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A Prospective Randomized Clinical Trial of Vacuum Therapy Device Versus Occlusive Dressing for Wound Care

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Abstract

Simplified vacuum wound therapy systems have been used as an effective alternative to wound care in low-resourced hospitals due to their reduced cost. However, the dissemination of devices has been discouraged due to the application of uncontrolled materials and sub-atmospheric pressures and the limited availability of studies on the subject. The objective of this work was to evaluate a streamlined vacuum therapy system model as an alternative device for negative pressure therapy. To this end, the proposed device was used for managing acute or chronic wounds in a randomized prospective trial, with the results showing increased granulation tissue development and wound cleansing in the streamlined vacuum therapy system model use and absence of deaths or severe adverse effects. The device required fewer dressings but a more complex application and higher economic cost. In conclusion, the streamlined vacuum therapy system model provided effective, safe, and feasible as long as the application professionals master the procedure and there are few dressing changes (up to three).

Keywords: Topical negative pressure; Hydrofiber; Comparative effectiveness research; Feasibility studies; Costs; Cost analysis

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Introduction

Simplified vacuum wound therapy systems (SVT) are non-standardized vacuum devices claiming to be similar to conventional, well-known brands like KCI-VAC or Smith & Nephew-Renasys devices. Because of their reduced cost compared to regular negative pressure wound therapy (NPWT) have been proposed as an alternative to wound management in hospitals with poor economic and technological resources [1-4]. However, the dissemination of SVT has been discouraged due to several structural problems in the equipment, mainly due to the application of improvised materials and uncontrolled sub-atmospheric pressures on the injuries [5]. Also, few studies are available on SVT, with most presenting non-comparable methodologies [4,6].

This research aimed to evaluate the performance (effectiveness, safety, and feasibility) of an SVT Model (SVTM) about a standard occlusive dressing (silver hydrofiber - SHF).

Methodology

This paper is a superiority, randomized, prospective, single-blind clinical trial carried out from September 2017 to August 2019 at Roberto Santos General Hospital (teaching institution, 640 beds, the largest public hospital in the state of Bahia - Brazil). The study was registered with the Brazilian Registry of Clinical Trials (RBR-5c8y6v), followed CONSORT 2010 recommendations. Included subjects signed a Free and Informed Consent Form.

Patients were included using eligibility criteria (Table 1). Randomization was applied by a list of random numbers. The result was the formation of two groups of the same size (n=25): study group (SVTM) and control group (SHF: Silver hydrofiber; Aquacel Ag Convatec Inc., North Caroline - USA).

The treatment protocol was the statistical analysis applied, that is, patients who fully followed the proposed treatments and, consequently, excluding losses (followed by immediate replacement by recruiting new patients), whether due to abandonment of clinical trial or deaths due to factors not attributable to the use of SVTM or SHF, such respiratory infection, clotting disorders, heart attack, etc.

