Prophylactic Single-use Negative Pressure Dressing in Closed Surgical Wounds After Incisional Hernia Repair

A Randomized, Controlled Trial

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Objective: A randomized controlled trial (RCT) was undertaken to evaluate whether the prophylactic application of a specific single-use negative pressure (sNPWT) dressing on closed surgical incisions after incisional hernia (IH) repair decreases the risk of surgical site occurrences (SSOs) and the length of stay.

Background: The sNPWT dressings have been associated to several advantages like cost savings and prevention of SSOs like seroma, hematoma, dehiscence, or wound infection (SSI) in closed surgical incisions. But this beneficious effect has not been previously studied in cases of close wounds after abdominal wall hernia repairs.

Methods: An RCT was undertaken between May 2017 and January 2020 (ClinicalTrials.gov registration number NCT03576222). Participating patients, with IH type W2 or W3 according to European Hernia Society classification, were randomly assigned to receive intraoperatively either the sNPWT (PICO)(72 patients) or a conventional dressing at the end of the hernia repair (74 patients). The primary endpoint was the development of SSOs during the first 30 days after hernia repair. The secondary endpoint included length of hospital stay. Statistical analysis was performed using IBM SPSS Statistics Version 23.0.

Results: At 30 days postoperatively, there was significatively higher incidence of SSOs in the control group compared to the treatment group (29.8% vs 16.6%, $P < 0.042$). There was no SSI in the treatment group and 6 cases in the control group (0% vs 8%, $P < 0.002$). No significant differences regarding seroma, hematoma, wound dehiscence, and length of stay were observed between the groups.

Conclusion: The use of prophylactic sNPWT PICO dressing for closed surgical incisions following IH repair reduces significatively the overall incidence of SSOs and the SSI at 30 days postoperatively.

Keywords: hernia repair, incisional hernia, negative pressure therapy, PICO dressing

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Postoperative surgical site occurrences (SSOs), including surgical site infection (SSI), seroma, hematoma, and wound dehiscence, may affect closed surgical incisions and ultimately delay wound healing. These complications increase the average hospital stay. In particular, SSI is associated with the occurrence of other complications, significant cost increases, and a higher 30-day morbidity rate.[1]

Abdominal surgeries have the highest 30-day rate of SSO at >15%.[2] Consequently, hernia repair is one of the most performed abdominal surgery procedures. Incisional hernias (IHs) represent a high percentage and important volume in this group of repairs, and these can have a direct impact on patients' quality of life. In such cases, hernia repair achieves abdominal wall reconstruction and significatively improves recurrence rates with the use of meshes, but the cost of this is the high associated rate of SSOs.[3]

In most cases, hernia repair is considered a clean surgery (Type I) according to Center for Disease Control (CDC) classification,[4] although there are situations of repairs in contaminated fields. In cases of IH, the SSOs may reach an overall incidence of 3.9% to 20% in some populations.[5] In fact, in our country, global incidence of SSO in complex abdominal wall surgery represents 12% to 27%, including seroma in 12% to 20%, hematoma in 7% to 10%, SSI in 5% to 10%, and wound dehiscence in up to 5%.[6] Recently, research has reported a closed relation between the development of SSOs and the long-term risk of hernia recurrence.[7]

Negative pressure wound therapy (NPWT) is increasingly being used prophylactically on closed incisional wounds to prevent SSO, specifically SSI, and numerous metanalyses have been carried out on the data from these procedures.[8–16] Negative pressure dressings stimulate angiogenesis and cell-mediated immune responses and enhance granulation, encouraging other changes to the microenvironment of the wound by reducing bacterial contamination, edema, and exudate.[17] This effect, which improves lymphatic clearance, may contribute to stronger healing with reduced risk of infection, wound dehiscence, and length of hospital stay, as a recent meta-analysis reported.[8]

A single-use negative pressure wound (sNPWT) dressing has been associated with these advantages in recent trials and has shown considerable cost savings for preventing and treating SSOs in closed surgical wound incisions.[13,18] However, this beneficial effect has not been previously studied in incisional wounds of patients after IH repair. The aim of this randomized controlled trial (RCT) was to evaluate whether the prophylactic application of a specific sNPWT dressing on closed surgical incisions after hernia repair decreases the risk of SSOs (seroma, hematoma, infection, or wound dehiscence) and the length of stay when compared to standard non-negative pressure wound dressing.

METHODS

The RCT was undertaken between May 2017 and January 2020 in La Fe University Hospital. The trial was registered at the US National Institutes of Health (ClinicalTrials.gov), registration number NCT03576222. The present study was approved by the ethics committee of the hospital. The CONSORT reporting guidelines was followed to perform our RCT results.

