Published in final edited form as:

Gynecol Oncol. 2014 August ; 134(2): 233–237. doi:10.1016/j.ygyno.2014.06.012.

A phase II trial of a surgical protocol to decrease the incidence of wound complications in obese gynecologic oncology patients

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Abstract

Objectives—Obese women have a high incidence of wound separation after gynecologic surgery. We explored the effect of a prospective care pathway on the incidence of wound complications.

Methods—Women with a body mass index (BMI) ≥ 30 kg/m² undergoing a gynecologic procedure by a gynecologic oncologist via a vertical abdominal incision were eligible. The surgical protocol required: skin and subcutaneous tissues to be incised using a scalpel or cutting electrocautery, fascial closure using #1 polydioxanone suture, placement of a 7mm Jackson-Pratt drain below Camper's fascia, closure of Camper's fascia with 3-0 plain catgut suture and skin closure with staples.

Wound complication was defined as the presence of either a wound infection or any separation. Demographic and perioperative data were analyzed using contingency tables. Univariable and multivariable regression models were used to identify predictors of wound complications. Patients

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Conflict of Interest Statement

The authors declare that there are no conflicts of interest.

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were compared using a multivariable model to a historical group of obese patients to assess the efficacy of the care pathway.

Results—105 women were enrolled with a median BMI of 38.1. Overall, 39 (37%) had a wound complication. Women with a BMI of 30–39.9 kg/m² had a significantly lower risk of wound complication as compared to those with a BMI >40 kg/m² (23% vs 59%, $p<0.001$). After controlling for factors associated with wound complications the prospective care pathway was associated with a significantly decreased wound complication rate in women with BMI<40kg/m² (OR 0.40, 95% C.I.: 0.18–0.89).

Conclusion—This surgical protocol lead to a decreased rate of wound complications among women with BMI 30–39.9 kg/m².

Introduction

Approximately 500,000 surgical site infections occur annually in the US.[1, 2] Surgical site complications, including both wound infections and separations, may result from hematomas, seromas or infections of subcutaneous tissues. Surgical site complications lead to worse patient quality of life, more outpatient and emergency room visits, more readmissions, a higher rate of intensive care unit admissions, extended hospital length of stay as well as more home services, with an estimated increase in costs of at least \$3500 per complication. [3–6] These complications are associated with increasing body mass index (BMI)[7–9] and subcutaneous fat thickness.[10, 11] Given the current obesity epidemic, the burden of surgical site complications will likely increase.

Several interventions to reduce wound complications have been assessed, including pre-surgical antibiotic treatment and surgical site preparation,[2, 12] maintenance of normothermia, [13, 14] subcutaneous drain placement or suture closure, [15–20] subcuticular skin closure,[21–24] retention sutures,[25] wound protection devices,[26] negative pressure dressings[27] and skin sealants.[28] The results of these studies have been conflicting; many limited to obstetrical patients or have used varying definitions of obesity. Thus, there are limited data specific to gynecologic patients, particularly gynecologic oncology patients, a group with more co-morbidities and a high rate of obesity.

We previously reported a 46% wound complication rate in women undergoing abdominal surgery via a vertical midline incision with a BMI 30 kg/m². [7] Wound complications were associated with increasing BMI, prior abdominal surgery, co-morbidities, and length of surgery. In response, we instituted a quality improvement intervention for management of all women with BMI 30 kg/m² undergoing abdominal surgery. The goal of this Phase II study was to assess the effect of the intervention on wound complication rate and identify risk factors for wound complications.

Methods

Beginning January 1, 2012 the Division of Gynecologic Oncology at Washington University School of Medicine instituted as a quality improvement measure a consensus protocol for management of obese women undergoing surgery via midline vertical abdominal incisions.

The intervention was based on literature review and clinical experience. To allow prospective data collection, the study was approved by the Human Research Protection Office (HRPO) of the Washington University School of Medicine (HRPO# 201108303).