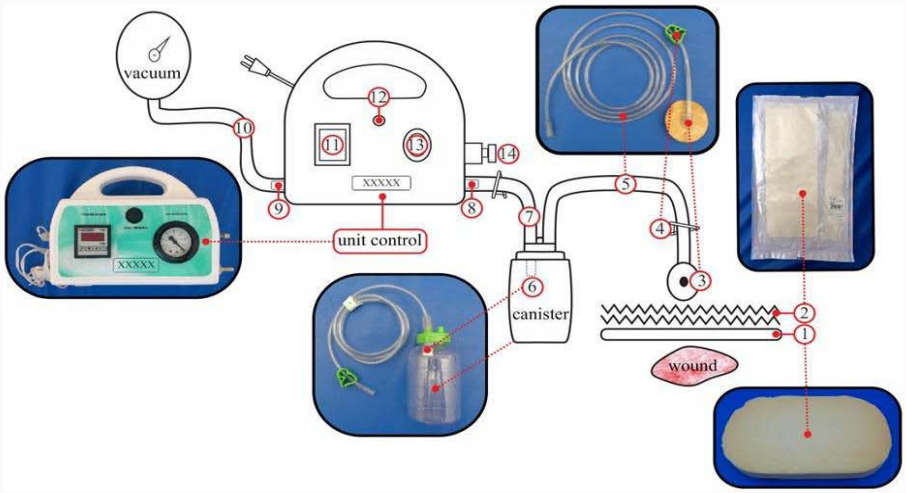

Figure 1: SVTM setup.
1) Foam. 2) Adhesive Film (Polyurethane). 3) Suction Cup. 4) Clip Cuts Flow. 5) Drainage Tube. 6) Filter. 7) Connecting Tube. 8) Inlet. 9) Air Outlet. 10) Connecting Tube. 11) Timer Display (digital). 12) Start Button. 13) Vacuum Gauge Display (analog). 14) Vacuum Adjustment Knob.

Based on a pilot study previously carried out by the corresponding author [7], an expected success rate (mean) of 98% for the SVTM group and 72% for the control group was assumed, with a margin of superiority of 25%, a test power of 80% and a significance level of 5%, a sample of 50 patients was obtained using the R Core Statistical software.

Figure 1 shows SVTM. The apparatus is powered by wall suction. The control unit adjusts sub-atmospheric pressure (0 to 200 mmHg, analog – Figure 1, Item 14). Foams (polyurethane, white, 80% porosity, 250 micrometer pores – Figure 1, Item 1) and conventional films (polyurethane, transparent - Figure 1, Item 2) are used on the wound. The drained liquids are stored in an interposed canister (500 ml, graduated) equipped with a small filter (High Molecular Weight Polyethylene - Figure 1, Item 6) to block the passage of exudates to the hospital network. The drainage tube can be double (for larger or multiple lesions) or single (for smaller lesions - Figure 1, Item 5). All tubes (Figure 1, Items 5, 7, and 10) and the canister are made of ordinary plastic (Polyvinyl Chloride, Transparent).

Vacuum therapy was applied intermittently regime with a negative pressure of - 125 mmHg. Changes were made at ≥ 50% saturation to avoid leaks, infection, and unpleasant odor. Selective surgical debridement's were performed whenever there was devitalized tissue in the lesions, both before placement of the first dressing and during subsequent dressing changes. Patients were followed for 14 days or until the lesion was deemed suitable for surgical closure (≥ 80% of the bloody bed covered by uniform, clean, and red shiny granulation tissue). Then, the patients were referred to the corresponding medical specialties for definitive closure of the wounds and were no longer followed up by the authors.

SVTM application followed the steps placing the foam on the lesion, immobilization and sealing of the foam over the lesion using a polyurethane film, placing suction cups on one hole (2 cm) made in the film on the foam, placement of connecting tubes and interposed canister, switch on the SVTM control unit and adjust to sub-atmospheric pressure.

The authors used hydrofiber as the comparison treatment (rather than usual wet gauze) due to ethical reasons: in experimental research, the best available treatment should be used as a control group. At the study's host hospital, SHF has been the most used occlusive dressing in the management of the type of wounds included in this research, being considered by the local medical team as the most effective for this purpose (despite its higher economic cost).

Wounded areas were obtained from digitized planographs using transparent acetate molds and the *SketchandCalc*™ software [8,9].

The device's effectiveness was evaluated by its power to clean (debris and scab removal) and granulate injuries (development of granulation tissue). The evaluation was performed, before and after the application of the dressings, blindly by two plastic surgeons previously calibrated through the observation of lesions of people who did not participate in the clinical trial (n=50). Agreement between raters was substantial to excellent (Kendall's W coefficient: 0.5 to 1.0). To adjust measures of association (Relative Risk [RR]; Absolute Risk Rise [ARR]; Number Needed to Treat [NNT]; Relative Risk Rise [RRR]: Direct measurement of efficacy), a Poisson regression was used to model the different frequencies of covariates that emerged between the groups after randomization (sex, age, diabetes, body mass, arterial hypertension, acute/chronic wound, and other comorbidities). The assumed research had an overall α error of 0.05.

The safety of SVTM was determined by analyzing the incidence of adverse effects and studying the risk-benefit ratio (efficacy adjusted for complications). Pain level was evaluated by adding the values obtained from all individuals who had the symptom in both study groups (VAS scale: a number between 0 and 10, where 0 corresponds to no pain and 10 to excruciating pain) [10,11].

