE PRESSURE METHODS FROM A TERTIARY CARE HOSPITAL IN SOUTH KERALA

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Abstract

Background: Diabetic foot ulcer have ever been a common cause and challenge as a of chronic disease burden in any surgical OPD. Many techniques for local ulcer treatment have been evaluated. Now a days, the negative pressure wound therapy (NPWT) is also being widely used as an alternative method. **Materials and Methods:** The present prospective cohort study was conducted in a tertiary care setup in South Kerala, India. We assessed the outcomes of conventional and negative pressure wound therapy among 102 diabetic foot ulcer patients. Present study intend to assess the number of days required for wound healing, wound infection rate and pain. **Results:** There was significant difference in the number of days to attain full granulation on comparing the two methods. (p value 0.000). The difference in wound infection reduction and pain score between the groups were however not significant. **Conclusion:** The study results suggests that NPWT is a good method to shorten the duration of treatment of leg ulcers towards an early skin grafting.

INTRODUCTION

Diabetes Mellitus is a global lifestyle associated epidemic disease. Over 60 million persons have the disease in India.^[1,2] According to the prevalence data, by 2030 diabetes is expected to be double.^[3]

With regards to the lower limbs, diabetic leg ulcers are a common and serious problem.^[4] The increased sugar content in the blood, the reduced blood supply and associated neuropathy are established contributing factors to diabetic foot ulcer for improving ulcer healing rates, the principles in wound care have been researched well. This includes a suitable host environment in the form of debridement, maintaining required moisture in the wound, and antibacterial therapy. Moisture content has to be just right so that growth factors and cells of different types can migrate and cause wound contraction. A dry wound needs rehydration and a excessively wet wound (due to exudative) need to be kept drained.^[4-8]

After initial debridement and antimicrobial therapy, local wound care plays an important role for wound healing. The available dressing methods include various forms of absorbent dressings. This is the

conventional wound dressing. Of late the innovation of sucking out the exudative fluid at the same time keeping the wound covered is practised by the application of negative pressure indirectly over the wound surface. This is called the negative pressure wound therapy or vacuum assisted wound closure. The benefits of vacuum assisted wound closure is that along with compartmentalising the wound from the external environment, the required moisture is maintained. Hence promoting both angiogenesis and granulation tissue growth. Here we are describing a simplified technique of negative pressure application which is economical and not described in literature. This study compared the two techniques of wound therapy – The conventional absorbent dressing based wound therapy (CWT) and negative pressure wound therapy (NPWT)-in diabetic leg ulcers in terms of mean days of dressing to prepare wound bed for skin cover, wound infection rate and pain.^[9,10]

MATERIALS AND METHODS

The study is a prospective, cohort study conducted between Dec 2017 and May 2019 in a 300 bedded

tertiary care and teaching hospital in South Kerala, India.

The objective of the study was to assess the number of days required for wound healing, wound infection rate and pain. Patients 40 years and above who presented in our surgical department with diabetic leg ulcers were chosen. A total number of 102 patients were included in the study. They were divided into 2 groups: Group 1: conventional dressing -51 Group 2: negative pressure wound therapy- 51.

All ulcers which were in healing state, 10 to 15cm² area and involving the lower limbs and had full thickness skin loss. Ulcers with bleeding risk or on anti coagulation or coexisting psychosis or chronic renal failure, associated complete occlusion of arterial vessels or osteomyelitis were excluded.

Sample size:calculated using the formula below was found to be 52 in each group

$$\text{Equation : } n/\text{group} \geq \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (\sigma_1^2 + \sigma_2^2)}{\delta^2}$$

This was a prospective cohort study including all the consecutive diabetic leg ulcer cases which fulfills inclusion criteria. All patients who presented to the outpatient department with features suggestive of diabetic leg ulcers are evaluated by a detailed history, systemic and local examinations.

After explaining the diagnosis to the patient and his/her relatives, consent for the procedure was obtained. Pre-anaesthetic assessment and relevant investigation are done including HbA1C and wound swab culture and sensitivity.

At the time of admission, all patients were started on empirical iv antibiotics. The type of wound therapy was decided on an alternate and consecutive basis. All patients underwent hand held doppler of the peripheral pulses to confirm the presence of flow signals.

Conventional absorbent dressing based wound therapy (C.W.T) technique-

Conventional dressing was done after thorough wound debridement. Hydrogen peroxide, Povidone Iodine 10% solution and normal saline was used as cleaning agents.Slough softener and local antibiotic ointments were used when needed. Gauze and Cotton gauze pad was wound and closed by cotton bandage. Dressing changed daily and in heavily infected wounds twice daily. The therapy was continued till the ulcer was well granulating and ready for skin cover procedures

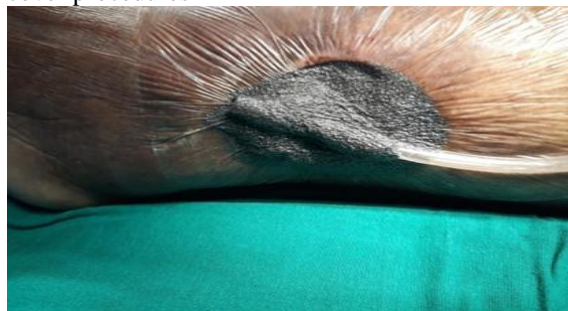


Figure 1: showing that when negative pressure is applied the ryles tube is seen more prominent

Negative Pressure based Wound Therapy (N.P.W.T) technique-

For this technique, a normal suction machine generating pressure of -120mmHg, naso-gastric tube, a sterilized piece of foam cut tailored to the ulcer dimensions and cling film were used. Continuous suction is applied for 1st 48 hrs followed by intermittent suction with 30mins on and 30mins off. The NPWT is kept continuously for 2-5 days. If the suction is not working, it will be changed earlier.