All women with surgery planned by one of the members of the Division of Gynecologic Oncology were identified in the outpatient clinics and approached to determine their eligibility and interest in participating in the study. Women were eligible if they were between the ages of 18–89, with a BMI ≤ 30 kg/m² undergoing a gynecologic procedure via a vertical abdominal incision. Exclusion criteria included planned laparoscopic surgery, planned panniculectomy or other plastic surgery procedure at the time of laparotomy, prior history of hernia repair with mesh or planned mesh hernia repair at the current procedure, enterotomy or intestinal surgery, a history of prior radiation to the abdomen or pelvis, concurrent pregnancy, current incarceration, or inability to provide informed consent, including inability to understand spoken English. In addition to their surgical consent form, women interested in participating in the study signed a separate consent form to participate in this surgical protocol prior to surgery.

Surgical Protocol

The skin and subcutaneous tissues were incised using a scalpel or cutting electrocautery. Use of coagulation current on the skin or subcutaneous tissues was not allowed, except focally to attain hemostasis. At the conclusion of surgery, the fascia was closed using two #1 looped polydioxanone sutures, each anchored in opposite ends of the incision and tied in the middle. After irrigation of the subcutaneous tissues, a 7mm Jackson-Pratt drain was placed below Camper's fascia, which in turn was closed with 3-0 plain catgut suture. The skin was closed with staples. Dressings were retained for at least twenty-four hours. Jackson-Pratt drains were removed just prior to hospital discharge. Staples were to be retained for at least two weeks.

Data Collection

Charts of all women who consented to participate in the trial were evaluated and demographic and clinical data were collected. The measurements of the surgical wound (length and depth) were recorded by the surgical team for each case, and this information was abstracted from operative notes. Operative notes were also reviewed to assess compliance with the surgical protocol. Nursing and anesthesia notes as well as post-operative charts were reviewed to identify surgical times, American Society of Anesthesiologists (ASA) class, nature and timing of antibiotic prophylaxis, procedure performed, administration of supplemental oxygen and minimum oxygen saturation. Both tight glucose control and maintenance of normothermia[13, 14] have been associated with a decreased rate of surgical site complications, as such, these data were also collected. All patients were seen one or more times in the clinic within eight weeks of surgery for an assessment of their surgical wound. Clinic notes were reviewed for the presence of wound complications and measurements of wound separation depth and length.

Statistical Analysis

The primary outcome for our study was a wound complication within eight weeks of laparotomy. Wound complication was defined as seroma, hematoma, separation, or infection requiring additional medical and/or surgical management within eight weeks of laparotomy. Descriptive statistics were used to characterize the clinical and demographic attributes of the study sample. Logistic regression was initially performed to identify the relationship between pre-operative, operative and post-operative variables in the database and the primary outcome of wound complication. Variables with $p < 0.20$ were candidates for entry into a multivariable logistic model used to assess the relative importance of pre-operative, operative and post-operative characteristics. We tested all candidate variables by a backwards selection procedure to identify factors that were independently correlated with wound separation.

We previously demonstrated a 40% risk of wound separation in women with BMI between 30 and 40 kg/m². A sample size calculation was performed that determined that we would need to enroll 105 patients to have 80% power to identify a 33% reduction in wound separation with an expected 20% non-evaluable cases with a two-sided $p < 0.05$.

To evaluate the efficacy of our surgical intervention protocol, we compared the outcome of wound complication in this patient population with those patients with a BMI 30 kg/m² reported in our prior paper. A multivariable logistic regression model was designed to assess for the effect of the surgical intervention on the incidence of wound complication after controlling for factors associated with wound complications. An interaction between BMI and treatment group was noted and as such, analyses were dichotomized by BMI $<$ or 40 kg/m².

All analyses were two-sided and significance was set at a p -value of 0.05. Statistical analyses were performed using Stata v9.2 (College Station, TX).