The operational viability (difficulty in applying and maintaining the apparatus) was evaluated by analyzing the outcomes quantity and installation time of the dressings, while the financial viability was by costs of changing the bandages. Due to the variability of the data obtained, descriptive statistics of the feasibility were performed using the median, interquartile range and standardized difference by the Wilcoxon test. The Benjamini and Yekutieli method was applied to adjust for four dependent comparisons of the *p* values obtained by the previous test. A robust regression model was used for cost estimates adjusted for dressing application time, number of dressings, and

Table 1: Eligibility criteria.

INCLUSION	NON-INCLUSION	EXCLUSION
Being hospitalized Wound area ≤ 5% of total body surface area (≤ 1000 cm^2); Clinically contaminated wounds (scabs or debris) Age ≥ 18 years	Decompensated disorders: - pain in the wound; - systemic disease (cardiac, thyroid, renal, pulmonary, hepatic, arterial hypertension, diabetes mellitus, morbid obesity); - signs of severity: severe anemia (hemoglobin <7 g/dl) or malnutrition (albumin <2.0 g/dl), hemodynamic instability; - uncontrolled infection (for example, osteomyelitis) or with systemic repercussions; - coagulation disorder; - unfavorable wounds (perilesional dermatoses, wounds with fistulas, neoplastic wounds, wounds with exposed vessels, nerves or viscera, periorificial wounds [mouth, nose, ears, anus], and purulent wounds); Use of immunosuppressants (steroids, chemotherapy, TNF inhibitors, etc.) Allergy to dressing components (acrylic adhesive and polyurethane materials)	Death not attributable to the use of dressings Abandonment of treatment Uncooperative patients

treatment time.

Results

Fifty patients (25 in each group) were selected after applying the eligibility criteria (Figure 2). The baseline of patients studied was middle-aged men, not obese, with wounds of moderate dimensions, post-surgical, preferably found in the lower limbs, and chronicles (more than 30 days of evolution), being the most common comorbidities compensated found arterial hypertension and diabetes (Tables 2-4).

The effectiveness of the SVTM to SHF after Poisson regression was 157%, with two patients needing to be treated to achieve success in the granulation and wound cleansing outcomes (NNT=2.3; p=0.0061 - Table 5). The chance of benefit or harm (LHH) of the SVTM is shown in Table 6. Bleeding, foam adhesion, and pain were the most common adverse effects observed in the SVTM group. As the SVTM NNT was 2.3, it is expected that for every 230 patients treated with SVTM, 100 granulated and clean wounds, 156 bleeding, and 9 hematomas will be obtained more than the SHF. Bleeding and foam adhesion were the adverse effects whose presence outweighed the benefit of SVTM treatment (LHH<1).

Table 2: Sample demographics.

	SVTM		SHF	
Variable	**Mean (SD) (CV%)**	**Min/Max**	**Mean (SD) (CV%)**	**Min/Max**
Age (years)	55 (14) (25)	29/85	50 (16) (32)	15/79
Height (cm)	164 (11) (6.9)	145/184	166 (12) (6.9)	154/180
Weight (Kg)	67 (16) (23.9)	47/108	68 (15) (21.8)	43/103
	n	**%**	**N**	**%**
BMI				
Low weight	2	8	3	12
Normal	10	40	11	44
Overweight	10	40	8	32
Obesity	3	12	3	12
Sex				
Men	13	52	17	68
Women	12	48	8	32
Ethnicity				
Brown	18	72	21	84
Black	5	20	2	8
White	2	8	2	8

SD: Standard Deviation; CV%: Coefficient of Variation (percentage); BMI: Body Mass Index (Kg/cm^2)

Table 3: Characterization of lesions.

Variable	SVTM		SHF	
	n	**%**	**N**	**%**
Evolution				
Acute (≤ 3 months of evolution)	15	60	12	48
Chronicle (>3 months)	10	40	13	52
Body part				
Trunk	7	28	7	28
Limbs	18	72	18	72
Types				
Post-surgical	7	28	7	28
Trauma	6	24	4	16
Infection	6	24	5	20
Bite	2	8	1	4
Pressure sore	2	8	3	12
Burn	1	4	2	8
Venous ulcer	1	4	2	8
Myiasis	-	-	1	4

Table 4: Comorbidities.

