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A Randomized Controlled Trial to Assess the Cost-effectiveness of a Novel, Simple Modification to the Negative Pressure Wound Therapy System

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Background: Negative pressure wound therapy (NPWT) has shown remarkable adaptation in wound management worldwide. Numerous studies have provided evidence that demonstrates both the medical and financial advantages of NPWT. In this study, the VAC Therapy System, one of the leading commercially used NPWT systems, has been utilized to treat patients with either acute or chronic wounds requiring surgical intervention, with the aim of demonstrating the efficacy of using a modified version of the VAC system while reducing the total associated cost.

Method: The patients were divided into two randomly selected groups using randomization generator software. A modification was made by replacing the disposable canister provided by Kinetic Concepts Inc., with an alternative reusable canister (Baxter, Inc.); one group was assigned to use the conventional VAC Therapy System, and the other was assigned to use the modified version. Our study aimed to investigate whether this modification would lower the cost of the VAC Therapy System while still achieving the desired outcome.

Results: The VAC Therapy System contributed to improving the wound bed score in both groups, which supports previous findings on the effectiveness of NPWT while reflecting that the modification did not negatively impact the functionality and the integrity of the VAC Therapy System. Furthermore, the average daily consumables cost was markedly reduced in the modified group compared with the standard group, which reduced the overall cost of treatment.

Conclusion: It is possible to use the VAC Therapy System to its full advantage, while minimizing the financial burden of using it. *(Plast Reconstr Surg Glob Open 2021;9:e3787; doi: 10.1097/GOX.0000000000003787; Published online 25 August 2021.)*

INTRODUCTION

It is estimated that around 300 million wounds are treated annually with negative pressure wound therapy (NPWT).[1] Numerous studies have provided evidence that demonstrates both the medical and financial advantages of NPWT, such as faster wound healing, earlier discharge from hospital, fewer readmissions, and improved quality of life.[2,3] NPWT has multi-disciplinary applications and has become a mainstay in managing several conditions, such as venous leg ulcers,[4] vascular surgical wounds,[5,6] skin grafts,[7,8] decubitus ulcers,[9] burns,[10] wound dehiscence following abdominal and thoracic surgery,[11] and traumatic[12] and infectious[13] orthopedic wounds.

The VAC Therapy System (Kinetic Concepts Inc., San Antonio, Tex.) is the first commercially available system to employ NPWT and is one of the most widely used. Although this system has several advantages, it can be expensive. The daily material cost of the components was estimated to be approximately $94.01 by Kim et al.[14] This can be prohibitive in settings with budgetary constraints, particularly for patients who require long-term treatments.

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Several authors have proposed alternative therapeutic interventions that are more cost-effective. A recent example is the utilization of subatmospheric wound therapy with a sealed gauze dressing.[14–17] Although this modality offers great promise as a less-costly alternative for delivering subatmospheric pressure to wounds, it has some limitations. The VAC Therapy System utilizes an open-cell polyurethane foam filler with a specific foam pore size, specifically selected to optimize tissue ingrowth and contraction.[18] Several authors have provided evidence that supports the importance of foam pore size in promoting granulation tissue formation,[19] myofibroblast recruitment, wound contraction,[20] and supporting mesenchymal stem cell differentiation and maturation.[21] Although there are level-1 clinical studies that provide evidence disputing the superiority of polyurethane foam over gauze in terms of wound volume, surface area and skin graft take,[16,22] these studies are limited in that they had small numbers, short follow-ups and did not examine wound quality. In addition, the VAC Therapy System device offers several functions that are beneficial to the user, such as more control over the therapeutic settings. The suction pressure can be varied with the VAC Therapy System and can be delivered as continuous or intermittent, with varied intensities. This may be beneficial, as several studies have proposed 125 mm Hg, in alternating cycles, as being optimal for wound healing.[23] In addition, the system can log treatment cycles and monitor them. In cases where suction is lost, an alarm system can alert staff, which minimizes periods where a system failure has occurred but has not been detected. This may reduce the duration of treatment by reducing the periods of time when the treatment is not functioning. The VAC Therapy System also offers various types of foam, such as silver foams, and instillations that can be helpful adjuncts in specific contexts, although their clinical efficacy is yet to be fully determined.[24,25] Lastly, the VAC Therapy System offers an important advantage over wall suction in that it can be portable and hence play an essential role in minimizing hospital stays for patients who require outpatient wound care.[26]