Results

Between January 2012 and March 2013, 125 women were prospectively enrolled in this study. Twenty women were excluded from the final analysis as screen failures, leaving 105 women evaluable. Reasons for exclusion included: Bowel surgery ($n=7$), Pfannenstiel incision ($n=4$), robotic/laparoscopic surgery ($n=4$), surgical protocol not followed ($n=3$) and BMI < 30 kg/m² ($n=2$). Table 1 summarizes the baseline demographics and clinical characteristics for the cohort. Median age at the time of surgery was 58.6 years (range: 19.2–85). Median BMI was 38.1 kg/m² (range: 30.0–76.4). Eighty percent of the patients were Caucasian and 20% were African-American. Thirty-three percent of the procedures were done for benign indications.

Surgical characteristics are summarized in Table 2. The median duration of surgery was 142 minutes and the median estimated blood loss (EBL) was 300 mL. Antibiotics were given in 99 (94%) of cases. Of the six cases that did not receive antibiotics, three of the procedures were clean procedures comprising only adnexectomy for which antibiotic prophylaxis was not indicated. Three cases (3%) did not have documentation of antibiotic administration. Of

the 99 cases where antibiotics were administered, 93 (94%) were administered prior to incision while in the remaining six cases antibiotics were administered after the incision had already been made. Median time from surgery to staple removal was 15 days (Interquartile range (IQR): 12–16).

Thirty-nine patients (37%) had a wound complication within eight weeks of surgery, with 33 of these (31%) having a wound separation. Median length and depth of wound separation, when recorded, were 5cm and 4cm, respectively (IQR: 5–8.5cm and 4–5cm, respectively). Of the 33 patients who had a wound separation, 25 (76%) required packing and/or a vacuum assisted closure device.

Factors associated with wound complications are summarized in Table 3. BMI 40 kg/m^2 , ASA class 3 and subcutaneous depth 4 cm were all associated with a higher risk of wound complication (HR: 4.61, 2.31 and 2.66, respectively). Longer duration of surgery, inappropriate dosing of antibiotics prior to incision, $\text{EBL} > 500 \text{ mL}$, history of prior surgery, prior tobacco use, diabetes mellitus and surgery for a cancer diagnosis were not associated with a higher risk of wound complication.

We investigated the effects of maintenance of normothermia during the operative procedure, hyperglycemia and oxygen saturation on the incidence of wound infections. No differences were found in the average nadir intraoperative temperature (35.8 vs 35.6, $p=0.08$), the average maximum glucose recorded during hospitalization (176 vs 179, $p=0.82$) nor in the lowest measurement on pulse oximetry (93.4% vs 94.0%, $p=0.42$) between women with and without wound infections.

A multivariable logistic regression model was fit, using those variables found to be associated with wound complication (BMI 40 , ASA Class 3, duration of surgery > 180 minutes, depth $> 4 \text{ cm}$, $\text{EBL} > 500 \text{ mL}$, cancer diagnosis and appropriate antibiotics given prior to surgery). After controlling for the effect of BMI on wound complication, none of the other variables were statistically associated with development of a wound complication.

We have previously reported our institution's experience with wound complications.[7] As such, we compared the incidence of wound complications in our prospective cohort to the retrospective cohort reported previously. Of the 373 women included in our prior study, 199 (53%) had a BMI 30 kg/m^2 and surgery via a midline vertical incision and were included in our comparison. Forty-six percent of the women in the historical cohort had a wound complication as compared to 37% in our prospective cohort, though this did not reach statistical significance ($p=0.16$).

An interaction between BMI and study group was noted, so further analysis was stratified by BMI $< 40 \text{ kg/m}^2$ vs 40 kg/m^2 . Women with BMI $< 40 \text{ kg/m}^2$ had a lower rate of wound complication after treatment with our new surgical protocol as compared to historical controls (23% vs 39%, $p=0.038$). No benefit to the new surgical protocol was seen in women with BMI 40 kg/m^2 (59% vs 56%, $p=0.76$).