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Patients undergoing elective midline hernia repair via laparotomy were recruited preoperatively. They were seen by both a physician and the nursing staff who they could discuss the study with before making their decision. Those who decided to participate first signed the written informed consent. Inclusion criteria included male and female patients >18 years' old with IH type W2 (transverse hernia defect with 4–10 cm) or W3 (transverse hernia defect over 10 cms) according to European Hernia Society (EHS) classification.[19] Exclusion criteria included patients under the age of 18 years, patients unable to give written consent, patients who had abdominal surgery reintervention within 30 days before the hernia repair, patients who had undergone emergency hernia surgery, pregnant patients, and patients with hepatic cirrhosis and IH not involving the midline.

The required intervention was the sNPWT PICO dressing, which is a small canister-free device that deals with exudate by absorption and evaporation and delivers −80 mm Hg negative pressure for 7 days. Participating patients were randomly assigned to receive intraoperatively either the sNPWT (PICO; Smith & Nephew, London, UK) or a conventional dressing (MEPORE pro; Molnlycke, Goteborg, Sweden) at the end of the hernia repair. Randomization was performed on a 1:1 basis to either the treatment group or the control group. The sequence was generated on www.randomization.com and allocation was concealed using closed envelopes.

Surgical Technique

All patients underwent hernia repair under general anesthesia with antibiotics in the form of a single dose of Augmentin 2 g intravenously and thromboembolic prophylaxis. Operations were performed by 5 consulting general surgeons of the Abdominal Wall Unit. The abdomen was prepared using chlorhexidine. Three abdominal wall reconstruction techniques to repair the IH were performed during the study: Rives-Stoppa repair (RSR), transversus abdominis repair (TAR), and anterior component separation (ACS). One of the techniques was used in each patient. All accesses were gained via midline laparotomy.

The RSR is a modification of the original technique.[20] It began with a midline incision, exposing the hernia sac and its associated fascial defect; this sac was preserved whenever possible to provide another layer of autogenous tissue interposed between intraperitoneal contents and the posterior surface of the prosthesis. The abdominal fascial level between the rectus muscle and the posterior sheath (or, when below the arcuate line, the transversalis fascia) was dissected to create space for the mesh—usually 5 to 10 cm from the margins of the hernia. During the dissection, epigastric vessels and nervous pedicle were preserved. The posterior fascia was closed with a 1 poli-4-hidroxibutirate (Monomax) running suture to wound length ratio of at least 4:1. A large-pore polypropylene (PPL) or polyvinyl (PVDF) mesh was placed over the posterior rectus sheath and fixed in 4 quadrants with absorbable sutures or cyanocrylate (glubran).

To perform the TAR, a retrorectus dissection is performed in all cases following the procedure described for RSR. The dissection is commenced medial to the neurovascular bundles by first dividing the posterior lamina of the internal oblique to reveal and cut the trasversus muscle fibers. As division continues downward toward the arcuate line, the transversus muscle becomes more aponeurotic. A ''down-to-up'' modification of TAR[21] requires an initial dissection into the space of Bogros below the level of the arcuate line with division of the lateral edge of the posterior rectus sheet in an upward direction. The preperitoneal plane so accessed is continuous posterolaterally with the retroperitoneum and is dissected bluntly until the psoas is visible. For the reconstruction, a combination of meshes was used: an absorbable mesh (GORE BIO-A Tissue Reinforcement) of 20 × 30 cm and a large 30 × 40 cm large-pore mesh (PPL). Both meshes were trimmed to fit the dissected space. The PPL mesh was cranially and caudally secured with slowly absorbable sutures.

We carried out a modification of the ACS as described by Ramirez and previously reported by our group.[22] The dissection began with a fasciotomy of the external oblique fascia, followed by dissection of the tissue plane between the external and internal oblique muscles before medial advancement of the rectus muscle. Division of the external oblique aponeurosis was performed 0.5 to 1 cm lateral to the lateral border of the rectus sheath, extending cranially to the costal margin, and caudally to the inguinal ligament. After the rectus muscles were reapproximated in the midline, a large-pore PPL or PVDF mesh was placed onlay and anchored with nonabsorbable (Prolene) sutures to the costal margin, anterior iliac spine, and pubis, while located between the internal and external muscles.

In all cases, midline laparotomy incisions were closed in a standard manner. The rectus fascia was closed with a slowly absorbable running suture (Monomax) with a wound-length ratio of at least 4:1. Subcutaneous tissue was then closed with absorbable sutures and clips were then inserted to close the skin. During the operation, 2 aspirative drainage tubes were used in all cases: one placed retromuscularly or under the external oblique flap areas, depending on the reconstruction technique (RSR, TAR, or ACS, respectively), and another one subcutaneously. Drainage tubes were maintained 3 to 4 days after hernia repair and removed once their output had decreased markedly (<20 ml/24 h).

