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Risk Factors for Venous Thromboembolism After Hysterectomy

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Abstract

Objective—To assess the prevalence of and risk factors for venous thromboembolism after hysterectomy.

Methods—This is a retrospective analysis of data from a voluntary, statewide surgical quality improvement collaborative. Demographics and perioperative data were obtained for hysterectomies performed from January 1, 2008 – April 4, 2014. Postoperative venous thromboembolism was defined as a deep vein thrombosis, pulmonary embolism, or both, diagnosed within 30 days of hysterectomy. Significant variables related to postoperative venous thromboembolism were identified using bivariate analyses, and then logistic mixed modeling was used to develop a final model for venous thromboembolism.

Results—The rate of postoperative venous thromboembolism was 0.5% (110/20,496). Women who had a postoperative venous thromboembolism more frequently had a body mass index ≥ 35 kg/m^2 (40.0% vs 25.2%, OR 1.96, 95% CI 1.08-3.56, p = 0.03), abdominal hysterectomy (referent nonabdominal hysterectomy; 61.8% vs 29.9%, OR 2.67, 95% CI 1.46-4.86, p = 0.001), and gynecologic cancer as the indication for surgery (16.4% vs 9.6%, OR 2.49, 95% CI 1.22-5.07, p = 0.01). Increasing surgical time (hours; referent one hour; OR 1.55, 95% CI 1.31-1.84, p <0.001) was also an associated factor. In bivariate analyses, women with, compared to without, venous thromboembolism more frequently received both preoperative and postoperative heparin (31.9% vs 15.2%, p <0.001 and 55.9% vs 33.5%, p <0.001, respectively) but this did not remain significant in the final model.

Conclusions—Body mass index ≥ 35 kg/m^2, abdominal hysterectomy, increasing surgical time, and cancer as the indication for surgery are risk factors for venous thromboembolism after hysterectomy.

Introduction

Venous thromboembolism is a potentially catastrophic event and one of the most dreaded postoperative complications. Despite increased monitoring of these adverse events and the increased use of thromboprophylaxis, the incidence of venous thromboembolism has

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changed little over the last 25 years [1]. The reported prevalence of venous thromboembolism after hysterectomy, the most common major gynecologic surgery performed in the U.S. [2], varies considerably (1-12%) [3-6]. The exact prevalence is unknown due to a paucity of hysterectomy-specific data and studies controlling for risk factors unique to gynecologic surgery. In addition, reliance on administrative data is a limitation of many existing studies [7]. Finally, regression analyses of large cohorts representing more than a single hospital should take into consideration hospital site effect (i.e. variation in practices, clustering of data, etc.) in order to accurately report the outcome(s) in question; however, to our knowledge no study on venous thromboembolism after hysterectomy has utilized this methodology. These factors make it difficult to draw robust conclusions regarding risk factors for, and overall prevalence of, venous thromboembolism after hysterectomy.

As with any complication, prevention strategies for venous thromboembolism start with the identification of risk factors that can be modified to reduce the prevalence of these events. Therefore, the aim of this study was to determine hysterectomy-specific factors associated with postoperative venous thromboembolism using a large state-wide database.

Materials and Methods

We used data from the Michigan Surgical Quality Collaborative, a Blue Cross Blue Shield of Michigan/Blue Care Network-funded database voluntarily populated by both academic and community hospitals throughout the state. Data from 51 hospitals participating in this collaborative were available for analyses. No sites were added or removed during the study time period. At each site, data are abstracted from charts by a specially trained, dedicated nurse abstractor. Patient characteristics, intraoperative processes of care, and 30-day postoperative outcomes from hysterectomy cases at member hospitals are routinely collected. To reduce sampling error, a standardized data collection methodology is employed that uses only the first 25 cases of an 8-day cycle (alternating on different days of the week for each cycle). Routine validation of the data is maintained by scheduled site visits, conference calls and internal audits [8]. The University of Michigan Institutional Review Board granted “Not Regulated” status to this study (HUM00073978), since the study is based on a de-identified database.

