Original Research

Prophylactic Negative Pressure Wound Therapy After Laparotomy for Gynecologic Surgery

A Randomized Controlled Trial

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OBJECTIVE: To estimate the effectiveness of prophylactic negative pressure wound therapy in patients undergoing laparotomy for gynecologic surgery.

METHODS: We conducted a randomized controlled trial. Eligible, consenting patients, regardless of body mass index (BMI), who were undergoing laparotomy for presumed gynecologic malignancy were randomly allocated to standard gauze or negative pressure wound therapy. Patients with BMIs of 40 or greater and benign disease also were eligible. Randomization, stratified by BMI, occurred after skin closure. The primary outcome was wound complication within 30 (±5) days of surgery. A sample size of 343 per group (N=686) was planned.

RESULTS: From March 1, 2016, to August 20, 2019, we identified 663 potential patients; 289 were randomized to negative pressure wound therapy (254 evaluable participants) and 294 to standard gauze (251 evaluable participants), for a total of 505 evaluable patients. The median age of the entire cohort was 61 years (range 20–87). Four hundred ninety-five patients (98%) underwent laparotomy for malignancy. The trial was eventually stopped for futility after an interim analysis of 444 patients. The rate of wound complications was 17.3% in the negative pressure wound therapy (NPWT) group and 16.3% in the gauze group, absolute risk difference 1% (90% CI −4.5 to 6.5%; P=.77). Adjusted odds ratio controlling for estimated blood loss and diabetes was 0.99 (90% CI 0.62–1.60). Skin blistering occurred in 33 patients (13%) in the NPWT group and in three patients (1.2%) in the gauze group (P<.001).

CONCLUSION: Negative pressure wound therapy after laparotomy for gynecologic surgery did not lower the wound complication rate but did increase skin blistering.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, NCT02682316.

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Surgical site infections, which lead to increased postoperative symptom burden, recovery time, hospital stay, readmissions and mortality, are one of the most common and costly types of hospital-acquired infections.[1,2] According to a study by the American College of Surgeons National Surgical Quality Improvement Program, the most common reason for unplanned readmission after surgery among 498,895 operations was surgical site infection.[3]

Superficial surgical site infections involve only the skin and subcutaneous tissue; deep surgical site infections involve the fascial and muscle layers; and organ–space surgical site infections involve anything deeper.[4] The overall surgical site infection rate after laparotomy for gynecologic malignancies ranges from 1–37%.[5–10] This high variation is due to the retrospective nature of published results, heterogeneity in the complexity of cases, and the use of surgical site infection–reduction bundles. The rates of only superficial surgical site infections are difficult to extrapolate from these publications owing to the heterogeneity of surgical site infection definitions, as well as patient and procedure variability. In obese and morbidly obese women, the rate of wound complications (ie, superficial surgical site infections) after laparotomy for benign or malignant indications is 27–33%.[11,12]

Negative pressure wound therapy is a noninvasive, superficially placed therapy that exerts a mechanical vacuum force on tissue, which theoretically leads to accelerated healing.[13] Negative pressure wound therapy, commonly used to manage acute and chronic wounds, despite limited data,[14] is now also approved by the U.S. Food and Drug Administration as a preventative intervention for closed surgical incisions.[15] A meta-analysis of randomized and nonrandomized trials suggested a reduction in surgical site infection rates, but not seroma or wound dehiscence for closed laparotomy incisions with the use of negative pressure wound therapy.[16] A recent Cochrane report of only randomized trials among various surgical incisions and procedures, however, failed to demonstrate a reduction in surgical site infections or other wound complications.[17]

The primary objective of our study was to evaluate whether prophylactic negative pressure wound therapy for laparotomy closure reduces the incidence of postoperative wound complications in patients who have undergone gynecologic surgery.

