Received: 30 March 2021 | Revised: 16 May 2021 | Accepted: 17 May 2021

DOI: 10.1111/iwj.13628

ORIGINAL ARTICLE

IWJ WILEY

Prophylactic incisional negative pressure wound therapy for gynaecologic malignancies

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Abstract

Wound complications are an important cause of postoperative morbidity among patients with gynaecologic malignancies. We evaluated whether the placement of closed-incisional negative pressure therapy (ciNPT) at the time of laparotomy for gynaecologic cancer surgery reduced wound complication rates. A retrospective cohort study with primary wound closure performed by a gynaecologic oncologist was carried out. We evaluated two cohorts of patients who underwent surgery in 2017 with standard closure and patients who underwent surgery in 2019 with the placement of prophylactic ciNPT. Postoperative outcomes were examined. A total of 143 patients were included, 85 (59.4%) vs 58 (40.6%) with standard closure and ciNPT, respectively. The total complication rate in our sample was 38.71%. The rate of surgical complications in patients treated with ciNPT was 6.9% compared with 31.8% ($P = .000$) in patients treated with standard closure. In the analysis of complications, a significant reduction in infections (17.1%), seromas (15.4%), and wound dehiscence (17.1%) were observed when ciNPT was applied. The median hospital stay was 8 vs 6 days in the standard closure vs ciNPT groups ($P = .048$). The use of the prophylactic ciNPT following a laparotomy may decrease wound complications and hospital stays in oncological patients. ciNPT could be considered as part of clinical practice in patients at high risk of wound complications, such as patients with gynaecological malignancies.

KEYWORDS

gynecologic neoplasms, laparotomy, negative-pressure wound therapy, postoperative care, wound healing

Key Messages

- surgical wound complications are currently a challenge for oncology gynaecologists with an impact on the morbidity and mortality of our patients
- a total of 143 patients underwent xipho-pubic laparotomy, 85 with standard closure and 58 with negative pressure incisional therapy were evaluated

- the application of negative pressure incisional therapy is presented as a prophylactic option that could reduce wound complications

1 | INTRODUCTION

Despite advances in the practice of minimally invasive surgery and the widespread adoption of these techniques, a significant proportion of the patients diagnosed with a primary gynaecologic malignancy will require surgical management with laparotomy in the treatment of disease.[1-3]

A balance between optimal surgical treatment and reduction of postoperative morbidity and mortality for these patients continue to challenge gynaecologic oncologists.

Wound complications could be as high as 40% to 60%[4] and lead to extended hospital stays and decreased quality of life.[5-7]

This category of adverse events related to surgery includes wound separation, hematoma, seroma, and superficial surgical site infection (SSI).

Most worrisome in the gynaecologic oncology patient is the adverse impact of wound complications at the primary surgical site on overall survival, as evidenced in patients with ovarian cancer, with a hazard ratio 1.69 (1.12-2.57) in patients with a superficial SSI.[2,8]

Increased operative time, surgical complexity, estimated blood loss, and medical comorbidities, such as obesity, have been identified as independent factors predisposing patients to wound complications.[3,8-10]

The prophylactic use of closed-incisional negative pressure therapy (ciNPT) over closed incisions reduced the incidence of SSIs and wound complications in surgical patients in other surgical disciplines.[5-7,11-13] However, there is scant literature regarding this therapy among gynaecologic patients.

The purpose of the current study was to determine whether prophylactic ciNPT decreases the wound complications in patients with gynaecologic malignancies undergoing laparotomy, compared with standard dressing.

2 | METHODS

2.1 | Patients

Two consecutive cohorts of patients who underwent abdominal laparotomy with a diagnosis of gynaecological neoplasia performed at the Bellvitge University Hospital, Barcelona, were retrospectively evaluated.

A cohort between January 2017 and December 2017 when ciNPT was not used, and a cohort who underwent surgery between January 2019 and December 2019 when a ciNPT protocol was fully standardised in our department.

The primary objective of this study was to compare the rate of postoperative wound complications between the two groups of patients.