	SVTM		SHF	
Comorbidity	**n**	**%**	**n**	**%**
SAH	8	32	12	48
DM	7	28	12	48
Smoking	2	8	5	20
Obesity	3	12	3	12
Alcoholism	3	12	6	24
Others	6	24	7	8

SAH: Systemic Arterial Hypertension; DM: Diabetes Mellitus

Despite the low occurrence of the symptom in both groups, SVTM had much higher pain intensity (9 times; VAS – 415 × 45).

The installation time for SVTM was approximately 6 times longer than that for SHF (Sd = 0.84; p = 0.0008). SVTM presented, for less, 4 days of treatment (Sd = 0.57; p = 0.0028) and 4 dressing changes (Sd = 0.85; p < 0.0027 - Table 7).

Table 8 shows financial viability in local values (R$). Estimated costs were adjusted using a robust regression model (with τ=0.5, median), with the outcome being application time per dressing, the number of bandages, and treatment time.

To facilitate understanding, these complex data were graphically

Table 5: Evaluation of wound cleanliness and granulation by Poisson regression.

Variable	Adjusted model			ΔRR %	Gross model (definitive)					
	RR	[CI] 95%	*p*		RR	[CI] 95%	*p*	ARR	RRR%	NNT
SVTM	-	-	0.0031	4.67	-	-	0.0061	0.44	157.0	2.3
Yes	2.45	[1.35-4.45]	-	-	2.57	[1.31-5.05]	-	-	-	-
No	1	-		-	1	-	-	-	-	-
Sex	-	-	0.1281	-	-	-	-	-	-	-
Men	0.71	[0.45-1.11]	-	-	-	-	-	-	-	-
Women	1	-	-	-	-	-	-	-	-	-
Age	-	-	0.7528	-	-	-	-	-	-	-
(50.0-85.1]	0.91	[0.52-1.60]	-	-	-	-	-	-	-	-
(14.9-50.0]	1	-	-	-	-	-	-	-	-	-
*__Diabetes__	-	-	0.4119	-	-	-	-			
Yes	0.68	[0.27-1.70]	-	-	-	-	-	-	-	-
No	1	-	-	-	-	-	-	-	-	-
BMI	-	-	-	-	-	-	-	-	-	-
Low weight (≤ 18.5)	1.82	[0.95-3.49]	0.0719	-	-	-	-	-	-	-
Normal (18.5–25.0)	1	-	-	-	-	-	-	-	-	-
Overweight (25.0–30.0)	0.36	[0.13-1.00]	0.0494	-	-	-	-	-	-	-
Obesity (≥ 30.0)	1.29	[0.64-2.60]	0.4854	-	-	-	-	-	-	-
SAH	-	-	0.7821	-	-	-	-	-	-	-
Yes	0.92	[0.50-1.67]	-	-	-	-	-	-	-	-
No	1	-	-	-	-	-	-	-	-	-
Other comorbidities	-	-	0.2888	-	-	-	-	-	-	-
Yes	1.28	[0.81-2.03]	-	-	-	-	-	-	-	-
No	1	-	-	-	-	-	-	-	-	-
Wound	-	-	0.3106	-	-	-	-	-	-	-
Acute	1.40	[0.73-2.67]	-	-	-	-	-	-	-	-
Chronicle	1	-	-	-	-	-	-	-	-	-
Recalcitrant wound	-	-	0.2964	-	-	-	-	-	-	-
Yes	0.72	[0.38-1.34]	-	-	-	-	-	-	-	-
No	1	-	-	-	-	-	-	-	-	-

