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ORIGINAL ARTICLE

Effectiveness of 3-Day Prophylactic Negative Pressure Wound Therapy on Closed Abdominal Incisions in the Prevention of Wound Complications: A Randomized Controlled Trial

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Abstract

Objective To determine the impact of negative pressure wound therapy of closed abdominal incisions on wound complications.

Background Surgical wound complications including surgical site infection complicating open abdominal operations are a burden on the economy. The outcomes of SSI include prolonged hospital stays, adjuvant treatment delay, and incisional hernias leading to a decrease in the quality of life. Prophylactic negative pressure wound therapy has recently been tried with promising results.

Methods A randomized controlled trial involving 140 patients post-laparotomy with primary wound closure was divided into 2 groups (70 patients each). For the first group, NPWT dressings were applied for the first 3 days and then conventional dressings for 4 days after. For the second group, conventional dressings were applied for 7 days. Patients were followed up for SSI, seroma, wound dehiscence, and hospital stay.

Results pNPWT was associated with a significantly lower rate of SSI development compared with gauze dressings (3/70 vs. 17/70) ($p = 0.001$). It also had a significant effect on lowering the incidence of seroma (0/70 vs. 7/70) ($p = 0.007$) and delayed wound healing (0/70 vs. 8/70) ($p = 0.006$) and on decreasing days of hospital stay (2.2 ± 0.6 vs. 3.5 ± 1.8) ($p < 0.00001$). No significant difference was observed with regard to hematoma (0/70 vs. 1/70) ($p = 0.5$) or wound dehiscence (0/70 vs. 2/70) ($p = 0.5$). No burst abdomens or NPWT complications were recorded in our study.

Conclusion Three-day NPWT applied to primarily closed incisions is effective in reducing the incidence of SSI, seroma, and delayed wound healing in abdominal operations compared to conventional gauze dressings.

Keywords Surgical site infection · Prophylactic negative pressure wound therapy · Seroma · Hematoma · Delayed healing · Wound dehiscence

Introduction

Surgical site infection (SSI), seroma/hematoma, and wound dehiscence are common postoperative wound complications after open abdominal operations. SSIs represent a true health economic burden. The highest rates of SSIs are recorded with colorectal operations (~45%)[1] owing to the inherent contaminated nature of the operations. The outcomes of SSI include long hospital stays, adjuvant treatment delay, and risk of incisional hernias, all leading to a decrease in patient quality of life.[2,3] Multiple patient-related, environmental, and surgical factors act together to cause SSI, and therefore, traditional care bundles were developed to tackle these factors and those included the use of antibiotic prophylaxis, aseptic surgical technique, maintenance of intraoperative patient temperature,

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and preoperative optimization of patient risk factors.[4] However, these measures have failed to decrease the incidence of SSI considerably. Laparoscopic surgery has significantly recorded lower SSI incidence compared to open; however, this approach does not suit all patients. Therefore, innovative preventive measures are needed to reduce the development of SSI after open operations.

Negative pressure wound therapy (NPWT) consists of negative pressure delivery to the wound bed via a vacuum device, acting to remove excess tissue edema and promote granulation tissue formation. NPWT was initially used with open wounds but has now been recently extended to include closed surgical incisions. A recent systematic review showed that NPWT decreased wound infection rates and seroma formation compared with non-pressure, standard dressings in closed wounds.[5] Most studies have investigated 7-day-long pNPWT's effect in reducing wound complications.

We aimed to determine the impact of 3-day NPWT applied to primarily closed abdominal incisions on the incidence of wound complications; due to the increased risk of NPWT complications with time of application, the higher is the cost of more than one dressing and the discomfort of the attachment to a suction device for a longer period of time (quality of life).

The primary outcome was to measure its effect in preventing SSI occurrence, whereas the secondary outcome was to measure its effect in preventing other wound complications such as seroma, hematoma, wound dehiscence, and delayed healing in addition to other parameters as hospital stay.

Patients and Methods

Our prospective randomized controlled study was conducted on 140 patients that presented to the Cairo University hospitals and underwent exploratory laparotomy from July 2021 to December 2022 after obtaining the approval of the "Research Ethics Committee" of the Faculty of Medicine, Cairo University.