Prophylactic measures for SSI were standardised according to hospital protocol in accordance with the US Centers for Disease Control and Prevention (CDC) guidelines.

2.2 | Inclusion and exclusion criteria

Patients were required to meet all the following eligibility criteria:

- Age older than 18 years;
- Diagnosis of gynaecologic malignancy by biopsy;
- Cytoreductive surgery that required a midline laparotomy;
- Written informed consent for surgery and data collection.

Patients who had a benign pathology, no consent for data collection or who underwent minimally invasive surgery, were not included in the analysis.

2.3 | Protocol

All patients (regardless of the cohort evaluated) received the same preoperative and postoperative care. They were shaven using surgical clippers when required, and the skin was prepared with povidone iodine solution.

Cefuroxime (1.5 g) was administrated 60 minutes before the incision in every surgery, and it was re-administered according to the length of surgery and blood loss. There was no administration of post-surgical antibiotic therapy.

In those patients who did not receive ciNPT, the placement of the sterile gas dressing was maintained for 24 to 48 hours.

- ciNPT device:
  The negative pressure therapy device was applied at the time of closing the wound incision.

Negative pressure dressings were applied to clean, dry incision sites after closure of intradermal sutures with the Quill bearded suture.

The device consisted of a dressing composed of KCI GranuFoam with bacteriostatic and bactericidal capacities and a vacuum-assisted closure system (Prevena Incision Management System, KCI, San Antonio, Texas) was applied with continuous negative pressure at 125 mmHg and a reservoir of 45 mL capacity.

If an ostomy was present, the incisional negative pressure system was placed after the ostomy devices.

The ciNPT dressings were continued between 2 and 9 days postoperatively. The wound was evaluated after removal of the device if there was no evidence of bleeding in the reservoir.

- Follow-up:
  Surgical wound complications, such as infections, seromas, haematomas, or superficial dehiscence, were reported until 30 days after surgery.
  The superficial surgical wound infection was classified when the infection involved the skin and subcutaneous tissue and occurred within 30 days of injury according to the definition by the CDC.[14,15]
  The clinical team recorded signs or symptoms of wound-related infections in the medical record per routine clinical practice.
  A seroma was recorded whenever fluid leaked from the wound. A haematoma was recorded when clots leaked through the wound. Dehiscence was recorded when the separation of skin and dermal surfaces was observed, without affecting the fascia.
  Clinical variables were collected and included age, ECOG status (ECOG scale is a practical way to measure the quality of life of a patient exclusively with cancer or oncology), type of cancer and FIGO stage (FIGO stage [International Federation of Gynaecology and Obstetrics] is the staging system for gynaecological cancers based on their extension and prognosis), body mass index (BMI, kg/m^2), tobacco use, diabetes mellitus, previous abdominal surgeries, and the use of abdominal mesh in the current surgery because of increased seroma in these cases.
- Data analysis:
  Categorical variables were analysed using chi-square test or Fisher's exact test, whereas continuous variables were analysed using Student's *t* test.
  The ANOVA statistical test was used to compare the means of both samples to show homogeneity.
  These analyses were carried out using IBM SPSS Statistics for Windows, version 25.0, and a 5% level of statistical significance was considered throughout the study.

3 | RESULTS

A total of 143 patients underwent middle laparotomy for gynaecologic oncological disease in the period reviewed. Of these patients, 85 patients received a conventional dressing and 58 patients received ciNPT.

The characteristics of the patients are identified in Table 1. The groups were similar in ages, prevalence of diabetes, numbers of previous abdominal surgeries, and rates of use of abdominal mesh in the wall closure. There were no significant differences in BMI in both groups.

The type of gynaecologic cancer and FIGO stages did not show significant differences in the global statistical analysis ($P = .239$ and .198, respectively) (Table 2). Although without significance, an increase in the proportion of ovarian cancer in the standard closure group compared with that in the ciNPT group, 71.8% (61) vs 56.9% (33), was observed (Table 2). This difference is not considered relevant, because all patients present the same type of surgical approach; laparotomy middle xiphopubic.