The operating surgeon was not blinded to the dressing being applied to the wound. At the end of the procedure, dressings were applied by the surgeon and the nursing staff under sterile conditions while still in the operating room. The vacuum device was switched on, and negative pressure was applied to the incisional wound. The dressing was kept on the wound during the hospital stay and left in situ for 6 days.

An SSO after open hernia repair was defined as the appearance of complications related to the surgical incisions, including SSIs, wound dehiscence, seromas, or hematomas.[23] An SSI was defined as an infection that occurred at the site of a surgical incision or in an organ space within 30 days of the surgery. Wound dehiscence was defined as the splitting apart or rupturing of the margins of a previously closed wound along some or all of its length. Patients were assessed again at 12 (wound clip removal) and 30 days in the outpatient clinic and the wound examined for evidence of SSOs by the same study assessor, who was a member of the operating surgical team and who was not blinded to the treatment group.

Data Analysis

The primary endpoint was the development of SSOs (eg, seroma, SSI, hematoma, wound dehiscence) during the first 30 days after hernia repair. The secondary endpoint was the length of hospital stay.

We reviewed the patients' electronic hospital records and outpatient office notes for operation details and follow-up information. Specifically, we prospectively analyzed demographic data, American Society of Anesthesiologists status, history of smoking, presence of chronic obstructive pulmonary disease, immunosuppression, diabetes mellitus, or obesity, hernia location by EHS classification, hernia defect diameter, type of surgical procedure, location of prosthesis, subcutaneous area dissection, duration of operation, SSOs, and length of hospital stay. Patients were followed up at 30 days post-surgery.

Statistical Analysis

Assuming that the percentage of patients developing SSOs at 30 days post-surgery following elective hernia repair is at most 30%

TABLE 1. Baseline Characteristics

Preoperative Variables	sNPWT Group (%) N = 72	Control Group (%) N = 74
Average age (SD)	51.6 (23.2)	51.3 (19.4)
Sex		
Male	41 (56.9)	52 (70.3)
Female	31 (43.1)	22 (29.7)
Obesity (BMI >30)		
Yes	18 (25)	19 (25.6)
No	54 (75)	55 (74.4)
Smoking		
Yes	29 (40.3)	28 (37.8)
No	43 (59.7)	46 (62.2)
Diabetes		
Yes	19 (26.4)	23 (31)
No	53 (73.6)	51 (69)
COPD		
Yes	14 (19.4)	13 (17.5)
No	58 (80.1)	61 (82.5)
Inmunosupression		
Yes	7 (9.7)	8 (10.8)
No	65 (90.3)	66 (89.2)
Anticoagulant therapy		
Yes	11 (15.2)	13 (17.5)
No	61 (84.8)	62 (82.5)
ASA scale		
I-II	35 (48.6)	34 (45.9)
III-IV	37 (51.4)	40 (54.1)

BMI indicates body mass index; COPD, obstuctive pulmonar disease; SD, standard deviation.

TABLE 2. Perioperative Variables and Wound Complications at 30 Days Postoperatively

Perioperative Variables	sNPWT Group (%) N = 72	Control Group (%) N = 74	Univariate *P*
Type of repair			
Rives Stoppa	48 (66.6)	45 (60.8)	0.135
ACS	13 (18)	14 (18.9)	
TAR	11 (15.4)	15 (20.3)	0.190
Type of hernia (EHS)			
M/M2M3	15 (20.8)	12 (16.2)	
M3M4	17 (23.6)	21 (28.3)	
M2M3M4	20 (27.7)	21 (28.3)	
M3M4M5	9 (12.5)	10 (13.5)	
M2M3M4M5	11 (15.2)	10 (13.5)	
W/W2	41 (57)	44 (59.5)	0.252
W3	31 (43)	30 (40.5)	
Subcutaneous area dissection, cm^2	166 ± 30.3	148 ± 30.3	0.192
Prosthesis location			
Suprafascial	13 (18)	14 (18.9)	0.412
Retromuscular	48 (66.6)	48 (64.8)	
Preperitoneal	11 (15.4)	11 (16.3)	
Average operative time in min (SD)	138 +/-35.7	128+/- 49	0.091
Global SSO (%)	12 (16.6)	22 (29.8)	**0.042**
Seroma (%)			
Yes	9 (12.5)	10 (13.5)	0.232
No	63 (87.5)	64 (86.5)	
Hematoma (%)			
Yes	1 (1.4)	2 (2.7)	0.332
No	70 (97.2)	72 (97.3)	
Wound infection (%)			
Yes	0 (0)	6 (8.1)	**0.002**
No	72 (100)	68 (91.9)	
Wound dehiscence (%)			
Yes	2 (2.8)	4 (5.4)	0.320
No	70 (97.2)	70 (94.6)	
Mean length of stay in days (SD)	6+/-2.1	7+/-2.3	0.154
Readmission 30 days postoperatively (%)	2 (2.8)	6 (8.1)	0.222
Surgical wound revision after discharge (%)	1 (1.4)	2 (2.8)	0.102
Need of open VAC after discharge	—	3 (4)	0.09

