

Original Research Article

Continuous versus intermittent negative pressure wound therapy on diabetic foot ulcerations

Pravalika Chavali*, M. Mallikarjuna Reddy

Department of General Surgery, NRI Medical college, Chinakakani, Guntur, Andhra Pradesh, India

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***Correspondence:**

Dr. Pravalika Chavali,

E-mail: drpravalika15@gmail.com

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ABSTRACT

Background: Among continuous and intermittent negative pressure therapies different clinicians have different choices and different school of thoughts. Very few studies have thrown light on this debate so far. Hence present study was done to know the better therapy in the healing of diabetic foot ulcerations between continuous and intermittent methods for best clinical outcomes.

Methods: This current study is a hospital based comparative prospective study.

Results: In present study, majority of the study population had wound closure by day 12 (41.4%) followed by day 9 (31%), followed by day 15 (13.8%). The difference between the groups regarding wound closure days distribution was not statistically significant.

Conclusions: The current study finds that negative pressure wound therapy (NPWT) therapy has higher rates of wound closure and that, for the healing of diabetic leg ulcers, applying either intermittent or continuous NPWT therapy is preferred for better wound closure rates and good bacterial clearance. No method was shown superior to other in terms of wound healing in diabetic foot ulcer.

Keywords: Diabetic foot ulcerations, Negative pressure wound therapy

INTRODUCTION

One of the most prevalent chronic illnesses and major worldwide health problems of the twenty-first century is diabetes mellitus (DM).¹ Types 1 and type 2 diabetes are becoming more common; 415 million persons globally were estimated to have had DM in 2015 according to WHO.¹ Clinicians now have access to improved drugs for treating diabetic foot ulcers, allowing for effective local therapy. Negative pressure wound treatment (NPWT) helps in treating chronic and complicated wounds and prepares the wound bed for surgical operations including skin grafts and flap surgery. NPWT has impressive outcomes, although its mechanisms of action are not fully known.² The most popular method for using negative pressure is the continuous mode, which maintains a constant pressure level, say at -80 mmHg. Intermittent pressure treatment (IPT) is the process of repeatedly turning on and off the negative pressure.²

Research question

Which method among continuous and intermittent negative pressure therapy, is more effective in terms of diabetic ulcer healing. Present study aim is to know the effective method of negative pressure technique among continuous and intermittent types for better and faster healing of diabetic foot ulcers in terms of Bates-Jensen wound assessment scale to decrease the morbidity (decrease the amputation possibility, lesser hospital stays etc) and to reduce the economic burden associated with it.

Primary objectives

To determine the difference in efficacy of both the methods (continuous and intermittent) in reduction in surface area of diabetic foot ulcer over the course of therapy by Bates-Jensen wound assessment scale. To determine the difference in time in achieving granulation

tissue of both the methods (continuous and intermittent) in of diabetic foot ulcer over the course of therapy.

Secondary objective

To know and compare the complications in terms of various microbiological infectious agents and their Presence in both the negative pressure methods (continuous and intermittent) in the therapy of diabetic foot ulcer.

METHODS

Study design

This current study is a hospital based comparative prospective study.

Study place

Study is carried out NRI General Hospital attached to Department of Surgery, Chinakakani, Andhra Pradesh.

Study duration

The study was conducted from May 2022 to April 2024 for a period of 2 years.

Inclusion criteria

It includes patients aged between 18 years and 70 years. Grade 1 or 2 ulcers as defined by Wagner's classification. Ulcer area ranging between 25 cm to 100 cm.

Exclusion criteria

Untreated osteomyelitis, Wounds with exposed blood vessels, malignant disease in a wound, patients being treated with corticosteroids, immunosuppressive drugs or on chemotherapy were excluded.

Sample size

60 (which is above the minimum sample size), each group consisting of 30 patients which were randomly allocated by simple random method.

Continuous NPWT (continuous NPWT) Even IP no (group-1) 30 patients. Intermittent NPWT (intermittent NPWT) Odd IP no (group-2) 30 patients.