The following question then arises: Are we still able to use the VAC Therapy System and benefit from its unique advantages while minimizing the daily consumable costs associated with using it? In a breakdown of the theoretical average daily costs of using the VAC Therapy System, Kim et al[14] estimated that the cost of the canister provided by Kinetic Concepts Inc. (KCI) represents almost 32% of the total daily consumable costs. Reducing the cost of regularly replacing the VAC Therapy System canister is a potential way to reduce the total treatment cost of using the VAC Therapy System while maintaining the several advantages that the system offers. To achieve this, we modified the VAC Therapy System by attaching a cheaper 1000 mL canister (Baxter Inc., Deerfield, Ill.), with an average cost of USD 10.00 per canister, as an intermediary drainage system between the foam dressing and the Activac canister. Our study aimed to investigate whether this modification resulted in lowering the cost of using the VAC Therapy System. We also sought to determine its safety in our patient population.

METHODS

Ethics

The Iraqi Health Ministry Ethical Committee approved this study. Informed consent was obtained from all study subjects, and all participants were provided with the option to receive the trial results on request.

Study Population and Design

This study was conducted at the Department of Plastic and Reconstructive Surgery, Teaching Hospital, Iraq, between July 2016 and March 2017. The study followed a specific flow chart (Fig. 1) to evaluate every step. Fifty-one patients were included, ranging from 17 to 77 years of age. All consecutive in-patients with either acute or chronic wounds requiring surgical intervention were included in this study. Patients were excluded from the study if they had wounds with evidence of malignancy, peripheral vascular disease, or osteomyelitis. One patient declined to participate after being allocated to a study group.

Surgical debridement of devitalized tissue was performed before applying the VAC Therapy System. Following debridement, patients were randomly assigned into two groups using randomization generator software. One group received NPWT using the VAC Therapy System in a conventional manner. The second group received NPWT via the VAC Therapy System with the modification protocol described below. In both groups, the VAC Therapy System foam and adhesive drapes were changed every three days. The NPWT continued until an objective assessor, blinded to the therapeutic groups, determined that the wound was ready for definitive closure. Definitive surgical wound closure was then carried out, utilizing primary closure, skin grafts, or locoregional flaps.

VAC Therapy System Modification Technique

After wound preparation and debridement, the foam dressing was applied to fully conform to the wound dimensions (see Figs. 2 and 3). An occlusive dressing was then applied to the foam to achieve an air-tight, water-tight seal. The supplied VAC Therapy System drainage tube was then attached to the occlusive dressing, after a small incision was made in it to allow the suction to be applied via the drainage tube. The end of the original drainage tube was then cut (patient side) to fit inside the suction tube of the reusable 1000 mL canister (Baxter Inc.). The original Activac canister drainage tube (device side) was also cut to fit inside the suction tube of the reusable canister. These connections created an air-seal construction, as shown in the Supplemental Video. (**See Video 1 [online],** which displays the VAC Therapy System modification technique utilizing a reusable 1000 ml canister to decrease the overall cost associated with using the NPWT system.)

Statistical Analysis

Data were collected pertaining to the total number of days that the VAC Therapy System was applied, the number of canisters required, and the average cost of the treatment per day. All data were collected and analyzed using Excel (Microsoft Inc., Redmond, Wash.).

