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Incidence of venous thromboembolism by type of gynecologic malignancy and surgical modality in the National Surgical Quality Improvement Program

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Introduction

Venous thromboembolism (VTE) occurs in the general population with an estimated incidence of 1 to 2 per 1,000 in the United States with fifty percent of patients experiencing long-term complications such as swelling, pain, discoloration, and scaling in the affected limb(1). VTE can potentially be a life-threatening complication. It is well known that patients with malignancies are at an increased risk of VTE (2, 3). This in part is due to Virchow's triad of hypercoagulability, stasis, and endothelial injury which forms the basis of understanding of the pathophysiology of VTE. It is established that VTE's occur more frequently in surgical oncologic patients (4, 5).

Cancer patients are at an elevated risk of VTE due to a myriad of factors -including endothelial injury secondary to tumor burden, prolonged central intravenous access, surgical trauma, chemotherapeutic agents, radiation, and relative immobility. Studies have reported varying incidences of VTE based on type of malignancy. Tateo et al. found the rate of VTE in epithelial ovarian cancer patients to be 16.6% in a single institutional study (6). Peedicayil et al also reported a single institution's incidence of VTE of 4% within all gynecologic cancer patients (7). However, large population based data and more descriptive analyses have been limited. Further, a distinctive working group consisting of the National Heart, Lung, and Blood Institute, Division of Blood Diseases and Resources, and the National Cancer Institute met in August of 2014 and determined the major areas of unmet needs in the field of cancer-related thrombosis. They believed more research was needed in the appropriate selection of cancer patients to receive thromboprophylaxis in the inpatient and outpatient settings (8). The current study was designed to help gynecologic surgeons identify

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patients at increased risk of VTE by defining the incidence, and the comparative risk of VTE amongst gynecologic cancers of different primary sites and surgical modalities.

Materials and Methods

After obtaining the University of Pennsylvania Institutional Review Board approval (IRB #820313), gynecologic surgeries performed between 2006 and 2012 were identified using the American College of Surgeons National Surgical Quality Improvement Program database (ACS-NSQIP). ACS-NSQIP is a nationally validated, risk-adjusted, outcomes-based program that captures and reports 30-day morbidity and mortality outcomes for all major inpatient and outpatient surgical procedures from across the nation. Data were collected by trained surgical clinical reviewers provided by the American College of Surgeons. Perioperative outcomes within NSQIP have been validated by the trained surgical clinical reviewers of individual patient charts per standard registry protocols. Pulmonary embolism (PE) was determined by the following: V-Q scan (interpreted as high probability of PE), a positive computed tomography (CT) exam, transesophageal echocardiogram, pulmonary arteriogram, CT angiogram, or any other definitive modality. Deep venous thrombosis (DVT) was diagnosed by duplex ultrasound, venogram, or CT scan (9).

Inclusion criteria included any patient that had surgery for gynecologic malignancy. These cases were identified using ICD9 codes (179, 180.x, 182.x, 183.x, 184.x, 233.1, 233.2) within the ACS-NSQIP database. The NSQIP database excludes patients that are less than 18 years old. There were no further exclusions.

Baseline demographic and clinical data collected included: age at diagnosis, primary gynecologic site of neoplasm, body mass index (BMI), race, comorbidities, American Society of Anesthesiologists (ASA) physical status classification, and preoperative ascites. Comorbidities included diabetes, dyspnea, chronic obstructive pulmonary disease, cardiovascular disease, hypertension, transient ischemic attacks and stroke. Surgical procedures including but not limited to open abdominal hysterectomy, minimally invasive hysterectomy, lymph node dissection, and upper abdominal procedures were captured. Data on perioperative outcomes including operative time, major complications, and death within 30 days were also collected. Major complications included organ surgical site infection, wound disruption, stroke, coma, myocardial infarction, cardiac arrest, pulmonary embolism, unplanned intubation, ventilator dependence greater than 48 hours, acute renal failure, sepsis, return to surgery, and VTE.

