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Randomized Clinical Trial

Negative-pressure wound therapy after stoma reversal in colorectal surgery: a randomized controlled trial

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Abstract

Background: Stoma-reversal surgery is associated with high postoperative morbidity, including wound complications and surgical-site infections (SSIs). This study aims to assess whether the application of negative-pressure wound therapy (NPWT) can improve wound healing compared with conventional wound dressing.

Methods: This was a single-centre, superiority, open-label, parallel, individually randomized controlled trial. Patients undergoing stoma reversal were randomized (1 : 1) to receive NPWT or conventional wound dressing. The primary endpoint of the study was the rate of wound complications and SSIs after stoma closure. The secondary endpoints were postoperative wound pain, rate of wound healing after 30 days from stoma closure, and wound aesthetic satisfaction.

Results: Between June 2019 and January 2021, 50 patients were allocated to the NPWT group (all received NPWT, 49 were analysed); 50 patients were allocated to the conventional wound dressing group (48 received the treatment, 45 were analysed). No significant difference was found in wound-complication rate (10 per cent NPWT *versus* 16 per cent controls; odds ratio 0.61 (95 per cent c.i. 0.18 to 2.10), $P = 0.542$) and incisional SSI rate (8 per cent NPWT *versus* 7 per cent controls; odds ratio 1.24 (95 per cent c.i. 0.26 to 5.99), $P = 1.000$). The NPWT group showed less pain, higher aesthetic satisfaction ($P < 0.0001$), and a higher proportion of wound healing (92 *versus* 78 per cent; $P = 0.081$) compared with the control group.

Conclusion: NPWT does not reduce the incidence of SSI after stoma-reversal surgery compared with conventional wound dressing. However, NPWT improved the healing of uninfected wounds, reduced wound pain and led to better aesthetic outcomes.

Registration number: NCT037812016 (clinicaltrials.gov).

Introduction

Stoma reversal in colorectal surgery is associated with high postoperative morbidity, with reported rates up to 33 per cent[1–4], including wound complications and surgical-site infections (SSIs). Patient-related factors, such as smoking[5], obesity[6] or preoperative immunomodulating therapies[7], and surgery-related factors, such as wound-closure techniques[8,9], are known risk factors for the occurrence of incisional SSIs and wound-related complications. Wound closure with a purse-string suture (PSS) provides lower rates of incisional SSI compared with direct closure[10–13]; however, it requires longer healing times[10,14] and often results in a cosmetically poor scar that leaves the patient dissatisfied[15].

Single-use negative-pressure wound therapy (NPWT) may represent a strategy to reduce the SSI rate while shortening healing times compared with conventional wound dressing. Previous randomized studies were focused on patients with either inflammatory bowel disease or cancer, and led to conflicting results[16,17]. Moreover, these trials failed to assess important patient-related outcomes, such as pain, aesthetic satisfaction and quality of life.

The aim of this randomized controlled trial was to assess the effectiveness of the prophylactic use of NPWT in reducing the rate of incisional SSIs and wound complications after stoma reversal in colorectal surgery performed for both oncological and benign indications, investigating unexplored outcomes, including pain and cosmetic satisfaction.

Methods

Study setting and design

This was a superiority, open-label, randomized controlled trial with two parallel intervention arms. The study was undertaken at a single tertiary referral centre, the IRCCS Humanitas Research Hospital (Rozzano, Milan, Italy). The study was approved by the local ethical committee (approval number: 2252/2019) and preregistered in clinicaltrials.gov (registration number: NCT037812016) before the study initiation. After trial registration, the authors made some changes in the methods of the outcome measures: postoperative pain was measured with a visual analogue scale (VAS) scale, instead of the

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McGill questionnaire, to simplify collection and interpretation of patients' responses, and the EQ5D5L questionnaire for quality of life was replaced with a VAS scale on general wound satisfaction, to comply better with the aim of the study. The modifications in the trial design were introduced before the ethical submission and approval. The study protocol is available in *Appendix S1*. The study was conducted according to the declaration of Helsinki, the Good Clinical Practice (GCP) and Italian legislation. The final report was prepared following the CONSORT checklist[18].