Data collection

Age and sex of the patient is noted along with clinical examination of the limb is done peripheral pulses noted to rule out PAD. Followed with filling up of preformed proformas, CBC, RFT, LFT, HBA1C done in all cases pus culture sent if pus discharge is present, X-ray of the affected part (Foot, leg) done glycemic control achieved

by insulin and OHA administration. Ulcer grading done by WG grading of ulcer Ultrasound doppler of the affected limb done to rule of deep venous thrombosis and PAD every 5 days wound swab sent for culture and antibiotic sensitivity wound inspected every 5 days and debridement done if needed. Wound inspected every 5 days until the wound got closed spontaneously or until completion of 21 days (3 weeks) assessment at the earliest.

Before starting the treatment-patients were made to understand in their local language and informed consent was taken.

Patients were then randomized into two groups. Group B composed of patients with an odd (in patient) IP number and group A composed of patients with an even (in patient) IP number.

Wounds of all the patients were debrided regularly and foam-based dressing is applied over ulcer areas under strict asepsis. Dressing covered with adhesive tape to maintain an airtight seal. An evacuation tube (Ryles tube) embedded in foam and connected to a Vacuum maintaining negative sub atmospheric pressures ranging from 75 to 125 mmHg. In group A patient's continuous VAC was applied for 72 hours. In group B patients intermittent VAC was applied for 1 hour every 3 hourly.

Data variable

Age, gender, Wagner grade, doppler status, wound closure status, bates Jensen score at day 5 and day 10, wound culture at 1, 2 weeks.

Diabetic foot ulcer

A full-thickness wound, through the dermis, below the ankle on a weight-bearing or exposed surface in an individual with diabetes.¹⁸

Diabetes

According to the American Diabetes Association (ADA), a diagnosis of diabetes is through any of the following: An HbA1c level of 6.5% or higher. A fasting plasma glucose level of 126 mg/dl (7.0 mmol/l) or higher (no caloric intake for at least 8 hours); A two-hour plasma glucose level of 11.1 mmol/l or 200 mg/dl or higher during a 75 g OGTT. A random plasma glucose of 11.1 mmol/l or 200 mg/dl or higher in a patient with symptoms of hyperglycemia (polyuria, polydipsia, polyphagia, weight loss) or hyperglycemic crisis.¹⁹

Data analysis

Data was entered in MS-excel 2007 and data was analyzed using IBM SPSS (Statistical Package for the Social Sciences) software trail version 22. Nominal data analysis (were presented in numbers and percentages.

Continuous data were expressed as mean and standard deviation. Appropriate statistical tests were applied, (chi-square test and Yates correction when At least 20% of expected frequencies are less than 5. student T test and ANOVA) and <0.05 p values considered as significant.

Consent

Consent was obtained from study participants before starting the study.

RESULTS

In present study, majority of the study population were in 51 to 60 years (36.7%) followed by 61 to 70 years (31.7%), followed by 41–50 years (23.3%). The difference between the groups regarding age distribution was not statistically significant.

In present study, majority of the study population were males (60%), followed by females (40%). The difference between the groups regarding gender distribution was not statistically significant.

In present study, majority of the study population had normal Doppler status, only 8.3% had biphasic flow. The difference between the groups regarding Doppler status distribution was not statistically significant.

In present study, majority of the study population had split thickness skin graft (68%) (continuous VAC (66.7%), intermittent VAC (70%)). Amputation was seen in only two cases one in each group. The difference between the groups regarding wound closure status distribution was not statistically significant. In present study, majority of the study population had wound closure by day 12 (41.4%) followed by day 9 (31%), followed by day 15 (13.8%). The difference between the groups regarding wound closure days distribution was not statistically significant.

In present study, majority of the study population had 31-40 BJS score of wound status by day 5 in both groups (continuous VAC (46.7%), intermittent VAC (33.3%)), followed by 21-30 BJS score (continuous VAC (16.7%), intermittent VAC (30%)). The difference between the groups regarding wound status on day 5 distribution was not statistically significant.

In present study, majority of the study population had 31-40 BJS score of wound status by day 10 in both groups (continuous VAC (46.7%), intermittent VAC (43.3%)), followed by 41-50 BJS score (continuous VAC (20%), intermittent VAC (23.3%)). The difference between the groups regarding wound status on day 5 distribution was not statistically significant.

In present study, majority of the study population Showed pseudomonas as a most common growth in both the groups in first wound culture. (continuous VAC (26.7%), intermittent VAC (33.3%)). No growth was seen in 10% continuous VAC group and 26.7% in intermittent VAC group. The difference between the groups regarding various bacterial growth status (in first culture) distribution was not statistically significant.