Inclusion Criteria

The inclusion criteria were as follows:

1. Patients who underwent exploratory laparotomy
2. Elective and emergency operations
3. Clean, clean-contaminated, contaminated, and dirty operations

Exclusion Criteria

The exclusion criteria were as follows:

1. Open abdominal incisions
2. Patients with a subcutaneous drain
3. Re-operated patients with an already infected surgical wound

Methodology in Details

The methodology in details used was as follows:

- Approval from the Research Ethics Committee of the Faculty of Medicine, Cairo University was obtained prior to the start of the study.
- Patients (aged 15–74) presented to the outpatient or emergency department, and those who underwent exploratory laparotomy were chosen.
- Full-body shower was undertaken with soap, hair was shaved on the operating table using hair clipper, and the skin was prepped with povidone iodine, which was chosen over chlorhexidine due to consistent availability for the sake of randomization.
- Patients with wounds closed in layers (continuous #1 PDS to sheath, interrupted 3-0 Monocryl to skin) were chosen, and those with wounds left open or those where subcutaneous drains were inserted were excluded.
- Patients were assigned to two groups, group A and group B, randomly using the sealed envelope method.
- All patients received at least one dose of ceftriaxone + metronidazole (as per hospital guidelines) just before skin incision, and further antibiotics were given guided by the wound classification.
- Intraoperative normothermia and glycemic control <200mg/dL were maintained.
- For group A, NPWT dressings were applied for the first 3 days then removed (1 dressing with a total cost of 300 EGP), then conventional dressings for 4 days after, and changed only once on the second day.

NPWT Technique

NPWT foam sponge (open-pore polyurethane ether foam sponge) was trimmed to fit the size and applied to the closed incision. Semi-occlusive adhesive sheet was then applied over the sponge, and a hole was formed for the suction port connected to the tubing. The tubing was then connected to a pump whose pressure was set at "minus100 mmHg" delivered in intermittent suction to reduce the foam volume by up to eighty percent.

- For group B, conventional gauze dressings were applied for 7 days changed on day 3 and 5 and then removed on day 7.

- Patients of both groups were followed up in the hospital for SSI, seroma, hematoma, wound dehiscence, burst abdomen, delayed wound healing, and hospital stay.
- Patients were evaluated in the outpatient clinic 14 days postoperatively for any wound complications before suture removal by a different team of surgeons not involved in the study.
- The following items were analyzed:

  – Age/sex distribution
  – Group comparison with regard to smokers, high BMI patients (>30 Kg/m^2), diabetics (diagnosed and established on treatment by the primary care physician), malignancies, hemoglobin (anemia diagnosed when Hb < 11.9g/dL in females or < 13.6 g/dL in males), and albumin (hypoalbuminemia diagnosed when albumin < 3.5 g/dL).
  – Effect of NPWT application on the development of SSI (clinically diagnosed through patient reporting of either wound erythema or purulent discharge followed by clinical examination and opening of the wound)
  – Effect of NPWT application on development of seroma (clinically diagnosed through patient reporting of swelling or clear wound discharge followed by clinical examination and opening of the wound with large collections)
  – Effect of NPWT application on the development of hematoma (clinically diagnosed through patient reporting or opening of the wound with large hematomas)
  – Effect of NPWT application on the development of wound dehiscence (clinically diagnosed)
  – Effect of NPWT application on the development of burst abdomen (clinically diagnosed)
  – Effect of NPWT application on having delayed wound healing (non-healed areas of the skin wound ≥ 2 weeks postoperatively)
  – Incidence of NPWT complications
  – Length of hospital stay

Statistical Analysis

Sample size calculation was performed using power and sample size calculator program version 3.0.43. It was based on the following inputs:

a) Power of 80% significance with level of 0.05 alpha error
b) Percentage of SSI without NPWT: 33%; with NPWT: 13%

The least calculated sample size was 140: 70 for each group.

All collected data was revised for completeness and accuracy. Pre-coded data was entered on the computer using the statistical package of social science software program, version 26 (SPSS) for statistical analysis.

Data was summarized using mean and SD for quantitative variables and number and percent for qualitative variable.

Comparison between qualitative variables was done using chi-square test, while independent *t* test was used for quantitative variables that are normally distributed and nonparametric Mann–Whitney tests for quantitative variables that are not normally distributed. One-way ANOVA was used to compare quantitative variables between more than two categories for quantitative variables that are normally distributed and nonparametric Kruskal–Wallis tests for quantitative variables that are not normally distributed. *p* value <0.05 will be considered significant. Tests for validity and reliability were estimated in the form of sensitivity, specificity, positive predictive value, and negative predictive value.