Post-procedure patients of both groups were reviewed and ulcers are reassessed on

1. 3 days after first dressing
2. After 1 week
3. Weekly subsequently

All patients are given a questionnaire or data collected verbally along with the lab investigations and analyzed statistically.

Wound bed is said to be prepared for skin cover once the whole wound bed shows granulation tissue. This is assessed by the colour and nature of the wound bed. The wound infection rates are expressed in terms of the colony counts from the culture and sensitivity reports.Colony count above 10⁵ was considered infected. Pain will be analyzed based on Visual Analogue Scale (VAS). Parenteral Analgesics will be given if VAS pain scale is more than 5.

Statistical Methods

All patients data were entered on proforma sheets and tabulated to analyse the same. For calculating the significance in the study, the Student 't' test was used. For finding if there is an association of the study parameters, the Chi- square / Fisher Exact test (SPSS version 20) was used

Consent

All patients who were enrolled in the study had given their written informed consent. The study got the approval of the institutional ethics committee.

RESULTS

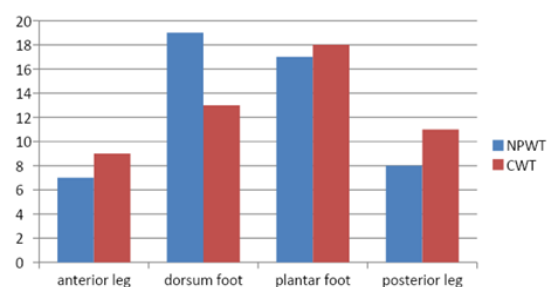


Figure 2: Site of ulcer

Table 1: Age distribution: The age group distribution were similar in both the groups

Age group	Frequency(%) NPWT gp	Frequency (%) CWT gp
Upto 60	23(45.1)	24(47.1)
between 60 and 70	13(25.5)	10(19.6)
Above 70	15(29.4)	17(33.3)
Total	51(100.0)	51(100.0)

Table 2: Sex distribution. The sex distribution is similar in both groups

Sex distribution	Frequency (%) NPWT GP	Frequency (%) CWT GP
F	22(43.1)	23 (45.1)
M	29(56.9)	28 (54.9)
Total	51(100.0)	51(100.0)

Table 3: Wound site. Wound site in Negative pressure wound therapy group

Wound site	Frequency(%) NPWT gp	Freq(%) CWT gp
Anterior leg	7(13.7)	9(17.6)
Dorsum foot	19(37.3)	13(25.5)
Plantar foot	17(33.3)	18(35.3)
Posterior leg	8(15.7)	11(21.6)
Total	51(100.0)	51(100.0)

Table 4: Pain score

Pain score	Frequency (%) NPWT	Freq (%) CWT
4	30(58.8)	30(58.8)
6	21(41.2)	21(41.2)
Total	51(100.0)	51(100.0)

The negative pressure wound therapy group has a mean age of 63.43 with age ranging from 48 to 84 years (standard deviation 9.339). Mean age of conventional wound therapy group is 63.90 (range 45-84) with standard deviation of 10.149.

The minimum duration of NPWT is 3 days and maximum is 14 days the mean being 8.20 (2.793 was the standard deviation). In the conventional wound therapy group minimum duration is 5 days, maximum is 18 days. (mean of 12.51 days and standard deviation of 3.289). The mean number of dressings in NPWT group is 2.41 (range 1-4) with standard deviation 0.804.

The pain scores were similar with a minimum of 4 and maximum of 6 and standard deviation of 0.994 in both groups.

The number of days of dressings required to attain full granulation, the day on which the culture turned negative first and the pain experienced during the dressing were assessed and compared using the paired t test for their significance.

