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Article in *Surgical Endoscopy* · July 2014

DOI: 10.1007/s00464-014-3678-4 · Source: PubMed

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Thromboembolic events in bariatric surgery: a large multi-institutional referral center experience

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Received: 1 April 2014 / Accepted: 26 May 2014
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Abstract

Introduction The risk of venous thromboembolic (VTE) events is increased in patients undergoing bariatric surgery. Population studies examining VTE rates after bariatric surgery often lack details and uniformity regarding the prophylactic regimens used. The aim of this study was to determine the incidence of VTE in patients undergoing laparoscopic bariatric surgery.

Methods Database searches from Cleveland Clinic bariatric surgery programs in Cleveland, OH, and Weston, FL, were conducted from January 2005 to January 2013. Mechanical and chemical prophylaxes were provided for all patients as per protocol. Data on age, gender, body mass index (BMI), interval between procedure and VTE, inpatient versus outpatient status, anticoagulation prophylaxis, type of surgery and mortality were collected.

Results A total of 4,293 patients underwent primary or revisional bariatric surgery during this 8-year time period.

VTE events were identified in 57 patients (1.3 %). Pulmonary embolism (PE) was identified in 39 patients (0.9 %), and 15 of these patients had negative duplex studies of the lower extremities. Deep venous thrombosis only was identified in 18 patients (0.4 %). VTE rates for gastric bypass ($n = 2,945$), sleeve gastrectomy ($n = 709$), gastric banding ($n = 467$) and revisional procedures ($n = 171$) were 1.1, 2.9, 0.2 and 6.4 %, respectively. Eight patients had VTE diagnosed during their inpatient stay. The mean time to VTE diagnosis after surgery was 24 days. Seventeen patients who developed VTE had been prescribed extended prophylaxis for 2–4 weeks after discharge. There was only one VTE-related mortality from PE reported in this cohort (0.02 %). Univariate and multivariate analyses revealed age, BMI, open and revisional surgery as predictive of VTE ($p < 0.05$).

Conclusion The risk of VTE among morbidly obese patients undergoing bariatric surgery is persistent despite use of laparoscopy and aggressive prophylactic anticoagulation policy. Patients with advanced age, higher BMI and

This article was presented at the SAGES 2014 annual meeting, April 2–5, 2014, Salt Lake City, Utah.

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those undergoing open or revisional surgery are at higher risk of postoperative VTE.

Keywords Bariatric · Intensive care · Obesity

Patients undergoing bariatric surgery are at increased risk of venous thromboembolic events (VTE) in the form of deep venous thrombosis (DVT) and pulmonary embolism (PE) [1]. Obesity in itself is a risk factor for VTE [2], and it is also associated with diabetes mellitus (DM), hypertension and venous stasis which are diseases known to increase risks of VTE [3].

The reported incidence of VTE varies in the literature from 0.2–3.5 %, with PE rates as high as 1.2 % [4], with large series reporting an incidence less than 1 % of VTE [5, 6]. The incidence of fatal PE is not well described, but PE is reported to be one of the top two causes of mortality post-bariatric surgery [7, 8].

The optimal prophylaxis regimen for prevention of VTE is not identified yet nor supported by level-one evidence. The American Society of Metabolic and Bariatric Surgeons (ASMBS) issued their first position statement on prophylactic measures to reduce the risk of venous thromboembolism in bariatric surgery patients in 2007 and updated it in 2013. The ASMBS considers all bariatric patients to be at moderate to high risk of VTE, and recommends the use of mechanical prophylaxis and early ambulation with or without chemoprophylaxis depending on clinical judgment and consideration of the risk of bleeding [9].

Several factors were identified to be indicative of high risk of VTE in bariatric patients including hypercoagulable condition, obesity hypoventilation syndrome, pulmonary hypertension, venous stasis disease, hormonal therapy, expected long operative time or open approach, and male gender [9]. With the identification of these high-risk factors and the use of prophylaxis against VTE in bariatric patients, the incidence of VTE should be decreasing. In this study, we evaluated our institutional experience to identify the incidence of VTE among our cohort after the adoption of laparoscopic access as the main method for performing bariatric surgery.