Confidence intervals and p values calculated from the Robust Standard Error estimated through the heteroscedasticity-consistent covariance matrix of model coefficients
*The diabetes variable was removed in the definitive model due to the non-convergence of the Poisson model for the calculation of adjusted ARR, RRR and NNT
Akaike Information Parameter (AIC): AIC^{Gross}: 83.65; AIC^{1}: 91.56; $AIC^{Definitive}$: 83.65
Adjustment Goodness Test for the Poisson model (Residual Deviation: RD^{Gross}: 0.61766 (p=0.98277); RD^{1}: 0.51721 (p=0.99098); $RD^{Definitive}$: 0.61766 (p=0.98277)
RR: Relative Risk; [CI] 95%: Confidence Interval to RR; ΔRR%: Difference of risks in% between definitive model and gross model (parameter be >10%); ARR: Absolute Risk Rise; RRR%: Relative Risck Rise (effectiveness); NNT: Number Needed to Treat; BMI: Body Mass Index (Kg/cm^2)

summarized in dollars in Figure 3, which presents both the cost difference found directly in the study (continuous lines) and the difference if the groups had the same number of dressings (dashed line), taking into account that more SHF dressings were changed (SHF: 7 × SVTM: 3). The results show that the costs would be higher for SVTM if the same number of bandages had been applied to both study groups since the final adjusted model found shows that the estimated cost difference between SVTM and SHF was US$ 242.04 (p<0.0001). Furthermore, the estimated costs for six bandages (minimum number of dressings performed in the SHF group) were: SVTM: US$ 339.09 × SHF: US$ 97.04; estimated costs for the median number of dressings in each group were SVTM (3 dressings): US$ 170.70 × SHF (7 dressings): US$ 153.17 (i.e., US$ 17.53 more per patient); finally, the estimated cost for 1 SVTM was US$ 58.44, which corresponds to an estimated cost for 5.31 SHF. Therefore, in all items evaluated, the SVTM estimated price was higher than that of the SHF.

Discussion

The SVT are a set of apparatuses adapted from NPTW that reduce the costs and complexities of using vacuum therapy. For this, SVT uses more elementary electrical and pneumatic components and fewer accessory materials without omitting fundamental characteristics of vacuum dressings, such as graduated suction and wound sealing [4,13].

In the current trial, the specific type of SVT used was called SVTM (Figure 1). The device is supplied by a hospital vacuum source readily available onward walls, which facilitates availability, as it does not require portable suction pumps regulated by software and digital displays to control sub-atmospheric pressure and intermittency

Table 6: Efficacy X adverse effect for SVTM in granulation and wound cleaning.

Complication	Incidence (%)	Expected number of complications taking NNT into account	NNH complication	LHH
NNT = 2.3				
Bleeding	68	1.56	1.67	0.7
Dressing adherence	60	1.38	1.9	0.8
Pain	52	1.18	2.5	1.1
Maceration	24	0.55	5	2.2
Contact dermatitis	8	0.18	12.5	5.4
Necrosis or hematoma	4	0.09	25	10.9

NNT: Number Needed to Treat; NNH: Number Needed to Harm; LHH: Likelihood of being Helped or Harmed = (1/NNT)/(1/NNH): LHH >1: The patient has more benefits concerning the risk of complications; LHH <1: there is more harm than benefit; LHH=1: The benefit equals damage [12]

Table 7: Operational feasibility according to the studied groups.

Variable	SVTM (n=25)			SHF (n=25)			Sd	p^*
	Md (IQR)	Min/Max	CVMd%	Md (IQR)	Min/Max	CVMd%		
Dressing application (min)	22.71 (10.0)	16.5/38.7	44.0	4.0 (3.0)	2.2/10.4	75.6	0.84	0.0008
Treatment time (days)	10 (5)	3/15	50.0	14 (0)	7/15	0.0	0.57	0.0028
Dressings/patient	3 (1)	1/4	33.3	7 (2)	6/14	28.6	0.85	0.0027

Md(IQR): Median and Interquartile Range; CVMd%: Coefficient of Variation (Median, in %); Sd: Standardized difference (a measure of statistical association): Cohen parameters for Sd: [0-0.2]: absent; (0.2-0.5]: small; (0.5-0.8]: moderate; >0.8: large; p^*-value adjusted for multiple comparisons under dependency relationships

