HHS Public Access

Author manuscript

Obstet Gynecol. Author manuscript; available in PMC 2017 July 01.

Published in final edited form as:

Obstet Gynecol. 2016 July ; 128(1): 121–126. doi:10.1097/AOG.0000000000001492.

Venous Thromboembolism in Minimally Invasive Compared With Open Hysterectomy for Endometrial Cancer

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Abstract

Objective—To evaluate whether minimally invasive surgery for endometrial cancer is independently associated with a decreased odds of venous thromboembolism compared with open surgery.

Methods—We performed a secondary analysis cohort study of prospectively collected quality improvement data and examined patients undergoing hysterectomy for endometrial cancer from 2008–2013 recorded in the National Surgical Quality Improvement Program database. Patients undergoing minimally invasive (laparoscopic or robotic) versus open surgery were compared with respect to 30-day postoperative venous thromboembolism. Demographic and procedure variables were examined as potential confounders. Data regarding receipt of perioperative venous thromboembolism prophylaxis was not available. Bivariable tests and logistic regression were used for analysis.

Results—Of 9,948 patients who underwent hysterectomy for the treatment of endometrial cancer, 61.9% underwent minimally invasive surgery and 38.1% underwent open surgery. Patients undergoing minimally invasive surgery had a lower venous thromboembolism incidence (0.7%, n=47) than open surgery patients (2.2%, n=80) ($p<0.001$). In a multivariate model adjusting for age, BMI, race, operative time, Charlson comorbidity score, and surgical complexity, minimally invasive surgery remained associated with decreased odds of venous thromboembolism (aOR 0.36, 95% CI 0.24–0.53) compared with open surgery.

Conclusions—Minimally invasive surgery for the treatment of endometrial cancer is independently associated with decreased odds of venous thromboembolism compared with open surgery.

PRECIS

Minimally invasive surgery for endometrial cancer is associated with a lower incidence of venous thromboembolism compared with open surgery.

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Presented in at the Society for Gynecologic Oncology Annual Meeting March 18th–22nd, 2016.

Financial Disclosure

The authors did not report any potential conflicts of interest.

INTRODUCTION

Minimally invasive surgery, both laparoscopic and robotic, is increasingly being used to treat endometrial cancer (1, 2). Many have documented that gynecologic oncology minimally invasive surgery is associated with a low incidence of venous thromboembolism, ranging from 0.4–2.2% (3–7). However, with the exception of one study, all have been single institution retrospective series with less than 10 venous thromboembolism events. Additionally, all studies have not had a comparative open surgery group. Patients who undergo open surgery may have a higher prevalence of venous thromboembolism risk factors, such as age, obesity and other comorbid conditions. Thus, a direct comparison of incidence without adjustment for these factors is insufficient to conclude that patients undergoing minimally invasive surgery are lower risk.

Given the low incidence of venous thromboembolism in gynecologic oncology minimally invasive surgery, some have advocated that these patients are low risk enough to not require prophylaxis (8). However, endometrial cancer is associated with other risk factors for venous thromboembolism, such as age, operative time, obesity and medical comorbidities. Given the high prevalence of risk factors for venous thromboembolism among endometrial cancer patients, there may be minimally invasive surgery patients that are at sufficient risk to warrant prophylaxis.

Our primary objective was to evaluate whether minimally invasive surgery for the treatment of endometrial cancer is independently associated with a decreased odds of venous thromboembolism compared with open surgery. Our secondary objective was to develop a risk assessment score to predict venous thromboembolism in the minimally invasive surgery endometrial cancer patient.

MATERIALS AND METHODS

This was a secondary analysis cohort study of prospectively collected surgical quality data. The study population was patients who underwent surgery, including a hysterectomy, for endometrial cancer between 2008 and 2013 identified from the American College of Surgeons National Surgical Quality Improvement Program Database using International Classification of Diseases, Ninth Revision codes and Current Procedural Terminology (CPT) codes. The Institutional Review Board at the University of North Carolina at Chapel Hill reviewed this study and declared it exempt from formal review as it does not constitute human subjects research.

The National Surgical Quality Improvement Program database is a national surgical quality database. Trained clinical reviewers prospectively collect preoperative variables and post-operative outcomes for each individual procedure for 30 days following surgery. Periodic auditing, including for data points occurring after hospital discharge, ensures high quality data specifically for post-discharge complications (9). Details of methods of data collection and reliability have been previously reported (10).

