ELSEVIER

Surgery for Obesity and Related Diseases 7 (2011) 181–188

SURGERY FOR OBESITY AND RELATED DISEASES

Original article

Venous thromboembolism after bariatric surgery performed by Bariatric Surgery Center of Excellence Participants: analysis of the Bariatric Outcomes Longitudinal Database

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Received May 11, 2010; accepted December 15, 2010

Abstract

Background: Venous thromboembolism (VTE) is an uncommon complication of bariatric surgery but a leading cause of postoperative mortality. Studying the factors predictive of low-incidence complications requires the analysis of large cohorts. The Bariatric Outcomes Longitudinal Database, the world's largest prospective database for bariatric surgery, has provided a suitable medium for analyzing low-frequency events.

Methods: The data in the Bariatric Outcomes Longitudinal Database from 73,921 research-consented patients who had undergone bariatric surgery by a participant in the American Society for Metabolic and Bariatric Surgery Bariatric Surgery Center of Excellence program before September 22, 2009, were analyzed for VTE events within 90 days after surgery.

Results: The overall risk of VTE within 90 days after surgery was .42%, and 73% of these events occurred after discharge, most within 30 days after surgery. The risk of VTE was greater in the patients undergoing gastric bypass than in those undergoing adjustable gastric banding (.55% versus .16%). VTE was more frequent when the procedure was performed using an open than a laparoscopic approach (1.54% versus .34%). Patients with a VTE event were older (+4.9 yr), had had a greater preoperative body mass index (+3.9 kg/m^2), and were more likely to have a history of VTE (16.5% versus 3.7%). The risk of VTE was greater in men (hazard ratio 2.32, 95% confidence interval 1.81–2.98) and in patients with an inferior vena cava filter (hazard ratio 7.66, 95% confidence interval 4.55–12.91).

Conclusion: The overall risk of VTE was low in the population treated by participants in the Bariatric Surgery Center of Excellence program, where clinical pathways to prevent VTE have been mandated. Analysis of this large study population allowed the identification of patient characteristics correlating with increased risk of postoperative VTE and the variable effectiveness of VTE prophylaxis methods. (Surg Obes Relat Dis 2011;7:181–188.)

Keywords: Bariatric surgery; Gastric bypass; Adjustable gastric banding; Complications; Venous thromboembolism; Deep vein thrombosis; Pulmonary embolism; Prophylaxis; Anticoagulation; IVC filter; Bariatric Outcomes Longitudinal Database; BOLD

Obesity has reached epidemic proportions in the United States, with nearly two thirds of the adult population considered overweight and one third considered obese [1]. This has led to a substantial increase in the number of bariatric procedures performed annually to treat morbid obesity. An estimated 220,000 weight loss procedures were performed in the United States in 2008 [2].

Morbidly obese patients undergoing bariatric surgery have typically been burdened by a host of obesity-related co-morbidities that increase their risk of developing complications from surgery. Venous thromboembolism (VTE) is a serious complication and a major cause of postoperative mortality in bariatric surgery patients. The incidence of VTE, presenting as deep vein thrombosis (DVT) or pulmonary embolism (PE), has varied widely across published

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1550-7289/11/$ – see front matter
doi:10.1016/j.soard.2010.12.008

studies. However, it has generally been reported at 1–3% for DVT and .3–2% for PE [3–6]. VTE prophylaxis (VPX) has been recommended for all patients undergoing bariatric surgery; however, no clear consensus has been reached regarding the best regimen or optimal treatment period [3,4,7–9].

Several studies have explored the risk factors for VTE in the bariatric surgery population but have generally been limited to small study cohorts, most at single sites [3,5,8,10–12]. The patient-derived risk factors implicated in these studies included previous DVT/PE, increasing age, high body mass index (BMI), and smoking, with anastomotic leak and prolonged immobilization as triggering events.

