#### ORIGINAL ARTICLE



# Incisional negative pressure wound therapy to reduce perineal wound infection after abdominoperineal resection

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#### Abstract

We explored the effects of incisional negative pressure wound therapy in perineal wound infections after abdominoperineal resection. We retrospectively evaluated 146 patients who underwent abdominal perineal resection from December 2004 to December 2019 and compared conventional gauze dressing (controls) with incisional negative pressure wound therapy. We compared patients' characteristics, surgical factors, and perineal infection rates between groups, and patients' characteristics, surgical factors, and negative pressure therapy use between perineal infection vs non-infection groups, as well as the risk factors for perineal infections. In the negative pressure therapy group, compared with controls, the number of men, smoking prevalence, blood transfusion, drainage via the perineal wound, and intraoperative blood loss were significantly lower (p < 0.05, p < 0.05, p < 0.05, p < 0.001, p < 0.01, respectively), and operation time was significantly longer (p < 0.05). Infections were significantly less common in the negative pressure group (p < 0.05). In the univariate analysis, the infection-positive group had significantly higher laparoscopic surgery (p < 0.01) and negative pressure wound therapy-free rates (p < 0.01) 0.01), and significantly more intraoperative blood loss (p < 0.05). Multivariate analysis using these three factors and preoperative radiotherapy showed that incisional negative pressure wound therapy-free status was a risk factor for infection. Incisional negative pressure wound therapy was beneficial in managing perineal wound infections after abdominoperineal resection.

#### **1** | INTRODUCTION

After abdominoperineal resection (APR), a large cavity is created by resecting the rectum and anus. In the pelvic dead space, blood clots and fluids accumulate and increase the risk of developing a pelvic abscess and wound infection. Furthermore, the rigidity of the structures around the pelvis increases wound tension after suturing the wound closed.<sup>1</sup> Therefore, the perineal wound complication rate is high (39%-57%).<sup>2,3</sup> Wound complications result in prolonged hospital stay, home nursing wound care needs, and significantly increased medical costs.<sup>4,5</sup>

Methods of preventing perineal complications include omentoplasty<sup>6,7</sup> and myocutaneous flaps.<sup>8,9</sup> However,

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omentoplasty is technically difficult to perform in cases of metastatic involvement, previous omental resection, and contracture owing to inflammation. Myocutaneous flaps require both longer operation time and special techniques in plastic surgery. Furthermore, myocutaneous flaps have a risk of flap necrosis and, especially for vertical rectus abdominis myocutaneous (VRAM) flaps, carry a risk of donor site hernia and functional impairment of the vertical rectus abdominis muscle.<sup>7,8</sup>

Negative pressure wound therapy (NPWT) is a wound treatment that facilitates and accelerates wound healing by applying negative pressure.<sup>10,11</sup> The benefits of NPWT for difficult open wounds such as diabetic foot wounds and mediastinitis have been widely reported.<sup>12,13</sup> Incisional negative pressure wound therapy (INPWT) is a new use of NPWT for closed wounds with a high risk of complications. Recently, successful management using INPWT to reduce complications has been demonstrated for various incisions, especially in orthopaedics.<sup>14,15</sup> Some studies have evaluated INPWT management for perineal wounds after APR, and Cahill and Fowler<sup>16</sup> reviewed five such reports (n = 169 patients). The review showed that INPWT management reduced perineal wound complications (surgical site infection, SSI) from 41% to 9%, indicating that INPWT might effectively prevent perineal wound complications. Gologorsky et al<sup>17</sup> reviewed five studies (n = 76 patients) of INPWT management after APR for malignancy. The review showed reduced rates of surgical site complications using INPWT compared with either rate reported in the literature or in control groups. However, in both reviews, definitive conclusions were not achieved because the number of subjects in each study was small, and there were limitations, such as differences in methods, backgrounds, and missing data, depending on the paper.

To address the issues in the existing literature, in this study, we examined whether perineal wound management by INPWT reduces SSI. The aim of this study was to evaluate the impact of INPWT in preventing SSI in perineal wounds after APR.

### 2 | MATERIAL AND METHODS

This retrospective study was approved by the Ethics Committee of our hospital (M20019).