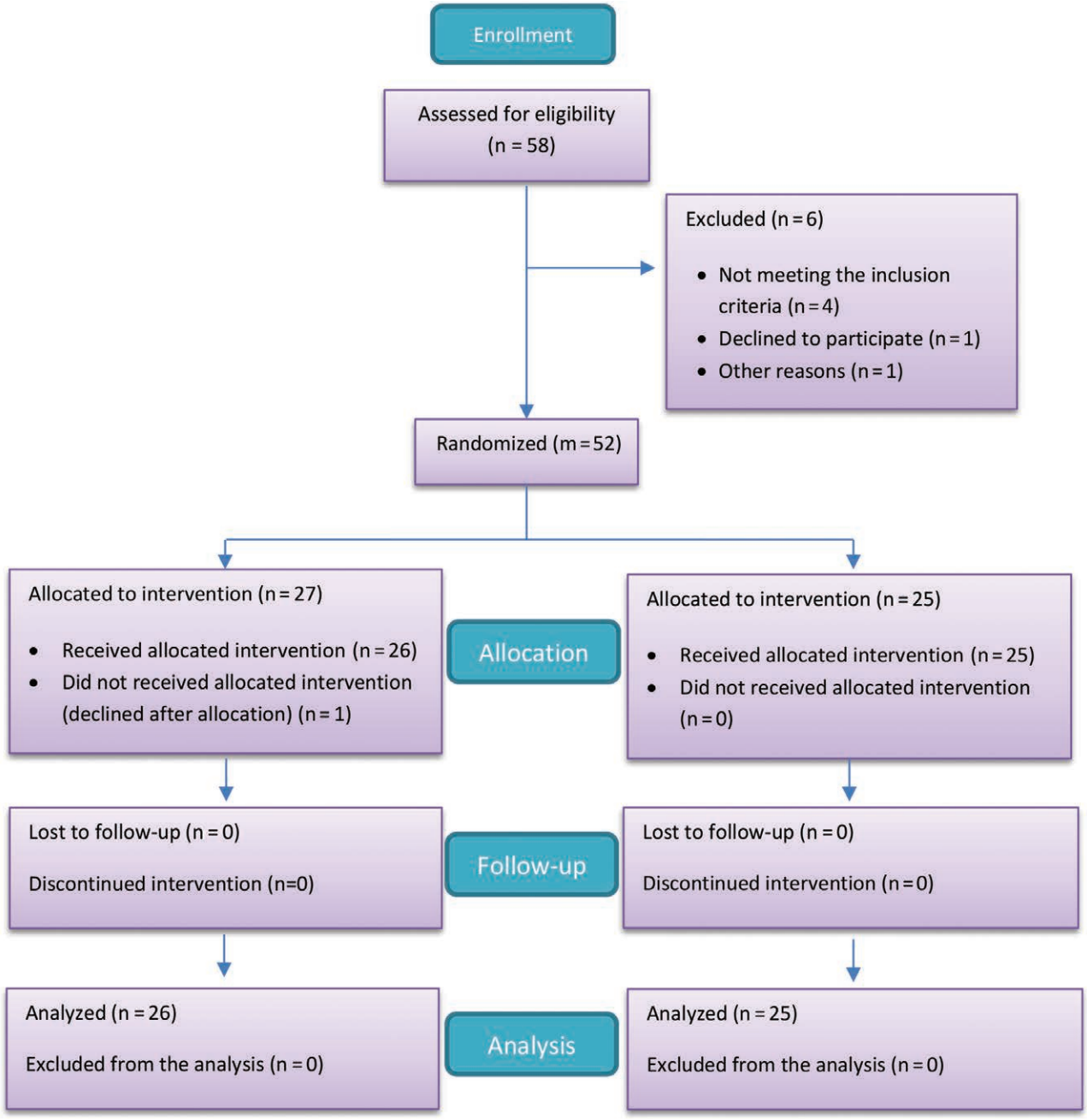

Fig. 1. Study flow chart.

Wound Bed Score

The wound bed score (WBS)[27] was used to measure the efficiency of the VAC system in the treatment and closure of wounds. The WBS includes the following parameters: (a) healing edges; (b) black eschar; (c) greatest wound depth/granulation tissue; (d) amount of exudate, edema, peri-wound dermatitis, peri-wound callus and/or fibrosis; and (e) a pink wound bed. Each individual parameter receives a score from 0 (worst score) to 2 (best score), and all the parameter scores are then added to give a total score. A wound can have a maximum WBS of 16 (the best possible score) and a minimum WBS of 0 (the worst possible score).

RESULTS

A total of 51 patients were included in the study: 26 patients underwent treatment with the standard VAC system, and 25 patients underwent treatment with the modified VAC system. The results are shown in Tables 1–3 and demonstrate that there were no statistical differences ($P \geq 0.05$) between the two study groups with regard to age, gender, site and size of the wound, cause, comorbidity, chronic diseases and comparable WBS before using the NPWT system.

