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A Comparative Study of Efficacy of Vacuum Assisted Closure Therapy and Conventional Moist Dressings in the Management of Diabetic Ulcers

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Abstract

Diabetic foot ulcers (DFUs) are a common and severe complication of diabetes mellitus, often leading to amputations and significant morbidity. Negative pressure wound therapy (NPWT) has emerged as an advanced alternative to conventional moist dressings for the management of DFUs. This study aims to compare the efficacy of NPWT with conventional moist dressings in enhancing the healing process of diabetic wounds. A prospective, randomized comparative study was conducted with 112 patients diagnosed with chronic diabetic wounds. Patients were divided into two groups: 56 patients received NPWT (Group 1), while the remaining 56 underwent conventional moist dressing therapy (Group 2). Wound size, depth, and granulation tissue formation were assessed at regular intervals using a Vernier caliper and the Wagner ulcer classification system. Patient satisfaction and the rate of minor and major amputations were also recorded. Statistical analysis was performed using SPSS software. NPWT significantly reduced ulcer size ($P = 0.04$) and improved granulation tissue formation (80% in NPWT vs. 40% in conventional dressing). Patient satisfaction was notably higher in the NPWT group, with a significant reduction in minor and major amputations. The Wagner score also demonstrated better outcomes in the NPWT group compared to the conventional dressing group. NPWT is a superior treatment modality for diabetic foot ulcers, offering faster healing, reduced ulcer size, enhanced granulation tissue formation, and improved patient satisfaction. It also decreases the likelihood of amputation, making it a preferred choice for diabetic wound management.

INTRODUCTION

The most prevalent problems associated with diabetes mellitus are foot ulcers and the further incapacitating complications they cause^[1,2]. These are major risk factors for amputations and result in persistent wounds that do not heal and therapeutic challenges^[3-5]. Advanced moist wound dressings, bioengineered tissue or skin substitutes, growth hormones, electromagnetic stimulation, low-potential laser therapy, and negative pressure wound therapy (NPWT) are some of the several therapeutic options for diabetic foot ulcers^[6-12]. The noninvasive NPWT approach is a recently developed wound healing therapy that works by applying localized negative subatmospheric pressure. This therapy works by continuously applying subatmospheric pressure through a designated pump that is attached to the durable, foam-surfaced dressing that gathers the wound exudates^[13,14]. This technique was widely supported by many case series, clinical evidences, small cohort studies and multicentric randomised clinical trials^[15-18]. Hence the aim of our study is to assess the efficacy of topical negative pressure moist wound dressing as compared to conventional moist wound dressings in improving the healing process in diabetic wounds and to prove that negative pressure dressings can be used as a much better treatment option in the management of diabetic wounds.

MATERIALS AND METHODS

This is a prospective randomized comparative study conducted after getting approval from Scientific Research Committee and Institutional Ethics Committee. Among 112 patients with chronic diabetic wounds, of which 56 patients underwent topical negative pressure dressings in Group 1 and remaining 56 patients underwent conventional moist dressings in Group 2. The Exclusion criteria were renal failure, poor medical compliance, radiation therapy or chemotherapy, and an ischemic ulcer requiring open or endovascular revascularization.

We looked at the size and depth of the wound every three days during the study period. The ulcers were washed with sterile serum, bandaged and then conventional moist dressings applied twice a day. All participants in the study had their type of diabetes mellitus and their control status (in the initial diagnosis, with control or without control), the duration of the ulcers, the history of ulcer therapy, the location of wounds and the frequency of the underlying disease evaluated. Using a Vernier calliper, the ulcers scale was used to define improvement. A written informed consent was obtained from all patients before inclusion in our study. After the study was initiated, the level of satisfaction among patients in two groups was considered. The final results were

categorized as complete treatment, minor amputations (less than amputations under the knee, front or front of the leg), and main amputations (above or below the knee).

Statistical Analysis: The SPSS version (SPSS Inc., Chicago, Illinois, USA) was used for data analysis. The percentage or average \pm standard deviation (SD) as a function of the sample size is used to express digital data. The non-parametric parallel test or the paired T test was used to compare the results before and after treatment. Before and after therapy, the two groups were noted with sizes and depths of ulcers using the Man-Whitney test. The values of P below 0.05 were considered to be statistically significant.

RESULTS AND DISCUSSIONS

The study included 112 participants who were randomly assigned to one of two treatment arms: Group 1 - 56 patients (29 males and 27 females) underwent topical negative pressure dressings and in Group 2 - 56 patients (30 males and 26 females) underwent conventional moist dressings ($P > 0.05$). Table 1 shows the demographic features of our study participants. Males in both groups had the highest frequency. Osteomyelitis was diagnosed in 54 patients (48.2%), with 36 (66%) receiving topical negative pressure dressings and 18 (34%) receiving moist dressing, respectively. Malnutrition was seen in 2 patients (3.7%) in the Group 1 and 3 (5.5%) in the Group 2. The study participants had the highest number of ulcers in the left forefoot, followed by the right hind foot and left hind foot. Table 1

Moreover, there was no significant statistical difference between the groups in the type of diabetes mellitus and its control (primary diagnosis, with control and without control) ($P = 0.37$; $P = 0.38$). History of ulcer treatment (medical and surgical) was significant in the study participants ($P = 0.04$). However, history of ulcer treatment in most of the patients in the Group 1 was medical therapy but it was medical and surgical therapies in the Group 2.