A multivariable logistic regression model was constructed after stratifying by BMI. Predictors of wound complications both in this study and in our prior study were included

and are shown in Table 4. In women with a BMI $< 40\text{kg/m}^2$, surgical management in accordance with this prospective trial was associated with a 60% reduction in the incidence of wound complication (OR 0.40, 95% C.I.: 0.18–0.89). Prior surgery, duration of surgery > 180 minutes and inappropriate dosing of antibiotics prior to surgery were all significantly associated with a higher risk of wound complication in patients with BMI $< 40\text{kg/m}^2$ (OR: 2.85, 2.53 and 9.57, respectively). In women with a BMI $\geq 40\text{kg/m}^2$ no benefit to the surgical pathway was seen (OR 1.32, 95% C.I.: 0.59–2.96). In this latter group, only duration of surgery > 180 minutes was significantly associated with a higher risk of wound complication (OR: 3.01, 95% C.I.: 1.32–6.91).

Discussion

In this study a surgical wound management protocol was associated with a decrease in the high rate of wound complications seen in obese patients undergoing gynecologic and gynecologic oncology surgeries with a BMI $30\text{--}39.9\text{kg/m}^2$, but not in patients with a greater BMI. Of the 105 women enrolled in the study only twenty-five (24%) of patients had a clinically significant wound separation that required packing. The remainder had either a wound infection managed with antibiotics or a wound separation that did not require packing.

We assessed for factors associated with wound complications. While BMI $> 40\text{kg/m}^2$, ASA class 3 and duration of surgery > 180 minutes were associated with a higher risk of wound infection after controlling for BMI $> 40\text{kg/m}^2$ the remaining factors were not significantly associated with a higher rate of wound complications. Factors previously associated with a higher risk of wound complication (appropriate dosing of antibiotics prior to incision, history of prior surgery, prior tobacco use and diabetes mellitus) were not found to be significantly associated with wound complications in patients with a BMI $> 40\text{kg/m}^2$. This may be due to the relatively small number of patients in this study but suggests that interventions to optimize these factors are unlikely to lead to large improvements in wound separation rates.

To determine if this surgical protocol resulted in a decreased rate of wound complication we compared the 105 women treated with our new protocol to 199 historical controls previously reported with a BMI $30\text{--}39.9\text{kg/m}^2$. After controlling for relevant factors, women treated with a BMI $< 40\text{kg/m}^2$ treated with the new surgical protocol had a 60% lower risk of wound complications. Women with a BMI $\geq 40\text{kg/m}^2$ did not appear to benefit from these surgical interventions. This may reflect that interventions that decrease the risk of complications in those women with a BMI $< 40\text{kg/m}^2$ are insufficient to compensate for the significantly higher risk of wound complications seen in those women with a BMI $\geq 40\text{kg/m}^2$.

Factors that were significantly associated with risk of wound complication in women with a BMI $< 40\text{kg/m}^2$ were not found to be significantly associated with wound complication in women with a BMI $\geq 40\text{kg/m}^2$. While prior studies have found that duration of surgery, higher estimated blood loss and tardy administration of antibiotics were associated with a higher rate of wound complications. Our results were consistent, though they did not achieve statistical significance.

Particular strengths of this study include that it was designed and implemented in a prospective fashion. Most of the data was collected prospectively limiting the bias introduced by chart review. Additionally, this is amongst the larger prospectively designed studies assessing techniques to decrease the incidence of wound complications in gynecologic patients.

Our study has a number of limitations. Though patients were enrolled prospectively in this quality improvement protocol, some of the data analyzed was compiled as the study progressed from review of patients' charts and is limited by completeness of the documentation. Additionally, while we attempted to determine the benefit of the surgical pathway by comparing outcomes to a group of historical controls this was not a randomized controlled trial and so our ability to prove causality is limited. Similarly, while our data suggests that the surgical protocol leads to improved outcomes compared to historical controls the possible impact of other confounders can not be fully evaluated in this study. As multiple interventions were combined in this protocol, the benefit of each individual intervention can not be determined. Lastly, the majority of the women in this study were non-Hispanic, Caucasian, limiting generalizability to women of other ethnicities or races.