ROLE OF THE FUNDING SOURCE

The protocol was supported in part by KCI/Acelity. The authors had access to relevant aggregated study data and other information (such as study protocol, analytic plan and report, validated data table, and clinical study report) required to understand and report research findings. The authors take responsibility for the presentation and publication of the research findings, have been fully involved at all stages of publication and presentation development, and are willing to take public responsibility for all aspects of the work. All individuals included as authors and contributors who made substantial intellectual contributions to the research, data analysis, and publication or presentation development are listed appropriately. The role of the sponsor in the design, execution, analysis, reporting, and funding is fully disclosed. The sponsor reviewed the manuscript and provided general funding for research purposes. The authors' personal interests, financial or nonfinancial, relating to this research and its publication have been disclosed.

METHODS

This investigator-initiated, open-label randomized controlled trial was approved by the Institutional Review Board of Memorial Sloan Kettering Cancer Center and was conducted at four centers within the Memorial Sloan Kettering Cancer Alliance (NCT02682316).

Eligible patients included women aged 18 years or older irrespective of body mass index (BMI, calculated as weight in kilograms divided by height in meters squared) who were planning to undergo laparotomy for either a confirmed or presumed gynecologic malignancy. Women with BMIs of 40 or higher who were undergoing laparotomy for a benign indication also were eligible. Exclusion criteria included those with laparotomy incisions left open for any reason, or laparotomy incisions that were unable to be closed primarily owing to tissue or fascial damage. Eligible women were randomized intraoperatively after the skin had been completely closed to either standard gauze or a U.S. Food and Drug Administration–approved negative pressure wound therapy system used for the healing of clean or clean-contaminated closed surgical incisions (Prevena Customizable Incision Management System). The system consists of a self-adhesive foam dressing with a configuration that allows the clinician to alter the dressing to cover closed surgical incisions of different sizes and shapes. It is connected to a V.A.C. ULTA Therapy Unit to maintain a constant pressure of negative

125 mm Hg. The randomization sequence was computer generated by the Department of Epidemiology and Biostatistics at the Memorial Sloan Kettering Cancer Center by using randomly permuted blocks stratified by a BMI of more than 40 regardless of whether planned surgery was for malignancy or benign disease. Sequentially numbered, sealed, opaque, nonresealable envelopes that contained the randomization assignment were used and opened intraoperatively by the surgical team only after skin closure.

Per institutional protocol, all women received prophylactic antibiotics within 60 minutes of skin incision. Of note, all four participating sites had adopted surgical site infection–reduction bundles and enhanced recovery after surgery protocols before the initiation and independent of this study. Specific skin preparations were left to institutional standards and were not protocol-mandated. Skin layer closure was performed with surgical staples. Intraperitoneal or subcutaneous drains or both were allowed at the surgeon's discretion. Women randomized to the control group had the gauze removed on postoperative day 2. The negative pressure wound therapy system was removed at the time of discharge or on postoperative day 7, whichever came first.

The primary outcome of the study was the development of a wound complication within 30 (±5) days of surgery, which was a composite endpoint inclusive of any of the following alone or in combination: wound infection, wound separation, wound seroma, or wound hematoma. Secondary outcomes consisted of the individual types of wound complications. The tertiary outcome was the development of skin blistering or contact dermatitis, and wound pain. Wound pain was determined using standard visual analog scale. Evaluations for wound complications were performed using a provider-completed assessment and data form.

Based on institutional data that showed a wound complication (as defined above) rate of 7.6%, we chose a baseline wound complication rate of 10% to account for an error rate in the institutional database as well as differing rates among the four sites. With a baseline rate of 10%, we chose a 50% decrease in the rate of wound complication as clinically significant. To achieve 80% power with a type I error of 10% (two-sided test), it was determined we would need to enroll 686 evaluable patients (343 per group).