#### 2.1 | Patients

Among 147 patients who underwent APR from December 2004 to December 2019, the study group comprised 146 patients, excluding one patient who left the

- incisional negative wound therapy reduced perineal wound infection after abdominoperineal resection compared with conventional wound management (7.3% vs 32.6%, respectively; P < 0.05)
- when evaluating the risk factors for perineal wound infection after abdominoperineal resection, our study revealed that INPWT-free status was a risk factor [adjusted OR, 5.88(95% CI, 1.79-19.25); P < 0.01]
- to maintain stable wound management using INPWT for perineal wounds, it was necessary to devise ways to apply INPWT devices for women and to address skin complications

INPWT management group because of skin blister formation.

Patients who underwent operation from December 2004 to August 2014 were managed by conventional gauze dressing as a control group, and patients who underwent operation from September 2014 to December 2019 were managed by INPWT.

#### 2.2 | Method

- 1. We compared patients' characteristics, surgical factors, and SSI rates between the INPWT group and control group, and
- We compared patients' characteristics, surgical factors, and the presence or absence of INPWT management between the SSI group and non-SSI group, and examined the risk factors for SSI.

The following patient characteristics and surgical factors were examined in this study: age, sex, obesity (body mass index  $\geq 25 \text{ kg/m}^2$ ), chronic obstructive pulmonary disease, uncontrolled diabetes (glycated haemoglobin > 6.5%), hypoalbuminemia (albumin concentration < 3.0 g/dL), American Society of Anaesthesiologists physical status ( $\geq 3 \text{ vs } < 3$ ), neoadjuvant chemotherapy (NAC), preoperative chemoradiotherapy (pre-CRT), abdominal wound SSI, blood transfusion, approach (laparoscopic/open), operation time, blood loss volume, drain insertion route (via the abdomen or via the perineal wound), and whether INPWT was used for wound management.

# 2.3 | Surgical procedure

In all cases in the INPWT group, conventional APR was performed; extralevator abdominoperineal excision was not performed. The operations were performed in the lithotomy position. In patients with malignant tumours, total mesorectal excision with high ligation of the inferior mesenteric artery was routinely performed. In patients with benign disease, high or low ligation was performed. If there were no oncological problems, such as tumour invasion into the hypogastric nerve and pelvic plexus, the hypogastric nerve and pelvic plexus were preserved. The suction drain was inserted into the bottom of the pelvic floor via the abdomen. For the perineal wound closure, the subcutaneous layers were closed with 1-0 absorbable sutures, and the skin was closed using vertical mattress sutures with 2-0 non-absorbable monofilament sutures. No patients in the INPWT group underwent pelvic floor reconstruction, omentoplasty, mesh repair, or flap repair. The APR technique did not differ between the control group and the INPWT group, and there were no cases of extralevator abdominoperineal excision in the control group, as in the INPWT group. However, in the control group, flap repair of the perineal wound was performed in 3.2% (3/95) of cases, and drains were inserted via the perineal wound in 42.1% (40/95) cases.

### 2.4 | Wound management by INPWT

The ACTIV.A.C. Therapy System (KCI, San Antonio, Texas) was used as the INPWT device. The device was attached immediately after surgery, and negative pressure of 125 mmHg was applied on a continuous setting for 5 days. Thereafter, the device was removed, and wound management was performed using only film dressing. If there were no wound problems, skin sutures were removed 2 weeks later.

When the device was applied, to avoid direct contact between the foam and the skin, film tape was applied on the sides of the perineal suture line and on the thigh where the foam is placed because of direct contact with the vacuum foam might cause skin damage (Figure 1). INPWT management requires an airtight seal to maintain negative pressure. However, in some women, it was difficult to apply the film without air leakage because the perineal wound on the vagina side was irregular. To maintain an airtight seal, we applied ostomy paste, to eliminate the unevenness. In particular, if there was a wound up to the vagina, it was difficult to obtain a seal because exudate from the vagina increased. In these cases, we used polyurethane foam to control the exudate and covered the foam with a film dressing over the whole vaginal opening, to prevent air leakage (Figure 2).

## 2.5 | Antibiotics

As a prophylactic antibiotic, cefmetazole sodium was used for a median of 3 days, (range, 1-6 days). In one case with an allergy to cefmetazole sodium, levofloxacin hydrate was used for 2 days.