In present study, majority of the study population Showed pseudomonas as a most common growth in both the groups in second wound culture. (continuous VAC (30%), intermittent VAC (30%)). No growth was seen in 36% continuous VAC group and 50% in intermittent VAC group. The difference between the groups regarding various bacterial growth status (in second culture) distribution was not statistically significant. In present study, majority of the study population Showed No growth (continuous VAC (76.7%), intermittent VAC (83.3%)). The difference between the groups regarding various bacterial growth status (in third culture) distribution was not statistically significant.

Table 1: Age distribution in years.

Age groups (in years)	Group		Group		Total count	
	Continuous count	%	Intermittent count	%	Total count	%
30-40	3	10.0	2	6.7	5	8.3
41-50	6	20.0	8	26.7	14	23.3
51-60	12	40.0	10	33.3	22	36.7
61-70	9	30.0	10	33.3	19	31.7
Total	30	100.0	30	100.0	60	100.0

P value-0.8.

Table 2: Gender distributions.

Gender	Group		Group		Total count	
	Continuous count	%	Intermittent count	%	Total count	%
Female	10	33.3	14	46.7	24	40.0
Male	20	66.7	16	53.3	36	60.0
Total	30	100.0	30	100.0	60	100.0

P value-0.29.

Table 3: Doppler status distributions.

Doppler status	Group					
	Continuous count	%	Intermittent count	%	Total count	%
Biphasic	3	10.0	2	6.7	5	8.3
Normal	27	90.0	28	93.3	55	91.7
Total	30	100.0	30	100.0	60	100.0

P value-0.6.

Table 4: Wound closure status distributions.

Wound closure status	Group					
	Continuous count	%	Intermittent count	%	Total count	%
Amputation	1	3.3	1	3.3	2	3.3
Spontaneous	9	30.0	8	26.7	17	28.3
SSG	20	66.7	21	70.0	41	68.3
Total	30	100.0	30	100.0	60	100.0

P value-0.9.

Table 5: Wound closure day distributions.

Wound closure day	Group					
	Continuous count	%	Intermittent count	%	Total count	%
Day 6	1	3.4	2	6.9	3	5.2
Day 9	8	27.6	10	34.5	18	31.0
Day 12	12	41.4	12	41.4	24	41.4
Day 15	5	17.2	3	10.3	8	13.8
Day 18	3	10.3	2	6.9	5	8.6
Total	29	100.0	29	100.0	58	100.0

P value-0.8.

Table 6: Comparison of day 5 wound status with VAC.

BJS on day 5	Group					
	Continuous count	%	Intermittent count	%	Total count	%
13-21	5	16.7	4	13.3	9	15.0
21-30	5	16.7	9	30.0	14	23.3
31-40	14	46.7	10	33.3	24	40.0
41-50	5	16.7	6	20.0	11	18.3
51-60	1	3.3	1	3.3	2	3.3
Total	30	100.0	30	100.0	60	100.0

P value-0.7.

Table 7: Comparison of day 10 wound status with VAC.

BJS day 10	Group					
	Continuous count	%	Intermittent count	%	Total count	%
13-21	5	16.7	5	16.7	10	16.7
21-30	3	10.0	4	13.3	7	11.7
31-40	14	46.7	13	43.3	27	45.0
41-50	6	20.0	7	23.3	13	21.7
51-60	2	6.7	1	3.3	3	5.0
Total	30	100.0	30	100.0	60	100.0

P value-0.9.

Table 8: Comparison between 1st wound culture with VAC.

Wound culture-1	Group					
	Continuous count	%	Intermittent count	%	Total count	%
No growth	3	10.0	8	26.7	11	18.3
<i>E. Coli</i>	8	26.7	4	13.3	12	20.0
<i>Staphylococcus</i>	4	13.3	2	6.7	6	10.0
<i>Klebsiella</i>	7	23.3	6	20.0	13	21.7
<i>Pseudomonas</i>	8	26.7	10	33.3	18	30.0
Total	30	100.0	30	100.0	60	100.0

P value-0.3.

Table 9: Comparison between 2nd wound culture with VAC.