Table 5: Paired Samples Statistics - Test for number of days for complete granulation of wound

		Mean	N	Standard Deviation	Standard Error Mean
Pair 1	NPWT	2.41	51	0.804	0.113
	Conventional dressing	12.51	51	3.289	0.460

Table 6: Paired Samples Test

		Paired Differences				t	df	p value	
		Mean	Standard Deviation	Standard Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	NPWT vs Conventional	10.098	3.132	0.439	10.979	9.217	23.024	50	.000

There is significant difference in the number of days for complete granulation formation between negative pressure wound therapy and conventional wound dressing with a p value of 0.000

T-Test for the significance of day of dressing on which culture was found to be negative:

Table 7: Paired Samples Statistics

		Mean	N	Standard Deviation	Standard Error Mean
Pair 2	NPWT	1.76	51	0.839	0.117
	Conventional dressing	1.88	51	0.711	0.100

Table 8: Paired Samples Test

		Paired Differences					t	df	p value
		Mean	Standard Deviation	Standard Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 2	NPWT vs Conventional	0.118	0.931	0.130	0.379	0.144	0.903	50	.0471

Negative pressure wound dressing is more effective compared to conventional dressing with respect to the wound infection reduction rates (i.e no of days to reach culture negative) with a p value of 0.47, hence it was not considered as significant

T-Test for pain difference

Table 9: Paired Samples Statistics

		Mean	N	Standard Deviation	Standard Error Mean
Pair 3	NPWT	4.82	51	.994	.139
	Conventional	4.82	51	.994	.139

Table 10: Paired Samples Test

		Paired Differences					t	df	p value
		Mean	Standard Deviation	Standard Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 3	NPWT – Conventional Dressing	0.000	1.497	0.210	0.421	0.421	0.000	50	1.000

No significant difference in pain scores between the two groups with a p value of 1.00.

DISCUSSION

In the study on a total of 102 diabetic patients, the negative pressure wound therapy group has a mean age of 63.43 with age ranging from 48 to 84 years (standard deviation 9.339). Mean age of conventional wound therapy group is 63.90 (range 45-84) with standard deviation of 10.149.

The minimum duration of NPWT for granulation tissue to cover the wound is 3 days and maximum is 14 days with a mean of 8.20 and standard deviation of 2.793 while in the conventional wound therapy group minimum duration is 5 days and maximum is 18 days with a mean of 12.51 days and standard deviation of 3.289. The mean number of dressings in NPWT group is 2.41 (range 1-4) with standard deviation 0.804.

Hence as per the study, Negative pressure wound dressing seems more effective compared to conventional dressing with respect to the wound infection rates but were not significant (p value 0.47) Some limitations of the study are that it is not a double blinded RCT. Features of wound area reduction, cost of procedure and follow up treatment modalities were not assessed.

In study by Ali M Lone et al in 2014, 56 diabetic patients were assessed. The age group was 47-64 years with mean of 53.79 years for NPWT and 48-62 years with mean of 54.57 yrs for conventional dressings.^[5]

In study of 30 patients by Biplav Singh et al in 2015, the mean age was 54.4 years with 22 males and 8 females.^[6]

In randomised control trial by Aslam R in 2015, the mean age of patients in NPWT group was 55.45 years

(SD±6.279) and conventional dressing group was 55.23 years (SD±6.220).^[7]

In prospective randomized study conducted by Mahmoud S Shehata on 100 patients with follow up every week for 6 weeks it was found that there was a rapid formation of healthy granulation tissue for VAC group (6.04 days) compared to for the traditional moist dressing group (9.67 days).^[8]

In study by Ali M Lone et al in 2014, 100% granulation was achieved in 77.8% (21 patients) at end of 5 weeks with NPWT while only 10% (40) achieved the same using conventional dressings. Armstrong and Lavery also observed increased rate of granulation tissue formation with Negative pressure wound therapy.^[9]

In study of 30 patients by Biplav Singh et al in 2015 randomised to 2 groups of 15 each, the mean time for appearance of 100% granulation was 25.1 days versus 41.1 days (NPWT versus conventional dressings). The average time of complete wound healing was 41.2 days with NPWT while 58.9 days with conventional dressings. The end point of study was complete wound healing defined as 100% re epithelisation despite of the method used for closure - secondary closure/SSG/Flap.

In randomised control trial by Aslam R in 2015, the minimum duration of wound healing was 5 days versus 10 days and maximum was 18 days versus 22 days (NPWT versus conventional dressing) with a mean of 11.366±3.488 versus 16.41±3.104. (p-value-0.00).

In study by Etoz A et al, mean number of days for wound healing was 9.64±4.65 days for NPWT compared to 14.22±2.78 days for conventional dressings. (p value-0.05).^[10]

Studies comparing the pain scores were not available though there is no significant difference on comparing both groups.

Gabriel et al showed a significant decrease in the mean time required for reduction of bio burden (25.9 ± 6.6 versus 6.0 ± 1.5 days). Moues et al randomised wounds to vacuum assisted closure and conventional wound therapy. Healing was characterised by development of a clean granulating wound bed ready or surgical therapy and reduction of wound surface area. No significant difference was seen in time needed for wound bed preparation with significant reduction in the wound surface area.

CONCLUSION

- Negative pressure wound dressing is more effective compared to conventional dressing with respect to the wound infection reduction rates with a p value of 0.47 with paired t test.
- No significant difference in pain scores between the two groups using paired t test with a p value of 1.00.
- There is significant difference in the number of days of dressing between negative pressure wound therapy and conventional wound dressing with a p value of 0.00 when compared using paired t test.
- The major advantage of Negative pressure wound dressing is reduced number of wound dressings and time for formation of granulation tissue
- Early clearance of infection along with the good granulation tissue cover allow early closure of wound.

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