Study participants

Patients scheduled for elective stoma-reversal surgery were screened for eligibility and included in the trial after providing signed informed consent. The inclusion criteria were: planned elective stoma-reversal surgery; age 18 years or older; previous colorectal surgery with stoma formation (ileostomy or colostomy) regardless of the reason for the index operation; normal contrast enema prior to stoma closure. Pregnant or breastfeeding women, patients with an underlying psychiatric or neurodegenerative disorder that may impair the consent procedure, and patients with a known hypersensitivity to the investigational device components were excluded from the trial.

Randomization

Patients were randomized by the study investigators to receive NPWT (NPWT group) or conventional wound dressing (control group) after being included and admitted to the ward by the study staff and were informed of the outcome of the randomization by the study investigators prior to surgery. Randomization was achieved with a random numbers sequence generated by a statistician using an online-based system (http://www.ibismed.it/public/homepage.php) with a four-block, 1 : 1 ratio and stratification according to diagnosis (oncological *versus* benign) to ensure allocation concealment from the study investigators. The operating surgeons, research staff and study participants were unblinded regarding the treatment allocation.

Study procedures

The study procedures are detailed in *Fig. S1* and *Table S1*. Briefly, after informed consent was obtained and eligibility checked, the investigators collected the patients' demographic and clinical information. Patients were randomized and informed of the outcome of the randomization prior to surgery at hospital admission. Details on the surgical procedure and data on early postoperative outcomes were collected during hospitalization. Postoperative pain scores were collected at 1, 2, 3 and 7 (±3) days after surgery. Itching and aesthetic wound-evaluation scores were collected 7 days after surgery. A complete clinical evaluation, including wound inspection, was performed at 7 days, and approximately 30 (±7) days after surgery by an unblinded outcome assessor.

Perioperative care

Perioperative care followed the principles of enhanced recovery protocols[19,20]. All patients received antibiotic prophylaxis with 20 mg/kg of cefazolin 30 min before the incision. On the first postoperative day, patients were encouraged to mobilize and received a standard oral liquid diet. Solid diet was restored from postoperative day 2.

Interventions

Stoma construction was performed during laparoscopic surgical procedures with oncological (anal cancer, rectal cancer, sigmoid cancer and right colon cancer) or benign (ulcerative colitis, Crohn's disease and diverticulitis) indications. The trial included patients with end/loop ileostomy or end/loop colostomy. Stoma-reversal surgery followed similar principles in both allocation groups and consisted of circumferential incision of the skin around the stoma and lysis of the adhesions between the bowel and surrounding tissues. In case of loop ileostomy closure, a side-to-side antiperistaltic anastomosis was fashioned with an Endo-GIA™ linear stapler (Medtronic, Minneapolis, Minnesota, USA), the enterotomy closed with 3/0 absorbable monofilament suture (Ethicon Monocryl™, Cincinnati, Ohio, USA) and the stapled line reinforced with a running 4/0 suture of the same material. In case of loop colostomy closure, the authors performed an end-to-end closure with a double running suture with 3/0 and 4/0 absorbable monofilament suture. End-ileostomy reversal was achieved by securing the anvil of a circular stapler into the open end of the distal ileum, after mobilization of the end ileostomy. Subsequently, a GelPOINT® Advanced Access Platform (Applied Medical, Rancho Santa Margherita, California, USA) single-port access device was placed at the stoma site and a laparoscopic end-to-end ileorectal circular stapled anastomosis was fashioned. The anastomosis was tested routinely with indocyanine green real-time fluorescence angiography and by performing an air-leak test. End-colostomy closure was performed laparoscopically by using the same single-port access device and creating an end-to-end colorectal circular stapled anastomosis. The integrity of the anastomosis was routinely tested as described above. Stoma site was closed in the same fashion, regardless of the type of ostomy. The peritoneum and abdominal fascia were closed with interrupted 3/0 absorbable braided polyfilament sutures (Vicryl®, Ethicon, Cincinnati, Ohio, USA). Skin closure was performed with the PSS method in both study groups, reaching an 8 mm skin opening, calibrated with the tip of the suction instrument.

For patients allocated to the NPWT group, the NPWT device was applied by the surgeons in a sterile fashion in the operating room, immediately after skin closure. No filling material was employed. The single-use PICO-7™ portable device (Smith and Nephew Healthcare, Hull, UK) was applied directly to the wound and maintained in place for 7 days, as indicated by the manufacturer. The NPWT device consists of a sterile pump maintaining a negative pressure of 80 mmHg (nominal) ± 20 mmHg and two sterile dressing kits. Exudate is managed by the dressing through a combination of absorption and evaporation of moisture through the outer film. According to the manufacturer's instructions, the NPWT device is intended for use in wound sizes up to 400 cm^3, which are low-to-moderately exuding. If a wound infection was suspected (for example, fever or increase in inflammatory markers), the NPWT dressing was removed to allow visual inspection of the wound: if normal, the device was definitively removed.