Our study suggests that this surgical care pathway may decrease the incidence of wound complications in obese women with a BMI $<40\text{kg/m}^2$. Despite these interventions nearly 25% and 60% of women with BMI 30–39.9 and $\geq 40\text{kg/m}^2$ had a wound complication. These data highlight the need for additional studies and interventions to decrease post-operative wound complications. Future studies are necessary to assess the benefit of individual components of this protocol as well as other interventions, such as subcuticular skin closure.

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Highlights

- A surgical protocol to reduce the rate of wound complications was instituted.
- We found a 60% decrease wound complications in women with BMI 30–39.9.

Table 1

Patient Demographic and Clinical Characteristics (n=105)

	n (%)
Age (years)	
<40	14 (13)
40–49	19 (18)
50–59	23 (22)
60–69	32 (30)
70	17 (16)
Body mass index (kg/m ²)	
30–39.9	64 (61)
40–49.9	30 (29)
50	11 (10)
Race	
Caucasian	84 (80)
Non-Caucasian	21 (20)
Prior abdominal surgery	
No	38 (36)
Yes	67 (64)
Indication for surgery	
Uterine cancer	55 (52)
Ovarian cancer	14 (13)
Cervical cancer	1 (1)
Benign	35 (33)
Prior Tobacco Use	
No	75 (71)
Yes	30 (29)
ASA Class	3
No	54 (51)
Yes	51 (49)

Table 2**Surgical Characteristics (n=105)***

Estimated blood loss (mL)	300 (150–400)
Duration (minutes)	142 (120–163)
Antibiotics given [†]	99 (97)
Antibiotics given before surgery	93 (94)
Procedure	
Adnexectomy alone	11 (11)
TAH-BSO [‡]	45 (43)
Cancer staging with lymph nodes	38 (36)
Debulking surgery	7 (7)
Radical hysterectomy	1 (1)
Other	3 (3)
Lowest intraoperative temperature (celsius)	35.9 (35.4–36.2)
Maximum inpatient glucose level (units)	163 (145–193)
Minimum O2 saturation within 24 hours postoperatively (%)	94 (93–96)

* Categorical variable are presented as n (%) and continuous variables are presented as median (interquartile range).

[†] Data reflects exclusion of 3 patients who underwent a clean procedure and antibiotics were not indicated.

[‡] TAH-BSO: Total abdominal hysterectomy, bilateral salpingo-oophorectomy.

Table 3

Association between clinical factors and wound complication (n=105)

	OR (95% CI)
Body mass index 40 (kg/m ²)	4.61 (1.97–10.78)
ASA class 3	2.31 (1.03–5.20)
Subcutaneous depth 4cm	2.66 (1.01–7.05)
Duration >180 minutes	3 (0.98–9.21)
Antibiotics before surgery	2.83 (0.83–9.60)
Estimated blood loss >500mL	2.5 (0.89–7.01)
Prior surgery	0.6 (0.27–1.37)
Prior tobacco use	0.79 (0.33–1.93)
Diabetes Mellitus	0.96 (0.36–2.54)
Cancer diagnosis	1 (0.43–2.32)

Table 4

Multivariable logistic regression model assessing the effect of the prospective surgical pathway on wound complication.

	BMI <40kg/m² (n=175)	BMI ≥40kg/m² (n=129)
	OR (95% CI)	OR (95% CI)
New surgical pathway study	0.40 (0.18–0.89)	1.32 (0.59–2.96)
Prior surgery	2.85 (1.38–5.89)	1.35 (0.65–2.81)
Duration > 180 minutes	2.53 (1.17–5.48)	3.02 (1.32–6.91)
Antibiotics not given prior to incision	9.57 (1.66–55.25)	0.62 (0.07–5.10)
Diabetes mellitus	2.10(0.95–4.67)	0.81 (0.38–1.73)