The primary outcome of the study was the occurrence of VTE by malignancy site, which was further subcategorized as PE, DVT, or both within 30 days post-operatively. Additionally, subset analyses of VTE risk in patients undergoing minimally invasive surgery. Disseminated disease was used as a surrogate for advanced cancer and was also evaluated for risk of VTE. Disseminated disease was defined by the NSQIP database as cancer that: 1) has spread to one site or more sites in addition to the primary site, AND; 2) in whom the presence of multiple metastases indicates the cancer is widespread, fulminant, or near terminal.

Means, standard deviations (SD), percentages and interquartile ranges (IQR) were computed to describe continuous and categorical variables. Chi-square and multivariable logistic regressions were used to assess the association of potential risk factors for VTE according to the primary gynecologic cancer site. Odds ratio (OR) and 95% confidence intervals (CI) were reported. Stata/MP 13.0 was used for analysis. A two-sided P value of 0.05 was considered statistically significant.

Results

A total of 104,368 gynecologic surgeries were identified and a total of 0.53% (n=492) of these patients developed VTE. Specifically, 242 (0.23%) patients had a DVT and 299 (0.29%) patients had a PE. Forty-nine patients diagnosed with a PE also had a diagnosed DVT.

Of all gynecologic surgeries, 10.9% (n=11,427) were performed with a diagnosis of gynecologic malignancy. Patient characteristics are shown in Table 1. Within gynecologic cancer surgeries, 24.5% (n=2800) were performed for ovarian cancer; 62.3% (n=7114) for uterine cancer; 9.0% (n=1026) for cervical cancer; and 4.3% (n=487) for vulvar cancer. The overall median age was 61 (IQR 53–69) years old for women who underwent gynecologic cancer surgery, and the median BMI was 30.2 mg/kg² (IQR 25.0–37.3). The majority of patients were White (76.5%, n=8732), and just over half had one or more comorbidities (55.5%, n= 6343). Demographic features differed amongst the various types of gynecologic cancer. Notably, cervical cancer patients were significantly younger and had less comorbidity, while uterine cancer patients, as expected, were older and had a higher BMI (mean 32.5 kg/m²). Overall perioperative outcomes of all gynecologic malignancy surgery were favorable, as only 6% had any major complication. The median operative time was 2.65 hours (IQR 1.85–3.70)

For gynecologic cancer surgeries (n=11,427), the overall frequency of VTE was 1.8 % (n=202), which was higher than that seen in all gynecologic surgery (n=92,941) with a VTE frequency of 0.53% (n=492). Amongst gynecologic cancers, VTE was more frequently seen in patients undergoing ovarian cancer surgeries (3.0% P<0.0001), versus those with uterine cancer (1.4%), for cervical cancer (1.5%), and for vulvar cancer (1.2%). The rate of VTE in those patients that underwent lymph node dissection (n=4688) was 1.9% which is similar to the overall rate of VTE in the entire cohort. The overall frequency of DVT was 0.96% and PE was 0.98%. With emergence of VTE prophylaxis guidelines, the rate of VTE decreased over time, from 9.1% in 2006 to 1.8% in 2012 (Table 2). There was an overall mortality rate of 4% (n=8) within those with diagnosed VTE (n=202), however, the cause of death was not documented by the NSQIP database.

After adjusting for race, age, BMI, ascites, comorbidities, major complications, operative time, upper abdominal surgery and lymph node dissection, the adjusted risk of VTE remained statistically higher for those undergoing ovarian cancer surgeries. Ovarian cancer patients were found to be 1.8 (95% CI 1.19–2.65) times more likely to have a DVT and 1.7 (95% CI 1.11–2.51) times more likely to have a PE than uterine cancer patients. Compared

to all patients with other types of gynecologic cancer, ovarian cancer patients were 1.5 times more likely to be diagnosed with a VTE (95% CI 1.10–2.16).