# 2.6 | SSI diagnosis

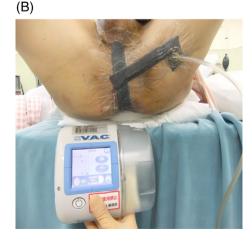
Any wound SSI was recorded for a period of 30 days postoperatively. The presence of an SSI was diagnosed according to the Centres for Disease Control and Prevention criteria, by two surgeons.<sup>18</sup>

# 2.7 | Statistics

We used the chi-square test and Fisher's exact test for discrete variables and the Mann-Whitney U test for continuous

**FIGURE 1** A, When the device was applied, we attached film tape on both sides of the wound and on the thigh to prevent skin damage caused by direct contact with the foam. B, The foam was arranged in a T-shape from the perineal wound to the thigh so that the device would not interfere with the patient's sitting position





(B)

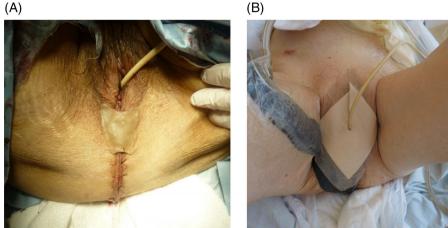


FIGURE 2 A, In women, stoma paste was used to prevent air leaks caused by the unevenness of the vaginal side. B, In addition to unevenness, in cases with heavy discharge, the whole vaginal opening was covered with polyurethane foam to achieve an airtight seal

variables for comparisons of patients' characteristics and surgical factors between the INPWT and control group and between the SSI(+) and SSI(-) group.

When evaluating the SSI risk factors, all patient characteristics and surgical factors were first analysed in a univariate analysis. Factors with a P-value of <0.1 were then entered into a multivariate logistic regression model.

Statistical analyses were performed using commercial software (SPSS for Windows, version 13.0 J; SPSS Japan Inc., Tokyo, Japan). All analyses were two-sided, and a P-value of <0.05 was considered statistically significant.

#### 3 RESULTS

The control group constituted 65.1% (95/146) of the patients, and the remaining 34.9% (51/146) constituted the INPWT group.

## 3.1 | INPWT group (n = 51) vs the control group (n = 95)

The results of the comparison between the INPWT group and the control group are shown in Table 1.

The INPWT group comprised 51 patients (25 men, 26 women; median age, 71 years; range, 35-91 years). Their surgical indications were rectal cancer (74.5% [38/51]), anal cancer (15.6% [8/51]), rectal cancer local recurrence (3.9% [2/51]), inflammatory bowel disease (2.0% [1/51]), faecal incontinence after intersphincteric resection (2.0% [1/51]), and malignant melanoma (2.0% [1/51]). The control group comprised 95 patients (66 men, 29 women; median age, 67 years; range, 33-90 years). Their surgical indications were rectal cancer (69.4% [66/95]), anal cancer (13.7% [13/95]), rectal cancer local recurrence (11.5% [11/95]), faecal incontinence after intersphincteric resection (2.1% [2/95]), gynaecological cancer (1.1% [1/95]), peritoneal dissemination of gastric cancer (1.1% [1/95]), and Paget's disease (1.1% [1/95]).

#### 3.1.1 | Patients' characteristics

In the INPWT group, the rates of male sex (P < 0.05), smoking (P < 0.05), blood transfusion (P < 0.05), and drainage via the perineal wound (P < 0.01) were significantly lower, and the intraoperative blood loss volume (P < 0.05) was significantly lower than in the control group. In addition, the operation time in the INPWT group was significantly longer than in the control group (P < 0.01).

# 3.1.2 | SSI rate and wound dehiscence rate

The SSI rate in the INPWT group was significantly lower than in the control group (P < 0.05; 7.8% vs 32.6%, respectively), and the wound dehiscence rate in the INPWT group was lower than in the control group. However, the difference was not statistically significant (P = 0.32; 3.9% vs 9.5%, INPWT vs control, respectively).All SSI or wound dehiscence cases were diagnosed during patients' hospital stay.

#### 3.1.3 Length of hospital stay

The median length of hospital stay was 27 days (range, 11-156 days) in the INPWT group and 26 days (range, 11-105) days in the control group. There was no significant difference between the two groups (P = 0.96).