Results

Demographic Data

Age Distribution

For the "NPWT" group, the age range was 18 to 69 with a mean of 45.2 ± 13.7 years compared to a range of 15 to 74 with mean of 42.1 ± 14.8 years for the "conventional" group.

No statistical significance was observed with a p value of 0.21 (Table 1).

Sex Distribution

Of the 140 patients who presented to us, forty-seven were females (33.6%): 24 in the "NPWT" group and 23 in the "conventional" group.

Ninety-three were males (66.4%): 46 in the "NPWT" group and 47 in the "conventional" group.

Table 1 Age distribution

	Group	Mean	SD	Median	Minimum	Maximum	*p* value
Age	NPWT (*n*=70)	45.2	13.7	45	18	69	0.21
	Conventional (*n*=70)	42.1	14.8	42	15	74	

No statistical significance was noted with a p value of 0.86 (Fig. 1).

Risk Factor Distribution (Fig. 2)

The only parameter which showed a statistically significant difference ($p = 0.001$) between the groups was the percentage of patients with hypoalbuminemia. Low albumin levels were found in 19/70 patients in the "NPWT" group compared to 4/70 in the "conventional" group. No significant difference was observed between numbers in both groups in the rest of the factors which are smoking (15/70 vs. 12/70) ($p = 0.67$), diabetes (12/70 vs 14/70) ($p = 0.83$), malignancy (9/70 vs 11/70) ($p = 0.81$), high BMI (36/70 vs. 41/70) ($p = 0.50$), anemia (11/70 vs. 14/70) ($p = 0.66$), and emergency operation (61/70 vs. 54/70) ($p = 0.19$).