We sought to consider advanced intra-abdominal disease by applying the surrogate variable, disseminated disease, which consisted of 8.0% of the entire cohort (n=913). After adjusting for disseminated disease within the entire gynecologic cancer cohort, disseminated disease (OR 1.55, 95% CI 1.03–2.34) was another overall risk factor for VTE diagnosis (Table 3).

Minimally invasive surgery (MIS) was performed in 37.7% (n=4304) of all gynecologic cancer surgeries; 6.7% (n=187) were performed for ovarian cancer and 52.8% (n=3755) for uterine cancer. When controlling for MIS, ovarian cancer was not associated with an increased risk of VTE. Overall, those who underwent MIS were 66% less likely to develop a VTE (OR 0.34 P 0.0001) (Table 4). When accounting for advanced cancer, disseminated disease in those undergoing MIS was present in 17.1% of patients with endometrial cancer (n=228) and 2.3% of patients with ovarian cancer (n=663). If patients had MIS with disseminated disease present, they had a 6 times greater likelihood of developing VTE post-operatively (OR 5.96, 95% CI 1.2–29.0) (Table 5).

Discussion

For women undergoing gynecologic cancer surgery, ovarian cancer surgery appears to have the highest risk for post-operative VTE. Using the American College of Surgeons National Surgical Database, we found that ovarian cancer patients had 1.5 times the risk for VTE compared to other gynecologic cancer patients. This risk is evident in patients who undergo open abdominal procedures. This is further illustrated by the decreased risk of VTE for patients who underwent MIS surgery, regardless of the primary site of malignancy. To date there have been multiple studies in the general surgical and medical literature regarding risk factors for VTE, rates of VTE, and medical treatments associated with incident VTE (10). However, this study is one of the first to capture and differentiate VTE rates amongst women undergoing surgery for different types of gynecologic cancers and via different modalities.

Currently, VTE prophylaxis guidelines are applied to all women undergoing surgery for gynecologic cancers undergoing an open procedure. All women with malignancy are considered high risk for VTE regardless of tumor site. Further, guidelines are not cohesive in regards to VTE prophylaxis for MIS. Our results suggest that gynecologic cancer patients are at potentially different risk for development of VTE depending on cancer type as well as modality. Therefore, pre-operative and post-operative VTE prophylaxis and post-operative treatment of gynecologic malignancy may benefit from adjusting guidelines based on the specific site of neoplasm and surgical procedure performed. Post-operative prophylaxis for open abdominal procedures is supported by this data, moreover, those who undergo MIS may benefit from less extended prophylaxis. Controlled studies would be needed to test these hypotheses.

Literature regarding VTE prophylaxis is widely comparable. The American Society of Clinical Oncology (ASCO) in 2007 suggested all hospitalized cancer patients be given anticoagulation as well as those undergoing major surgery for malignant disease (11).

Further, the National Comprehensive Cancer Network (NCCN) in 2006 shared similar recommendations with the ASCO guidelines (12).

Following publication of the ASCO and NCCN guidelines, two prospective studies conducted in multi-institutional cohorts have suggested administering prolonged anticoagulation for surgical oncologic patients for up to 4 weeks post operatively. They included patients who underwent major abdominal and pelvic surgery, who had residual malignant disease, obesity and previous history of VTE. Extended prophylactic anticoagulation resulted in a 55–60% reduction of DVT (13, 14). With these studies in mind, the CHEST guidelines in 2008 recommended against prophylaxis for laparoscopic procedures unless additional VTE risk factors are present. Further, if open oncologic surgery was performed, they suggested continuing pharmacologic prophylaxis for 28 days after discharge (15). The CHEST guidelines were confirmed in 2012 and recommended, with grade 1B evidence, extended-duration pharmacologic prophylaxis (4 weeks) with low molecular weight heparin in patients undergoing abdominal or pelvic surgery for cancer (16).