A comparison in WBS before and after the VAC system was used in each study group is presented in Table 2. In both groups, the mean WBS significantly improved after

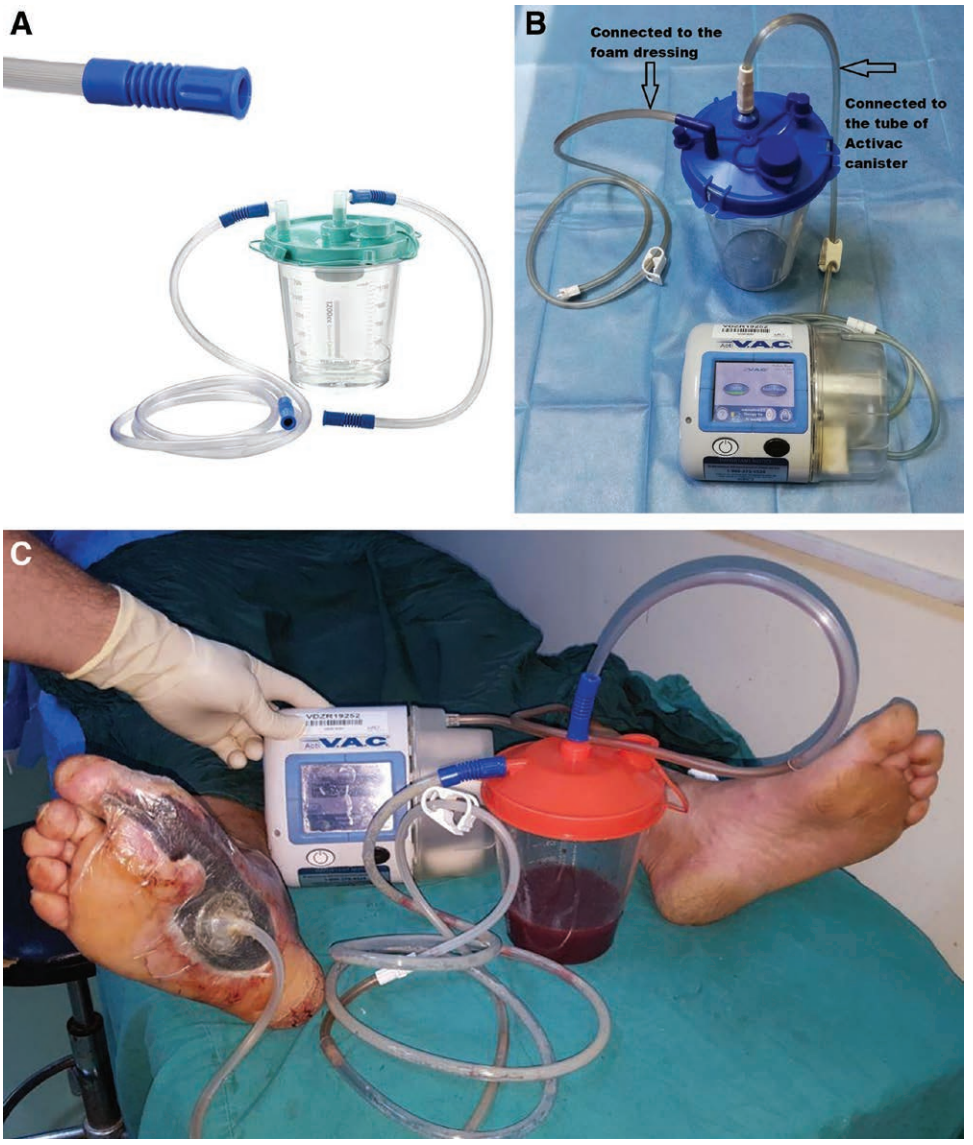

Fig. 2. VAC Therapy System modification technique. A, The 1000 mL canister with connection tube. B, The 1000 mL canister connected to the standard VAC system. C, The modified VAC system applied to the patient (notice the fluid is collected in the 1000 mL canister).

treatment (*P*-value = 0.001), which further proves the VAC system's efficacy in the management of wounds in both the standard and modified version. Furthermore, statistical analysis shows no significant difference between the standard and modified VAC systems in terms of efficacy in achieving high comparable WBS ($P = 0.97548$).

