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

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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 a BMI of 30–39.9.

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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/m^2 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 7 mm 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 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/m^2 had a significantly lower risk of wound complication as compared to those with a BMI >40 kg/m^2 (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 <40 kg/m^2 (OR 0.40, 95% C.I.: 0.18–0.89).

Conclusion. This surgical protocol leads to a decreased rate of wound complications among women with a BMI of 30–39.9 kg/m^2.

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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 normothemia [13,14], subcutaneous

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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 $\geq$30 kg/m^2 [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 $\geq$30 kg/m^2 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 $\geq$30 kg/m^2 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 7 mm 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 24 h. 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/m^2. 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 $\geq$30 kg/m^2 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 $\geq$40 kg/m^2.

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/m^2 ($n = 2$). 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/m^2 (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 min 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

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