The patients allocated to the control group were treated by filling the wound cavity loosely with iodoform gauze. The wound dressing remained in place for 24 hours, and was then removed; this was followed by irrigation with normal saline solution and loose packing with iodoform gauze. After another 24 hours, the dressing was removed, followed by irrigation with saline solution but no packing.

After the first evaluation in the ambulatory clinic, patients from both groups were instructed on self-medicating their wound by irrigating the wound with normal saline and disinfecting with povidone–iodine solution on a daily basis.

Study endpoints

The primary endpoint of the study was to evaluate the difference in the rates of wound complications and incisional SSI between the control and intervention groups within 30 days after stoma closure. Wound complications included: superficial and deep incisional SSI; haematoma; seroma; and wound dehiscence. SSI was defined according to the criteria listed by the Centers for Disease Control and Prevention[21].

The secondary endpoints were: the mean difference in the wound pain scores reported by the control and intervention groups at 1, 2, 3 and 7 days after surgery; the difference in the wound-healing rate within 30 days after stoma closure; and the mean difference in the aesthetic-satisfaction scores reported 7 days after stoma reversal.

Postoperative wound pain was measured using a VAS ranging from 0 (no pain) to 10 (excruciating pain). At 7 days, the authors added an evaluation of wound itchiness, using a VAS ranging from 0 (no itch) to 10 (unbearable itch). Wound healing was defined as complete wound closure without wound tears or secretion. Wound-healing assessment was integrated with the Vancouver Scar Scale (VSS)[22] at the 7- and 30-day visits. Aesthetic satisfaction was measured using a VAS ranging from 0 (not satisfied) to 10 (completely satisfied).

Data collection

Data were collected prospectively at each study visit and during hospitalization. Demographic and baseline clinical data collected during the screening visit included all the relevant risk factors for wound complications and SSIs. A comprehensive list of demographic and clinical data collected in the case report form is detailed in *Table S2*.

Sample-size calculation

The incidence of wound complications and infections among patients undergoing stoma closure is about 33 per cent[1,4]. SSIs were defined as 'infections of the incision or organ or space that occurred after surgery'[21]. Previous studies on the use of NPWT devices in colorectal surgery reported a reduction in closed-wound complications of 65–70 per cent[23,24]. A sample size of 94 patients, including 47 patients per arm, was needed to achieve 80 per cent power with α equal to 0.05, considering a reduction of wound complications of 70 per cent in the interventional arm. The sample size was increased to 100 patients—50 per arm—estimating a 5 per cent loss to follow-up.

Statistical analysis

Categorical and dichotomous variables were presented as percentage over the total and were compared using a χ^2-test, with Yates' correction of Fisher exact test, where needed. Continuous data were tested for normal distribution, using the D'Agostino K^2 test, and were presented as mean(s.d.) or median (i.q.r.), according to the distribution. Continuous data were analysed using a two-sided unpaired *t*-test or a Mann–Whitney unpaired test, depending on the distribution. The results were considered statistically significant for $P < 0.050$ or if the 95 per cent confidence interval did not cross 1. A binary logistic regression model was used to identify possible risk factors for wound healing within 30 days from stoma closure. Multiple comparison was performed using one-way ANOVA and Kruskal–Wallis tests. The statistical analysis was performed with SPSS®, version 24.0 (IBM Corp, Armonk, New York, USA). Reported graphs were performed using GraphPad Prism 5 Software (GraphPad Software Inc., San Diego, California, USA).

Results

Study participants

The study enrolled 100 patients between 18 June 2019 and 15 January 2021. After randomization, 50 patients were allocated to receive NPWT after stoma closure and 50 patients were allocated to the control arm. All the patients allocated to the NPWT group received NPWT after stoma reversal, while 48 in the control group received the conventional dressing. Two patients allocated to the control group withdrew their consent before surgery, because they were unable to undergo follow-up at the authors' institution. All the allocated patients completed the 30-day follow-up. Four patients (3 in the control group and 1 in the NPWT group) were excluded from the final analysis of wound complications and SSI, due to the need for reoperation due to complications, not related to the wound, that required stoma reconstruction within 10 days from stoma reversal. None of the excluded patients developed wound complications before or after the reintervention. *Figure 1* shows the participants' inclusion process.