In the same sense, the patients with diagnosis of a metastatic tumour, recurrence, or absence of tumour in the surgical intervention did not present with differences in the two subgroups evaluated.

Overall, 51.8% (44) vs 43.1% (25) of the patients were stage III among the two groups, respectively, although again without a significant difference in the global statistical study ($P = .198$).

The incidence of wound complications in our study population was 38.71% in total, of which 31.8% occurred in the standard closure group, and only 6.9% in the ciNPT group. ($P = .000$).

The wound complications experienced by patients included in this study are described in Table 3. We observed a lower incidence of superficial SSIs, seromas, and wound dehiscence in the ciNPT group with significant differences when compared with those in the standard closure group.

The length of hospital stay was reduced in patients who received ciNPT compared with patients who received standard closure (6.18 days vs 8.86 days, respectively; $P < .05$).

In the subgroup analysis of patients with a BMI ≥ 30 kg/m^2 (obesity), we observed lower rates of seromas, infections, wound dehiscence, and haematomas with significant differences in the ciNPT group than those in the standard closure group (Table 4).

TABLE 1 Patient demographic data

	Standard closure (85)	ciNPT (58)	*P*
Age	61.51	63.28	.366
BMI, kg/m^2	27.59	28.59	.323
Diabetes (n)	22.4% (19)	20.7% (12)	.813
Abdominal mesh[a] (n)	25.9% (22)	22.4% (13)	.636
Previous abdominal surgery (n)	58.8% (50)	53.4% (31)	.529

Note: Data are presented as mean and % and were analysed using ANOVA statistical test, which was used to compare the means of both samples to show homogeneity.
Abbreviation: ciNPT, closed-incisional negative pressure therapy.
[a]Patients who received abdominal mesh at the time of surgery.

TABLE 2 Cancer data

	Standard closure (85)	ciNPT (58)	*P*
ECOG ≤1 (N)	100% (85)	100% (58)	1
NACT (n)	25.9% (22)	22.4% (13)	.636
Pathology (n)			.239
Ovarian cancer	71.8% (61)	56.9% (33)	
Cervical cancer	1.2% (1)	0%	
Endometrial cancer	23.5% (20)	34.5% (20)	
Vulvar cancer	1.2% (1)	0%	
No tumour	2.4% (2)	0%	
Metastasis	2.4% (2)	17.2% (5)	
Recurrence	5.9% (5)	17.2% (10)	
FIGO stage (n)			.198
I	15.3% (13)	19% (11)	
II	11.8% (10)	6.9% (4)	
III	51.8% (44)	43.1% (25)	
IV	10.6% (9)	5.2% (3)	

Note: Data are presented as mean and % and were analysed as categorical variables using chi-square test or Fisher's exact test, whereas continuous variables were analysed using Student's t test.
Abbreviation: ciNPT, closed-incisional negative pressure therapy.

TABLE 3 Results of postoperative outcomes

	Standard closure (85)	ciNPT (58)	*P*
Postoperative stay (days, mean)	8.86	6.16	.036
Complications (n)	31.8% (27)	6.9% (4)	.000
Superficial infection (SSI)	18.8% (16)	1.7% (1)	.000
Seroma	18.8% (16)	3.4% (2)	.002
Wound dehiscence	18.8% (16)	1.7% (1)	.000
Haematoma	9.4% (8)	1.7% (1)	.064

Note: Data are presented as mean and % and were analysed as categorical variables using chi-square test or Fisher's exact test, whereas continuous variables were analysed using Student's t test.
Abbreviation: ciNPT, closed-incisional negative pressure therapy.