The primary analysis of our study was performed via a two-sample test for binomial proportions to compare the difference in wound complication proportions between the two groups. Univariate and multivariate logistic regression were performed to test for differences in wound complications between groups after controlling for other variables. The distributions of patient demographic and clinical factors between the two groups were tested by applying the Fisher exact test for categorical and the Wilcoxon rank sum test for continuous variables. The secondary analysis of each separate type of wound complication, namely wound infection, separation, and formation of hematoma or seroma, was performed in separate logistic regression models in which the outcome was the presence or absence of the wound complication and the covariate of interest was the treatment group (control or experimental). This secondary analysis was hypothesis-generating, and *P* values were not adjusted for multiplicity. The Fisher exact test was used to analyze the tertiary objective of the incidence of skin blistering and contact dermatitis between groups. Complications were assessed and graded as per the published Memorial Sloan Kettering Cancer Center Secondary Surgical Events system.[18] In brief, the Memorial Sloan Kettering Cancer Center Secondary Surgical Events system grading is as follows: grade 1 requires only bedside care or oral medications; grade 2 requires intravenous medications or transfusion; grade 3 requires radiologic, endoscopic, or operative interventions; grade 4 leads to chronic disability or organ resection; and grade 5 is death.[18] Blinding was not possible owing to the nature of interventions. However, the principal investigator (M.M.L.) was blinded to the composite results of the primary outcome of wound complications throughout trial conduct.

The study was terminated early after an interim analysis demonstrated low probability of showing a difference between the two groups at the end of the study. For the interim analysis (n=444/684 planned patients for enrollment), the Z-test statistic was 0.328 (with *P*=.797 by adjusting for second look). A post hoc design with two planned interim analyses provided a first-look futility boundary of ±0.29 and a second-look futility boundary of ±0.61. The z of 0.328 fell within the second-look futility boundaries. Also, the conditional power,[19] which calculates the probability that the final results at n=684 would be statistically significant given the data observed at n=444, was 3.9%. A complete description of study methods, including statistical design, can be found in the protocol (Appendix 1, available online at http://links.lww.com/AOG/C173).

RESULTS

Of 663 screened patients, 289 were randomized to negative pressure wound therapy (254 evaluable

participants) and 294 to standard gauze (251 evaluable participants), for a total of 505 evaluable patients (Fig. 1). Reoperations within 30 days of surgery all were performed to manage a postoperative complication unrelated to the laparotomy wound. Baseline patient demographics, as well as clinical and perioperative factors, were generally well balanced (Table 1).

The rate of wound complications was 17.3% (n=44) for the negative pressure wound therapy (NPWT) group and 16.3% (n=41) for the gauze group, for an absolute risk difference of 1% (90% CI −4.5 to 6.5%; *P*=.77) (Table 2). The diagnosis of wound complication was made after hospital discharge in 78 (92%) of the 85 patients who developed a wound complication (42 [95%] of 44 in the NPWT group and 36 [88%] of 41 in the gauze group). The number and severity of wound complications was also similar between groups; the majority of patients had only one type of wound complication and a grade 1 complication. No patient required surgical intervention for a wound complication. A multivariate logistic regression model was used to account for the statistical difference in diabetes and median estimated blood loss between the groups in which the association of treatment group with rate of wound complication remained nonsignificant (odds ratio [OR] 0.99; 95% CI 0.62–1.60).

The individual rates of wound infection, separation, seroma, and hematoma (secondary endpoints) were similar between the groups (Appendix 1, http://links.lww.com/AOG/C173). In the group of women with BMIs of 40 or higher, 7 (47%) of the 15 randomized to the NPWT group, compared with 6 (35%) of the 17 in the gauze group, developed a wound complication (*P*=.51). In the NPWT group only, the median length of stay was 5 days (range 3–43 days) in those who developed a wound complication, compared with 6 days (range 2–26) in those who did not (*P*=.95).

Skin blistering occurred in 33 patients (13%) in the NPWT group and three (1.2%) in the standard gauze group (*P*<.001) (Table 3). Contact dermatitis occurred in six (2.4%) and four (1.6%) patients, respectively (*P*=.75). The rate and severity of wound pain was low overall, and similar between groups (*P*=.29). All other complications and serious adverse events were not related to the negative pressure wound therapy device or gauze.