Baseline characteristics

Baseline characteristics and clinical features of the study participants, including the most common risk factors for SSI are reported in *Table 1*.

The mean age at screening and gender distribution were similar between study arms. More than 50 per cent of patients in both groups underwent faecal diversion for oncological indications, including sigmoid, anal or rectal cancer (28 patients in the NPWT group and 25 in the control group) and right colon cancer (1 patient in the control group). Benign disease indications for stoma creation included Crohn's disease (2 patients in the NPWT group and 10 in the control group), ulcerative colitis (15 patients in the NPWT group and 10 in the control group), and diverticular disease (5 patients in the NPWT group and 2 in the control group). After index surgery (stoma creation), 15 patients in the NPWT group and seven patients in the control group had experienced an intra-abdominal septic complication. Most of the patients in both groups had an ileostomy, while nine patients (18 per cent) in the NPWT group and 10 (21 per cent) in the control group had a colostomy. The median time from stoma construction to reversal was similar between study arms.

The most common risk factors for wound complications and SSI were analysed. To evaluate the presence of significant co-morbidities in the study population, the participants were classified according to the Charlson Co-morbidity Index[25]: most of the patients (76 per cent in the NPWT group and 71 per cent in the control group) had a Charlson Co-morbidity Index score between 0 and 4. The proportion of patients with diabetes or congestive heart failure was similar between the study groups. Neoadjuvant and adjuvant treatments were more frequent in the NPWT group (neoadjuvant: 36 per cent in the NPWT group *versus* 19 per cent in the control group; adjuvant: 34 per cent in the NPWT group versus 21 per cent in the control group), and no difference was observed in immunomodulating treatments (including biologicals, steroids and azathioprine) within 5 weeks from stoma