With respect to certain clinical information, as shown in Table 4 and Figure 4, the mean number of canisters used was significantly lower in the modified group compared with the standard group (11.3 versus 1.0, $P = 0.001$). On the other hand, there was no statistical difference ($P \geq 0.05$) in the number of foams used and the duration of therapy between study groups.

Analyzing the cost between the two groups, the mean total cost was markedly lower in the modified group compared with the standard group ($P = 0.001$), as shown in Table 5. In addition, the average percentage of individual total cost of components (canister cost, device cost, and granuofoam cost) is shown in Table 6 and demonstrates that the average percentage of the canister cost to the total cost is lower in the modified group compared with the standard group ($P = 0.00249$). Table 7 compares the average daily cost of individual components (canister cost and granuofoam cost) of both study groups to the average daily cost of consumables and demonstrates that the average percentage of the daily canister cost to the daily consumable cost is lower in the modified group.

DISCUSSION

This study has been conducted on patients (N = 51) with wounds of different causes treated with NPWT provided by the VAC Therapy System (KCI). The study population was divided into two randomly selected groups: one group used the standard system with the disposable (300 mL) original

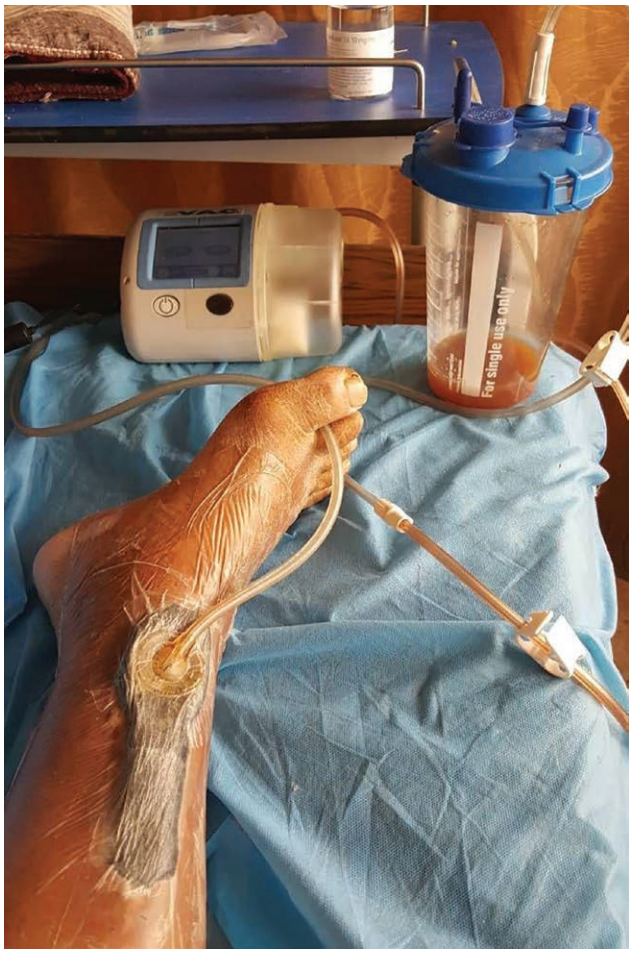

Fig. 3. Modified VAC system applied to a patient with lower leg trauma and soft tissue loss. Note that the drained fluid is collected in the 1000 mL reusable canister, while the original 300 mL canister is empty.

canister (N = 26), and the second group used the modified system with the reusable (1000 mL) canister (N = 25).

The aim of the study was to investigate the possibility of using the VAC Therapy System and benefiting from its unique advantages while minimizing the daily consumable costs associated with using it; thus, maintaining the integrity of the VAC Therapy System and not hindering its performance.