Wound culture-2	Group					
	Continuous count	%	Intermittent count	%	Total count	%
No growth	11	36.7	15	50.0	26	43.3
<i>E. coli</i>	5	16.7	1	3.3	6	10.0
<i>Staphylococcus</i>	2	6.7	1	3.3	3	5.0
<i>Klebsiella</i>	3	10.0	4	13.3	7	11.7
<i>Pseudomonas</i>	9	30.0	9	30.0	18	30.0
Total	30	100.0	30	100.0	60	100.0

P value-0.4.

Table 10: Comparison between 3rd wound culture with VAC.

Wound culture-3	Group					
	Continuous count	%	Intermittent count	%	Total count	%
No growth	23	76.7	25	83.3	48	80.0
<i>E. coli</i>	3	10.0	1	3.3	4	6.7
<i>Staphylococcus</i>	3	10.0	0	0.0	3	5.0
<i>Klebsiella</i>	0	0.0	3	10.0	3	5.0
<i>Pseudomonas</i>	1	3.3	1	3.3	2	3.3
Total	30	100.0	30	100.0	60	100.0

DISCUSSION

Diabetic foot refers to foot issues in individuals with diabetes mellitus. Diabetes mellitus often leads to foot diseases such as ulceration, infection and gangrene, which may lead to increased mortality and morbidity as well as economic burden. The appropriate treatment for diabetic foot ulcers is unclear. Traditionally, saline-moistened gauze has been used, but maintaining a moist wound environment has proven challenging. Hydrocolloid wound gels have been developed to improve moisture retention and consistency.

Topical ointments have been refined to include pharmacological ingredients such as growth hormones and enzymatic debridement chemicals. The vacuum-assisted closure device (VAC) is a newer noninvasive adjunctive therapy system called Negative Pressure Wound Therapy (NPWT). It uses controlled negative pressure to remove fluid from open wounds through a sealed dressing and tubing that is connected to a collection container. This process helps promote wound healing. It has been demonstrated that using sub-

atmospheric pressure dressings which are sold commercially as a VAC device is an efficient technique to hasten the healing of a variety of wounds. Present study aim is to know the effective method of negative pressure technique among continuous and intermittent types for better and faster healing of diabetic foot ulcers in terms of Bates-Jensen wound assessment scale to decrease the morbidity (decrease the amputation possibility, lesser hospital stays etc) and to reduce the economic burden associated with it. This current study is a hospital based comparative prospective study conducted From MAY 2022 to APRIL 2024 for a period of 2 years in NRI General Hospital attached to Department of Surgery, Chinakakani, Andhra Pradesh.

Age

In present study, majority of the study population were in 51 to 60 years (36.7%) followed by 61 to 70 years (31.7%). The cumulative consequences of hyperglycemia, the lengthier duration of diabetes and a larger incidence of micro- and macrovascular problems are all strongly associated with an increased risk of

Diabetic Foot Ulcer (DFU) with aging. Syaut et al, study had 50-59 years as most common age for DFU presentation, which goes in line with our study.⁷

Akther et al and Maisuria et al, also showed similar age a most common in their studies which supports present study of age group 51-60 years.^{6,8} According to Zhang et al, 2016 systematic review and meta-analysis, individuals with diabetic foot ulceration exhibited the following traits, lower body mass index, longer duration of diabetes and older age.⁹

Additionally, prior research has demonstrated that one of the primary variables linked to more severe diabetic foot ulcers is advanced age.¹⁰

Gender

In present study, majority of the study population were males (60%), followed by females (40%). Men with diabetes have a 1.5 times greater incidence of DFU than women have.¹¹ Men are also more likely to have minor and severe amputations; many large studies have shown that men's risk estimations for these conditions range from 1.4 to 3.5 times greater.¹¹ Screening, treatment adherence, underlying risk factors and availability to care all play a role in explaining gender discrepancies.¹²

Although women have a more unfavorable view towards therapeutic footwear, compliance with it is equal between the sexes; nonetheless, women are more likely to do suggested self-care and foot care.¹³ Most of the reported sex differences in DFU risk are explained by the increased incidence of PN, PAD and cardiovascular disease in men with diabetes.¹³ On the other hand a Pakistan based study, Akhtar et al, more DFU prevalence seen in their study population women 66.4 % which doesn't support present study male % is 60%.¹⁴