Hysterectomy cases done for any indication between January 1, 2008 and April 4, 2014 at a Michigan Surgical Quality Collaborative member hospital were analyzed as part of the study. Cases of deep vein thrombosis (DVT) and pulmonary embolism diagnosed within 30 days of surgery were identified. The following variables were assessed using bivariate analyses to identify characteristics significantly associated with venous thromboembolism after hysterectomy: age, parity, race, body mass index, cancer as the indication for the hysterectomy, peripartum indication, American Society of Anesthesiology classification [9], history of venous thromboembolism, smoking status, diabetes, chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease, hypertension, dialysis, thrombophilia, route of hysterectomy, estimated blood loss, surgical time, urine output, and postoperative admission to the intensive care unit. After analyzing the prevalence of venous thromboembolism with respect to body mass index, threshold values for an increased risk was identified based on the World Health Organization Classification of body mass index. For the final model, body mass index was dichotomized at ≥35, a value corresponding to "Class II" obesity [10].

Route of hysterectomy was categorized as abdominal, vaginal, and laparoscopic, the latter of which included laparoscopic, robotic-assisted laparoscopic and laparoscopic-assisted vaginal hysterectomy routes. The use of venous thromboembolism prophylaxis was also analyzed and included preoperative and postoperative use of sequential compression devices, unfractionated heparin, and low-molecular weight heparin. Differences in the total number of patients for whom information was available is a reflection that certain variables (age, surgical time) were collected from the beginning of the collaborative while others (indication for surgery, parity, family history of venous thromboembolism, use of thromboprophylaxis) were initiated at a later time. Cases missing data for the variables used to create the final model were excluded from analysis.

Significance between postoperative venous thromboembolism and categorical variables in Table 1 was analyzed using Chi-square test unless there were insufficient numbers of events. In those cases, Fisher's Exact test was applied. Continuous variables were tested for normality using the Shapiro-Wilk test. All continuous variables were deemed non-normal; therefore, nonparametric testing using the Wilcoxon-Mann-Whitney test was applied for significance between postoperative venous thromboembolism and continuous variables.

A hierarchical multivariate logistic regression model (also referenced as a mixed model) was developed to select patient and hospital risk factors associated with postoperative venous thromboembolism for final risk adjustment. Candidate variables to be included in the model required initial exploratory analysis and associated variables with greater than 30% of missing values for hysterectomy cases were excluded. Categorical variables that were included for subsequent analyses were assessed for significance using Chi-square in the bivariate relationship with postoperative venous thromboembolism with a p-value cutoff of 0.01. Similarly, continuous variables were assessed for bivariate relationship using logistic regression with a p-value cutoff of 0.01. Significant variables found to be collinear were excluded. All candidate covariates were entered into an automated variable selection process that used stepwise logistic regression to select a potential model. Iterative selection of clinically relevant variables was included until an appropriate logistic regression model was developed. The hospital effect was entered into the model and a final mixed logistic regression model was obtained with patient and hospital-level adjustment. Age was included in the final model due to its clinical significance. Statistical analyses for this paper were generated using IBM SPSS ® Statistics software, Version 20.0 (copyright 2011 IBM Corporation) for bivariate analyses and SAS, Version 9.3 (copyright 2014 SAS Institute Inc.) for multivariable mixed modeling.

Results

Data for 20,496 hysterectomies were available and analyzed. The overall rate of postoperative venous thromboembolism was 0.5% (110/20,496). Of those with a postoperative venous thromboembolism, DVT only occurred in 38.2 % (42/110), pulmonary embolism only occurred in 50.9% (56/110) and both DVT and pulmonary embolism occurred in 10.9% (12/110). One death was reported in the pulmonary embolism-only group for a postoperative death rate of 0.91% (1/110) compared to 0.10% (21/20,386) in the group without venous thromboembolism (p = 0.11). Variables regarding the use of perioperative thromboprophylaxis were collected starting on July 3, 2012, a time point after which 16, 548 of the hysterectomy cases were performed. Overall, use of sequential compression devices was documented for 98.2% (14,013/14,263) preoperatively and for 94.9% (11,650/12,273) postoperatively. Of the 873 women who had no perioperative sequential compression devices, three had a postoperative venous thromboembolism for a rate of 0.3%, which was similar to the overall rate of 0.5% (p = 0.63).