There remains some uncertainty of how to apply these guidelines amongst patients with different gynecologic cancers who will undergo different types of gynecologic surgery. Prior studies have shown that VTE by the origin of malignancy have varied widely. Tateo et al found a VTE risk of 16.6% in patients with ovarian cancer. Other authors reported the risk of VTE within ovarian cancers ranging from 1.2 to 5.2% (17–19). These studies only investigated the rate of peri-operative VTE for ovarian cancer patients but never compared this risk to that for patients with other sites of disease undergoing surgery. Morimoto et al evaluated 750 patients in a University Hospital with gynecologic malignancies and found ovarian cancer patients to have VTE more frequently than other sites of malignancy at 4.5% (20).

We have found an overall incidence of VTE within ovarian cancer surgical patients to be 3.0% with roughly equal incidences of PE and DVT (1.5% and 1.6% respectively). Additionally, VTE rates were 1.4% for uterine cancer, 1.5% for cervical cancer, and 1.2% for vulvar cancer. The rate of VTE within ovarian cancer was similar to the historic rates in the literature. However, the rate of VTE for other gynecologic cancers has been infrequently reported as 0%–2.8% secondary to small sample size or limited documentation (20, 21).

As previously stated, current guidelines refrain from making concrete recommendations for VTE prophylaxis for any laparoscopic surgery. This stems from the low rate of VTE that has been found in past literature. Bouchard-Fortier et al found that in 352 patients who did not receive any VTE prophylaxis (anti-coagulation or compression devices) and underwent MIS for gynecologic cancer, only 2 patients developed a VTE (0.57%)(22). Overall, it has been found that the rate of VTE in women with a gynecologic malignancy undergoing MIS ranges from 0.5 to 1.2% (23–25). Our data supports that VTE risk is significantly lower in patients undergoing MIS. However, it is pertinent to note that our data suggests that not all laparoscopic surgeries are equal in VTE risk, even when adjusting for patient demographics. Of patients who underwent MIS surgery, those with disseminated disease had 5.96 times the likelihood of VTE regardless of the primary site of malignancy.

We acknowledge there are limitations of this study including its retrospective nature, although data were prospectively collected by the American College of Surgeons. The NSQIP database is a nationwide collection and represents the largest data set of this kind; however it accounts for only a fraction of patients undergoing gynecologic cancer surgeries in the United States. Given its large size and patient characteristics we believe it to be representative of national practices and therefore relevant. Another limitation was the lack of information regarding type of VTE prophylaxis used peri-operatively. Third, it is possible that uptake of VTE prophylaxis may have lagged behind recommended guidelines, and guidelines have been updated over time, for example the 2012 (CHEST Guidelines). Notably, we found a downward trend in the incidence of VTE from 2006 to 2012 which may reflect the gradual implementation of VTE prophylaxis by surgeons. Additionally, we acknowledge that NSQIP is limited to 30 day post-operative data. However, most VTEs are known to occur in this immediate post-operative period. NSQIP also lacks pathology information such as stage or histology. However, we used surrogate variables, such as disseminated disease and lymph node dissection, to adjust for extent of malignancy. Lastly, the sample size of patients who underwent MIS for disseminated ovarian cancer was small, however remained sufficient to perform the multivariable analysis.

Conclusion

We have found an overall incidence of VTE in gynecologic oncology surgery to be relatively low at 1.8% with a low mortality rate of 4%. Of gynecologic cancer surgeries, ovarian cancer patients had the highest rate of VTE. Most ovarian cancer patients undergo open surgical procedures, which were found to have a higher risk of VTE. If ovarian cancer patients had disseminated disease and underwent MIS, they remained at higher risk of VTE. However, overall VTE rates were significantly lower with MIS. It may be warranted to extend post-operative prophylactic anticoagulation to all ovarian cancer patients as well as those that undergo MIS with disseminated disease, which has not been previously suggested. We further suggest that routine MIS patients remain at a lower risk of VTE and do not warrant extended VTE prophylaxis. Further research is needed to compare current institutional protocols and rates of VTE to further determine the need for extended prophylaxis in these subpopulations.

