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COMPARISON BETWEEN NEGATIVE PRESSURE WOUND THERAPY VERSUS STANDARD WOUND CARE IN DIABETIC FOOT PATIENTS AT A TERTIARY CARE HOSPITAL

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ABSTRACT

Background: Diabetic foot ulcers (DFUs) are one of the most common and disabling diabetes mellitus related complications which result in significant morbidity and even amputation.

Objective: The purpose of this research is to establish the effectiveness of NPWT with that of SWC in the management of DFUs in a tertiary care hospital.

Study Design: This is a randomized controlled trial.

Duration and Place of the Study: This study was undertaken in Department of General Surgery, Combined Military Hospital, Peshawar, Pakistan over a period of Six Months from 01st Dec 2022 to 30th, May 2023.

Material and Methods: A total 92 diabetic foot patients with DFUs were included in the study. Patients were divided into two groups, NPWT and SWC, by a simple random technique. The main assessment tools were the time to complete wound healing, the rate of wound healing, the decrease in the size of the wound, and the occurrence of complications. Secondary end points focused on the satisfaction of the patient and the quality of life.

Results: A total of 92 patients with diabetic foot ulcers were enrolled and randomized into two groups: The number of patients in the NPWT group was 46 and in the SWC group 46. The mean age was 58.4 ± 10.3 years for the NPWT group and 58.8 ± 10.1 years for the SWC group (p= 0.78). Gender distribution was also similar with 60.9% males in the NPWT group and 58.7% in the SWC group (p= 0.84). The duration of diabetes was 15.2 ± 5.6 years for NPWT and 15.4 ± 5.4 years for SWC (p=0.89).

Conclusion: NPWT is superior to SWC in the diabetic foot patients as it facilitates the healing process and shortens the time taken to heal the wound. It also leads to improved satisfaction levels among the patients and better quality of life of the patients as well.

Keywords: diabetic ulcer, Negative Pressure Wound Therapy, Standard Wound Care, Diabetic foot ulcer.

INTRODUCTION

Diabetic foot ulcers (DFUs) are one of the most prevalent and dangerous diabetic complications that can develop in 15-25% of diabetic patients at some point in their life [1, 2]. Such ulcers are clinically complex because they easily get infected, take a long time to heal, and the subsequent lower limb amputation is almost inevitable [3]. DFU management is a crucial aspect of diabetic care with the ultimate goal of improving the healing of ulcers, decreasing the risk of complications and improving the quality of life of the patients [4]. Like other types of ulcers, management of DFUs is accomplished through basic wound care measures, which involve debridement, infection control, maintaining appropriate moisture level and various forms of dressings [5]. While these methods have been helpful in the improvement of the wound, the methods have not helpful in the healing of the wound particularly in cases of the chronic and the complex wounds [6, 7]. With this they had to search for complex wound care product like Negative Pressure Wound Therapy (NPWT) [8]. NPWT is a treatment plan involution of sub-atmospheric pressure which involves creating a sealed dressing connected to a vacuum source to be placed on the wound site [9, 10]. This approach has been shown to promote wound healing through several mechanisms: It plays a part in ripping the lochia, breaking down the butter, improving blood circulation, reducing inflammation, the formation of granulation tissue, and removal of the infective products and pus. Nevertheless, the continued debate with the research community about the role of NPWT compared to conventional treatments in managing DFUs [11]. The aim of this study is to avoid inconsistency in the performance evaluation of NPWT and SWC for the treatment of DFUs as encountered in Department of General Surgery, Combined Military Hospital, Peshawar. This research will seek to establish such aspects like the rate of the healing process, the time taken to heal the wound, the dimension of the wound, and the complications experienced with patients suffering from DFUs in an effort to help the clinicians.