EHS indicates European Hernia Society; SD, standard deviation; SSO, surgical site occurrences; TAR, transversus abdominis release; VAC, vacuum assisted closure.

and can be reduced to 10% in the treatment group, a sample size of 150 patients was required to achieve 80% power with an at-risk of 5%, including an anticipated 10% loss to follow-up. Thus, 75 patients were required in each group.

Statistical analysis was performed on a per-protocol basis. Descriptive statistics including means and standard deviations for continuous variables were used. Frequency tables for the recorded variables and corresponding dispersion measures were constructed. Univariate analyses were performed using Student *t* tests to explore quantitative variables and χ^2 or Fisher tests if they were dichotomous. A *P* value of <0.05 was considered statistically significant.

RESULTS

Patient and perioperative characteristics are presented in Tables 1 and 2, respectively. A total of 150 patients were recruited and randomized to the study, of which 146 patients were included in the analysis (Fig. 1). One patient in each group had their dressing removed on postoperative days 2 and 3 due to need of emergent hematoma evacuation after hernia repair, respectively, and excluded from data analysis, since hematoma formation was not a result of the treatment. The emergent reoperation showed epigastric vessels injuries directly related to the hernia repair (wide retromuscular dissection) in both patients. An additional 2 patients in the treatment group were excluded because of accidental dressing removal on postoperative days 3 and 4. There were not any SSOs that caused dressing removal, just the error from the patients, despite of our clear information during the protocol.

In total, 72 patients in the treatment group and 74 patients in the control group completed the study protocol and were included in the analysis.

There was no statistically significant difference between both groups regarding preoperative variables (Table 1). At 30 days postsurgery (Table 2), there was a significantly higher incidence of SSOs in the control group compared to the treatment group (29.8% vs 16.6%, $P < 0.042$). The incidence of seromas was similar in both groups, but there were no SSIs in the treatment group compared to 6 cases in the control group (0% vs 8%, $P = 0.002$). Of these patients, 5 had been operated on using ACS and 1 with RSR. The 6 SSIs that occurred in the control group were superficial infections that responded to oral antibiotics, but in 3 patients, reoperation with open vacuum-assisted therapy was required to treat the infection. The remaining cases only required intravenous antibiotics for 10 days. There were no significant differences in terms of incidence of postoperative hematoma in both groups (5% vs 2.5%).

Wound dehiscence occurred in 2 patients in the treatment group and 4 patients in the control group. Of these 6 cases, 4 patients had undergone ACS and 2 had undergone TAR. All cases of dehiscence required vacuum-assisted treatment, and 2 patients in the control group also required surgical revision with delayed closure.