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Table 1
Characteristics of patients undergoing surgery for gynecologic malignancy using the NSQIP database.

	Total (IQR or %)	Ovarian CA (IQR or %)	Uterine CA (IQR or %)	Cervical CA (IQR or %)	Vulvar CA (IQR or %)	P value
Sample Size	11427	2800(24.5)	7114(62.3)	1026(9.0)	487(4.3)	
Age (median)	61(53–69)	61(52–69)	63(55–70)	47(38–57)	66(56–78)	0.0001
BMI (median)	30.2(25.0–37.3)	27.0(23.3–32.4)	32.5(26.7–39.9)	27.1(23.0–32.4)	28.3(24.3–33.6)	0.0001
Race						<0.0001
White	8732(76.4)	2154(76.9)	5491(77.2)	703(68.5)	384(78.9)	
Black	853(7.5)	181(6.5)	547(7.7)	94(9.2)	31(6.4)	
Other	1121(9.8)	261(9.3)	665(9.4)	155(15.1)	40(8.2)	
Unknown	721(6.3)	204(7.3)	411(5.8)	74(7.2)	32(6.6)	
Comorbidity						
0	5084(45.5)	1440(52.1)	2735(39.5)	729(71.7)	180(38.1)	<0.0001
1	3988(35.7)	934(33.8)	2657(38.3)	210(20.7)	187(39.5)	
2	2111(18.9)	390(14.1)	1538(22.2)	77(7.6)	106(22.4)	
Operative time (hrs)	2.65(1.85–3.70)	2.82(1.92–3.90)	2.62(2.62–3.55)	2.97(1.93–4.53)	1.57(0.82–2.65)	0.0001
Major complications						
0	10747(94.0)	2563(91.5)	6781(95.3)	959(93.5)	444(91.2)	<0.0001
1	450(3.9)	157(5.6)	212(3.0)	50(4.9)	31(6.4)	
2	230(2.0)	80(2.9)	121(1.7)	17(1.7)	12(2.5)	
Lymph Node Dissection	4778 (41.8)	957 (34.2)	3051 (42.9)	610 (59.4)	160 (32.8)	<0.0001
Upper Abdominal Surgery	195 (1.7)	175 (6.25)	18 (0.25)	2 (0.19)	0 (0)	<0.0001

Table 2

Frequency of VTE in surgical gynecologic oncology patients

Year	Total # Venous thromboembolism	N (%)
2006	22	2 (9.09)
2007	201	5 (2.49)
2008	666	9 (1.35)
2009	1126	26 (2.31)
2010	1403	24 (1.71)
2011	3393	53 (1.56)
2012	4616	83 (1.8)
Total	11427	202 (1.77)

Table 3

Risk for VTE adjusted for disseminated disease. Disseminated disease is a risk factor for clot formation

	Odds Ratio	P value	95% CI
Age	1.02	0.012	1.004 1.031
Race			
White	Ref.*	–	– –
Black	1.08	0.77	0.644 1.811
Other	0.98	0.927	0.589 1.620
Unknown	0.74	0.407	0.358 1.517
BMI [†]	1.00	0.669	0.986 1.022
Cancer Type			
Uterine	ref	–	– –
Ovarian	1.74	0.002	1.230 2.450
Cervical	1.11	0.733	0.611 2.014
Other	0.69	0.401	0.287 1.647
Charlson Comorbidity Index			
0	ref	–	– –
1	0.94	0.709	0.659 1.329
2	1.05	0.837	0.687 1.590
Major Complications			
0	ref	–	– –
1	4.10	<0.001	2.694 6.254
2	6.21	<0.001	3.872 9.958
Operative Time (hrs)	1.19	<0.001	1.110 1.287
Disseminated Disease	1.55	0.037	1.027 2.339
Upper Abdominal Surgery	1.25	0.51	0.649 2.388
Lymph Node Dissection	1.19	0.24	0.888 1.604