We performed additional post hoc exploratory analyses to test the association of various clinicopathologic factors with the primary outcome of wound complication (Appendices 2 and 3, available online at http://links.lww.com/AOG/C173). The median BMI was 26 (range 17–60) for those who did not develop a wound complication and 32 (range 17–56) for those who did (*P*<.001). A wound complication occurred in 13 (41%) of those with BMIs of 40 or higher and in 72 (15%) of those with BMIs less than 40 (*P*<.001).

On multivariate analysis, only increasing BMI (unit of 1) was independently associated with the

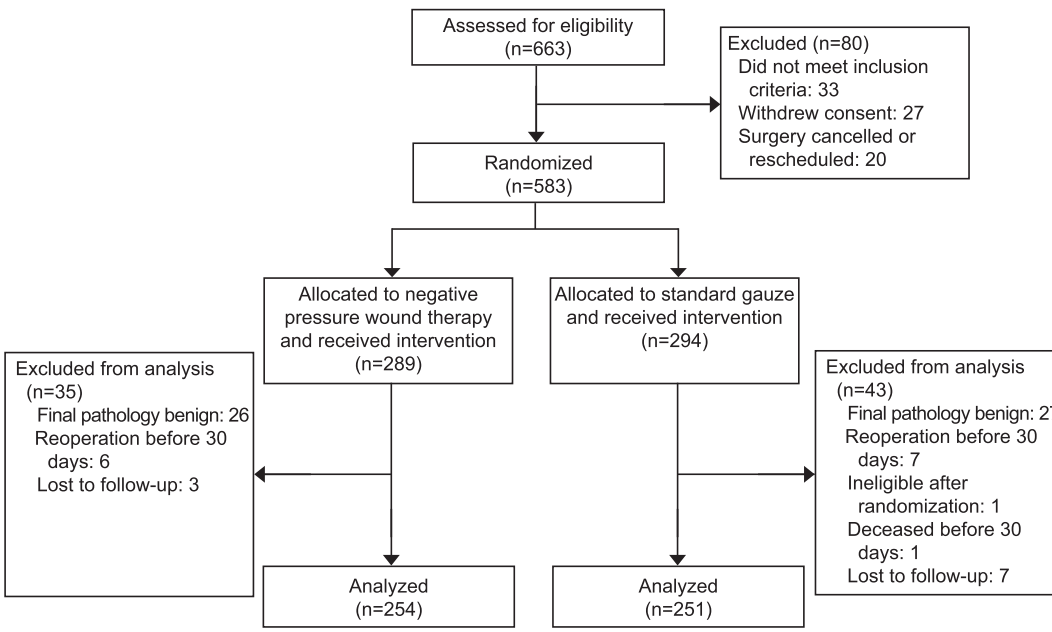

Fig. 1. CONSORT (Consolidated Standards of Reporting Trials) protocol flow diagram.
Leitao. Postoperative Negative Pressure Wound Therapy. Obstet Gynecol 2021.