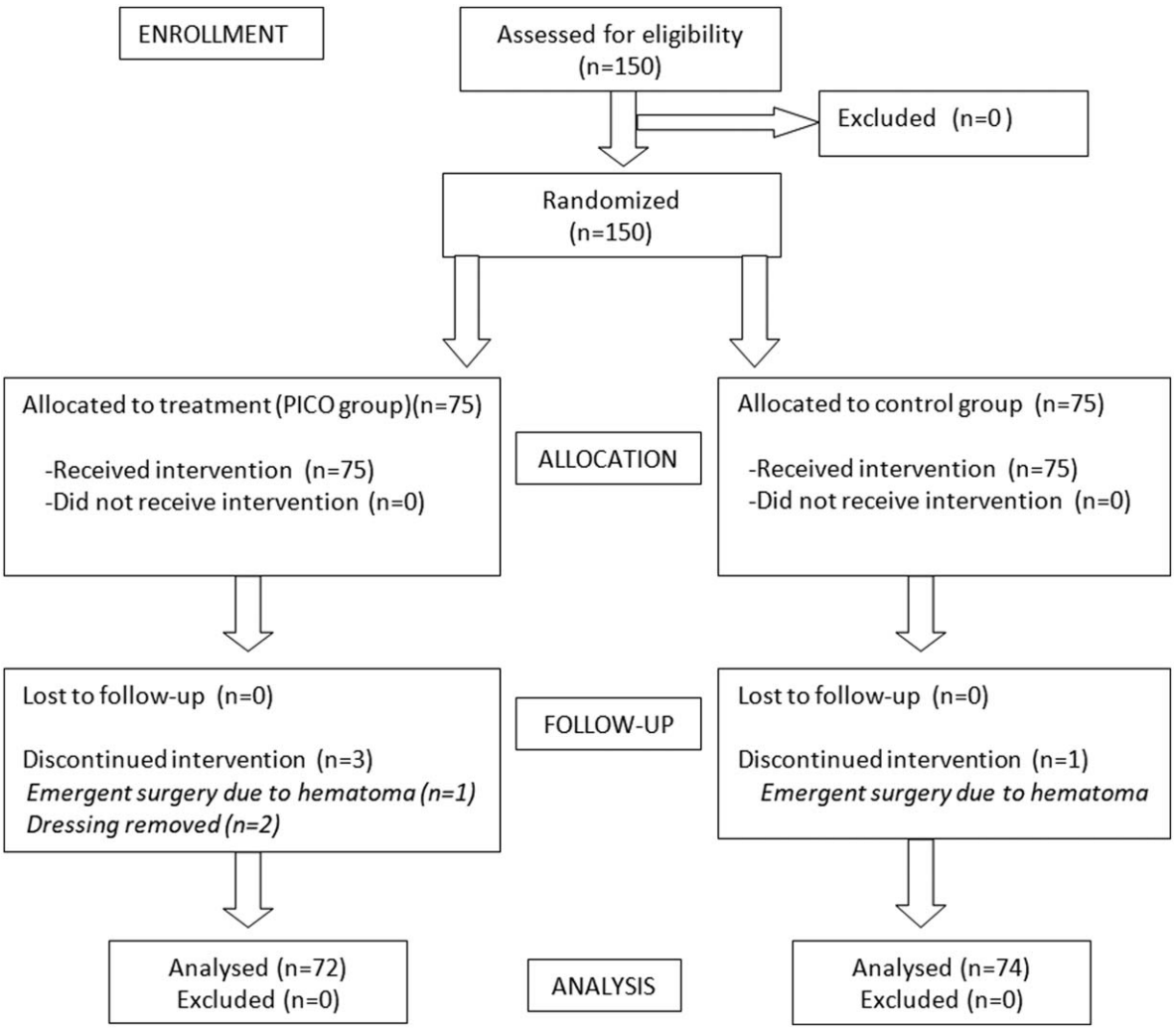

FIGURE 1. Consort diagram of the randomized clinical trial.

There were no reported adverse events attributable to the sNPWT dressing. There were no enterotomies or need for concomitant bowel resection during hernia repair. The mean length of stay tended to be shorter in the patients of the treatment group compared with the control group, but this was not statistically significant (6 vs 7 days, $P = 0.154$).

Univariate analysis was performed to identify risk factors related to SSI development after hernia repair. Obesity (body mass index >30) and the use of the ACS technique for hernia repair were predictive of SSI after surgery. The use of sNPWT PICO dressings conferred a significant protective effect against infections (Table 3).

DISCUSSION

Our study demonstrates that prophylactic use of sNPWT PICO significantly reduces the overall 30-day postoperative SSO rate, especially for SSIs, in patients with IH who underwent hernia repair when compared with standard dressings. There is no evidence that sNPWT dressings reduce the risk of postoperative seroma, hematoma, or dehiscence after surgery.

This is the first RCT evaluating a sNPWT system on closed midline wounds after hernia repair. Theoretically, dead space reduction, excess fluid removal, release of wound tension, and resorption of lymphatic drainage are thought to be additional benefits of this therapy. Furthermore, the sNPWT PICO system appears to be better suited for managing wounds with smaller fluid clearance requirements, such as those associated with elective hernia repair.

Multiple techniques have been described for treating IH. All procedures share aspects such as defect closure, midline reconstruction, anatomic relaxation techniques, and the use of meshes.[24] In our study, we performed 3 of the most frequent repair techniques used to treat these hernias. However, despite tremendous improvements in prosthetic materials and perioperative care, there are still problems associated with these surgical incisions. The large surgical incisions and extended dissections necessary for these repairs lead to a high rate of SSOs.[25]

SSOs may delay healing and result in considerable morbidity and costly or invasive interventions, necessitating the use of adequate prevention practices. The sNPWT PICO is an intervention that has been shown to decrease SSOs and the subsequent socioeconomic sequelae.[26,27] This dressing promotes wound healing by stimulating angiogenesis and enhancing wound granulation, and provides benefits such as a reduction in the number of dressing changes, exudate

TABLE 3. Risk Factors Related to SSI Development After Hernia Repair. Univariate Analysis