Results of bivariate analyses are shown in Table 1. Women with, versus without, a postoperative venous thromboembolism were older, of higher body mass index, more likely to have cancer as the indication for surgery and more likely to have: hypertension, history of venous thromboembolism, American Society of Anesthesiology classification >3, received preoperative heparin, received postoperative heparin, abdominal hysterectomy, greater estimated blood loss, and longer surgical time. When body mass index was dichotomized, women with, versus without, a postoperative venous thromboembolism more often had a body mass index ≥ 35 kg/m^2 (40.0% vs 25.2%, p = 0.001).

The prevalence of venous thromboembolism by route of hysterectomy was also examined. Of the 110 women with postoperative venous thromboembolism events, 61.8% (68) had undergone an abdominal hysterectomy. Overall, the rate of postoperative venous thromboembolism for women undergoing abdominal hysterectomy was 1.1% which was higher than rates seen with for laparoscopic hysterectomy (0.3%, p <0.001) and vaginal hysterectomy (0.2%, p <0.001). No difference was seen between vaginal and laparoscopic hysterectomy (p = 0.22).

Because uterine size often precludes a minimally invasive approach to hysterectomy, we analyzed specimen weights by hysterectomy route. The specimen weights may include adnexa(e), if removed, and therefore may actually overestimate actual uterine weight in some cases. On average, we found that specimen weights were greatest in the abdominal hysterectomy group compared to laparoscopic and vaginal groups (392.5 ± 637.5 g vs 166.4 ± 211.0 g and 95.2 ± 74.6 g, respectively, p < 0.001). However, of the abdominal hysterectomies done for benign indications, 73.3% had specimen weights ≤ 200 g.

Although the overall postoperative venous thromboembolism rate for all 51 hospitals was 0.5%, per site, the rate ranged from 0-2.2%. Test for the covariance parameters indicated that the hospital effect was significant (p < 0.001) and therefore it was adjusted for using mixed logistic regression. After controlling for age, variables that remained significant in the final model were body mass index ≥ 35 kg/m^2 (OR 1.96, 95% CI 1.08-3.56), abdominal hysterectomy (referent non-abdominal hysterectomy; OR 2.67, 95% CI 1.46-4.86), increasing surgical time (hours; referent one hour; OR 1.55, 95% CI 1.31-1.84), and cancer as the indication for hysterectomy (OR 2.49, 95% CI 1.22-5.07) (Table 2). The Pearson's residuals (p=0.95) suggests that this model has a high goodness of fit. The use of any type of preoperative or postoperative thromboprophylaxis did not remain significant in our final model.

Finally, we analyzed the prevalence of bleeding complications in our database. Overall, the postoperative blood transfusion rate was 2.6% (541/19,955). Data regarding the use of preoperative venous thromboembolism chemoprophylaxis were available for 13,941 women, 15.2% (2,114) of whom received either preoperative unfractionated heparin or low-molecular weight heparin. Estimated blood loss during surgery was statistically greater in women who received preoperative heparin versus those who did not however median values were similar (100 mL (interquartile range: 50, 250) vs 100 mL (interquartile range: 50, 200); $p < 0.001$). Overall, women who received preoperative heparin, compared to those who did not, underwent more frequent blood transfusions (4.4% vs. 2.3%, $p < 0.001$) and more frequent reoperation within 30 days (3.3% vs. 2.3%, $p=0.008$).

Discussion

In this analysis of hysterectomies using a statewide database, we found an overall prevalence of postoperative venous thromboembolism of 0.5%. We identified four risk factors associated with venous thromboembolism after hysterectomy: body mass index, abdominal route of surgery, surgical time, and gynecologic cancer as the indication for surgery. This study extends the existing literature by providing the largest analysis of risk factors for venous thromboembolism specific to hysterectomy [11-13].

Of the factors identified, abdominal route of hysterectomy had the biggest effect on postoperative venous thromboembolism risk in our model. This finding supports those of prior studies that have consistently shown abdominal hysterectomy, compared to vaginal and laparoscopic routes, to be associated with more complications [14]. Despite a national trend toward decreased use of abdominal hysterectomy over the last decade, the percentage of abdominal hysterectomies done in the United States in 2010 was 54.2% [15]. In our study, over a third of hysterectomies were done using the abdominal approach and of these, approximately 95% were done for benign indications.