Our primary outcome was venous thromboembolism (pulmonary embolism or a deep vein thrombosis) diagnosed within 30-days postoperatively (11). Our exposure was route of surgery, either minimally invasive surgery (total laparoscopic, laparoscopically assisted vaginal or robotic hysterectomy) or open surgery (total abdominal hysterectomy). Of note, CPT codes for laparoscopic-assisted and robotic-assisted hysterectomy are the same and so we were unable to distinguish between these two surgical approaches.

Demographic, medical and operative characteristics were evaluated as potential confounders. Medical factors included body mass index (BMI), smoking, diabetes, hypertension and comorbid conditions measured by the Charlson comorbidity index which was calculated for as previously described (12, 13). Operative factors included total operative time, lymphadenectomy (pelvic or para-aortic) and surgical complexity, defined as the sum of the work relative value units for all CPT codes listed for a given procedure (14). Total relative value units are a commonly used and accepted measure of surgical complexity (15–17). There were no changes in the assigned work relative value units for all included CPT codes during the study period. Potential confounders not available for evaluation were cancer specific variables, such as stage, and data regarding receipt of perioperative thromboembolism prophylaxis.

We initially examined the characteristics of the sample using descriptive statistics. To identify potential confounders, we examined whether independent variables were unequally distributed by route of surgery. Bivariable comparisons were performed using a 2-sample t-test and a Mann Whitney U test for continuous variables, depending on the normality of the distribution, and Pearson’s chi-square test for categorical variables. We fit a logistic regression model, using an analysis of covariance strategy, to estimate the odds ratio for venous thromboembolism by route of surgery, adjusted for confounders.

To construct our minimally invasive surgery venous thromboembolism risk score, we limited our analysis only to minimally invasive surgery patients as defined above. A logistic regression model was used to identify potential predictors of venous thromboembolism. Potential predictors and binary cut points were selected based on previously literature (4, 6). The calibration of this risk score was tested using the goodness of fit test and the discrimination of the model was assessed using the area under the receiver operating characteristic curve. All analyses were performed using SPSS version 20.0 (IBM Corp, Armonk, NY).

RESULTS

We identified 9,948 patients with the demographic and operative characteristics as listed in Table 1. The majority of patients (61.9%) underwent minimally invasive surgery and 38.1% underwent open surgery. Patients who underwent minimally invasive surgery were significantly different than those who underwent open surgery in many ways (Table 2). Patients who underwent minimally invasive surgery were younger and more likely to be White compared to open surgery patients. Patients who underwent minimally invasive surgery were also healthier with lower rates of hypertension, smoking, diabetes, and lower Charlson comorbidity scores. Minimally invasive surgery cases were also longer.

Patients undergoing open surgery had a venous thromboembolism incidence of 2.2% whereas the incidence was 0.7% in minimally invasive surgery patients (p<0.001). Mean time to venous thromboembolism diagnosis was 10.5±8.8 days in the minimally invasive surgery group and 13.6±9.3 days in the open group (p=0.07). Minimally invasive surgery patients with venous thromboembolism were more likely to have their venous thromboembolism diagnosed after hospital discharge compared with open surgery patients (72.7% v. 42.7%, p=0.001). Older age, race, longer operative time, higher work relative value unit, lymphadenectomy, and higher Charlson co-morbidity score were all associated with venous thromboembolism (Table 3). In a logistic regression model adjusting for the confounders age, race, BMI, operating room time, Charlson comorbidity score and surgical complexity, minimally invasive surgery remained associated with decreased odds of venous thromboembolism compared to open surgery (aOR 0.36, 95% CI 0.24–0.53).

We constructed another logistic regression model among only the minimally invasive surgery patients to identify predictors of venous thromboembolism (Table 4). Age, BMI, and operative time were all associated with venous thromboembolism. The discrimination of the model was fair with an area under the receiver operating characteristic curve of 0.72 (95%CI 0.65–0.79, p<0.001).

A risk score was calculated for each patient and the incidence of venous thromboembolism for each score was calculated (Table 5). The relative risk of venous thromboembolism increased for each 2 points above the referent risk score group. If a binary score is created using a cut point of greater than 2, patients with a score of 4–8 have 7.8 times the risk of venous thromboembolism compared to patients with a score of 0–2. Using this cut point (>2), the sensitivity of the score is 95.6% and specificity is 27.6% while the positive predictive value is 0.8% and the negative predictive value is 99.9%.

DISCUSSION

Our results agree with previous studies: the incidence of venous thromboembolism among women undergoing minimally invasive surgery for gynecologic malignancies is low (3–6, 18). Additionally, the incidence depends heavily on the route of surgery. Minimally invasive surgery patients have one-third the risk compared to open surgery patients. This relationship persisted even after adjustment for age, race, operative time, surgical complexity and patient comorbidities. Currently, the American College of Chest Physicians and the American College of Obstetricians and Gynecologists do not recommend that thromboembolism prophylaxis differ for minimally invasive versus open surgery (19–21). We have provided evidence that open surgery is an independent predictive factor and thus, open surgery patients likely require more prophylaxis than minimally invasive surgery patients.