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TABLE 1 Comparison of patients' characteristics and surgical factors in the INPWT group and control group

	INPWT ( $n = 51$ )	Control $(n = 95)$	P-value
Surgical indication			0.5 <sup>a</sup>
Rectal cancer	38 (74.5%)	66 (69.4)	-
Anal cancer	8 (15.6%)	13 (13.7)	-
Local recurrence	2 (3.9%)	11 (11.5)	-
IBD	1 (2.0%)	0	-
Faecal incontinence	1 (2.0%)	2 (2.1)	-
Malignant melanoma	1 (2.0%)	0	-
Gynaecological cancer	0	1 (1.1)	-
Peritoneal dissemination	0	1 (1.1)	-
Paget's disease	0	1 (1.1)	-
Male sex	25 (49.0%)	66 (69.5%)	< 0.05
Age	71 (35-91)	67 (33-90)	0.06 <sup>b</sup>
Obesity	7 (13.7%)	18 (18.9%)	0.42
COPD	12 (23.5%)	25 (26.3%)	0.71
Diabetes mellitus	5 (9.8%)	14 (14.7%)	0.39
Hypoalbuminemia	5 (9.8%)	12 (12.6%)	0.37
Smoking	10 (19.6%)	39 (41.1%)	< 0.05
ASA $PS > 3$	5 (9.8%)	10 (10.5%)	0.89
NAC	5 (9.8%)	8 (8.4%)	0.76 <sup>c</sup>
Pre-CRT	7 (13.7%)	13 (13.7%)	0.99
T4 <sup>d</sup>	4 (8.0%)	15 (18.3%)	0.1
Laparoscopic surgery	25 (49.0%)	38 (40%)	0.29
Operation time (min)	433 (228-699)	356 (144-859)	< 0.05 <sup>b</sup>
Blood loss (mL)	193 (24-6134)	624 (70-5245)	< 0.05 <sup>b</sup>
Blood transfusion	14 (27.5%)	43 (45.3%)	< 0.05
Drain via perineal wound	0 (0%)	40 (42.1%)	< 0.01 <sup>c</sup>
Abdominal wound SSI	3 (5.9%)	9 (9.5%)	0.54 <sup>c</sup>
Length of hospital stay (day)	27 (11-156)	26 (11-105)	0.96 <sup>b</sup>
Wound dehiscence	2 (3.9%)	9 (9.5%)	0.32 <sup>c</sup>

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Note: Data are presented as number (%) for discrete variables or median (range) for continuous variables.

4 (7.8%)

Abbreviations: ASA PS, American Society of Anaesthesiologists physical status; COPD, chronic obstructive pulmonary disease; IBD, inflammatory bowel disease; INPWT, incisional negative pressure wound therapy; NAC, neoadjuvant chemotherapy; pre-CRT, preoperative chemoradiotherapy; SSI, surgical site infection.

<sup>a</sup>We compared rectal cancer vs anal cancer vs other diseases.

<sup>b</sup>Mann-Whitney *U* test was used.

Perineal wound SSI

<sup>c</sup>Fisher's exact test was used; otherwise, the chi-square test was used.

<sup>d</sup>Values in one case in the INPWT group and 13 cases in the control group were unknown.

#### SSI(+) group (n = 35) vs SSI(-)3.2 group (n = 111)

In the univariate analysis, the SSI(+) group had a significantly higher laparoscopic surgery rate (P < 0.01) and INPWT-free rate (P < 0.01), and significantly higher intraoperative blood loss volume (P < 0.05) than the SSI(–) group (Table 2). We added the preoperative radiotherapy rate (P = 0.09) to these three factors and performed multivariate analysis for all four factors. The results showed that INPWT-free status was a risk factor for perineal wound SSI (adjusted OR, 5.88; 95% CI, 1.79-19.25; *P* < 0.01) (Table 3).

31 (32.6%)

< 0.05

	SSI(+) (n = 35)	SSI(-) (n = 111)	P-value
Male sex	24 (68.6%)	67 (60.4%)	0.38 <sup>a</sup>
Age	70 (40-83)	69 (33-91)	0.99 <sup>a</sup>
Obesity	9 (25.7%)	16 (14.4%)	0.12
COPD	10 (28.6%)	27 (24.3%)	0.65
Diabetes mellitus	5 (14.3%)	14 (12.6%)	0.77 <sup>b</sup>
Hypoalbuminemia	6 (17.1%)	10 (9.0%)	$0.21^{b}$
Smoking	12 (34.3%)	37 (33.3%)	0.91
ASA PS $> 3$	3 (8.6%)	13 (11.7%)	0.76 <sup>b</sup>
NAC	3 (8.6%)	10 (9.0%)	$1^{b}$
T4 <sup>c</sup>	9 (26.5%)	15 (15.3%)	0.14
Pre-CRT	8 (22.9%)	12 (10.8%)	0.09 <sup>b</sup>
Laparoscopic surgery	29 (82.9%)	34 (30.6%)	< 0.01
Blood transfusion	16 (45.7%)	41 (36.9%)	0.35
Blood loss (mL)	720 (80-3065)	390 (24-6134)	<0.05 <sup>a</sup>
Operation time (min)	433 (205-719)	361 (144-859)	0.24 <sup>a</sup>
Drain via perineal wound	10 (28.6%)	30 (27.0%)	0.85
Abdominal wound SSI	4 (11.4%)	8 (7.2%)	0.48 <sup>b</sup>
INPWT	4 (11.4%)	47 (42.3%)	< 0.01