The present study used the Bariatric Outcomes Longitudinal Database (BOLD) to identify the factors that correlated with VTE in the bariatric surgery population. BOLD is a large, prospective registry of bariatric surgery information collected of all patients undergoing bariatric surgery at centers participating in the Bariatric Surgery Center of Excellence (BSCOE) program [13]. As of September 2010, BOLD contained >300,000 patient records, with an average accrual rate of nearly 12,000 patients/mo. The data are currently entered into BOLD by >1000 surgeons and 600 facilities, providing a large, geographically diverse population for analyzing low-frequency events, such as VTE.

Methods

Database

BOLD was created by Surgical Review Corporation in 2007 as a tool to monitor and track the outcomes of surgeries performed by participants in the American Society for Metabolic and Bariatric Surgery (ASMBS) BSCOE program. BSCOE participants are required to enter prospective data for all bariatric surgery patients during all phases of care, including data collected at the preoperative visits, during the hospital stay, and at the postoperative visits.

BOLD data are used to ensure compliance with the requirements of the BSCOE program and for research. The use of the BOLD data for research to develop general knowledge about optimal bariatric surgery practices was approved by the University and Medical Center Institutional Review Board (2007–2009) and the Copernicus Group Independent Review Board (2010). The BOLD study was registered with the National Institutes of Health (NCT01002352; available from www.clinicaltrials.gov).

On request from Surgical Review Corporation's Research Department, the data from patients who have agreed to allow their information to be used for research purposes can be extracted from BOLD and de-identified to create a "research" database used for aggregate data analysis. Because BOLD is a prospective database with new patients enrolled daily, it does not have a traditional study enrollment period with defined data entry start points and endpoints. Therefore, each research database created represents a snapshot in time. Some patients will have complete surgical records and up-to-date postdischarge follow-up. Others will have only a preoperative visit entered because their surgery had not yet occurred. Still other patients will have had the surgical data entered but no postdischarge follow-up visits because they had not yet reached the 30- or 90-day postoperative point. Verification of the data entered into BOLD occurs through site inspections in which the data captured from patient charts is reconciled with BOLD data.

Study population

The present study included research-consented patients aged 18–85 years, with a BMI of 30–90 kg/m^2, who had undergone bariatric surgery before September 22, 2009 and were eligible for a 90-day postoperative follow-up visit. A total of 73,921 patients met the inclusion criteria. This population was used to identify all the patients with a VTE event within 90 days after surgery. The data had been submitted by 555 facilities participating in the BSCOE program.

Data definitions

A description of the patient data entered into BOLD for the preoperative and postoperative encounters and during the facility stay has been previously reported [13]. The principal baseline data used in the present study were limited to age, gender, race, BMI, excess body weight, and a history of DVT, lower extremity edema, and pulmonary hypertension. The intraoperative data used in the present study included the procedure performed, surgical approach, American Society of Anesthesiologists patient classification, VPX methods used (i.e., anticoagulation, thromboembolic deterrent [TED] stockings, foot pump, intermittent venous compression device), and concurrent procedures, including inferior vena cava (IVC) filter placement. The primary outcomes monitored were complications of DVT, PE, and death from DVT or PE. Deaths in which the cause was reported as indeterminate, cardiac failure, stroke, myocardial infarction, respiratory failure (including acute respiratory distress syndrome), bleeding, or other cause were also included as an outcome measure, because VTE could not be excluded as a cause of these events.

DVT/PE event: reporting of a complication of PE or DVT or a death from the causes mentioned occurring during surgery or within 90 days of surgery.

DVT/PE history: defined as a history of DVT/PE if any of the following conditions were selected as the patient's preoperative status: "history of DVT resolved with anticoagulation," "recurrent DVT with long-term anticoagulation medications," "previous PE," "recurrent PE," "recurrent PE, decreased function, hospitalization" or "vena cava

filter." A patient was defined as not having a history of DVT/PE if "no history of DVT/PE" was selected as their preoperative status.