Based on the results of the statistical analysis, it can be clearly shown that demographic parameters, such as

Table 1. Comparison of General Information between Study Groups

Variable		Standard Group (%) n = 26	Modified Group (%) n = 25	*P*
Age (y)	(Mean ± SD)	(48.15 ± 17.2)	(48.48 ± 18.1)	**0.948**
	(Range)	(18–74)	(17–77)	
Gender	Men	20 (76.9)	20 (80.0)	**0.53**
	Women	6 (23.1)	5 (20.0)	
Site	Lower limb	25 (96.2)	23 (92.0)	**0.817**
	Upper limb	1 (3.8)	2 (8.0)	
Cause	Trauma	10 (38.5)	12 (48.0)	**0.744**
	Diabetic foot	12 (46.2)	9 (36.0)	
	Pressure ulcer	4 (15.3)	4 (16.0)	
Comorbidity	No	9 (34.6)	9 (36.0)	**0.634**
	One	9 (34.6)	5 (20.0)	
	More than one	8 (30.8)	11 (44.0)	
Chronic diseases	Yes	17 (65.4)	16 (64.0)	**0.319**
	No	9 (34.6)	9 (36.0)	

Bold text indicates *P*-value. $P \leq 0.05$ is statistically significant while $P > 0.05$ is insignificant.

Table 2. Comparison in WBS before and after VAC in Each Study Group

Study Group	Wound Bed Score (WBS) Before VAC (Mean ± SD)	After VAC (Mean ± S.D)	*P*
Standard group	6.96 ± 1.1	13.61 ± 0.8	**0.001**
Modified group	7.04 ± 1.2	13.08 ± 1.2	**0.001**
Standard versus modified group before VAC therapy		***P* = 0.66603**	
Standard versus modified group after VAC therapy		***P* = 0.97548**	

Bold text indicates *P*-value. $P \leq 0.05$ is statistically significant while $P > 0.05$ is insignificant.

Table 3. Comparison between Wound Size in Each Study Group

Wound Size, cm (Mean ± S.D.)	Standard Group	Modified Group	*P*
	21.7 ± 2.2	22.3 ± 1.9	0.2378

Table 4. Comparison between Study Groups by Clinical Information

Variable	Standard Group (Mean ± SD)	Modified Group (Mean ± SD)	*P*
No. of canister (300 mL) used	11.3 ± 3.4	1.0 ± 0	**0.001**
No. of foam used	6.03 ± 1.77	5.44 ± 2.25	**0.299**
Duration of therapy (d)	19.65 ± 4.9	16.4 ± 6.9	**0.06**

Bold text indicates *P*-value. $P \leq 0.05$ is statistically significant while $P > 0.05$ is insignificant.

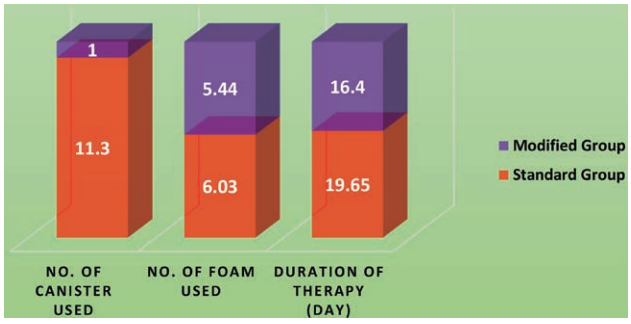

Fig. 4. Certain clinical information in study groups

Table 5. Comparison between Study Groups by the Total Cost

Total Cost ($)	Standard Group (Mean ± SD)	Modified Group (Mean ± SD)	*P*
	1900.22 ± 496.8	1341.7 ± 545.6	**0.001**

Bold text indicates *P*-value. $P \leq 0.05$ is statistically significant while $P > 0.05$ is insignificant.

Table 6. Comparison between Study Groups by the Average Percentage of Individual Total Cost of Components

Study Group	Avg. % Canister Cost	Avg. % Device Cost	Avg. % Granuofoam Cost	*P*
Standard group	18 (10.50) [5.36]	69 (75.00) [0.48]	13 (14.50) [0.16]	**0.00249**
Modified group	3 (10.50) [5.36]	81 (75.00) [0.48]	16 (14.50) [0.16]	

Table 7. Comparison of the Average Daily Cost of Individual Components (Canister and Granuofoam) of Both Study Groups to the Average Daily Cost of Consumables

Study Group	Avg. Canister Daily Cost (Mean + SD)	Avg. G.Foam Daily Cost (Mean + SD)	Avg. Total Consumables Cost (Canister+G.Foam) (Mean + SD)	% of Canister Cost (Mean + SD)	% of G. Foam Cost
Standard	17.14 ± 3.16	13.00	30.14 ± 3.17	56.43% ± 4.31	43.57%± 4.31
Modified	2.85 ± 1.07	13.00	15.85 ± 1.07	20.45% ± 0.0	79.55% ± 0.0

age and gender, as well as medically-related parameters, such as wound site, size, cause of the wound, and presence of comorbidities and chronic diseases, do not statistically contribute to differentiation between the two groups (Tables 1–3). This finding supports the adopted random selection process and the homogeneous findings in the study population. In addition, the above-mentioned parameters do not contribute to the evaluation of the impact of the VAC system modification.