Age, BMI, and operative time were all associated with venous thromboembolism in a multivariable model among minimally invasive surgery patients. The identification of these as significant risk factors for minimally invasive surgery patients agrees with a previous study that found more blood loss, higher BMI and longer operative time were all associated with venous thromboembolism (6). However, this study only included seven thromboembolism events and only used bivariable tests to examine the relationship.

Therefore, our confirmation of their findings in a larger cohort and use of a multivariable model to quantify the relative independent contribution of each factor is an important addition to the literature.

We developed a model to predict venous thromboembolism among minimally invasive surgery endometrial cancer patients. If validated in an additional population, surgeons could use this model to guide prophylaxis. Patients with a score of >2 have 7.8 times the risk of venous thromboembolism compared to those with a score of 0 or 2. This cut point maximizes negative predictive value and sensitivity which is desirable in venous thromboembolism where the use of prophylaxis is low risk and the consequences of a thromboembolism event are great. Using this cut point, we were able to identify 2,184 patients or 35% of the minimally invasive surgery population that have a significantly lower and low absolute risk of venous thromboembolism. Rather than not using any prophylaxis for all minimally invasive surgery cancer patients, as has been advocated (8), this score could allow us to identify lower risk patients and selectively use less prophylaxis, such as mechanical prophylaxis alone, for them.

Minimally invasive surgery patients were more likely to have their venous thromboembolism diagnosed after discharge compared with open surgery patients. Current recommendations are extended duration prophylaxis of 28 days after abdominal or pelvic cancer surgery (19, 22). Given the low incidence of venous thromboembolism in minimally invasive gynecologic oncology surgery, many do not use extended prophylaxis (23). However, a recent study of minimally invasive surgery colorectal cancer patients found a 10-fold decrease in venous thromboembolism incidence with 28-day prophylaxis compared to 1-week prophylaxis (24). Although extended duration prophylaxis for all minimally invasive gynecologic oncology surgery patients is likely unnecessary, its use may be indicated for a small group at the highest risk.

Strengths of this study include a large population to study a rare outcome and an open surgery comparator group, which allows adjustment of confounding factors and quantification of the effect of route of surgery. Additionally, data collection methods in our data source have been found to be reliable and accurate (10) and are robust in detecting postoperative complications, particularly those that occur after hospital discharge, compared to claims-based data sources (9). Finally, this data source has been used to study venous thromboembolism in many surgical disciplines and was the data source for the highly cited validation of the Caprini score (25–29).

Limitations include a lack of data regarding use of mechanical or pharmacologic prophylaxis. Although, it is likely that as cancer patients undergoing surgery, nearly all patients received some form of prophylaxis as per the Surgical Care Improvement Guidelines. As patients likely received some prophylaxis, but which type is unknown, we cannot comment on the ability of prophylaxis to further decrease venous thromboembolism incidence, and thus, our recommendations for prophylaxis should be interpreted with caution. We also did not have information regarding personal or family history of venous thromboembolism, and therefore, these patients should be considered high risk independent of route of surgery or the absence of other risk factors presented here. Additionally, our predictive model was developed in this cohort and must be validated in an additional population before it can be used clinically. Despite these limitations, our data provides evidence that the incidence of venous thromboembolism after surgery for endometrial cancer is independently associated with the route of surgery.

Acknowledgments

Dr Barber is supported by NIH T32 HD040672-15.

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Table 1

Demographic and Operative Characteristics

Characteristics	N=9,948
Age (years)	63 (56–70)
BMI (kg/m^2)	32.9 (27.1–40.2)
Race	
White	7797 (78.4)
Black	789 (7.9)
Asian	353 (3.5)
Alaska/American native	80 (0.8)
Unknown	929 (9.3)
Smoking	907 (9.1)
Diabetes	2124 (21.4)
Hypertension	5654 (56.8)
Charlson comorbidity index	
0	7246 (72.8)
1	2143 (21.5)
2	367 (3.7)
3+	192 (1.9)
Lymphadenectomy	5620 (56.5)
Length of stay (days)	2 (1–3)
Operating time (min)	157 (116–210)
Surgical complexity (wRVU)	30.9 (17.7–34.6)

Data is presented as n(%) for categorical variables and median (interquartile range) for continuous variables.