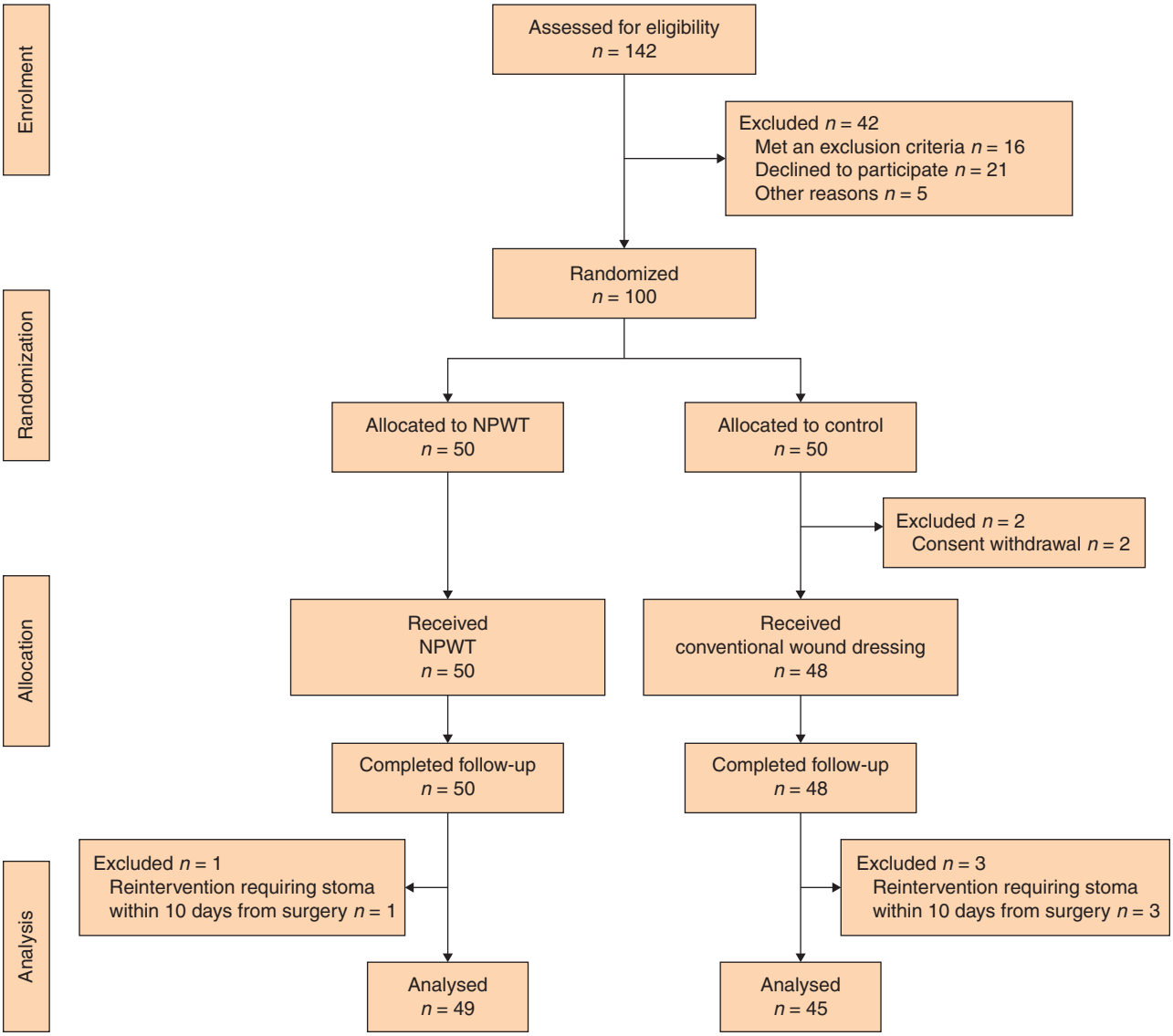

Fig. 1 Flow chart of the participant-inclusion process

NPWT, negative-pressure wound therapy.

reversal (8 per cent in both groups). The mean BMI, proportion of active smokers, distribution according to ASA classification and mean preoperative haemoglobin level were comparable between the study groups.

Postoperative outcomes

The median operative time and the length of stay after stoma-reversal surgery were similar in the NPWT and control groups. Patients receiving NPWT maintained the dressing for a median time of 7 days. The rate of overall postoperative complications was comparable between the groups: most of the complications were classified as Clavien–Dindo[26] I–II (*Table 2*). One patient in the control group had anastomotic bleeding requiring endoscopic treatment. Anastomotic leak occurred in one patient in the NPWT group and in three patients in the control group, requiring reoperation and faecal diversion within 10 days from stoma reversal, thus these patients were excluded from the main outcome analysis. Conversely, the analysis retained one patient from the NPWT group who had an anastomotic leak requiring reintervention and faecal diversion 26 days after stoma reversal surgery. The Comprehensive Complication Index[27] of complicated patients, which accounts for multiple postoperative complications, was similar between the study groups (*Table 2*).

Wound complications and incisional surgical-site infection

Wound complications were analysed in 49 patients of the NPWT group and 45 patients of the control group. No statistically significant difference was found in the wound complications rate within 30 days from stoma closure between study groups: 10 per cent in the NPWT group *versus* 16 per cent in the control group (odds ratio 0.61 (95 per cent c.i. 0.18 to 2.10); $P = 0.542$). The rate of incisional SSI within 30 days from stoma reversal was comparable between study groups, occurring in 8 per cent of NPWT patients and 7 per cent of controls (odds ratio 1.24 (95 per cent c.i. 0.26 to 5.99); $P = 1.000$) (*Table 3*).

Table 1 Baseline demographics and clinical characteristics

Characteristics	NPWT group ($n = 50$)	Control group ($n = 48$)	P
Age (years)*	56.32 (12.92)	55.08 (16.25)	0.677§
Gender, females	15 (30)	17 (35)	0.668‡
Indication			1.000‡
Oncological disease	28 (56)	26 (54)	
Benign disease	22 (44)	22 (46)	
Type of stoma			0.801‡
Ileostomy	41 (82)	38 (79)	
Colostomy	9 (18)	10 (21)	
Type of surgery			0.068‡
Ileostomy closure	38 (76)	27 (58)	
Colostomy closure	7 (14)	6 (13)	
Ileorectal anastomosis	3 (6)	11 (21)	
Hartmann's reversal	2 (4)	4 (8)	
IASC at baseline surgery	15 (10)	7 (14)	0.549‡
Previous neoadjuvant therapy	18 (36)	9 (19)	0.072‡
Previous adjuvant therapy	17 (34)	10 (21)	0.178‡
Previous immunomodulating treatments	4 (8)	4 (8)	1.000‡
Time from surgery to stoma closure (days)†	262 (143–370)	217 (127–334)	0.263¶
Charlson Comorbidity Index			0.141‡
0	5 (10)	10 (21)	
1	7 (14)	4 (8)	
2	8 (16)	11 (23)	
3	9 (18)	3 (6)	
4	9 (18)	6 (13)	
≥5	12 (24)	14 (29)	
Diabetes	5 (10)	2 (4)	0.436‡
CHF	2 (4)	4 (8)	0.431‡
BMI (kg/m^2)*	23.81 (3.38)	23.45 (3.66)	0.618§
Smoker	9 (18)	5 (10)	0.551‡
ASA classification			0.904‡
I	30 (60)	28 (58)	
II	17 (34)	16 (34)	
III	3 (6)	4 (8)	
Haemoglobin (g/dl)*	13.78 (1.69)	13.75 (1.77)	0.946§