**TABLE 2** Comparison of patients' characteristics and surgical factors in the SSI(+) group and SSI(-) groups

*Note:* Data are presented as number (%) for discrete variables or median (range) for continuous variables.

Abbreviations: ASA PS, American Society of Anaesthesiologists physical status; COPD, chronic obstructive pulmonary disease; INPWT, incisional negative pressure wound therapy; NAC, neo-adjuvant chemotherapy; pre-CRT, preoperative chemoradiotherapy; SSI, surgical site infection. <sup>a</sup>Mann-Whitney U test was used.

<sup>b</sup>Fisher's exact test was used; otherwise, the chi-square test was used.

<sup>c</sup>Values for one case in the INPWT group and 13 cases in the control group were unknown.

	Odds Ratio	95% Confidence Interval	P-value	TABLE 3 results	Multivariate analysis
INPWT-free status	5.88	1.79-19.25	< 0.01		
Pre-CRT	2.75	0.94-8.04	0.06		
Laparoscopic surgery	0.80	0.27-2.36	0.68		
Blood loss	0.99	0.99-1.00	0.63		

Abbreviations: INPWT, incisional negative pressure wound therapy; pre-CRT, preoperative chemoradiotherapy.

# 3.3 | Complications

Blister formation occurred in 9.6% (5/52) of the patients on the skin at the edge of the film tape (Figure 3). Because in 80% (4/5) of the cases, blisters occurred in only a small area, INPWT was continued for 5 days. However, the remaining 20% (1/5) of the patients discontinued INPWT after 2 days owing to extensive blisters. The fifth case, who left the INPWT management group, was excluded from this study.

#### 4 | DISCUSSION

Our study showed that perineal wound management using INPWT reduced the SSI rate compared with conventional wound management (P < 0.05; 7.8% vs 32.6%, respectively) and that INPWT-free status was a predictor of developing SSI in the perineal wound (adjusted OR, 5.88; 95% CI, 1.79-19.25; P < 0.01). We successfully managed perineal wounds using INPWT for 16 patients who underwent APR and total pelvic exenteration.<sup>19</sup> Our



**FIGURE 3** Skin blisters tended to develop at the edge of the film tape where tension was applied

results demonstrated the benefit of using INPWT management to decrease the SSI rate of perineal wounds after APR.

Chadi et al<sup>20</sup> compared the SSI rate between 27 patients receiving INPWT for perineal wound management after APR with 32 patients who underwent standard dressing management. The infection rate in the INPWT group was significantly lower than in the control group (15% vs 41%, respectively; P = 0.02). As a result, the authors reported that INPWT was an independent predictor of not developing an SSI (adjusted OR, 0.11; 95% CI, 0.04-0.66; P = 0.01).<sup>20</sup> Our study supported these results.

Possible reasons why INPWT decreases wound complications are less lateral tension on the wound<sup>21</sup> and lower hematoma/seroma formation.<sup>22,23</sup> In particular, lower lateral tension may decrease stress in the tissue surrounding the insertion site of sutures and staples, and prevent ischaemia, which reduces the ability to fight infection and can lead to necrosis.<sup>21,24</sup> Based on the effect of INPWT in decreasing wound tension, INPWT may be particularly beneficial for high-tension wounds in the lower extremities, in obese patients, or in locations where there is movement, such as wounds over a joint.<sup>21,25</sup> Perineal wounds have similar characteristics to these wounds, and, therefore, INPWT may effectively decrease the rate of SSIs.