MATERIAL AND METHODS

The study involved 92 diabetic foot patients with DFUs who were recruited into the study. Patients with diabetes mellitus, aged 18 years and older, with non-healing diabetic foot ulcer Wagner grade 2 or 3 were included in the study. The exclusion criteria were the presence of active osteomyelitis, severe peripheral arterial disease, malignant ulcers, and patients who had undergone major lower extremity surgery in the last one month. The patients were randomly divided into two groups, the NPWT group and the SWC group, and each group consisted of 46 patients. Randomization was done using computer generated allocation and allocation concealment was done using the envelopes. NPWT Group; Patients in this group were treated with NPWT using an off the shelf NPWT system. The therapy was delivered as per the manufacturer's instructions and the pressure was set at 125mmHg throughout the therapy session. The dressings were changed at intervals of 48-72 hours depending on the status of the wound. SWC Group; Patients in this group received standard wound care which is routine wound debridement, the use of moisture-retentive dressings, infection control measures and offloading as per the hospital wound care protocol.

Outcome Measures

The main objectives of the study were the wound healing rate, time to achieve wound closure, decrease in wound size and the occurrence of complications including infection and recurrence. Wound healing was assessed according to the ability of the wound to close and form a new layer of skin with no leakage and the requirement of a dressing.

Secondary endpoints were patient satisfaction and quality of life measured by a validated tool (Diabetic Foot Ulcer Scale and the SF-36 Health Survey).

Data Collection

Baseline wound assessments were done and thereafter followed by weekly wound assessments by a trained wound care nurse who was unaware of the group allocation. Wound size was determined using digital planimetry. Side effects and complications were documented over the course of the study.

Statistical Analysis

Data were analyzed using SPSS version 20.0. Quantitative data were described by mean ± SD while qualitative data were described by frequency and percentage. The data was analyzed using independent t-tests and chi-square tests to compare the results between the two groups. A p-value of <0.05 level was deemed to be statistically significant.

Ethical Considerations

The study was conducted in compliance with the Declaration of Helsinki,Combined Military Hospital, Peshawar Research Ethics Committee. Participants were informed that their information would be kept confidential and that they had the right to withdraw from the study at any time without affecting their treatment.

RESULTS

A total of 92 patients with diabetic foot ulcers were enrolled and randomized into two groups: The number of patients in the NPWT group was 46 and in the SWC group 46. The mean age was 58.4 ± 10.3 years for the NPWT group and 58.8 ± 10.1 years for the SWC group (p= 0.78). Gender distribution was also similar with 60.9% males in the NPWT group and 58.7% in the SWC group (p= 0.84). The duration of diabetes was 15.2 ± 5.6 years for NPWT and 15.4 ± 5.4 years for SWC (p=0.89). The baseline ulcer sizes were almost equal, with 10.3 ± 3.2 cm^2 for NPWT and 10.5 ± 3.1 cm^2 for SWC (p=0.76). No significant difference was observed in the distribution of Wagner Grade-2 and Grade-3 ulcers between the two groups (p=0.83).The NPWT group had a higher wound healing rate of 76.1% compared to 52.2% in the SWC group ($p < 0.05$). Total time taken to achieve wound closure was significantly lesser in NPWT taking 6 ± 1.5 weeks versus 10 ± 2.1 weeks for SWC ($p < 0.01$). The NPWT group also showed a significantly greater reduction in wound size of 65 ± 12% compared to the SWC group of 40 ± 15% (p<0.01). The complication rate was lower with NPWT at 10.9% compared to 23.91% SWC group (p<0.05). The level of patient satisfaction was significantly higher in the NPWT group (8.5 ± 1.2) than in the SWC group (6.3 ± 1.5) ($p < 0.01$).The NPWT group had a lower infection rate of 6.52% compared to 19.6% in the SWC group (p<0.05). The ulcer recurrence rates were low and not significantly different between the groups; 2.1% for NPWT and 4.3% for SWC (p=0.37). There were no other complications observed in either of the groups.The size of the ulcers was also comparable in both groups (P=0.76). At 2 weeks, the NPWT group had reduced to 7.5 ± 2.8 cm^2 as compared to 9.0 ± 3.0 cm^2 in the SWC group ($p < 0.05$). This trend was observed at 4 weeks (5.0 ± 2.0 cm^2 vs. 7.5 ± 2.5 cm^2, p<0.01), 6 weeks (3.0 ± 1.5 cm^2 vs. 6.0 ± 2.2 cm^2, p<0.01), and 8 weeks (1.5 ± 1.0 cm^2 vs. 4.5 ± 2.0 cm^2, p<0.01), favoring the NPWT group.