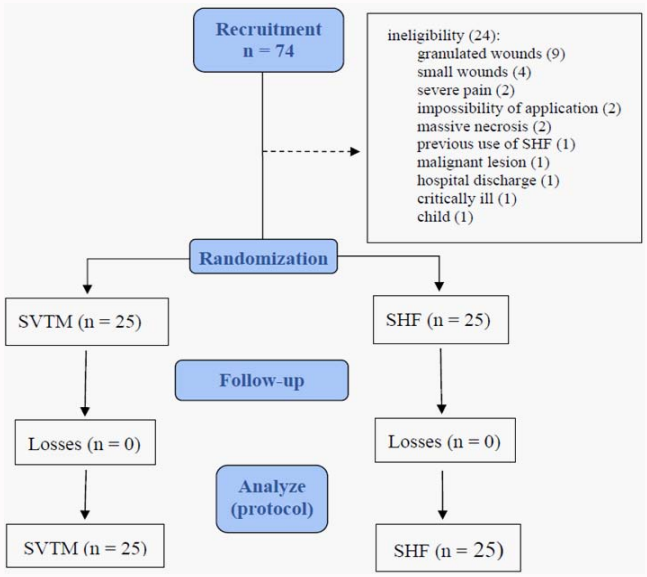

Figure 2: Flow diagram.

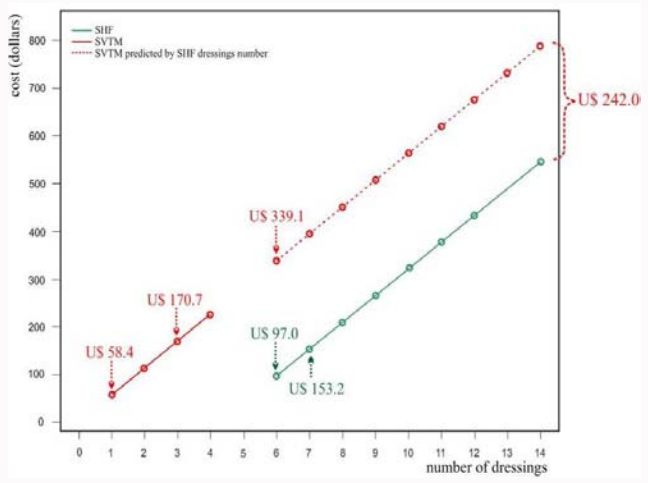

Figure 3: Cost based on a robust regression model with τ = 0.5 (median) as a function of the number of dressings according to the type of dressing.

[14,15]. With the SVTM, the authors achieved sustained sealing, adequate control of sub-atmospheric pressure, and drainage of exudates without loss of dressings. We obtained intact and fully functioning dressings for up to four days.

The bridge concept applies to procedures that favor secondary healing, functioning as a connection between the wound beds from first manipulation to definitive closure through invasive procedures. In this spectrum, the SVTM improved the factors considered essential for managing the lesions (cleaning and granulation) [16], thus acting as a platform capable of simplifying surgical methods by optimizing the injuries and allowing, for example, closure by direct suture or grafts instead of flaps [2,4,6,17].

Microdeformations are millimetric evaginations (1 to 2 mm) that develop on tissue surfaces due to the penetration of the injured surface into pores of the vacuum therapy foam with the application of suction. The cells contained in the microdeformations undergo deformation in their cytoskeleton, triggering mitotic divisions [14,15,18]. The deformations are intensely stimulated by the action of NPWT and are related to the early and abundant emergence of granulation tissue [18-20]. In the present study, microdeformations were observed in all cases of SVTM; however, they were not noticed with hydrofiber, which was usually associated with the smooth and pale appearance of granulation tissue. Other studies have also associated vacuum therapy with the profuse and rapid growth of granulation tissue from the first dressing [2,6,14,21,22]. The continuous drainage of exudates and foam removal resulting in the avulsion of debris that penetrated the material's pores was assumed responsible for the more excellent cleaning found in the SVTM group [15].

The most frequently encountered adverse effects in our clinical

Table 8: Cost (R$) adjusted by robust regression.