In addition to Chadi et al's report, several papers have evaluated whether INPWT management decreases perineal wound complications after APR. Wiegering et al<sup>26</sup> examined the impact of INPWT for complication-free healing of perineal wounds in five APR cases and in one total pelvic resection case with wound reconstruction by VRAM flap. All patients underwent neoadjuvant radiochemotherapy, and the report showed that 83% (5/6) of the patients experienced complication-free healing. Furthermore, Sumrien et al<sup>27</sup> evaluated whether INPWT management decreased the perineal wound complication rate in 32 patients who underwent extralevator abdominoperineal excision (ELAPE) with the reconstruction of the pelvic floor using a biological mesh. Outcomes in this group were compared with outcomes in 25 patients who underwent primary closure and conventional wound management after standard APR. The major wound complication rate in the INPWT group was significantly lower compared with the control group (9% [9/32] vs 40% [10/25], respectively; P = 0.01). In contrast, Van der Valk et al<sup>28</sup> evaluated the incidence of wound complications and compared the time to wound healing between 10 patients in an INPWT group and 10 patients in a control group treated with conventional wound care after APR, excluding ELAPE. The study showed that the incidence rate of wound complications was 70% (7/10) in the INPWT group and 60% (6/10) in the control group and that the incidence rate of wound complications was not decreased using INPWT. As a result, the authors reported that the use of INPWT did not reduce the incidence of perineal wound complications; however, wound infections occurred slightly later and appeared to have a less severe clinical course. In addition, the duration of wound healing was shorter. These reports show the effect of INPWT in reducing wound complications, excluding Van der Valk's report. However, sample sizes in these reports were small, and the study design, study subjects, and the use of INPWT were heterogeneous, including in our study; therefore, further investigation with uniform conditions is necessary to conclude whether using INPWT prevents perineal wound complications.

In Chadi et al's study, the length of hospital stay in the INPWT group was longer than in the control group (11 days vs 8 days, respectively; P = 0.03); therefore, INPWT did not reduce the length of hospital stay.<sup>20</sup> The authors explained that the higher rate of SSI diagnosis during the inpatient stay in the INPWT group compared with the control group likely explained the longer length of stay.

In the current study, we found no difference in hospital stay between the INPWT group and the control group (P = 0.96), indicating that INPWT did not reduce the length of hospital stay, as in Chadi et al's study. All SSI cases were diagnosed during the hospital stay in our study, and there was no bias due to diagnosis timing, unlike in Chadi et al's study. However, the hospital stay in our study (27 days in the INPWT group and 26 days in the control group) was much longer than in Chadi et al's study. Furthermore, in our study, time was required during the hospital stay for patient stoma education, preparation for the home care environment, and adjustment to WILEY\_IWJ

post-discharge rehabilitation and nursing care, especially in older patients or patients with psychosis. This was possible because, in Japan's insurance system, everyone is insured, and the burden on the patient is lower than in other countries. However, prolonged hospital stay related to patient education, preparation, and adjustment might have introduced bias when evaluating whether INPWT reduces the length of hospital stay.

In this study, blister formation occurred in 9.6% (5/52) of cases, and only one case could not continue INPWT because of the blisters. However, Howell et  $al^{29}$  examined the effect of INPWT management on the wound after total knee arthroplasty and reported that INPWT was terminated early because blisters occurred in 15/24 knees (63%) during the study. Therefore, we considered it important to apply the adhesive tape with care in patients with blisters, to continue management by INPWT.

# 4.1 | Limitations

There are limitations in this study. First, this was a retrospective study, so patients' backgrounds differed between the INPWT group and the control group. Second, we could not obtain information about the amount of intraabdominal irrigation from patients' operation records. Intra-abdominal irrigation with 3000 mL of normal saline before abdominal wall closure was routinely performed. However, the amount of saline for irrigation in laparoscopic surgery was not constant and could be less than in open surgery. The higher SSI rate of perineal wounds in the laparoscopic surgery group compared with open surgery may be related to the amount and method of irrigation; however, we could not evaluate this because of a lack of information. Similarly, intraoperative rectal perforation is an important risk factor for wound infection; however, information describing the presence or absence of intraoperative rectal perforation also could not be obtained from patients' surgical records. Finally, operations were performed by experienced staff surgeons, and our surgical procedure was standardised. However, bias caused by differences in the surgeons' skills is possible.

Despite these limitations, this study suggested that using INPWT decreased perineal wound infection rates. However, this was a retrospective study with different patients' backgrounds, and large-scale prospective clinical trials with uniform conditions are required to provide clear conclusions.

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#### **CONFLICT OF INTEREST**

The authors declare no conflicts of interest.

#### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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