Table 2

Association between patient factors and surgical approach

Characteristics	Open surgery (n=3788)	MIS (n=6160)	p value
Age (years)	63.5 (±11.6)	62.7 (±10.9)	0.001[1]
BMI (kg/m2)	34.8 (±10.2)	34.4 (±9.8)	0.026[1]
Race			<0.001[2]
White	2749 (72.6)	5048 (81.9)	
Black	432 (11.4)	357 (5.8)	
Asian	119 (3.1)	234 (3.8)	
Other	29 (0.8)	51 (0.8)	
Unknown	459 (12.1)	470 (7.6)	
Smoking	384 (10.1)	523 (8.5)	0.006[2]
Diabetes	886 (23.4)	1238 (20.1)	<0.001[2]
Hypertension	2272 (60.0)	3382 (54.9)	<0.001[2]
Charlson comorbidity index			<0.001[2]
0	2537 (67.0)	4709 (76.4)	
1	859 (22.7)	1284 (20.8)	
2	238 (6.3)	129 (2.1)	
3+	154 (4.1)	38 (0.6)	
Lymphadenectomy	3549 (57.6)	2071 (54.7)	0.004[2]
Length of stay (days)	3 (3–5)	1 (1-1)	<0.001[3]
Operating time (min)	143 (104–196)	165 (124–219)	<0.001[3]
Surgical complexity (wRVU)	30.8 (21.1–37.1)	31.6 (17.7–34.6)	0.30[3]

[1]T-test,

[2]Chi-square test,

[3]Mann Whitney U test.

Data is presented as mean (SD) for continuous variables that are normally distributed and median (interquartile range) for continuous variables that are non-normally distributed.
Data is presented as n(%) for categorical variables.

MIS – minimally invasive surgery; wRVU – work relative value unit

Table 3

Association between patient factors and venous thromboembolism

Characteristics	No VTE (n=9821)	VTE (n=127)	p value
Age (years)	62.9 (±11.2)	65.6 (±10.6)	0.007[1]
BMI (kg/m2)	34.5 (±9.9)	35.7 (±9.9)	0.17[1]
Race			0.02[2]
White	7700 (78.4)	97 (76.4)	
Black	772 (7.9)	17 (13.4)	
Asian	351 (3.6)	2 (1.6)	
Other	77 (0.8)	3 (2.4)	
Unknown	921 (9.4)	8 (6.3)	
Smoking	898 (9.1)	9 (7.1)	0.42[2]
Diabetes	2096 (21.3)	28 (22.0)	0.85[2]
Hypertension	5579 (56.8)	75 (59.1)	0.61[2]
Charlson comorbidity index			<0.001[2]
0	7161 (72.9)	85 (66.9)	
1	2119 (21.6)	24 (18.9)	
2	359 (3.7)	8 (6.3)	
3+	182 (1.9)	10 (7.9)	
Lymphadenectomy	5536 (56.4)	84 (66.1)	0.03[2]
Length of stay (days)	2 (1–3)	5 (3–9)	<0.001[3]
Operating time (min)	157 (116–210)	186 (121–265)	<0.001[3]
Surgical complexity (wRVU)	30.9 (17.7–34.6)	31.0 (23.1–42.8)	0.02[3]

[1] T-test,

[2] Chi-square test,

[3] Mann Whitney U test.

Data is presented as mean (SD) for continuous variables that are normally distributed and median (interquartile range) for continuous variables that are non-normally distributed.
Data is presented as n(%) for categorical variables.

VTE – venous thromboembolism

Table 4

Predictors of venous thromboembolism among minimally invasive surgery patients

Characteristics	OR	95% CI	Adjusted OR	95% CI	MIS VTE score points
BMI > 40 kg/m^2	1.7	0.9–3.1	1.8	1.0–3.4	2
Operative time > 180 minutes	2.3	1.2–4.2	2.3	1.2–4.2	2
Age > 60 years	3.9	1.8–8.8	4.3	1.9–9.7	4

A logistic regression model was constructed to identify predictors of venous thromboembolism among MIS patients (n=6160).
All adjusted odds ratios are adjusted for BMI, operative time and age.

MIS VTE – minimally invasive surgery venous thromboembolism; BMI – body mass index
OR – odds ratio, CI – confidence interval

Table 5

Venous thromboembolism incidence by MIS VTE score

MIS VTE score	MIS Patients (N)	Observed VTE (N)	Observed VTE (%)	RR	95% CI
0–2	2184	2	0.1%	referent	referent
4	2077	17	0.8%	6.0	1.7–20.4
6	1505	17	1.1%	7.8	2.3–26.3
8	348	9	2.6%	18.9	5.1–71.4

MIS VTE – minimally invasive surgery venous thromboembolism
RR – relative risk CI – confidence interval