The results indicate that the average cost of the canister constituent part of the daily consumables cost (canister + granuofoam) was 56.43% in the standard group and 20.45% in the modified group (Table 7). Although this result reflects the increased average daily cost of the canister in a third world country (such as Iraq) in the standard group, in comparison with the previous finding of 32% by Kim et al,[14] the modified group clearly showed an improved daily canister cost. Additional observations were made during the study in relation to the functionality of the standard canister. The standard canister contains a gel bag that absorbs the odor and turns the collected fluid into semi-solid form. The particular design of the VAC system requires support while positioning, such as attachment to the wall or foot of the bed. The misplacement of the device, with its canister in the horizontal position instead of the vertical position, in addition to the semi-solid content, leads to early blockage, thus requiring unnecessary replacement of the standard 300 mL canister. This occurred up to seven times during the study, which in turn increased the overall cost burden of using the standard VAC therapy device.

The mean cost value of treatment was $1900.22 ± $496.80 in the standard group and $1341.7 ± $545.6 in the modified group, which clearly indicates the significant improvement in overall cost between the two groups. In view of the average canister cost in terms of the total cost of treatment in the standard group (18%) compared with the modified group (3%), there is a clear indication that the modification to the VAC system, replacing the standard (KCI) canister with an alternative (Baxter, Inc.) canister, markedly decreases the cost of the treatment.

On the other hand, one can pay attention to the WBS, before and after applying the VAC system (6.96 ± 1.1 and 13.61 ± 0.8, respectively, for the standard group, and 7.04 ± 1.2 and 13.08 ± 1.2, respectively, for the modified group), which clearly indicates the effectiveness of the NPWT system in improving wound healing, and hence the overall treatment, in both groups, supporting the findings of previous studies. Moreover, the comparable improvement in WBS following the application of NPWT in both groups is evident from the mean value of the WBS of the standard and modified systems (13.61 and 13.08, respectively, $P = 0.97548$). This indicates that the modification did not negatively alter the performance of the standard VAC system and may have similar efficacy.

Based on the above, this study can conclude, without a doubt, that it is possible to use the VAC Therapy System while minimizing the daily consumable costs associated with using it.

LIMITATIONS

It is necessary to highlight some of the limitations that surround this study. The modification of replacing the standard canister with an alternative canister might be considered an off-label use, outside the original manufacturer's (KCI) design; thus, possibly altering the functionality of the VAC system. This view is worth considering when it comes to a fundamental component of the system; however, it is not the case with the canister, because it does not interfere with the optimum function of the system, as shown in the results above.

The alternative canister might be tricky to apply to outpatients due to the care needed and the proper instruction that patients would need to carefully follow to avoid complications; however, this also applies to the standard canister. Additionally, the exudate collected in the alternative canister remains in a fluid form, which may leak for reasons associated with positioning, among other things.

Finally, the sample size of the study (51) might be considered statistically small and could be increased to optimize the study outcome.

CONCLUSIONS

The use of NPWT is an integral part of the therapeutic advancement and optimal management of different wounds, aiding overall healing and accelerating wound closure. Multiple previous studies have established the efficacy of the VAC system as a type of NPWT. The high

cost related to its use has been discussed in previous studies, with alternative methods and modifications identified in an attempt to lower the associated costs. This study has confidently established that the cost of daily consumables, and thus the overall cost, can be reduced by the simple modification described, while still achieving the desired outcome. In addition, this method is economically feasible and can easily be adopted by other centers, especially in countries that lack the financial support to acquire the standard canisters or where they are simply unavailable. The utilization of reuseable canisters is more environmentally-sound, as it reduces plastic waste, which is paramount in light of increasing pollution and climate change. In conclusion, this method has shown considerable evidence and could be an acceptable alternative for other centers aiming to reduce the overall cost while using the VAC system.

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