Pulmonary hypertension history: defined as a history of pulmonary hypertension if any of the following were selected as the patient's preoperative status: "confirmed PH diagnosis," "well controlled with anticoagulants and/or calcium channel blockers," "stronger medications and/or oxygen," or "patient needs or has undergone lung transplantation." A patient was defined as not having a history of pulmonary hypertension if "no symptoms or indication of pulmonary hypertension" or "symptoms associated with pulmonary hypertension (i.e., tiredness, shortness of breath, dizziness, fainting)" were selected as their preoperative status.

Lower extremity edema history: defined as a history of lower extremity edema if any of the following were selected as the patient's preoperative status: "symptoms requiring treatment, diuretics, elevation, or hose," "stasis ulcers" or "disability, decreased function, hospitalization." A patient was defined as not having a history of lower extremity edema if "no symptoms of lower extremity edema" or "intermittent lower extremity edema, not requiring treatment" were selected as the preoperative status.

VPX used during surgery: defined as having used VPX during surgery if ≥1 of the following were selected to indicate use during bariatric surgery: "anticoagulation," "TED stocking," "foot pump" or "intermittent venous compression device." A patient was defined as having not used VPX during surgery if "none" was selected or if no options were selected for "DVT prophylaxis" at their intraoperative visit.

IVC filter use: defined as having a previous IVC filter if "vena cava filter" was selected as their preoperative status. A patient was defined as having an IVC filter placed during surgery if "IVC filter" was selected as a concurrent procedure at their intraoperative visit.

Statistical analysis

The summary statistics generated to describe the sample population included the mean and standard deviation for the continuous variables and the frequency and percentage for the categorical variables. The Cochran-Mantel-Haenszel test was used to compare the prophylaxis methods used by surgical procedure. The VTE risks were estimated using the Kaplan-Meier method. Cox proportional hazards regression models were used to evaluate the predictors of VTE within 90 days of surgery. The risk of VTE associated with each independent predictor has been expressed as hazard ratios and 95% confidence intervals (CIs). All statistical analyses were performed using Statistical Analysis Systems statistical software, version 9.2 (SAS Institute, Cary, NC).

Data limitations

The present study had several limitations. The data entered into BOLD by the BSCOE participants was self-reported. Designated individuals at the various sites, many of whom were involved in the care of patients, were responsible for data entry. Training was available to assist with data entry and promote consistent reporting of outcomes, including complications, such as DVT and PE. The surgical practices were responsible for entering all postdischarge complications, even if they were managed by another healthcare provider. These postdischarge events may have been underrepresented in the database. Finally, variations in practice management among the BSCOE participants could have resulted in differences in the time it took to enter an event in the BOLD relative to its occurrence. Therefore, at a given point, the follow-up data could appear to be incomplete for some patients owing to delayed data entry.

Results

A total of 73,921 patients in the BOLD research database met the inclusion criteria. Patients were included if they were eligible for a 90-day postoperative follow-up visit or if they had died of any cause within 90 days after surgery. Of the 73,921 patients, 63.2% had had a follow-up visit at ≥90 days and .11% had died within 90 days after surgery. The majority of patients (79%) were women. The mean age at surgery was 45.8 ± 11.74 years, and the mean BMI was 46.0 ± 7.85 kg/m^2. Of the patients, 3.7% had a history of VTE, 4.3% had a history of pulmonary hypertension, and 26.9% had a history of edema (Table 1). Also, 626 patients (.8%) had had an IVC filter placed either before or concurrent with their bariatric surgery.

Roux-en-Y gastric bypass (RYGB) and adjustable gastric banding (AGB) were by far the most common surgical procedures performed within the cohort, accounting for 53.2% and 39.8% of all procedures, respectively (Table 2). Therefore, this analysis of VTE events focused on these 2 procedures.