Table 1. Baseline Characteristics of the 505 Evaluable Participants

Characteristic	NPWT Group (n=254)	Standard Gauze Group (n=251)
Age (y)	60 (20–85)	61 (23–87)
BMI (kg/m^2)	26 (18–60)	26 (17–56)
Medical comorbidities		
Hypertension	85 (34)	86 (35)
Diabetes	36 (14)	20 (8)
Vascular disease	7 (2.8)	12 (5)
Pulmonary disease	22 (9)	23 (9)
Liver disease	4 (1.6)	2 (0.8)
Kidney disease	1 (0.5)	1 (0.5)
Smoking status		
Never	143 (57)	152 (61)
Current	10 (4)	11 (4)
Former	97 (39)	87 (35)
No data	4	1
Prior abdominal surgery	175 (70)	168 (68)
Current alcohol use (any)	116 (47)	124 (50)
Prior radiation therapy exposure	7 (2.8)	8 (3.2)
Prior chemotherapy exposure	85 (34)	79 (32)
Indication for current laparotomy		
Ovary, fallopian tube, peritoneal cancer	203 (80)	207 (82)
Uterine cancer	37 (15)	32 (13)
Cervical cancer	4 (1.6)	2 (0.8)
Other	5 (2)	5 (2)
Benign	5 (2)	5 (2)
Preoperative hemoglobin (g/dL)	12 (7.6–15)	12 (7.5–16.4)
Preoperative serum albumin (g/dL)	4.1 (0.9–4.9)	4.1 (1.6–5.3)
Presence of ascites	49 (20)	40 (16)
Bowel resection at current laparotomy	92 (37)	92 (37)
Estimated blood loss (mL)	400 (5–3,200)	300 (5–3,300)
Transfusion given	46 (18)	31 (12)
Operative time (min)	291 (56–701)	256 (60–786)
Wound classification		
Clean	16 (6)	11 (4)
Clean-contaminated	229 (91)	236 (94)
Contaminated or dirty	6 (2.4)	3 (1.2)

NPWT, negative pressure wound therapy; BMI, body mass index.
Data are median (range) or n (%).
Categorical variables were tested with the Wilcoxon rank sum test. For yes–no variables, only "yes" counts are shown. Continuous variables were tested with the Fisher exact test.

development of a wound complication (adjusted OR 1.10; 95% CI 1.06–1.14; Appendix 3, http://links.lww.com/AOG/C173). Multivariate logistic regression to predict wound complication for only BMI and trial group showed an adjusted OR of 1.11 (95% CI 1.07–1.14) for BMI and an adjusted OR of 0.99 (95% CI 0.60–1.61) for gauze compared with negative pressure wound therapy.

DISCUSSION

The results of our randomized trial do not support the routine use of prophylactic negative pressure wound therapy at the time of laparotomy incision closure in women who are undergoing surgery for gynecologic malignancies or in morbidly obese women who are undergoing laparotomy for benign indications. The trial was appropriately terminated based on futility, with resulting wound complication rates of 17% for the NPWT group and 16% for the standard gauze group. Exploratory analyses showed that only increasing BMI was associated with the development of a wound complication, which is in line with the known risks of increasing BMI and overall surgical morbidity. Even after adjusting for BMI, negative pressure wound therapy did not lower the rate of wound complications.

A recent meta-analysis of 44 randomized clinical trials among a wide range of surgical specialties and procedures using various available negative pressure wound therapy systems reported a reduction in

Table 2. Wound Complication Rates (Primary Endpoint) and Number or Grade of Complication Subtypes (Secondary Endpoints)

	NPWT Group (n=254)	Standard Gauze Group (n=251)	*P*
Overall wound complication	44 (17.3)	41 (16.3)	.77
Inpatient*	2	5	
Outpatient†	42	36	
No. of wound complication subtypes per patient			.49
1	33 (13)	27 (11)	
2	7 (2.8)	12 (5)	
3	4 (1.6)	2 (0.8)	
No complication	210 (83)	210 (84)	
Maximum wound complication grade‡			.80
1	35 (14)	36 (14)	
2	5 (2)	3 (1.2)	
3	4 (1.6)	2 (0.8)	
No complication	210 (83)	210 (84)	

NPWT, negative pressure wound therapy.
Data are n (%) unless otherwise specified.
* Inpatient based on assessment while inpatient until discharge or postoperative day 7, whichever came first.
† Outpatient based on assessment from discharge or postoperative day 7 until postoperative day 30 (±5 days).
‡ Per the Memorial Sloan Kettering Cancer Center Secondary Surgical Events system.[18]

overall surgical site infection, wound dehiscence, and wound seroma but not wound hematoma or skin blistering.[20] A statistically significant pooled 40% reduction in surgical site infection risk was reported. The type of negative pressure wound therapy system used was not reported in many of the studies, there was concern for significant biases, and some used patient-based assessments of primary outcome. The authors concluded that the overall evidence for surgical site infection use was moderate. A Cochrane analysis reported negative pressure wound therapy systems may reduce the rate of surgical site infections but not wound dehiscences,[17] which seems somewhat counterintuitive because these devices are superficially placed, mechanical, nondrug devices. One would expect to see the most benefit in superficial surgical site infections or wound dehiscence rates. The authors concluded the available evidence was of low or very low certainty for all outcomes, with very serious risk of bias and imprecision.[17]