Variables	No Infection (%) N = 140	Infection (%) N = 6	Univariate *P*
Average age	53.6 ± 17.2	49.3 ± 19.4	0.121
Sex			
Male	84 (61.8)	2 (40)	0.112
Female	56 (38.2)	4 (60)	
Obesity (BMI >30)			
Yes	30 (21.3)	5 (100)	**0.002**
No	110 (78.7)	1	
Smoking			
Yes	57 (41.2)	3 (60)	0.401
No	83 (58.8)	3 (40)	
Diabetes			
Yes	41 (29)	4 (80)	0.092
No	99 (71)	2 (20)	
COPD			
Yes	29 (19)	2 (40)	0.432
No	111 (81)	4 (60)	
Inmunosupression			
Yes	12 (6.8)	2 (20)	0.091
No	128 (93.2)	4 (80)	
Anticoagulant therapy			
Yes	24 (17.5)	1 (20)	0.105
No	116 (82.5)	5 (80)	
ASA scale			
I-II	63 (45)	3 (60)	0.320
III-IV	77 (55)	3 (40)	
Repair techniques			
ACS	22 (17.5)	5 (80)	**0.001**
RSR	92 (62.5)	1 (20)	
PCS/TAR	26 (21)	0	
Use of PICO dressing			
Yes	67 (44.3)	0	**0.001**
No	64 (55.7)	6 (100)	
Type of hernia (EHS)			
W2	80 (55.7)	1 (40)	0.333
W3	56 (44.3)	5 (60)	
Subcutaneous area dissection, cm^2	133 ± 20.5	138 ± 30.3	0.129
Mean surgical time, min	131 ± 33	119 ± 41	0.541

control, and better patient tolerance.[28] The PICO device applies a pressure of −80 mm Hg and has a capacity to absorb approximately 200 mL of exudate before it becomes ineffective.

When sNPWT dressings are compared with standard care for closed surgical incisions, a significant benefit in favor of prophylactic sNPWT in reducing SSI, wound dehiscence, and length of stay has been reported. In this regard, Strugala et al[8] published a meta-analysis on the association between prophylactic use of this therapy and SSI risk, and they noted a decrease in SSIs. This conclusion is in line with the results of systematic reviews on closed incisions and NPWTs in breast, groin, or post-cesarean wounds, which also report shorter mean durations of hospital stays compared with those of standard dressings.[10,13,14,16,26] Our results also confirmed these observations, reporting that all cases of SSI occurred in the control group, with 3 cases requiring reoperation using open vacuum-assisted therapy to treat the infections.

NPWT has also been associated with reduced seroma and hematoma formation by removing fluid across the wound edges and changing microvascular perfusion. In either case, both seromas and hematomas can increase tension at the incision, making these sites more prone to infection and possibly causing dehiscence.[29] A systematic review on NPWT for closed surgical wounds found a reduction in the rate of SSIs and seromas in the treatment group.[11]

However, due to the low quality of the available evidence, it remains uncertain whether NPWT reduces seroma volume compared with standard dressings. For instance, in another trial, there was no clear difference between NPWT and standard dressings in terms of hematoma formation in closed groin incisions.[30] In a recent meta-analysis, Sahebally et al[9] also concluded that the use of this therapy on laparotomy wounds in general and colorectal surgery was associated with reduced SSI rates but similar rates of seroma and wound dehiscence compared with conventional nonpressure dressings. Likewise, in our study, we did not find significant differences when hematoma, seroma, and wound dehiscence were compared in both groups at 30 days post-surgery.

The main risk factors for SSI after hernia surgery include diabetes, advanced age, obesity, immunosuppression, tobacco use, emergent surgery, and prolonged operative time.[2] Open approaches for treating IHs are associated with a high rate of SSOs, especially in high-risk populations. A recent study reported the advantages of applying NPWT on closed incisions in ventral hernia repair with concurrent panniculectomy and the resulting reduction in the rate of wound complications in a high-risk population.[31] Many other studies have echoed these findings, reporting favorable results for the NPWT group for different types of surgical wounds.[32–34] In our study, the high SSI rate in the control group was mainly associated with the use of the ACS technique in treating the IH. Although this technique allows a high degree of transversal relaxation, it involves extensive dissection, which is in turn associated with a high global SSO rate.[22] In our study, the use of prophylactic sNPWT dressings conferred protection against SSIs after hernia repair, especially in obese patients or those undergoing the ACS technique, who would otherwise be at a high risk for SSI. Therefore, PICO dressings could be used as an alternative to standard care for preventing SSOs in patients at risk of developing surgical wound complications and for treating those who develop such complications.