Across the RYGB and AGB patients, 93.4% received some form of VPX during surgery. The methods captured in BOLD included IVC filter placement, anticoagulation, and mechanical methods (i.e., TED stockings, foot pump, and intermittent venous compression devices). Of the RYGB and AGB patients, 13.2% received mechanical methods without anticoagulation, 8.0% received anticoagulation alone, and 72.3% received both mechanical methods and anticoagulation (Table 3). In addition, 536 patients (.78%) had had an IVC filter placed either before surgery or concurrent with bariatric surgery. Overall, patients with an IVC filter were less likely to receive additional anticoagulation and/or mechanical VPX

Table 1
Patient characteristics

Characteristic	Overall (n = 73,921)
Age at surgery (yr)	45.8 ± 11.74
Body mass index (kg/m^2)	46.0 ± 7.85
Gender	
Female	58,158 (78.7)
Male	15,763 (21.3)
Race	
White	57,502 (77.8)
Black	7,656 (10.4)
Other	8,763 (11.9)
VTE history	2,760 (3.7)
IVC filter	626 (.8)
Edema history	19,852 (26.9)
PH history	3,177 (4.3)

VTE = venous thromboembolism; IVC = inferior vena cava; PH = pulmonary hypertension.

Data presented as mean ± standard deviation or numbers, with percentages in parentheses.

than patients without a filter. Finally, 12.9% of the filter patients and 6.6% of the nonfilter patients did not receive anticoagulation and/or mechanical VPX.

The percentage of patients receiving mechanical VPX and anticoagulation either alone or in combination was similar across the RYGB and AGB groups. The use of an IVC filter, however, was greater in the RYGB patients than in the AGB patients (.94% versus .60%).

VTE risk

The primary endpoint measured was the occurrence of a VTE event within 90 days after surgery. A total of 260 patients experienced ≥1 VTE event within 90 days postoperatively; 14 patients experienced >1 event. Of these events, 2% occurred during surgery, 25% occurred before discharge from the hospital, and 73% occurred after discharge through 90 days after surgery. The median interval to a VTE event was 14 days (range 0–87). Of those experiencing a VTE event, 97 (37.3%) developed DVT without an ensuing PE and 84 (32.3%) experienced PE. Of the patients, 6 died of PE and 60 died of other specified causes that might or might not have been related to a VTE. The overall risk of VTE was .42% (95% CI .37–.47%) within 90 days. Patients undergoing RYGB had an incidence of .55% compared with .16% for AGB patients (Table 2). VTE was more frequent when the procedure was performed by open access (1.54%) than with laparoscopic access (.34%). In the cohort studied, 92.5% of all surgical procedures were performed with laparoscopic access.

Univariate analysis of risk factors for VTE

The estimated risk of VTE within 90 days based on patient demographic and baseline characteristics is given in Table 4. The risk of VTE was greater for older patients and for patients with a greater BMI, with a hazard ratio of 1.04 (95% CI 1.03–1.05) and 1.05 (95% CI 1.04–1.06), respectively. Men were more likely to experience VTE than were women (HR 2.32, 95% CI 1.81–3.98). The risk of VTE was more prevalent in blacks than in whites (HR 1.65, 95% CI 1.19–2.29). A history of VTE (HR 4.96, 95% CI 3.58–6.88), IVC filter placement (HR 7.66, 95% CI 4.55–12.91), and a history of lower extremity edema (HR 2.23, 95% CI 1.75–2.85) were significant factors for VTE after surgery. Patients with a history of pulmonary hypertension also had an increased risk of VTE (HR 1.80, 95% CI 1.14–2.84).