Our findings are also consistent with two recently published, large, well-designed and conducted randomized clinical trials. Hussamy et al[21] randomized 441 morbidly obese women who were undergoing cesarean delivery to standard dressing or negative pressure wound therapy. This study was designed to find a 50% reduction in the wound complication rate, not overall surgical site infection, similar to our study. The overall wound complication rate was 17% in the NPWT group and 19% in the standard group (P=.54).[21] Costa et al[22] recently reported the results of their randomized trial of 1,548 patients who were undergoing surgery for lower limb fractures in whom the skin was closed. They too reported that negative pressure wound therapy did not reduce the rate of wound complications.[22] Furthermore, a recent randomized trial that evaluated prophylactic negative pressure wound therapy compared with standard dressing immediately after cesarean delivery was also terminated early after a planned interim analysis demonstrated increased adverse events among the former group, as well as futility for the primary outcome—rate of superficial or deep surgical site infections.[23]

Table 3. Wound Dressing–Specific Events (Tertiary Endpoint)

	NPWT (n=254)	Standard Gauze (n=251)	*P*
Skin blistering	33 (13)	3 (1.2)	<.001
Contact dermatitis	6 (2.4)	4 (1.6)	.75
Wound pain* (yes)	6 (2.4)	2 (0.8)	.29
VAS pain level			
4	1 (0.4)	0 (0)	
5	1 (0.4)	1 (0.4)	
6	2 (0.8)	0 (0)	
8	1 (0.4)	1 (0.4)	
10	1 (0.4)	0 (0)	

NPWT, negative pressure wound therapy; VAS, visual analog scale.
Data are n (%) unless otherwise specified.
* Using VAS—highest value captured at either the inpatient or outpatient assessment form.

A key strength of our study is that randomization occurred only after full skin closure. Randomization at the last possible moment is critical to further ensure a significant reduction in clinician bias. Of note, the other two recent negative trials also randomized after skin closure.[21,22] Another strength of our study is that primary outcome assessments were performed directly by trained professionals. Additionally, the principal investigator was blinded to the overall composite rate of the primary outcome during the enrollment and conduct of the trial. The majority of patients enrolled in our study were at high risk for wound complications, because the vast majority underwent extensive cytoreductive surgeries for ovarian cancer, and nearly 40% also underwent a concurrent bowel resection.

One of the limitations of our study is that the number of morbidly obese patients was low (n=32). Therefore, the generalizability to the morbidly obese patient undergoing laparotomy is limited. We did not note an obvious benefit within this small subgroup, but this analysis is limited. Another potential limitation is that we chose a composite endpoint of wound complication and we did not look at fascial or organ–space surgical site infection rates. We also were not able to blind surgeons or patients to the randomization group owing to the nature of the interventions used (gauze vs negative pressure wound therapy system).

Negative pressure wound therapy systems may be useful in certain settings, such as in the management of wounds left open primarily or complex disrupted postoperative wounds. The associated cost and material waste, however, is not merited as a prophylactic intervention to reduce wound complications after incision closure, because it did not reduce the rate of wound complications in our study. Furthermore, there was significantly more skin blistering with the negative pressure wound therapy system.

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Authors' Data Sharing Statement

Will individual participant data be available (including data dictionaries)? *Yes.*

What data in particular will be shared? *All data will be shared upon reasonable request.*

What other documents will be available? *The study protocol and statistical analysis plan will be made available.*

When will data be available (start and end dates)? *The data will become available starting on the publication data for up to 3 years.*

By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? *Data will be shared through institutional agreements.*

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