Variable	Gross model		Adjusted model 1			Adjusted model 2		Saturated model		Final adjusted model	
	Cost (R$)	*pG*	Cost (R$)	*pAj1*	VIF	Cost (R$)	*pAj2*	Cost (R$)	*pS*	Cost (R$)	p_{Ajf}
Intercepto (β_0)	931.26	<0.0001	-1139.05	<0.0001	-	-1269.37	<0.0001	-894.75	0.1960	-1270.55	<0.0001
SVTM (β_1)	-31.19	0.8470	1112.96	0.0001	2.10	1275.15	<0.0001	890.53	0.1978	1282.82	<0.0001
Application per dressing (min) (β_2)	-	-	0.74	0.7080	2.52	0.31	0.9138	-	-	-	-
Number of dressings (β_3)	-	-	246.00	0.0017	55.89	297.17	<0.0001	245.92	0.0137	297.48	<0.0001
Treatment time (days) (β_4)	-	-	17.03	0.4032	47.72	-	-	-	-	-	-
SVTM (β_1) × number of dressings (β_3)	-	-	-	-	-	-	-	58.20	0.5462	-	-

Cost: Predicted median cost; *pG:* p-value of the Gross model; *pAj1*: p-value of the Adjusted model 1; VIF: Variance Inflation Factor - acceptable VIF: ≥ 10; *pAj2*: p-value of the Adjusted model 2; *pS*: p-value of the Saturated model; p_{Ajf}: p-value of the Final adjusted model.

trial were bleeding and pain during foam removal due to adherence of the foam to the wound. Bleeding was the statistically most relevant problem, as it occurred in most participants in the study group (about 70%) and had the least favorable risk-benefit ratio (LHH ≤ 1.1). However, all the bleedings were practically inconspicuous, nothing more than mild hematic discharges of short duration (1 to 2 min) that did not cause discomfort to the patients. Current research has found that adherence is a clear disadvantage associated with vacuum therapy. Foam adherence and consequent pain showed a favorable risk-benefit ratio, despite greater clinical significance since they resulted in bleeding, longer exchange time of dressings (in case of adherence), and direct suffering of patients (in case of pain). Adherence can also result in infection due to the retention of foam fragments [6].

In patients with one or more episodes of pain (SVTM: 16 × SHF: 2), the symptom was of short duration and, in general, of low intensity. The problem was more intense in the SVTM group (nine times). In line with the findings of the present study, pain is hardly found during the use of vacuum therapy; however, it is frequent during foam removal, being occasionally necessary to perform local or general anesthesia to change dressings [2,6,23-25]. The other adverse effects found were rare and of minor severity: epitheliosis on the wound edge (single case), and small hematoma (50 ml); there were no deaths, worsening of wounds, systemic repercussions, or intensive interventions. Other authors have also attested to the procedure safety, relating NPWT with mild and self-limiting complications [1,4,23,26,27].

SVT general (including SVTM) must be safe despite the reduction of technological resources made in these devices to reduce prices and facilitate handling [1,5]. In this way, the apparatus must contain components capable of accurately regulating negative pressures and avoid reduced or excessive applications to prevent loss of functioning of the dressings or damage to the bed of the wounds (for example, necroses and exsanguinations). The SVTM was equipped not only with these security elements (Figure 1, Items 13 and 14) but also with a specialized filter (high molecular weight polyethylene - Figure 1, Item 6) that blocks outflows of exudates beyond the collection canister and white foams that facilitate the observation of their degree of saturation and debris retention. Translucent covers can reduce vacuum therapy costs, as they allow continuous monitoring of wound beds and adjacent skin without violating the film, thus reducing the chance of changes [28]. The advantage is lost in regular NPTW, which uses dark foams that block the free injuries visualization [1].

The greater complexity of installing and using the SVTM about the SHF was manifested in the more prolonged application time (about six times more), evidencing the need for training to master the procedure. The main factor responsible for this was the multiple steps required for placement of the SVTM (six steps - SVTM × two steps - SHF), especially obtaining adequate sealing over the lesions. Injuries located in contoured areas (*e.g.*, buttocks), in places with notches (*e.g.*, interdigitates), in regions close to natural holes (*e.g.*, face), or when perilesional skin is continuously moist (*e.g.*, dermatoses) are very difficult to seal [19,29,30]. Furthermore, vacuum dressings require the additional effort of daily monitoring to prevent leakage [13,19]. The difficulty of use is so significant that conventional NPWT is performed by highly trained nursing teams who do not work in the hospital that hires them, making it difficult for this team to access it at night, on weekends, in intensive care units, and operating rooms.

