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Risk of postoperative venous thromboembolism after minimally invasive surgery for endometrial and cervical cancer is low: A multi-institutional study

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HIGHLIGHTS

- The 30-day risk of venous thromboembolism after minimally invasive surgery for endometrial and cervical cancer is extremely low (0.5%).
- The value of routine use of heparin thromboprophylaxis is uncertain in this patient population.
- New risk prediction models for venous thromboembolism specific to minimally invasive surgery are urgently needed.

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ABSTRACT

Objective. To determine the 30-day prevalence of venous thromboembolism (VTE) after minimally invasive surgery (MIS) for endometrial (EC) and cervical cancers (CC).

Methods. A retrospective cohort study at two large tertiary care centers between 2006 and 2011. Patients having MIS for EC or CC were included. Cases converted to laparotomy were excluded. The primary outcome measure was clinically diagnosed VTE within 30 days of operation.

Results. Of the 558 patients, 90% had EC and 10% had CC. Modalities of hysterectomy included robotic (88%), vaginal (9%), and laparoscopic (3%). A total of 66% had pelvic and 35% had paraaortic lymphadenectomy. The VTE prophylaxes were sequential compression devices (100%) and heparin (39%). There were no VTE events during hospital stay (95% CI, 0.0%–0.7%). The 30-day prevalence of VTE was (0.5%; 95% CI, 0.1%–1.6%). The hitherto recommended risk criteria for giving extended 30-day thromboprophylaxis by the American College of Obstetrics and Gynecologists (ACOG) or by the American Society of Clinical Oncology (ASCO) did not predict risk of VTE in our population.

Conclusions. The prevalence of VTE in EC and CC undergoing MIS is very low. The existing 30-day risk prediction models proposed by the ACOG and ASCO stem from open surgery patients and do not appear to apply to MIS patients. Certainly, we found no evidence supporting the use of extended prophylactic heparin in this setting. Further research is urgently needed to define the role of any duration of thromboprophylaxis in MIS patients with endometrial or cervix cancer.

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Introduction

Endometrial and cervical cancers are diagnosed in 47,000 and 12,000 women respectively, in the United States every year [1]. For the vast majority of these women, surgery plays a major role in therapy. Of all the potentially life-threatening perioperative complications, venous thromboembolism (VTE) is potentially one of the most preventable [2]. In fact, perioperative VTE has been classified by the Centers for Medicare and Medicaid Services as a "never event" in certain surgeries [3].

Historically, VTE prophylaxis has been recommended for the duration of hospitalization starting shortly before surgery [4]. However, more than half of VTE events associated with gynecologic cancer surgery occur more than 7 days after surgical procedures [5,6]. Naturally, these observations have shifted the focus of VTE prophylaxis from short-term (the duration of hospitalization) to long-term prophylaxis lasting for 4–6 weeks for patients undergoing high-risk surgical operations for cancer [7]. In fact, in the practice bulletin on the prevention of VTE, the ACOG urges for consideration of VTE prophylaxis for up to 28 days postoperatively [4] for high-risk cancer patients. The Society of Gynecologic Surgeons

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Systematic Review Group had a similar stance for high-risk patients undergoing gynecologic cancer surgery [8].

Recently, minimally invasive surgery (MIS) has demonstrated lower complication rates and shorter hospital stay for women with gynecologic cancers and is being adopted with increasing frequency in EC and CC. [9–12]. In a variety of non-gynecological surgical procedures, MIS is associated with a much lower prevalence of VTE when compared to open surgery [13]. Despite the increased use of MIS for gynecologic malignancies, the evidence to guide thromboprophylaxis after MIS for EC and CC is insufficient. As such, the ACOG recommends, "Until more evidence is accumulated, patients undergoing laparoscopic surgery should be stratified by risk category (and provided prophylaxis) similar to patients undergoing laparotomy" [4]. This summary statement provides strong incentive to investigate the risk profile of MIS cases for EC and CC.

Several studies have reported a low prevalence of VTE after MIS as a part of reporting general complications but none provided details of the pharmacologic prophylaxis and risk factors specific to VTE [10,14–18]. To date, there have been two dedicated investigations reporting on the prevalence of VTE after laparoscopic gynecologic surgery. The first report had the limitation of being comprised of more than half benign cases and only a small number ($n = 109$) of patients having complex, and potentially higher risk, cancer operations such as lymphadenectomy or radical hysterectomy [19]. Most recently, Sandadi et al. [20] reported on a large series of EC cases treated by MIS and found an overall incidence of VTE of 1.2%. Importantly, the authors noted that only 22% of patients received some type of postoperative heparin anticoagulation, and this allowed them to identify a specific high-risk group (obese women undergoing long surgeries) where the risk could be as high as 10%. The study was limited by relatively small number of high-risk patients (42 cases in the highest risk group). Needless to say, additional comprehensive investigations reporting on the prevalence of VTE after MIS for EC and CC are urgently needed.

Given the paucity of data on VTE after MIS for EC and CC, we undertook the present study. Our objectives were to determine the prevalence of VTE within 30 days of MIS for EC and CC and to investigate the relevance of current guidelines for extended prophylaxis in this cancer cohort treated with MIS.

Methods

This study was approved by the Institutional Review Boards of the Mayo Clinic Rochester, MN, and Wayne State University, Detroit, MI. The study included patients treated at both institutions between 2006 and 2011 with a new diagnosis of EC or CC, requiring at least a hysterectomy for their primary treatment.