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.), †values are median (i.q.r.). ‡χ^2-test with Fisher's exact test; §Two-sided unpaired *t*-test; ¶Mann–Whitney unpaired test. NPWT, negative-pressure wound therapy; IASC, intra-abdominal septic complications; CHF, congestive heart failure.

Table 2 Postoperative outcomes

Outcomes	NPWT group ($n = 50$)	Control group ($n = 48$)	P
Operative time (min)*	92 (69–116)	98 (70–140)	0.325‡
Length of hospitalization (days)*	4 (3–7)	4 (3–5)	0.816‡
Application of NPWT (days)*	7 (4–7)	—	
Overall postoperative complications	22 (44)	21 (44)	1.000†
Clavien–Dindo I	3 (6)	3 (6)	
Clavien–Dindo II	17 (34)	14 (30)	
Clavien–Dindo IIIa	—	1 (2)	
Clavien–Dindo IIIb	2 (4)	3 (6)	
30-day reintervention	2 (4)	3 (6)	0.612†
Number of patients with complications	22	21	
CCI in patients with complications*	9 (3–24)	2 (3–23)	0.359†

Values in parentheses are percentages unless indicated otherwise; *values are median (i.q.r.). †χ^2-test with Fisher's exact test; ‡Mann-Whitney unpaired test. NPWT, negative-pressure wound therapy; CCI, Comprehensive Complication Index.

Postoperative wound pain

Wound pain was measured at postoperative days 1, 2, 3 and 7, using a 0–10 VAS. During the 7-day inspection, once all the patients in the NPWT group had had the device removed, the pain scores were integrated with the evaluation of wound itchiness, using a 0–10 VAS. The median (i.q.r.) values of reported pain at postoperative day 1 (NPWT: 0 (0–2) *versus* control: 2 (0–4); $P = 0.061$) and postoperative day 2 (NPWT: 0 (0–2) *versus* control: 0 (0–2); $P = 0.170$) were comparable between the study groups. At postoperative day 3, patients in the NPWT group reported a significantly lower pain score than that of patients in the control arm (0 (0–2) *versus* 0 (0–2); $P = 0.025$) (*Fig. S2*).

At 7 days, median (i.q.r.) scores for wound pain (NPWT: 1 (0–2) *versus* control: 3 (1–5); $P < 0.0001$) and wound itchiness (NPWT: 0 (0–1) *versus* control: 1 (0–2); $P = 0.0002$) were significantly lower in the NPWT group compared with those of the control group (*Fig. 2*).

Table 3 Wound complications within 30 days from stoma reversal

Outcomes	NPWT group ($n = 49$)	Control group ($n = 45$)	P*
Wound complications	5 (10)	7 (16)	0.542
Haematoma	1 (2)	3 (7)	0.344
Seroma	—	1 (2)	—
SSI	4 (8)	3 (7)	1.000

Values in parentheses are percentages. *χ^2-test with Fisher's exact test. NPWT, negative-pressure wound therapy; SSI, surgical site infection.

Table 4 Wound healing within 30 days from stoma reversal

Outcomes	NPWT group ($n = 49$)	Control group ($n = 45$)	P
Healed wounds	45 (92)	35 (78)	0.081†
VSS score, 7-day*	0 (0–1)	2 (1–3)	<0.0001‡
VSS score, 30-day*	0 (0–0)	0 (0–2)	0.003‡

Values in parentheses are percentages unless indicated otherwise; *values are median (i.q.r.). †χ^2-test with Fisher's exact test; ‡Mann-Whitney unpaired test. NPWT, negative-pressure wound therapy; VSS, Vancouver Scar Scale.