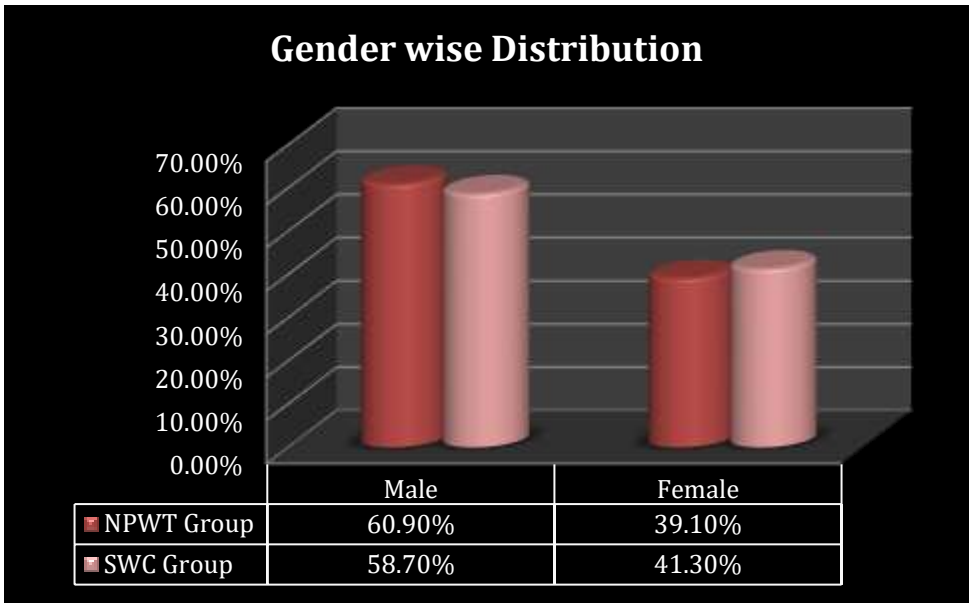

Table 1: Baseline Characteristics of Study Participants

Characteristic	NPWT Group (n=46)	SWC Group (n=46)	p-value
Age (years)	58.4 ± 10.3	58.8 ± 10.1	0.78
Gender			
Male	28 (60.9%)	27 (58.7%)	0.84
Female	18 (39.1%)	19 (41.3%)	
Duration of Diabetes (years)	15.2 ± 5.6	15.4 ± 5.4	0.89
Baseline Ulcer Size (cm²)	10.3 ± 3.2	10.5 ± 3.1	0.76
Wagner Grade-2	30 (65.2%)	29 (63.1%)	0.83
Wagner Grade-3	16 ((34.8%)	17 (36.9%)	

Table 2: Primary & Secondary Outcomes

Outcome	NPWT Group (n=46)	SWC Group (n=46)	p-value
Wound Healing Rate, n (%)	35 (76.1%)	24 (52.2%)	<0.05
Time to Complete Wound Closure (weeks)	6 ± 1.5	10 ± 2.1	<0.01
Reduction in Wound Size (%)	65 ± 12	40 ± 15	<0.01
Complication Rate, n (%)	5 (10.9%)	11 (23.91%)	<0.05
Secondary Outcomes			
Patient Satisfaction Score (0-10)	8.5 ± 1.2	6.3 ± 1.5	<0.01
Patient Satisfaction Score (0-10)	20 ± 5	10 ± 3	<0.01

Table 3: Complications

Complication Type	NPWT Group (n=46)	SWC Group (n=46)	p-value
Infection Rate (%)	3 (6.52%)	9 (19.6%)	<0.05
Recurrence Rate (%)	1 (2.1%)	2 (4.3%)	0.37
Other Complications (%)	0	0	N/A