Uterine size may be an important factor influencing the decision to perform an abdominal hysterectomy for benign indications. Although overall average specimen weight was greatest in the abdominal hysterectomy group, when we analyzed only the abdominal hysterectomies done for benign indications, nearly three-quarters had specimen weights ≤ 200 g. This finding suggests that there is still room for improvement regarding the utilization of minimally invasive hysterectomy. The American College of Obstetricians and Gynecologists recommends a vaginal approach to hysterectomy whenever feasible for benign disease and using the laparoscopic approach if a vaginal hysterectomy is not feasible [16]. Although our study design precludes determination of causality, our data suggest that increased utilization of minimally invasive approaches to hysterectomy may decrease the prevalence of postoperative venous thromboembolism.

The remaining factors we found to be associated with venous thromboembolism after hysterectomy are gynecologic cancer as the indication for surgery, body mass index (≥ 35 kg/m^2), and increasing surgical time, all of which have precedence in the literature [6, 17]. Awareness of these associations is important and may influence aspects of patient care such as preoperative patient counseling and decisions regarding perioperative thromboprophylaxis.

Although not included in our final model, our results regarding the use of thromboprophylaxis warrant discussion. Overall, the use of sequential compression devices preoperatively and postoperatively was high and similar in women who did and did not have a postoperative venous thromboembolism. Because so few women in either group did not have sequential compression devices, we were unable to detect a significant protective effect of this type of thromboprophylaxis. Our finding that preoperative and postoperative heparin use was higher in women with postoperative venous thromboembolism likely represents the fact that these women had more risk factors which prompted surgeons to initiate chemoprophylaxis. We also found that women who received preoperative heparin underwent more frequent blood transfusions, more frequent reoperation within 30 days, and had a greater estimated blood loss during surgery. Because these findings were the result of bivariate analyses, they are not adjusted for risk factors, comorbidities, indication for hysterectomy or operative factors.

Our study is limited by the use of data from a single state, which could potentially limit the generalizability of our results. Additionally, there was potential for missing venous thromboembolism events that may have occurred after the 30-day postoperative time frame or may have been diagnosed and treated at a non-member hospital. We were also unable to control for the complexity of cases in our study and recognize that more difficult cases may be more likely to be done abdominally and require longer surgical times.

Strengths of this study include the use of a large database of academic and community hospitals as well as data from patients of all insurance types. Our data also represent the usual practice in various hospital settings for things such as choice of hysterectomy route and thromboprophylaxis. We were also able to track outcomes for 30 days postoperatively. The methodology for our study is also a notable strength. Our data are collected using a validated methodology and by specially trained, dedicated nurse data abstractors. Furthermore, we optimized the development of our final model by utilizing a mixed model approach and therefore controlling for variation in practices between sites, which previously has not been done. Finally, the inclusion of hysterectomies done for any indication allows for greater generalizability of our findings.

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Table 1

Demographics and variables analyzed for postoperative venous thromboembolism within 30 days of hysterectomy

Variable	Postoperative Venous Thromboembolism		P value
	No (N=20,386)	Yes (N=110)	
Age, years	46.9 (41.0, 55.0)49.0 ± 11.7	51.9 (44.6, 63.9)54.3 ± 13.6	<0.001
Parityy, median (IQR)*	2 (1,3)	2 (1,3)	0.69
Race			0.002
White	71.9 (14,662)	62.7 (69)	
Black	17.8 (3,638)	32.7 (36)	
Other/Unknown	10.3 (2,086)	4.6 (5)	
Body Mass Index, kg/m^2	30.7 ± 8.129.3 (25.0, 35.0)	34.6 ± 9.032.3 (27.5, 40.8)	<0.001
Indication Cancer*	9.6 (937/9,790)	16.4 (18)	<0.001
Obstetric Indication*	0.2 (16/9,790)	0 (0/47)	1.00
Current Smoker	22.7 (4,632)	10.9 (12)	0.003
Hypertension	31.1 (6,343)	49.1 (54)	<0.001
Cancer	0.6 (114/20,352)	4.6 (5/109)	<0.001
Diabetes:			
Non-Insulin Dependent	7.4 (1466/19,903)	12.3 (13/106)	0.06
Insulin Dependent	2.6 (483/18,920)	4.1 (4/97)	0.32
Chronic Obstructive Pulmonary Disease*	3.3 (463/14,187)	7.2 (5/69)	0.76
Congestive Heart Failure	0.1 (20/20,386)	0 (0)	1.00
Coronary Artery Disease*	2.7 (385/14,187)	2.9 (2/69)	0.71
Dialysis	0.09 (18/20,386)	0.9 (1/110)	0.10
Thrombophilia	1.1 (231/20,386)	5.5 (6/110)	0.002
History of Venous Thromboembolism*	2.9 (414/14,220)	8.7 (6/69)	0.02
American Society of Anesthesiology Classification > 3	0.7 (134)	3.6 (4)	0.01
Preoperative Thromboprophylaxis*:			
Mechanical†*	98.2 (13,945/14,194)	98.6 (68/69)	0.85
Heparin‡†	15.2 (21,60/14,194)	31.9 (22/69)	<0.001
Dual§‡	14.9 (2,116/14,194)	31.9 (22/69)	<0.001
None	1.4 (1,97/14,194)	1.4 (1/69)	0.62
Postoperative Thromboprophylaxis*:			
Mechanical†*	94.9 (11,584/12,205)	97.1 (66/68)	0.42
Heparin‡†	33.5 (4,086/12,203)	55.9 (38/68)	<0.001
Dual§‡	32.3 (3,940/12,203)	55.9 (38/68)	<0.001
None	3.1 (381/12,203)	1.5 (1/68)	0.73
Route of Hysterectomy			<0.001
Abdominal	29.9 (6,101)	61.8 (68)	