The use of VPX during surgery had variable effects on the risk of 90-day VTE. Patients undergoing AGB who had received some method of VPX had a decreased risk of VTE compared with those who had not received VPX, although this difference was not statistically significant (HR .50, 95% CI .20–1.28; Table 5). The AGB patients who had received mechanical VPX or anticoagulation either alone or in com-

Table 2
VTE within 90 days of surgery by surgical procedure

Surgical procedure	Overall (n = 73,921)	Patients with VTE within 90 d (n = 260)*	VTE risk (95% CI)†
Procedure			
RYGB	39,350	181	.55 (.48–.64)
Adjustable gastric banding	29,384	40	.16 (.11–.21)
Sleeve gastrectomy	1,806	9	.63 (.32–1.21)
Other	1,377	10	.89 (.48–1.66)
Banded gastric bypass	819	2	.32 (.08–1.34)
Biliopancreatic diversion with duodenal switch	647	14	2.53 (1.50–4.25)
Vertical banded gastroplasty	185	0	
RYGB with distal gastrectomy	97	1	1.03 (.15–7.09)
Nonadjustable gastric banding	72	0	
Gastric balloon	83	2	3.48 (.88–13.20)
None; surgery canceled after induction	62	0	
Biliopancreatic diversion	25	1	5.56 (.80–33.36)
Gastric bypass, mini loop	13	0	
Gastric pacing	1	0	
Surgery approach			
Laparoscopic	68,370	200	.34 (.30–.40)
Open	4,467	54	1.54 (1.18–2.02)
Other	1,084	6	.60 (.27–1.34)

VTE = venous thromboembolism; CI = confidence interval; RYGB = Roux-en-Y gastric bypass.

* VTE events included DVT, PE, 6 deaths from PE, and 60 deaths from other causes.

† VTE risks estimated using Kaplan-Meier method presented as percent with 95% CI.

Table 3
VTE prophylaxis method used by procedure and IVC filter history

VTE prophylaxis method used	Adjustable gastric banding		Gastric bypass		Total	
	No IVC filter (n = 27,219)	IVC filter (n = 165)	No IVC filter (n = 38,978)	IVC filter (n = 371)	No IVC filter (n = 68,197)	IVC filter (n = 536)
None	2,073 (7.09)	7 (4.24)	2,406 (6.17)	62 (16.71)	4,479 (6.57)	69 (12.87)
Mechanical	4,275 (14.63)	25 (15.15)	4,728 (12.13)	32 (8.63)	9,003 (13.20)	57 (10.63)
Anticoagulation alone	1,926 (6.59)	7 (4.24)	3,519 (9.03)	16 (4.31)	5,445 (7.98)	23 (4.29)
Both	20,945 (71.68)	126 (76.36)	28,325 (72.67)	261 (70.35)	49,270 (72.25)	387 (72.20)

Abbreviations as in Table 1.
Data presented as numbers, with percentages in parentheses.

bination also had a lower risk of VTE events within 90 days after surgery compared with patients who had not received these methods. The small number of AGB patients with an IVC filter as their only method of VPX showed an increased risk of VTE (HR 9.83, 95% CI 2.37–40.75).

In contrast, among the RYGB patients, the risk of 90-day VTE was greater for those receiving some method of VPX compared with those receiving no method (HR 5.90, 95% CI 1.46–23.75; Table 6). This increase in VTE risk appeared to be greater for the patients who had received anticoagulation, either alone or combined with other methods, than for the patients who had received mechanical VPX. As with the AGB patients, the RYGB patients with an IVC filter as their only method of VPX had an increased risk of postoperative VTE (HR 5.90, 95% CI 3.02–11.54).

Discussion

DVT and PE remain serious complications of bariatric surgery, despite the widespread use of prophylactic therapy and the trend toward less-invasive surgical procedures. Although these events have been relatively uncommon, PE is a major cause of postoperative mortality in bariatric surgery patients [3–6].

Large patient populations are required for the study of factors that predict the risk of low-incidence complications, such as VTE. Although a single center might need to track the outcomes for many years to obtain sufficient cases for a study, BOLD provides a large patient cohort suitable for studying such events.