Wound healing

Wound healing was evaluated after device removal on postoperative day 7 and at 30 days. The clinical assessment was integrated with the compilation of the VSS at each time point. At the 30-day assessment, 92 per cent of the wounds treated with NPWT were completely healed, compared with only 78 per cent of those treated with conventional dressing (odds ratio 0.31 (95 per cent c.i. 0.90 to 1.07); $P = 0.081$). VSS mean scores differed significantly between NPWT and control patients at 7 and 30 days after stoma reversal (*Table 4*, *Fig. S3*).

To identify possible factors affecting wound healing, a binary logistic regression model was performed. The model was statistically significant ($\chi^2(12) = 23.80$; $P = 0.022$) and explained 39 per cent (Nagelkerke R^2) of the variance, correctly classifying 88 per cent of cases. Patients in the NPWT group had a lower chance of experiencing delayed wound healing (longer than 30 days from stoma reversal) (odds ratio 0.14 (95 per cent c.i. 0.02 to 0.86); $P = 0.03$), while incisional SSI was a significant risk factor for delayed wound healing (odds ratio 68.91 (95 per cent c.i. 1.44 to 3288.60); $P = 0.03$) (*Table 5*).

Patient-reported aesthetic evaluation

Aesthetic evaluation was measured at postoperative day 7, after NPWT removal, asking patients to report their satisfaction grade on a 0–10 VAS. The median (i.q.r.) score of the NPWT group at 7 days was significantly higher (NPWT: 9 (9–10) *versus* control: 8 (6–9); $P < 0.0001$) (*Fig. S4*). *Figure S5* shows an NPWT-treated wound at 7 days (*Fig. S5a*), in comparison with a wound treated with conventional dressing at 7 days (*Fig. S5b*). The photographs are from patients without wound complications or incisional SSI.

Discussion

In this randomized controlled trial, NPWT after stoma reversal led to similar incidence rates of SSIs and wound complications but resulted in improved wound healing compared with conventional wound dressing.

So far, three randomized trials have investigated the use of NPWT in stoma reversal[16,17,28]. The subgroup analysis on stoma reversal performed in the NEPTUNE trial found similar rates of SSI in the NPWT and standard-dressing groups but did not report the rate of overall wound complications and the time of wound closure[28]. The study performed by Uchino and colleagues found no differences in the rate of SSI and wound complications[16]. Wierdak and co-workers found a significant decrease in the rate of SSI and wound complications and a significantly shorter healing time using NPWT[17].

The reduced rate of wound complications and SSI reported by Wierdak and co-workers, in contrast with the results of the present study, may be explained by several technical differences. In the previous study, NPWT was applied on linear-closure wounds using a negative pressure of 125 mmHg, while the authors of the present study applied the NPWT on wounds closed with PSS using a negative pressure of 80 mmHg[17].

Multivariable analysis suggested that NPWT-treated wounds have a higher chance of healing within 30 days, while SSI was a risk factor for delayed wound healing, suggesting that NPWT may reduce the healing time of uninfected wounds. The assessment of wound healing was integrated with the compilation of the VSS[22], showing significantly better scores in the NPWT group compared with those for the control group. These findings are in line with the outcomes reported in the studies by Uchino and colleagues[16] and Wierdak and

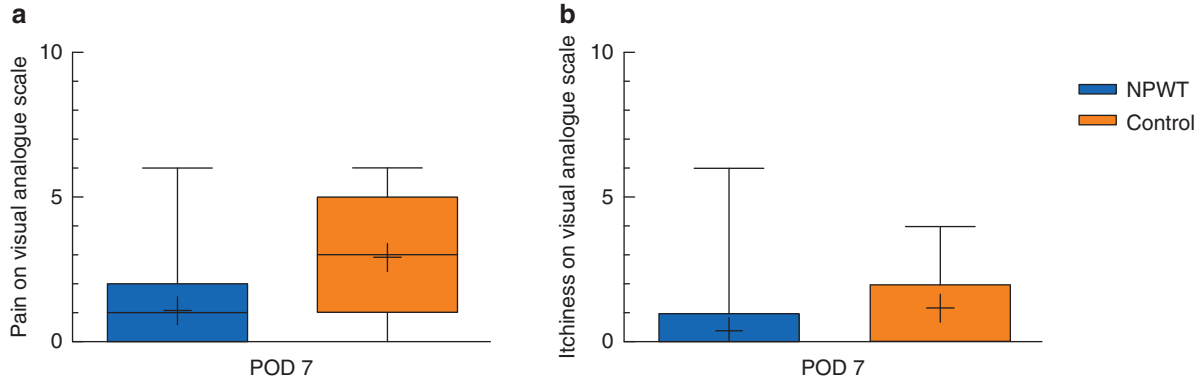

Fig. 2 Wound pain and itchiness.