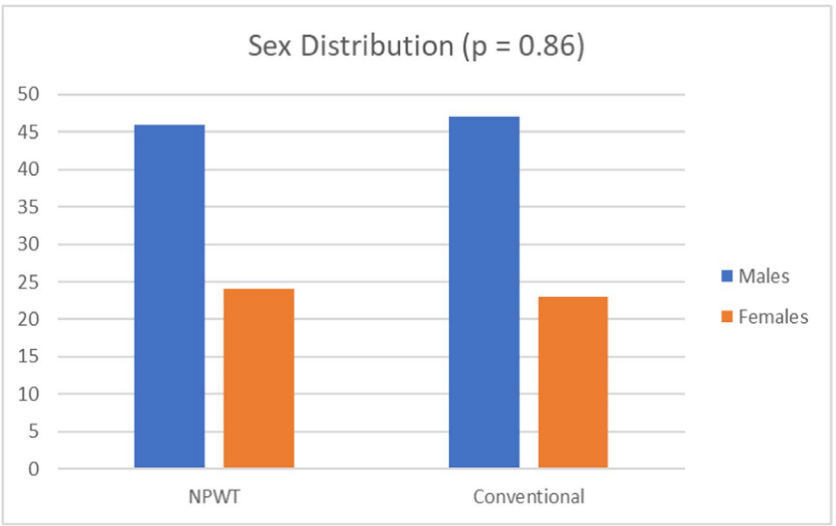

Fig. 1 Sex distribution

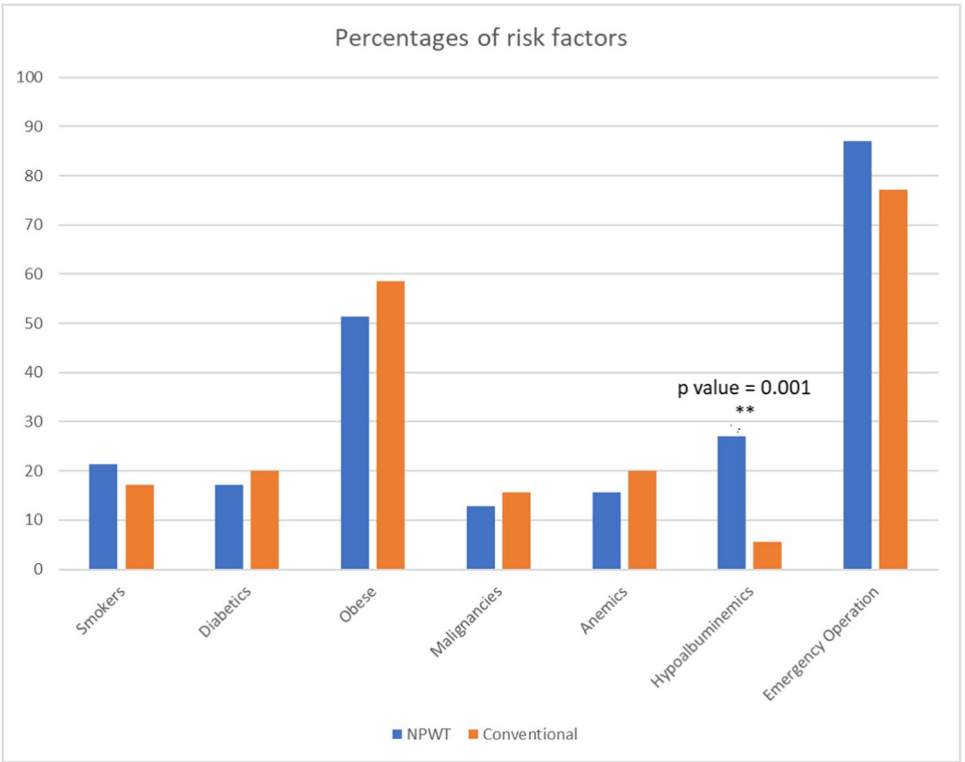

Fig. 2 Risk factors' distribution

Wound Classification in Each Group

There was not a statistically significant difference between both groups ($p = 0.56$) (Fig. 3).

Distribution of Wound Complications

There was a statistically significant relation ($p = 0.001$) between NPWT application and reduction of SSI development. From the "conventional" group, 14 patients developed a superficial SSI (20%) and 3 (4.3%) developed a deep SSI compared to 3 and 0 for the "NPWT" group, respectively. A significant relation ($p = 0.007$) was also demonstrated for the development of seroma. Seven patients from the "conventional" group developed a seroma compared to 0 from the "NPWT" group. Finally, delayed healing was also significantly reduced with pNPWT ($p = 0.006$) as 8 patients developed that complication in the "conventional" group compared to none in the "NPWT" group. No patients developed hematomas or wound dehiscence from the "NPWT" group compared to 1 and 2, respectively, from the "conventional" group (Fig. 4).