Evaluation of the size of ulcer before ($37.8 \pm 9.3 \text{ cm}^2$) and after ($55.3 \pm 11.3 \text{ cm}^2$) the moist dressing treatment was not statistically significant ($P = 0.3$), although this difference was significant for topical negative pressure dressings ($P = 0.04$; $40.4 \pm 9.2 \text{ cm}^2$ before vs. $27.7 \pm 8.3 \text{ cm}^2$ after treatment). The difference between the size of ulcers in the topical negative pressure dressings versus moist dressing was significant ($P = 0.05$)

We performed the Wagner score for the study patients before and after the treatment [Table 2]. Mean analysis of the Wagner score showed that in both the study groups, this decreased, although this decrement was not significant in the moist dressing

Table 1: Demographic characteristics of participants in study groups

	Group 1(topical negative pressure dressings) n=56		Group 2 (conventional moist dressings) n=56		P-value
	Count	Percent	Count	Percent	
Sex					
Male	29	52	30	54%	0.48
Female	27	48	26	46%	
Type of diabetes mellitus					
Type 1	3	5	2	4	0.37
Type 2	53	95	54	96	
Control of diabetes mellitus					
Primary diagnosis	1	2	2	4	0.38
With control	55	98	54	96	
Without control	0	0	0	0	
History of ulcer treatment					
None	2	4	1	2	0.04
Medical	29	52	28	50	
Surgical	25	44	28	50	
Wound location					
Right foot	26	46	29	52	0.6
Left foot	30	54	27	48	

Table 2: Wagner score before and after treatment in the two study groups

WAGNER SCORE	Group 1(topical negative pressure dressings)		Group 2 (conventional moist dressings)		P value
	Count	Percent	Count	Percent	
BEFORE					
1	1	2	1	2	0.33
2	12	21	14	25	
3	16	29	18	32	
4	27	48	23		
AFTER					
1	2	4	1	2	0.31
2	30	54	29	52	
3	24	43	19	33	
4	0	0	8	13	

group. Evaluation of formation of granulation tissue showed that 80% and 40% of the study patients in the topical negative pressure dressings and moist dressing groups, respectively, had formation of granulation tissue during the two weeks of treatment. Table 2

There was a statistically significant difference between satisfaction levels of the two groups ($P = 0.05$). All of the study patients in the topical negative pressure dressings were satisfied with their therapy procedure and its result, whereas 11 patients in the moist dressing were not satisfied. Due to the consideration of major and minor amputation as final results of the present intervention, significant difference was seen between the two groups ($P = 0.05$). No patient in the topical negative pressure dressings underwent major or minor amputation and seven patients (90%) were cured completely.

This study aimed to compare topical negative pressure dressings with moist dressings for tissue regeneration and enhancement of diabetic foot ulcers. Our study indicated that the dimensions, depth, and Wagner class in topical negative pressure dressings were substantially lessened in comparison to moist dressings. Approximately 80% and 40% of the groups using topical negative pressure dressings and moist dressings, respectively, exhibited granulation tissue. One study examined topical negative pressure dressings following diabetic foot amputation in two groups using topical negative pressure dressings against a group using moist dressings. They modified

the topical negative pressure dressings every two days and subsequently daily for a total of 112 days. They discovered that 56% and 39% of the topical negative pressure dressings and moist dressing groups, respectively, achieved complete regeneration, with granulation tissue appearing sooner in the topical negative pressure dressings group. Moreover, Mc Callon et al. observed that the mean duration for therapy with topical negative pressure dressings and moist dressings was 22. 8 days and 42. 8 days, respectively. Additionally, in the group using topical negative pressure dressings, the average reduction in ulcer size occurred three weeks sooner than in the moist dressing group (28. 4% reduction vs. 9. 5% increase)^[16]. Although in the present study we did not evaluate complete regeneration, formation of granular tissue had obtained similar results. Eginton, et al.replaced the contrasting treatment after 2 weeks and thanked the corrections associated with negative pressure and moist dressing in a 4-week future randomized study^[17]. Another multicenter cohort study was estimated by 342 patients with diabetic ulcers in two study groups over 112 days (actual dressing with negative pressure on wet supply), and complete healing of the ulcer was estimated at observations of 3-9 months. They found that most relevant bandages with negative pressure (43.2%), unlike a wet supply group (28.9%), have improved during 112 days of treatment and experienced a lower frequency of new amputations. In addition, the evaluation of

complications such as cellulite and osteomyelitis showed that there were no significant differences between the two research groups^[18].

The results of our study on the effectiveness of relevant dressings with negative pressure in the formation of granulation tissue were confirmed by Armstrong, *et al.* ^[19] out of 31 patients with diabetes. In their study, initial treatment improved almost 90% of ulcers, with the average for local negative pressure dressing with rare complications being 7.9 ± 4.8 weeks.

CONCLUSION

To conclude from our study, we found that topical negative pressure dressings help in faster healing of diabetic wounds in 90% of patients with better graft take up and reduces hospital stay of our patients.

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