Variable	Postoperative Venous Thromboembolism		P value
	No (N=20,386)	Yes (N=110)	
Laparoscopic	57.6 (11,744)	34.6 (38)	
Vaginal	12.5 (2,541)	3.6 (4)	
Estimated Blood Loss (mL)	184.3 ± 271.9100 (50, 200)	389.9 ± 427.5250 (100, 500)	<0.001
Urine Output (mL)	182.0 ± 269.2200 (100, 391)	361.2 ± 406.8220 (120, 400)	0.65<0.001
Postoperative Admission to Intensive Care Unit	2.2 (263/12,169)	23.5 (16/68)	<0.001
Surgical Time (hours)	2.3 ± 1.12.0 (1.5, 2.8)	3.1 ± 1.52.9 (2.1, 3.8)	<0.001

Data presented as median (interquartile range), mean ± SD, % (n), , or % (n/N) unless otherwise specified. Chi-square and Fisher's Exact used for categorical variables, , Wilcoxon-Mann-Whitney test Student's t-test used for continuous variables.

[*]Variable collected starting July 3, 2012 (N=16,548)

[†]Sequential Compression Devices Includes both unfractionated or low-molecular weight heparin

[‡]Includes both unfractionated or low-molecular weight heparinPatient received both sequential compression devices and either unfractionated or low-molecular weight heparin

[§]Patient received both sequential compression devices and either unfractionated or low-molecular weight heparin

Table 2

Variables predictive of postoperative venous thromboembolism after hysterectomy

Variable	Crude Odds Ratio	Adjusted Odds Ratio	95% C.I.	Regression Coefficient	Standard Error	p value
Constant	-----	-----	-----	-8.53	0.78	<0.001
Age (years)	1.03	1.02	1.00-1.05	0.02	0.01	0.08
Body Mass Index ≥ 35 kg/m^2	1.99	1.96	1.08-3.56	0.67	0.30	0.03
Abdominal Hysterectomy	3.79	2.67	1.46-4.86	0.98	0.31	0.001
Surgical time (hours)	1.54	1.55	1.31-1.84	0.44	0.09	<0.001
Indication cancer	5.83	2.49	1.22-5.07	0.91	0.36	0.01

CI, confidence interval.

Mixed logistic regression was performed for the variables found to be significantly correlated with postoperative venous thromboembolism after hysterectomy in bivariate analyses, p ≤0.01 (age, race, body mass index ≥ 35 kg/m^2 (referent < 35 kg/m^2), indication cancer, smoker, hypertension, thrombophilia, cancer, use of preoperative heparin, use of postoperative heparin, American Society of Anesthesiology classification > 3, abdominal hysterectomy (referent non-abdominal hysterectomy), estimated blood loss, postoperative admission to the intensive care unit, and surgical time).

Referent groups: Body mass index < 35 kg/m^2, routes of hysterectomy other than abdominal.