4 | DISCUSSION

SSI remains stable despite efforts to standardise perioperative care, which contributes to an increase in surgical morbidity and medical costs.[16,17]

The reported historical rates of SSI are 5% to 15% for clean-contaminated (class II), 15% to 30% for contaminated (class III), and >30% for dirty (class IV).[18,19]

Furthermore, the rates of surgical complications in patients with gynaecologic cancers are between 40% and

TABLE 4 IMC ≥30

	Standard closure (85)	ciNPT (58)	*P*
Patients	59.3% (32)	40.7% (22)	
Complication (n)	31.3% (10)	13.6% (3)	.034
Infection (SSI)	15.6% (5)	4.5% (1)	.000
Seroma	21.9% (7)	9.1% (2)	.001
Wound dehiscence	15.6% (5)	4.5% (1)	.000
Haematoma	6.3% (2)	0	-
Postoperative stay (days, MEAN)	9.69	5	.045

Note: Data are presented as mean and % and were analysed using Student's test.
Abbreviation: ciNPT, closed-incisional negative pressure therapy.

60% because of the incidence of associated comorbidities, particularly obesity.[8,9,20,21]

According to our results, the complications of surgical wounds in both cohorts were lower than those published in similar populations, being 18.4% in patients with standard closure, decreasing to 2.7% in patients with ciNPT.

The use of ciNPT has shown inconclusive results in the literature.[9,12,22] Consequently, its implementation in the prevention of surgical wound complications remains in debate.

Our results show a significant reduction in superficial SSI (18.8% vs 1.7%), seromas (18.8% vs 3.4%), and wound dehiscence (18.1% vs 1.7%), which represents a reduction of 91% for superficial SSI and wound dehiscence, and 82% for seroma when ciNPT is applied after laparotomy for gynaecologic malignancies. Furthermore, this study shows that the differences obtained in surgical complications after ciNPT were maintained in the analysis of obese patients (BMI ≥30 kg/m^2).

The reduction in surgical site complications is because ciNPT decreases the fluid accumulation in a sealed manner, improving perfusion and oxygenation of the surgical wound, which reduces the risk to the surgical wound.[11,23]

According to our results, numerous studies have shown the reduction of surgical wound complications through the use of ciNPT.[22-24] In addition, an international multidisciplinary consensus recommends the use of ciNPT in patients classified as high risk for complications of surgical wounds, based on the evidence published in different types of surgical wounds.[11,16]

A second interesting finding of our study is the 3 days better difference in the mean hospital stay in the ciNPT group. In this regard, it is well studied that an SSI costs approximately $20 000 US per patient.[16]

ciNPT costs are increased by $200 to 500 US per patient compared with standard closure. However, ciNPT could be cost-effective because of its reduction in SSIs and hospital lengths of stay.[16]

Chopra et al described a savings of $1546 US per patient after abdominal procedures.[16,23]

The main limitations of our study are its retrospective nature and the presence of comorbidities in the patients. However, to diminish bias, we selected all consecutive patients who underwent laparotomy for gynaecologic cancer and were divided into two periods based on the application of ciNPT.

The preoperative and postoperative care is the same in these cohorts and both groups do not present significant differences between them.

Although it is a retrospective study that compares two cohorts of patients operated at different times, the comparable groups according to demographic data allow us to compare the results with a low risk for misinterpretation.

Despite the limitations described, our study highlights the significant reductions in surgical wound complications and lengths of hospital stay in patients in whom ciNPT has been used. Furthermore, it may decrease the healthcare costs derived by those complications.

5 | CONCLUSION

In conclussion, the use of ciNPT to closure after laparotomy for gynaecological cancer is safe and effective for decreasing SSIs and median hospital stay. The findings of this study suggest clinical benefit with less rate of wound complications. Consequently, the application of ciNPT might be a cost-effective approach.

Therefore, we recommend to consider ciNPT after laparotomy as part of clinical practice in patients at high risk of wound complications, such as patients with gynaecological malignancies.

CONFLICT OF INTEREST

The authors declare no potential conflict 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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How to cite this article: Martí MTC, Fernandez-Gonzalez S, Martí MD, Pla MJ, Barahona M, Ponce J. Prophylactic incisional negative pressure wound therapy for gynaecologic malignancies. *Int Wound J*. 2022;19(2):272–277. https://doi.org/10.1111/iwj.13628