Wound closure status continuous vs intermittent

Since its inception in 1997, NPWT has been used to treat a wide range of wounds, including pressure ulcers, open abdominal wounds, diabetic foot, chest wounds, skin grafts and wounds from trauma to the lower extremities.¹⁷

Although the exact mechanism of NPWT in wound healing is unknown, a large body of research has demonstrated its multifaceted benefits. By facilitating the removal of surplus fluid and debris, NPWT reduces interstitial oedema and bacterial counts while promoting the creation of granulation tissue and increasing local blood flow.¹⁸ A different approach to treating wounds is offered by negative pressure wound treatment (NPWT), which has become a cutting-edge medical technique. The purpose of this study was to evaluate this technique's effectiveness in treating chronic wounds. NPWT is a successful therapeutic option for long-term diabetic ulcers because it promotes quicker rates of total wound healing and the early emergence of granulation tissue

according to many studies.^{15,16,21} One of two modes is used by the traditional NPWT system: "intermittent" or "continuous." The intermittent mode generates a sub-atmospheric pressure of -125 mmHg for 5 minutes and a resting phase of 0 mmHg for 2 minutes, whereas the continuous mode maintains a sub-atmospheric pressure of -125 mmHg continuously.³ In present study, majority of the study population had split thickness skin graft (68%) (continuous VAC (66.7%), intermittent VAC (70%)). Amputation was seen in only two cases one in each group. Present study showed both the methods equally effective in terms of wound closure status. Majority of continuous VAC and intermittent VAC had wound closure at day 12.

Upon examination by Bates-Jensen Wound Assessment Scale on day 5 and 10 showed equal improvement in both the methods. No growth was seen in 10% in culture-1, 36% culture-2 in continuous VAC group and 26% in culture-1, 50% culture-2 in intermittent VAC group. Among positive growth pseudomonas was more prevalent both the groups in first second cultures. In 3rd culture in both groups' majority had no growth, which means both the methods were effective in controlling the bacterial growth in the DFU.

There were very few similar studies done to compare the outcomes between intermittent or continuous, as our study is one of its kinds. The wound bed responded more strongly to intermittent pressure treatment and VPT (varianble) than to continuous NPWT in a study done by Malmsjö et al, which is not correlated with present study.¹⁵

At day 7, there was no statistically significant difference in the average granulation thickness between the continuous (3.29 mm), intermittent (3.03 mm) and dynamic (3.40 mm) NPWT wounds, but overall outcome has no significant difference according to a study done by Lessing et al, which coincides with our study.¹⁶ Comparing the intermittent mode to the continuous mode in animal model trials, the former demonstrated higher levels of perfusion and the production of granulation tissue in the wound region according to Argenta LC et al, and Morykwas et al, which does not support present study.^{17,18}

While granulation tissue appeared early in both patient groups, a higher percentage of patients in the Intermittent VAC group reached 100% (full) granulation tissue earlier than in the Continuous VAC group, according to a recent study (2024) by Sandeep et al.¹⁹ On day 6, wound closure was attained by 3.3% of patients in the continuous VAC group and 6.7% of patients in the intermittent VAC group. Their research found that, despite the higher wound closure rates associated with VAXC therapy, intermittent VAC therapy is better for healing diabetic leg ulcers because the intermittent VAC group had a marginally higher percentage of wound closure rates than

the continuous VAC group which is not supporting present study.¹⁹

Borgquist et al, did a slightly different study where compared the effect of intermittent negative pressure and variable negative pressure.²⁰ Both intermittent and variable NPWT produce a positive mix of reduced blood flow, which is known to promote granulation tissue creation and angiogenesis and increased blood flow, which is known to enable nutrition delivery and oxygenation. When treating tissue that is not well vascularized, cycling the negative pressure may be very helpful. Variable treatment could be preferable when intermittent therapy is causing discomfort for the patient small sample size, element of bias.

Blood glucose monitoring for good hypoglycaemia control was not taken into consideration in study participants which can also have an impact on healing.

CONCLUSION

The current study finds that Negative pressure wound therapy (NPWT) therapy has higher rates of wound closure and that, for the healing of diabetic leg ulcers, applying either intermittent or continuous NPWT therapy is preferred for better wound closure rates and good bacterial clearance. No method was shown superior to other in terms of wound healing in Diabetic foot ulcer.

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