SVTM drained exudates without early dressing changes, controlled sub-atmospheric pressure, and maintained wound seals (three days), with results similar to those described for standard NPWT or SVT (two to four days) [13,31-33]. Vacuum dressings can be fully functional for ten days if the adhesive film is intact [2,3,19,30,33]. The lower number of bandages consumed in the SVTM group (four less) was assumed to be due to the continuous drainage of fluids, which kept dressings unsaturated and operating longer [18]. NPWT also reduces the need for changes due to the absorbent properties of the foams used. However, in exudative lesions, the dressings should be changed every two to three days make them non-functional, smelly, or adherent to wounds [1,2,11].

Variable NPWT consists of applications of cycles of gentle oscillations between less intense pressures (-80 to -10 mmHg) to maintain an uninterrupted sub-atmospheric environment, and in this way, foams always collapse [15,20]. The method has been proposed because the retention of exudates, the volume variation of dressings, and the entire foam expansion that occurs during intermittent may tear the film, resulting in leaks and loss of curatives. An additional advantage of SVT powered by wall suction, such as the SVTM, is that they mimic the benefits of a variable regime, as the pressure variations in the hospital network are automatically transmitted to the equipment.

The type of dressing (vacuum therapy or hydrofiber), the number of changes (SVTM: 3 × SHF: 2), and the sales price (SVTM unit: US$ 56.6 × SHF unit 15 cm × 15 cm: US$ 20.5) were the factors that determined the costs of the device. SVTM had a higher value both per exchange (US$ 58.4 - about five times more) and per patient treated (US$ 17.5 more), with the cost difference increasing if the number of SVTM exchanges is the same as the number of SHF exchanges (US$ 242.0 – Table 8 and Figure 3). In practice, as each SVTM dressing remained functional longer (one day more) and achieved the studied outcomes earlier, the equipment required fewer changes per subject

(four fewer). The results show that care to ensure operational quality is essential so that the number of SVTM dressings is limited (three shifts) to avoid a considerable increase in the total cost.

Economic studies in the field of wound care are incompletes, scarce, with poor methodology, and contrary to what was performed in the present trial, described without adjustments for covariates, making cost analyses challenging [1,2,4,13,34]. However, regular NPWT costs appear higher compared to simplified vacuum dressings. The cost of regular NPWT was estimated between US$ 1,800 to US$ 3,500 weekly, US$ 1,3000 to US$ 5,500 per patient [4,34] and in children; the monthly price was US$ 1,677/person [23]. SVT can become up to 20 times cheaper than conventional NPWT, reaching levels as low as US$ 6.4/dressing, US$ 15.0/day, or 2% of the average cost of the VAC System [1,4,13]. The use of simple, lower-cost, locally manufactured materials (foams, polyurethane films, canisters, tubes made of PVC plastic, *etc*.), supply by hospital vacuum systems that reduces specialized materials and, as demonstrated by the current study, the reduction in the number of dressings are the main reasons attributed to lower prices of SVT as a sub-atmospheric pressure therapy modality [2,4]. As fully functioning NPWT dressings for up to fourteen days have been described, a promising range of savings is theoretically possible [35].

Conclusion

SVTM is effective in cleaning and granulating treated wounds and is safe, with self-limiting complications and an acceptable risk-benefit ratio. However, it presented greater operational complexity and cost than the usual occlusive dressing, being feasible as long as the application professionals master the procedure and there are few dressing changes (up to three).

Limitations

Limitations include missed studies published in non-English languages or not cited in searched databases.

Due to the distinct appearance of materials (device/hydrofiber), blinding dressings used for patients and interventionists were impossible. This masking problem is frequent in the surgical field [36]. However, in the current monograph, general therapeutic procedures (washings, debridement's, etc.) were performed equally in both study groups.

The current study also failed to maintain the separation of work between investigators and interventionists due to the complexity of the application of the SVTM and the absence of a support team. Risks of bias from this omission were reduced through blind analysis of results by external evaluators.

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