a Reported wound pain scores on the visual analogue scale 7 days after surgery (POD 7). The crosses represent the mean values: negative-pressure wound therapy (NPWT) group, mean (s.d.) 1.06 (1.24); control group, 2.91 (2.00). $P = 0.0002$ (Mann–Whitney test). **b** Reported wound itch scores on the visual analogue scale at POD 7. The crosses represent the mean values: NPWT group, mean (s.d.) 0.42 (0.95); control group, 1.20 (1.21). $P < 0.0001$ (Mann–Whitney test).

Table 5 Binary logistic regression of delayed wound healing

Parameters	Odds ratio	P
Age (years)	0.98 (0.94, 1.04)	0.672
BMI (kg/m^2)	0.93 (0.73, 1.19)	0.566
Smoking	3.60 (0.47, 27.64)	0.218
Diabetes	0.26 (0.005, 13.45)	0.506
CHF	0.12 (0.002, 8.75)	0.333
Previous adjuvant therapy	0.28 (0.03, 2.57)	0.262
Previous immunomodulating treatments	0.62 (0.03, 11.87)	0.755
Indication: benign (*versus* oncological)	0.32 (0.04, 2.43)	0.270
Type of stoma: colostomy (*versus* ileostomy)	2.93 (0.47, 18.21)	0.250
Randomization: NPWT (*versus* control)	0.14 (0.02, 0.86)	0.035*
Wound complications	1.60 (0.11, 23.42)	0.731
SSI	68.91 (1.44, 3288.60)	0.032*

Values in parentheses are 95 per cent confidence intervals. *Statistically significant. CHF, congestive heart failure; NPWT, negative-pressure wound therapy; SSI, surgical site infections.

colleagues[17], which found a reduced duration of wound healing in the NPWT group.

The present study explored the effect of NPWT on postoperative pain. NPWT significantly decreased the reported postoperative pain, itchiness and discomfort compared with PSS closure. To the authors' knowledge, this is the first randomized trial on NPWT in stoma reversal evaluating pain and discomfort. The results of this trial are consistent with those of a previous observational study reporting a correlation between the use of the NPWT and patients' well-being, reduced discomfort and reduced need for wound-care help[29].

The present study reported a significant improvement in aesthetic satisfaction in patients receiving NPWT compared with that for standard PSS. These data may indicate that the use of NPWT after stoma reversal maintains its positive effects in terms of improved tissue microperfusion, angiogenesis and fibroblast proliferation[30].

Although NPWT failed to reduce the rate of wound complications after stoma reversal, the improved wound healing and better aesthetic outcomes obtained in the NPWT group suggest that its use might eventually help to overcome the main concerns about the PSS technique, consisting of extended healing time and unsatisfactory cosmetic effects[13,31,32].

The main limitation of the study is the sample size: based on the current literature reporting a putative rate of wound complications of 33 per cent[1,4], the study was considered sufficiently powered to detect the primary endpoint. However, the actual rate of wound complications in the study sample was 13 per cent, and the 6 percentage point difference (10 *versus* 16 per cent) in the primary outcome did not reach statistical significance. A second limitation is the open-label design: a blinded assessment would have provided more reliable results but might have become difficult to maintain due to the study intervention and time points. To simplify the trial design and avoid multiple clinic attendances, wound healing was evaluated at 30 days from stoma reversal. A daily assessment of the wound could have provided a more adequate analysis, although the integration of VSS may have partially overcome this limitation, allowing the time points comparison. Besides stratifying for the baseline diagnosis, a further stratification according to the stoma type (ileostomy *versus* colostomy) would have provided a better definition of the effectiveness of NPWT after stoma reversal. This study did not report a cost analysis on the use of NPWT in stoma reversal, which is of paramount importance to determine the real effectiveness of the procedure.

Supplementary material

Supplementary material is available at *BJS Open* online.

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