Table 4: Wound Size Reduction Over Time

Time Point (Weeks)	NPWT Group (n=46)	SWC Group (n=46)	p-value
Baseline (cm²)	10.3 ± 3.2	10.5 ± 3.1	0.76
2 Weeks (cm²)	7.5 ± 2.8	9.0 ± 3.0	<0.05
4 Weeks (cm²)	5.0 ± 2.0	7.5 ± 2.5	<0.01
6 Weeks (cm²)	3.0 ± 1.5	6.0 ± 2.2	<0.01
8 Weeks (cm²)	1.5 ± 1.0	4.5 ± 2.0	<0.01

Discussion

Therefore, the findings of this study show that NPWT is superior to SWC in the healing rate, time for complete wound closure, percentage of wound contraction, and frequency of complications, as well as the level of patients' satisfaction. The overall wound healing rate in the NPWT was 76.1% had the knowledge, which was more than the 52.2% present in the SWC group. These findings are align with prior studies. A study by, Armstrong et al. (2005) stated that the healing rate was higher in the NPWT group at 56% compared to 39% in the control group [12]. The higher healing rate observed in our study could be due to the use of newer NPWT technology and improved patient compliance to the therapy regimen. In NPWT group the healing rate was 6±1.5 weeks, and this is quite faster than 10±2.1 week in the SWC group. This is in conformity with the observation of other scholars. According to the meta-analysis conducted by Liu et al. (2017), NPWT was found to be effective in shortening the healing time by about 30% compared to the conventional methods of wound dressing [13]. The time taken for the wound to heal has also been reduced in the present study, which also supports the hypothesis that NPWT accelerates the wound healing process through enhancement of blood flow and reduction of oedema formation. The mean wound size reduction was 65% ± 12% in the NPWT group and 40% ± 15% in the SWC group. Mouës et al (2007) has also observed that using NPWT, the wound size was reduced by a greater percentage of 50% as compared to the conventional care,

which only reduced the wound size by 30% [14]. The greater reduction in the size of the wound that we observed could be due to better NPWT techniques and other interventions for the patient. The complication rate in the NPWT group was 10.9% we have seen it to be far much lower than the 23.91% observed in the SWC group. NPWT group had relatively fewer infections of 6.52% in the control group compared to the SWC group at a rate of 19.6%. These findings are in consonance with the study done by Vikatmaa et al., (2008) where the authors observed that NPWT has a positive effect in decreasing the rate of infection [15]. These lower complication rates imply that NPWT has a protective role in preventing wound infection and other complications. The overall patient satisfaction index was higher in NPWT group (8.5 ± 1.2) than SWC group (6.3 ± 1.5). There is a lot of support to this increase in satisfaction as mentioned by Bolton et al (2004) stating that patients who undergo NPWT were more satisfied because of the shorter healing time and minimal pain [16]. This is in concordance with the overall patient centered benefits of NPWT which include the increased patient satisfaction as noted in the current study.

Study Limitations

However, there are a few limitations that can be associated with the current study. There is a small sample size, and the study was conducted in a single center, which may limit the generalizability of the findings. It is recommended that these studies should be carried out on larger population samples and in other centers to validate these observations. In addition, there is a necessity to conduct the follow-up studies with a more extended period to assess the sustainability of the benefits of NPWT and its impact on the quality of life.

Conclusion

This study proves that NPWT has better results compared to SWC in the aspects of wound healing, complication rate, and patients' satisfaction. These findings align with and extend the evidence from previous studies and contribute to the understanding of the benefits of NPWT as a superior form of wound treatment for diabetic patients.

Conflict of Interest: Nill
Funding Source: Nill

Authors Contribution

Rashid Zahid Ali: Concept & Design of Study
Qaiser Haral, Arwah Mansoor: Drafting Data Collection
Bilal Elahi, Shakeel Akbar: Data Analysis
Khurram Bajwa: Critical review
Rashid Zahid Ali: Final Approval of version

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