The incidence of DVT and PE reported across published studies has been highly variable owing to the differences in the composition and size of the study population, the study

Table 4
90-Day VTE risk factors based on baseline characteristics

Characteristic	VTE risk (95% CI)*	HR (95% CI)	*P* value
Gender			
Female	.32 (.28–.38)		
Male	.76 (.62–.92)	2.32 (1.81–2.98)	<.0001
Race			
White	.42 (.36–.48)		
Black	.71 (.53–.96)	1.65 (1.19–2.29)	.0025
Other	.14 (.08–.26)	.35 (.19–.66)	.0012
Age (each 1-yr increment)	NA	1.04 (1.03–1.05)	<.0001
BMI (each 1-kg/m^2 increment)	NA	1.05 (1.04–1.06)	<.0001
VTE history			
No (referent)	.36 (.32–.41)		
Yes	1.76 (1.30–2.36)	4.96 (3.58–6.88)	<.0001
IVC filter			
No (referent)	.40 (.35–.45)		
Yes	2.95 (1.78–4.87)	7.66 (4.55–12.91)	<.0001
Edema history			
No (referent)	.31 (.26–.36)		
Yes	.70 (.59–.84)	2.23 (1.75–2.85)	<.0001
Pulmonary hypertension history			
No (referent)	.40 (.35–.46)		
Yes	.74 (.47–1.14)	1.80 (1.14–2.84)	.0117

HR = hazard ratio; BMI = body mass index; other abbreviations as in Tables 1 and 2.
VTE risks estimated using Kaplan-Meier method presented as percent with 95% CI.

Table 5
Risk of 90-day VTE according to methods of VTE prophylaxis used during adjustable gastric banding surgery

Prophylaxis	VTE risk (95% CI)*	HR (95% CI)	*P* value
Mechanical, anticoagulation, and/or IVC filter†		.50 (.20, 1.28)	.1505
No (referent)	.28% (.12–.68)		
Yes	.15% (.11–.20)		
Mechanical VPX‡		.60 (.28, 1.31)	.2030
No (referent)	.23% (.12–.47)		
Yes	.14% (.10–.20)		
Anticoagulation only‡		1.04 (.48, 2.25)	.9301
No (referent)	.15% (.08–.30)		
Yes	.16% (.11–.22)		
IVC filter‡		9.83 (2.37,40.75)	.0016
No (referent)	.15% (.11–.20)		
Yes	1.57% (.39–6.13)		
Mechanical and anticoagulation methods§			
No method (reference)	.28% (.12–.67)	—	—
Mechanical alone	.09% (.03–.28)	.30 (.07, 1.25)	.0977
Anticoagulation alone	.18% (.06–.57)	.63 (.15, 2.64)	.5281
Mechanical and anticoagulation	.15% (.11–.22)	.53 (.21, 1.37)	.1927

HR = hazard ratio; other abbreviations as in Tables 1 and 2.
* VTE risks estimated using Kaplan-Meier method, presented as percent with 95% CI.
† Comparing VTE risk in patients receiving some method of VPX versus no method.
‡ Comparing VTE risk in presence versus absence of given VPX method (other methods could be used).
§ Comparing VTE risk in patients receiving single method of VPX versus no method.

design (prospective versus retrospective), the surgical procedure performed, and the VPX methods used [3–6]. Bariatric surgery has been shown to have the lowest risk of inpatient VTE (.35%, unadjusted) among 8 major abdominal surgeries evaluated using the Nationwide Inpatient Sample (2001–2005) [14]. These findings have been attributed to greater awareness among bariatric surgeons of the increased risk of VTE in bariatric patients and the widespread use of VPX methods in this population.