* Ref indicates reference to the variable which was used to compare in the logistic regression

[†] Body Mass Index (kg/m^2)

Table 4

Risk of VTE controlled for minimally invasive surgery. Ovarian cancer is not associated with an increased risk of VTE

		Odds Ratio	P value	95% CI
Age		1.02	0.013	1.003 1.030
Race				
	White	Ref [*]	–	– –
	Black	0.98	0.938	0.584 1.644
	Other	0.92	0.731	0.552 1.516
	Unknown	0.65	0.247	0.317 1.345
BMI [†]		1.00	0.889	0.984 1.019
Cancer Type				
	Uterine	ref	–	– –
	Ovarian	1.20	0.308	0.845 1.707
	Cervical	0.91	0.761	0.498 1.666
	Other	0.43	0.059	0.176 1.032
Charlson Comorbidity Index				
	0	ref	–	– –
	1	0.93	0.703	0.658 1.326
	2	1.01	0.957	0.665 1.538
Major Complications				
	0	ref	–	– –
	1	3.77	<0.0001	2.485 5.733
	2	5.41	<0.0001	3.368 8.678
Operative Time (hrs)		1.22	<0.0001	1.002 1.004
Disseminated Disease		1.38	0.116	0.924 2.049
Minimally Invasive Surgery		0.34	<0.0001	0.222 0.518

* Ref indicates reference to the variable which was used to compare in the logistic regression

[†]Body Mass Index (kg/m²)

Table 5
Risk factors for VTE in patients that underwent open abdominal surgery and minimally invasive surgery

	Open Abdominal Surgery				Minimally Invasive Surgery (MIS)			
	Odds Ratio	P value	95% CI		Odds Ratio	P value	95% CI	
Age	1.01	0.056	1.000	1.028	1.04	0.055	0.999	1.074
Race								
White	Ref*	–	–	–	ref	–	–	–
Black	0.93	0.804	0.526	1.645	1.28	0.7	0.364	4.504
Other	0.92	0.771	0.538	1.583	1.03	0.971	0.233	4.525
Unknown	0.64	0.257	0.294	1.386	0.99	0.989	0.130	7.443
BMI [†]	0.99	0.349	0.971	1.011	1.05	0.005	1.015	1.084
Cancer Type								
Uterine	ref	–	–	–	ref	–	–	–
Ovarian	1.16	0.427	0.804	1.673	0.80	0.836	0.098	6.550
Cervical	0.82	0.562	0.428	1.587	1.31	0.734	0.273	6.316
Other	0.44	0.071	0.184	1.072	omitted	–	–	–
Charlson Comorbidity Index								
0	ref	–	–	–	ref	–	–	–
1	0.95	0.791	0.651	1.387	0.89	0.817	0.338	2.352
2	0.96	0.848	0.601	1.520	1.25	0.677	0.440	3.536
Major Complications								
0	ref	–	–	–	ref	–	–	–
1	3.56	<0.001	2.263	5.593	6.22	0.002	1.973	19.639
2	5.86	<0.001	3.594	9.558	3.24	0.263	0.415	25.262
Operative Time (hrs)	1.20	<0.001	1.109	1.293	1.37	0.006	1.093	1.726
Disseminated Disease	1.30	0.217	0.857	1.971	5.96	0.027	1.224	28.997
Upper Abdominal Surgery	1.19	0.601	0.621	2.276	omitted	–	–	–
Lymph Node Dissection	1.31	0.098	0.951	1.806	1.09	0.834	0.503	2.346

* Ref indicates reference to the variable which was used to compare in the logistic regression

[†] Body Mass Index (kg/m²)