The inclusion criteria were (a) diagnosis of EC/CC with the patient undergoing MIS for definitive primary treatment and (b) minimum of 30 days of postsurgical follow-up. The following procedures were considered minimally invasive: (a) vaginal hysterectomy with laparoscopic (including robotic) lymphadenectomy and (b) laparoscopic (including robotic) hysterectomy with/without laparoscopic or robotic lymphadenectomy. The exclusion criteria were (a) conversion to laparotomy during the surgical procedure, (b) incidental diagnosis of ovarian cancer, (c) vaginal hysterectomy without lymphadenectomy, and (d) history of surgery, radiation, or chemotherapy within prior 3 months of the index MIS operation. The study end point was a clinically evident VTE diagnosed by Doppler ultrasound or PE diagnosed by chest-computerized angiography within 30 days of the MIS. Data were collected by retrospective chart review. In addition to any anticoagulants administered, all patients received sequential compression devices (SCD) for the duration of surgery and when in bed in the hospital. Compliance with SCD use was not assessable.

Renal dysfunction was defined as a creatinine >1.0. Diabetes was defined as a fasting glucose value of >126 mg/dl. Hypertension was considered diagnosed if the patient used any antihypertensive medications. Cardiac comorbidity included a history of coronary artery disease, myocardial infarction, or congestive heart failure. The operative time was calculated from incision or insertion of cervical stitch or uterine manipulator, whichever occurred first, to wound closure time. Operative time included the time taken for the frozen section results to arrive from the pathology laboratory (utilized in all Mayo Clinic cases) as well. Estimated blood loss was recorded from the anesthesia records.

The American Society of Clinical Oncology (ASCO) guidelines recommend extended duration of heparin thromboprophylaxis for patients with cancer in the presence of residual disease, history of VTE, or obesity [21]. In our patient population, the patients who met these criteria were labeled as the "ASCO high-risk group" (Table 1). Similarly, the American College of Obstetrics and Gynecologists [4] recommends extended duration heparin thromboprophylaxis if patients have cancer, with a history of VTE or age > 60 years [4]. Patients meeting those criteria in our population were labeled as the ACOG high-risk group (Table 1).

The prevalence of VTE within 30 days after surgery was determined, and 95% confidence intervals (CI) were calculated with the exact Clopper–Pearson method. Comparisons of the VTE prevalence were compared between patients with versus without risk factors using the two-sided Fisher's exact test; however, given the rarity of the VTE, all of the calculated p-values were >0.05 and therefore were not reported.

Results

A total of 611 patients were identified. Of these, 36 (6%) were excluded for being converted from minimally invasive to open during the course of the procedure and 14 (2%) were excluded as they had only vaginal hysterectomy as the definitive surgical procedure for endometrial cancer. Finally, 3 patients (<1%) were excluded because the histology type of the tumor was of metastatic histology (one malignant melanoma, one gestational trophoblastic tumor, and one lobular breast cancer metastatic to uterus). The remaining 558 patients met the inclusion criteria. The baseline characteristics of these patients are given in Table 1. The majority of patients had EC with endometrioid histology and a tumor that was limited to the uterus. Most patients underwent robotic hysterectomy (88%) and the majority had a lymphadenectomy (66%). In terms of VTE prophylaxis, all patients had sequential compression devices (SCDs). Subcutaneous heparin was used for the perioperative duration in 39% (215/558) with an average of 3 doses per patient. Roughly 52% (112/215) of those receiving heparin received the first dose preoperatively with the remainder receiving postoperative therapy only. Two patients developed hematomas (1 incisional and 1 pelvic) that were potentially heparin related complications. Both of these resolved with observation without clinical consequence.

The majority of patients (74%) were obese: 29% had a BMI of ≥29 and <35 kg/m^2, 16% had a BMI of ≥35 and <45 kg/m^2, and 29% had a BMI >45 kg/m^2. The mean operative time was 225.3 min, the mean estimated blood loss was 166.7 ml, and the mean duration of hospital stay was 1.5 days. Hypertension was the most common comorbidity (43%) followed by diabetes and a history of smoking.

We observed only three VTE events (0.5%, 95% CI, 0.11%–1.6%) within 30 days of surgery (Table 2). The timing of occurrence of these events was postoperative days 15, 16, and 23. Hence, the prevalence of in-hospital VTE after MIS for gynecologic cancers was 0/558 (0.0%, 95% CI, 0.0%–0.7%). It is noteworthy that 2 of the 3 VTE events occurred in patients who did not receive perioperative heparin for VTE prophylaxis (2/343 = 0.6%, 95% CI, 0.0%–1.6%).

We evaluated if the ASCO and ACOG criteria were able to define a higher risk VTE population with our cohort of MIS patients. Patients are categorized within Table 1 by ASCO and ACOG criteria. A total of 357 patients would be classified as ASCO high risk, of which 1 (0.3%; 95% CI, 0.01%–1.6%) developed VTE, compared to 2 of the 201 patients (1.0%; 95% CI, 0.12%–3.6%) who were not classified as ASCO high risk. A total of 299 patients met the inclusion criteria for ACOG high risk, of which 2 (0.7%; CI 0.08%–2.4%) developed VTE, compared to 1 of the 259 patients

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