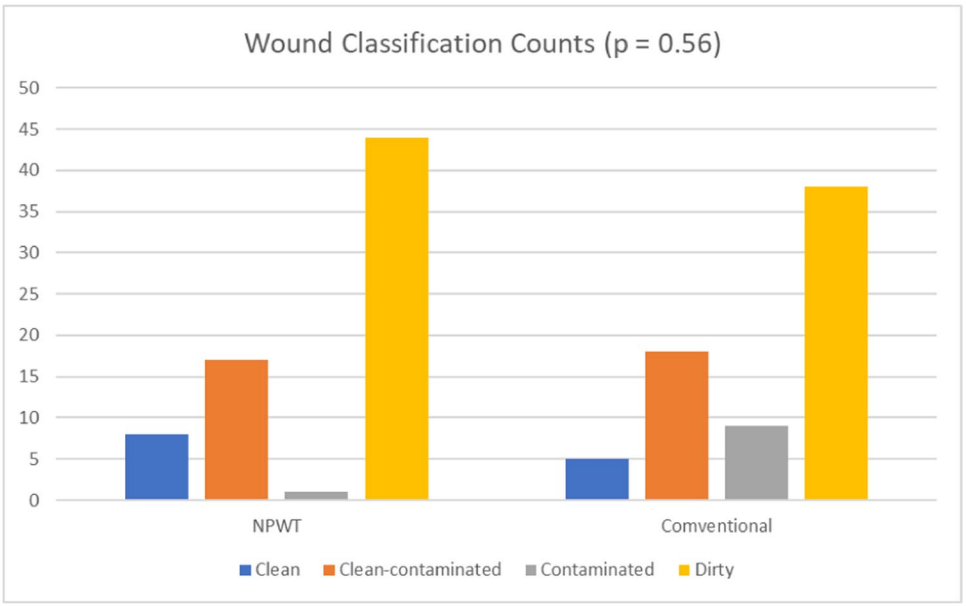

Fig. 3 Wound classification in each group

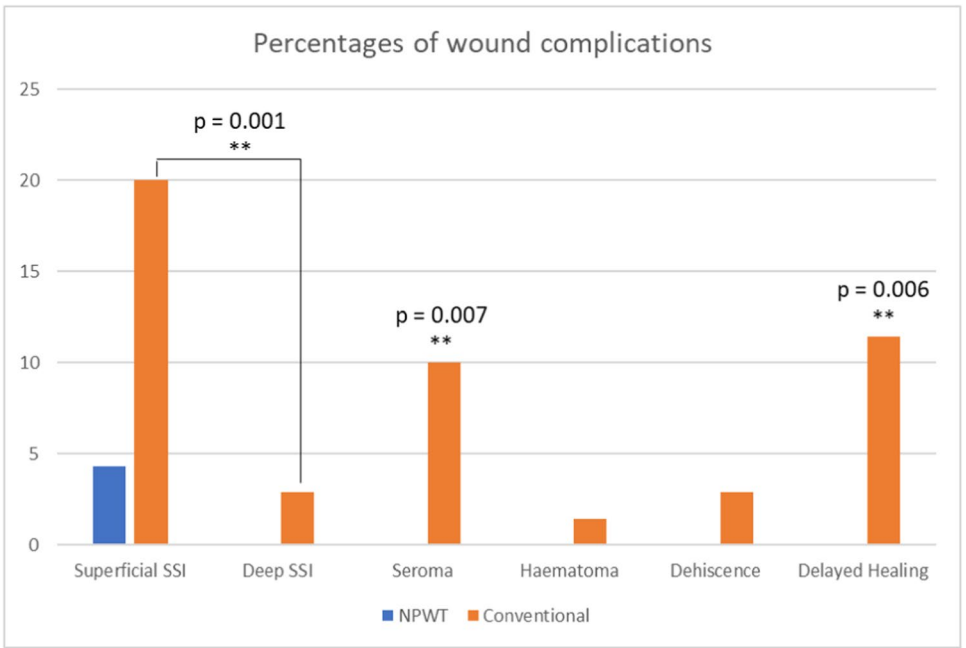

Fig. 4 Wound complications' distribution

Incidence of NPWT Complications

No break in the seal of the suction device was recorded.

No complications were recorded in this study.

Length of Hospital Stay

There was a statistically significant difference in hospital stay between both groups (Table 2).

Discussion

Although exact figures of incidence of SSI in our department are yet to be published, they remain quite high, and SSI accounts for a major part of the hospital-acquired infections in the postoperative period.

Strict adherence to current established SSI prevention guidelines remains the mainstay of ensuring low SSI rates. Those include full-body shower with soap/antiseptic agent before the operation, antibiotic prophylaxis according to guidelines and timed such that a bactericidal concentration of the agent is established in the incised tissues, skin prep with alcohol-based agent, glycemic control (<200 mg/dL), normothermia, and finally increasing FiO_2 during the operation and immediately post-extubation in patients with normal pulmonary functions.[6]

With growing rates of bacterial resistance to antimicrobials, the development of new non-antimicrobial techniques to combat SSI has become essential. Skin preparation, wound irrigation, negative pressure wound therapy, and triclosan-coated sutures for skin closure are some examples.[7,8]

Evidence suggests that there may be a role for pNPWT in reducing the incidence of SSI. Many trials have been performed in a variety of specialties including orthopedic, obstetric, and vascular and general procedures and have suggested that rates of SSI for some incision types may be lower if NPWT, rather than conventional gauze dressings, is used on overlying closed incisions.[5]

pNPWT dressings have shown superiority in reducing SSIs specifically in abdominal operations: emergency and elective.[9,10] The hypothesis is that negative pressure results in the reduction of tissue edema, drawing the edges of the wound together, promotion of release of growth factors, and formation of an unfavorable environment for microorganisms. All the previously mentioned factors result in decreased infection and accelerated healing.

Our prospective study was conducted on 140 patients who underwent laparotomy in the Cairo University Hospitals between July 2021 and December 2022. Those 140 were divided into "NPWT" and "conventional" groups, 70 patients in each. Forty-seven total patients were females (33.6%): 24 (34.3%) in the "NPWT" group and 23 (32.9%) in the "conventional" group. Ninety-three total patients were males (66.4%); 46 (65.7%) in the "NPWT" group and 47 (67.1%) in the "conventional" group. The mean age was 45.2 ± 13.7 for the "NPWT" group compared to 42.1 ± 14.8 for the "conventional" group. A systematic review and meta-analysis of five RCTs by Boland et al. (2020) studied a total of 519 males to 412 females with a slightly higher mean age of 63 for included patients.[11]

In our study, there was no significant difference between both arms in numbers of smokers, diabetics, or patients with high BMIs or malignancies nor was there a significant difference in wound category, type of operation, or hemoglobin levels between both arms. There was a significant difference in the albumin levels observed in favor of the control group. Controlling such factors was particularly important as we thought they were critical factors that could affect the results, which in turn would lead to an inaccurate comparison between groups. "ASA score," "operation time," and "amount of blood loss" were not analyzed in our study. Li et al. (2016)[12] and Murphy et al. (2019)[13] demonstrated no statistically significant difference between albumin levels or BMIs of the patients. Li et al., in addition, demonstrated no significance between ASA scores of patients in their study.