Previous studies demonstrate that in order for sNPWT dressings to become cost-effective.[35–37] Moreover, in the present study, SSO and SSI rates were reduced significantly in the treatment group. It is clear that the use of sNPWT PICO for closing surgical wounds would cost more than conventional dressings because of the cost of the device. However, this perception may have been based more on unit price considerations than on comparisons of total treatment costs.[26] These conclusions have been confirmed in 2 economic studies[35,37] comparing the cost-effectiveness of NPWT with conventional dressings. Specifically, the absolute cost of this therapy is 6 times greater than that of standard dressings, but the reduced rate of SSOs results in increased savings and improved health-related quality of life. Furthermore, if the sNPWT PICO method reduces the demand for health care resources by requiring less frequent dressing changes and lowering the rate of SSOs, particularly in patients with high risk, this additional cost may be offset. Although a cost-benefit analysis was not part of our study, the direct and indirect costs associated with SSOs are substantial.

Our RCT has several limitations. As this trial was designed as a single-center study, it may not have the robustness and generalizability that a multicenter RCT typically offers. Furthermore, all surgeons involved, as well as the assessor, were not blinded to the type of dressing used, increasing the possibility risk of observer bias. The trial would have been strengthened by having blinded evaluation. Lastly, the sNPWT PICO device only has the capacity to absorb approximately 200 mL of wound exudate; in the case of surgical wounds with more exudation, the dressing may become saturated and lose its function, as is the case in some larger hernia repairs. Although numerous trials have studied the prophylactic effects of NPWT

dressings, more prospective studies, such as ours and cost-benefit analyses, are needed to effectively evaluate advanced wound care technologies and novel NPWT dressings, which are purported to provide additional benefits to reduce the incidence of SSOs.

In conclusion, the use of prophylactic sNPWT PICO dressings for closed surgical incisions following hernia repairs significantly reduces the overall incidence of SSOs and SSIs at 30 days post-surgery. Our results also show that it is effective for preventing SSIs in high-risk wounds, in obese patients undergoing hernia repair for IH, or when ACS is chosen as the abdominal wall reconstruction technique for any patient.