The low overall incidence of VTE for the BOLD population was within the ranges reported in published studies. The estimated overall risk of VTE among the 73,921 patients who had undergone bariatric surgery by a BSCOE participant was .42% within 90 days after surgery. The risk

Table 6
Risk of 90-day VTE according to methods of VTE prophylaxis used during Roux-en-Y gastric bypass surgery

Prophylaxis	VTE risk (95% CI)*	HR (95% CI)	*P* value
Mechanical, anticoagulation and/or IVC filter†		5.90 (1.46,23.75)	.0126
No (referent)	.11% (.03–.42)		
Yes	.58% (.50–.67)		
Mechanical VPX‡		1.56 (.97, 2.51)	.0675
No (referent)	.37% (.24–.58)		
Yes	.58% (.50–.68)		
Anticoagulation only‡		2.44 (1.44, 4.14)	.0009
No (referent)	.25% (.15–.42)		
Yes	.62% (.53–.72)		
IVC filter‡		5.90 (3.02,11.54)	<.0001
No (referent)	.53% (.46–.62)		
Yes	2.90% (1.51–5.54)		
Mechanical and anticoagulation methods§			
No method (referent)	.10% (.03–.41)	—	—
Mechanical alone	.31% (.18–.56)	3.32 (.74,14.83)	.1159
Anticoagulation alone	.56% (.35–.90)	5.95 (1.38,25.74)	.0170
Mechanical and anticoagulation	.63% (.53–.73)	6.53 (1.62,26.33)	.0084

HR = hazard ratio; other abbreviations as in Tables 1 and 2.
* VTE risks estimated using Kaplan-Meier method presented as percent with 95% CI.
† Comparing VTE risk in patients receiving some method of VPX versus no method.
‡ Comparing VTE risk in presence versus absence of given VPX method (other methods could be used).
§ Comparing VTE risk in patients receiving single method of VPX versus no method.

of incurring such an event varied considerably depending on the type of procedure performed and the surgical approach. The risk of VTE was lowest for the patients undergoing AGB (.16%), a procedure almost exclusively performed laparoscopically, and greatest for patients undergoing biliopancreatic diversion (5.56%) and biliopancreatic diversion with duodenal switch (2.53%), procedures more commonly performed by open access. The risk of VTE was 4.5 times greater when the procedure was performed by open access than by laparoscopic access.

Univariate analysis showed that increased age, high BMI, male gender, and VTE history were risk factors for postoperative VTE. These results are consistent with the findings reported across several published studies [3,5,8,10–12]. Increased age and history of VTE are well-established VTE risk factors, having been studied in multiple patient cohorts, including the Nationwide Inpatient Sample [10]. Male gender is also a well-described risk factor for VTE in general surgery that has been implicated for bariatric surgery [10,15]. Other risk factors have been explored to a lesser extent. Gonzalez et al. [12] showed that in addition to age >50 years and a history of DVT/PE, anastomotic leak and smoking increased the likelihood of VTE. Carmody et al. [11] demonstrated an association of BMI, obesity hyperventilation syndrome, venous stasis disease, and anastomotic leak with an increased risk of VTE. Although information related to tobacco use, the status of obesity-related co-morbidities, including the severity of obesity hyperventilation syndrome, and the development of complications, including anastomotic leak, is recorded in BOLD, these factors were not included in the present initial analysis.

The current guidelines issued by the American College of Chest Physicians recommend the use of pharmacologic prophylaxis therapy for bariatric surgery patients [16]. The ASMBS position statement on prophylactic measures to reduce the risk of VTE recommends early postoperative ambulation and perioperative use of lower extremity compression devices, with adjunct anticoagulant regimens [7]. According to these guidelines, the ASMBS BSCOE program adopted a requirement that all bariatric programs implement a clinical pathway for the prevention of VTE. BSCOE participants are not required to follow a specific VPX regimen prescribed by Surgical Review Corporation; however, they are expected to demonstrate that they have a detailed plan in place and that the relevant staff exhibit practical knowledge of the plan, including how to recognize signs and symptoms of the complication. BOLD is used as a tool to monitor compliance with this program requirement. BOLD tracks the use of anticoagulation and mechanical methods of VPX (i.e., TED stockings, foot pump, and intermittent venous compression device) and IVC filter use. The use of aggressive early ambulation, either alone or combined with other VPX methods, is not presently tracked in BOLD.