Coming to "SSIs", our study has proven a significant relation between pNPWT application for 3 days and reduction in SSI incidence ($p = 0.001$). Most studies such as O'Leary et al. (2017),[14] Javed et al. (2019),[15] Zaidi and El-Masry (2016),[16] Blackham et al. (2013),[17] and Lozano-Balderas (2017)[18] are in agreement with our findings. Murphy et al. (2019),[13] Shen at al. (2017),[19] and Flynn et al. (2020)[20] both disagree and have proven no significant reduction in SSI incidence with pNPWT.

Concerning "seromas," most studies are in agreement that pNPWT showed no effectiveness in decreasing postoperative seroma. Andrianello et al. (2021)[21] was the only study to show a reduction in seroma incidence with pNPWT as opposed to the rest of the studies that included Shen at al. (2017),[19] Flynn et al. (2020),[20] Leitao et al. (2020),[22] and Kuncewitch et al. (2019).[23]

All studies reviewed were in agreement with our study that pNPWT had no effect on decreasing incidence of hematoma development. Examples include Shen at al. (2017),[19] Flynn et al. (2020),[20] Leitao et al. (2020),[22] Andrianello et al.

Table 2 Hospital stay

	NPWT (n=70)					Conventional (n=70)					p value
	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	
Hospital stay in days	2.2	0.6	2	1	4	3.51	1.81	3	2	10	<0.00001

(2021),[21] Borejsza-Wysocki et al. (2021),[24] and Wierdak et al. (2020).[25]

Regarding "wound dehiscence," most studies demonstrated no significant difference with pNPWT application agreeing with our findings. Such studies included Flynn et al. (2020),[20] Martin et al. (2019),[26] and Shen et al. (2017).[19] Gök et al. (2020),[27] on the other hand, demonstrated a positive effect for pNPWT on decreasing incidence of wound dehiscence.

With a p value of 0.006, our study has proven a positive effect for pNPWT on decreasing the incidence of delayed wound healing. Unfortunately, we could not find papers that have studied this parameter for comparison.

We have not observed any complications from the NPWT device. In addition, we have not performed an economic analysis. Of all the studies examined, only 1 study (Javed et al. in 2019)[15] performed an economic evaluation and concluded a 23.8% increase in the cost of hospitalization as a result of development of SSI.

Finally, our study has shown a significant decrease in the length of stay in favor of the pNPWT group. Brennfleck et al. (2020)[28] suggested the same, but on the other hand, Murphy et al. (2019)[13] showed comparable length of stays between the compared groups.

Conclusion

Prophylactic NPWT applied to primarily closed incisions for 3 days is effective in reducing the incidence of SSI in emergency and elective abdominal operations compared to conventional gauze dressings. It has also shown effectiveness in reducing the incidence of seroma and delayed wound healing. This definitely has a positive effect on the postoperative quality of life and leads to a decreased hospital stay which all lead to reduction in costs. No impact for prophylactic negative pressure wound therapy on incidences of hematoma and wound dehiscence was observed in this study. No NPWT complications were observed in our study.

Further economic analysis with full information on costs of management of SSI is needed which should then be compared to the costs of pNPWT. It might also be beneficial to analyze in subgroups, i.e., according to wound category (contaminated vs. contaminated or dirty vs. dirty) or according to type of operation (elective vs. elective or emergency vs. emergency). Our study, the first of its kind in our university hospital, will serve as a starting point for future substudies to be conducted where analysis will be undertaken for individual groups. Furthermore, when the official numbers about SSIs in our department along with the economic statistics are published, we will be able to conduct more studies tackling cost effectiveness.

Data Availability Data will be available upon the editor's request.

Declarations

Consent to Participate Informed consent was obtained from all individual participants included in the study.

Conflict of Interest The authors declare no competing interests.

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