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REFERENCES

1. Gabriel A, Gupta S, Orgill DP. Challenges and management of surgical site occurrences. *Plast Reconstr Surg*. 2019;143:7–10.
2. Willy C, Agarwal A, Andersen CA, et al. Closed incision negative pressure therapy: international multidisciplinary consensus recommendations. *Int Wound J*. 2017;14:385–398.
3. Deerenberg EB, Timmermans L, Hogerzeil DP, et al. A systematic review of the surgical treatment of large incisional hernia. *Hernia*. 2015;19:89–101.
4. Garner JS, Jarvis WR, Emori TG, et al. CDC definitions for nosocomial infections. *Am J Infect Control*. 1988;16:128–140.
5. Lindmark M, Strigård K, Löwenmark T, et al. Risk factors for surgical complications in ventral hernia repair. *World J Surg*. 2018;42:3528–3536.
6. Actualizacion Epine 2018-2019. Registro nacional de infecciones nosocomiales. Ministerio de Sanidad, Madrid. Available at: https://aulaplusformacion.es/wp-content/uploads/2019/05/Epine-2018-2019.pdf.
7. Jolissaint JS, Dieffenbach BV, Tsai TC, et al. Surgical site occurrences, not body mass index, increase the long-term risk of ventral hernia recurrence. *Surgery*. 2020;167:765–771.
8. Strugala V, Martin R. Meta-analysis of comparative trials evaluating a prophylactic single-use negative pressure wound therapy system for the prevention of surgical site complications. *Surg Infect (Larchmt)*. 2017;18:810–819.
9. Sahebally SM, McKevitt K, Stephens I, et al. Negative pressure wound therapy for closed laparotomy incisions in general and colorectal surgery: a systematic review and meta-analysis. *JAMA Surg*. 2018;153:e183467.
10. Svensson-Björk R, Zarrouk M, Asciutto G, et al. Meta-analysis of negative pressure wound therapy of closed groin incisions in arterial surgery. *Br J Surg*. 2019;106:310–318.
11. Hyldig N, Birke-Sorensen H, Kruse M, et al. Meta-analysis of negative-pressure wound therapy for closed surgical incisions. *Br J Surg*. 2016;103:477–486.
12. Kuper TM, Murphy PB, Kaur B, et al. Prophylactic negative pressure wound therapy for closed laparotomy incisions: a meta-analysis of randomized controlled trials. *Ann Surg*. 2020;271:67–74.
13. Hasselmann J, Björk J, Svensson-Björk R, et al. Inguinal vascular surgical wound protection by incisional negative pressure wound therapy: a randomized controlled trial-INVIPS Trial. *Ann Surg*. 2020;271:48–53.
14. Li HZ, Xu XH, Wang DW, et al. Negative pressure wound therapy for surgical site infections: a systematic review and meta-analysis of randomized controlled trials. *Clin Microbiol Infect*. 2019;25:1328–1338.
15. Wells CI, Ratnayake CBB, Perrin J, et al. Prophylactic negative pressure wound therapy in closed abdominal incisions: a meta-analysis of randomised controlled trials. *World J Surg*. 2019;43:2779–2788.
16. Cagney D, Simmons L, O'Leary DP, et al. The efficacy of prophylactic negative pressure wound therapy for closed incisions in breast surgery: a systematic review and meta-analysis. *World J Surg*. 2020;44:1526–1537.
17. Jeffery S, Leaper D, Armstrong D, et al. Using negative pressure wound therapy to prevent surgical site infection. *J Wound Care*. 2018;27(suppl 3):S5–S13.
18. O'Leary DP, Peirce C, Anglim B, et al. Prophylactic negative pressure dressing use in closed laparotomy wounds following abdominal operations: a randomized, controlled, open-label trial: The P.I.C. *O Trial Ann Surg*. 2017;265:1082–1086.
19. Muysoms FE, Miserez M, Berrevoet F, et al. Classification of primary and incisional abdominal wall hernias. *Hernia*. 2009;13:407–414.
20. Rives J, Pire JC, Flament JB, et al. Treatment of large eventrations. New therapeutic indications apropos of 322 cases. *Chirurgie*. 1985;111:215–225.
21. García-Ureña MÁ, López-Monclús J, Cuccurullo D, et al. Abdominal wall reconstruction utilizing the combination of absorbable and permanent mesh in a retromuscular position: a multicenter prospective study. *World J Surg*. 2019;43:149–158.
22. Torregrosa-Gallud A, Sancho Muriel J, Bueno-Lledó J, et al. Modified components separation technique: experience treating large, complex ventral hernias at a University Hospital. *Hernia*. 2017;21:601–608.
23. Kanters AE, Krpata DM, Blatnik JA, et al. Modified hernia grading scale to stratify surgical site occurrence after open ventral hernia repair. *J Am Coll Surg*. 2012;215:787–793.
24. Diamond S, Cryer HG. Revising recommendations and outcome measurements after complex open abdominal wall reconstruction. *Am Surg*. 2015;81:955–960.
25. Breuing K, Butler CE, Ferzoco S. Incisional ventral hernias: review of the literature and recommendations regarding the grading and technique of repair. *Surgery*. 2010;148:544–558.
26. Hyldig N, Joergensen JS, Wu C, et al. Cost-effectiveness of incisional negative pressure wound therapy compared with standard care after caesarean section in obese women: a trial-based economic evaluation. *BJOG*. 2019;126:619–627.
27. Adeyemi A, Waycaster C. Cost-minimization analysis of negative pressure wound therapy in long-term care facilities. *Wounds*. 2018;30:E13–E15.
28. Pappalardo V, Frattini F, Ardita V, et al. Negative pressure therapy (NPWT) for management of surgical wounds: effects on wound healing and analysis of devices evolution. *Surg Technol Int*. 2019;34:56–67.
29. Webster J, Scuffham P, Stankiewicz M, et al. Negative pressure wound therapy for skin grafts and surgical wounds healing by primary intention. *Cochrane Database Syst Rev*. 2014;10:CD009261.
30. Pleger SP, Nink N, Elzien M, et al. Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): a prospective, randomised, single-institution study. *Int Wound J*. 2018;15:75–83.
31. Diaconu SC, McNichols CHL, Ngaage LM, et al. Closed-incision negative-pressure therapy decreases complications in ventral hernia repair with concurrent panniculectomy. *Hernia*. 2020;24:49–55.
32. Kim S, Kang SI. The effectiveness of negative-pressure wound therapy for wound healing after stoma reversal: a randomised control study (SR-PICO study). *Trials*. 2020;21:24.
33. Zaidi A, El-Masry S. Closed-incision negative-pressure therapy in high-risk general surgery patients following laparotomy: a retrospective study. *Colorectal Dis*. 2017;19:283–287.
34. Hall C, Regner J, Abernathy S, et al. Surgical site infection after primary closure of high-risk surgical wounds in emergency general surgery laparotomy and closed negative-pressure wound therapy. *J Am Coll Surg*. 2019;228:393–397.
35. Heard C, Chaboyer W, Anderson V, et al. Cost-effectiveness analysis alongside a pilot study of prophylactic negative pressure wound therapy. *J Tissue Viability*. 2016.
36. Lewis LS, Convery PA, Bolac CS, et al. Cost of care using prophylactic negative pressure wound vacuum on closed laparotomy incisions. *Gynecol Oncol*. 2014;132:684–689.
37. Nherera LM, Trueman P, Schmoeckel M, et al. Cost-effectiveness analysis of single use negative pressure wound therapy dressings (sNPWT) compared to standard of care in reducing surgical site complications (SSC) in patients undergoing coronary artery bypass grafting surgery. *J Cardiothorac Surg*. 2018;13:103. doi: 10.1186/s13019-018-0786-6.