The results of the present study have shown that >93% of patients in BOLD received some form of VPX during surgery, with most patients receiving ≥2 methods. Most patients with an IVC filter in place also received anticoagulation or mechanical VPX. In a recent survey of the physician members of the ASMBS, 98% of respondents indicated they routinely used mechanical prophylaxis for VTE, and 94% reported chemical prophylaxis use [4]. In addition, 55% of members surveyed indicated the use of IVC filters in their high-risk patients.

For both AGB and RYGB patients, IVC filter placement was associated with an increased incidence of postoperative VTE. This might have reflected the general high-risk nature of the patients receiving a filter and/or it might be attributed to the finding that patients with an IVC filter were less likely to receive anticoagulation or mechanical VPX. Although the prophylactic use of filters has been recommended for patients with extreme obesity, a history of VTE, and limited ambulation, strong evidence supporting the efficacy of these devices in preventing VTE without the use of complementary methods of VPX is lacking [3,4,11].

For AGB patients, VPX treatment, in particular, mechanical methods alone, was protective within the first 90 days after surgery, improving the overall risk of VTE by greater than twofold, although the difference was not significant in our study. In contrast, in the RYGB patients, VPX treatment correlated with a trend toward an increased risk of VTE. This increase in risk tended to be greater when anticoagulants were used than with mechanical VPX. Additional analysis of this patient cohort is needed to fully understand the factors contributing to this finding and to inform the design of future studies in other populations.

Most VTE events in the present study occurred after discharge, consistent with published data showing that one quarter to one half of all VTE events occurred in bariatric surgery patients within the first 30 days after leaving the hospital [3,4,9,15,17]. With the trend toward shorter hospital stays, VTE has become more common in the postdischarge setting. Although the American College of Chest Physicians guidelines have recommended that VPX treatment be extended after discharge in high-risk patients [16], the issue remains controversial considering the limited evidence obtained from prospective, controlled trials suggesting the optimal duration and timing of VPX for bariatric surgery patients. BOLD currently allows information regarding VPX use to be entered into BOLD for intraoperative visits, but no tracking of VPX use is done once the patient has left the operating room. Thus, in the present study, it could not be determined whether VPX was continued postoperatively, and, if so, whether it offered protection against VTE. Additionally, BOLD currently captures the use of anticoagulants as a class, without distinguishing among the various anticoagulant agents. Low-molecular-weight heparin has been noted as the most common agent used for chemical prophylaxis, followed by unfractionated heparin [4]. These agents have been shown to have similar efficacy and safety, although low-molecular-weight heparin

has several advantages owing to its more favorable pharmacokinetic profile [3]. However, differences in the use and efficacy of low-molecular-weight heparin and unfractionated heparin could not be discerned in the present study cohort. Future adjustments to the BOLD data set should include specifying the type and dose of anticoagulant used during bariatric surgery, adding postoperative ambulation as an option for VPX, and allowing VPX use to be tracked beyond the intraoperative visit.

Conclusion

The overall risk of VTE was low in the population treated by BSCOE participants, where clinical pathways to prevent VTE have been mandated. Analysis of the present large patient cohort allowed the identification of patient characteristics correlating with an increased risk of postoperative VTE and the variable effectiveness of VPX methods. Additional analysis of BOLD to identify other risk factors for VTE is needed for these findings to be considered for clinical application.

Acknowledgment

Surgical Review Corporation acknowledges the surgeons and facilities that enter data into BOLD for their participation in this important initiative.

Disclosures

D. A. Winegar and B. Sherif are full-time employees of Surgical Review Corporation E. J. DeMaria is an educational or research grant recipient from Covidien/US Surgical and Stryker and has been a consultant to Affinergy and the Surgical Review Corporation.

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