Methods

After obtaining the IRB approval, we retrospectively reviewed the prospectively collected database from the Cleveland Clinic bariatric surgery programs in Cleveland, OH (CC), and Weston, FL (CCW), for patients who had a diagnosis of VTE from January 2005 to January 2013.

The electronic medical records were abstracted for baseline demographic characteristics, preoperative comorbid conditions, bariatric procedures, management of DVT

and outcomes of follow-up. Mechanical and chemical prophylaxes were provided for all patients as per routine (see below). Data on age, gender, body mass index (BMI), interval between procedure and VTE, inpatient versus outpatient status, anticoagulation prophylaxis, type of surgery and mortality were collected. We did not exclude patients based on their risk of VTE. Contraindications for bariatric surgery were mainly psychiatric contraindications which include as follows: substance abuse problem, psychiatric hospitalization, suicide attempt, psychiatric diagnosis that would impair ability to adhere to postoperative regimen, inability or unwillingness of patient to fully comprehend the surgery or consequences and inability or refusal to participate in lifelong medical surveillance. Medical contraindications include severe cardiorespiratory disease and end-stage liver disease.

Venous thromboembolism prophylaxis

There were two different prophylaxis used at the two centers involved in this study. At CC, routine prophylaxis included subcutaneous injection intraoperatively of 5,000 units of unfractionated heparin as well as the application of pneumatic compression device at the time of surgery. Postoperatively early ambulation the night of surgery was performed as well as the application of a pneumatic compression device intra- and postoperatively and routine anticoagulation in the form of LMWH (enoxaparin, Aventis Pharmaceuticals, Inc) 40 units BID. If the patient had a BMI above 50, the patient would receive 60 units BID of LMWH and an extended course of LMWH for 2 weeks postoperatively. At CCW campus, patients who were deemed high risk received an IVC filter prior to the operation. Preoperatively 5,000 units of unfractionated heparin was given subcutaneously. Pneumatic compression device was applied at the time of surgery and postoperatively. In the first 24 h postoperatively, patients received unfractionated heparin 5,000 units BID, then they received LMWH 40 U BID. Patients did also have routine ultrasound of the lower limb performed on postoperative day 1. No extended course of LMWH was given postoperatively.

At CC, prolonged prophylaxis would be given to the following patients; lymphedema, wheel chair bound, pulmonary hypertension and those with a BMI > 50. At CCW, an IVC filter is placed in the same category of patients.

Statistical analysis

Data are presented as mean \pm standard deviation for continuous variables and frequency percentages for categorical variables. The distribution of the data was checked for normality using the Shapiro–Wilk test. These characteristics

Table 1 Characteristics of patients with VTE events

	VTE (<i>n</i> = 57)	Non-VTE (<i>n</i> = 4,293)
Age (years)	49 ± 10.5	46.1 ± 9.8
Male (%)	26.1	31.6
Female (%)	73.9	68.40
Initial BMI (kg/m ²)	52.0 ± 11.7	48.4 ± 12.7
Comorbidities (%)		
Diabetes	35.1	29.9
Hypertension	59.6	56.1
Sleep apnea	49.1	32.7
History of VTE	10.5	7.5
Procedure (n, %)		
Gastric bypass	32 (56.1)	2,913 (67.8)
Sleeve gastrectomy	12 (21.0)	697 (16.2)
Gastric band	1 (1.7)	466 (10.8)
Duodenal switch	1 (1.7)	0 (0.0)
Revisional surgery	11 (19.2)	160 (3.7)

VTE venous thromboembolic, OR operative

were analyzed using unpaired Student's *t* test (or Mann-Whitney test) for continuous variables and chi-square test (or Fisher's exact test) for categorical variables. Uni- and multivariate analyses were used to evaluate the risk factors for VTE after bariatric surgery. Manual backward elimination was used to achieve a best-fit logistic regression model. All tests were two-tailed and the results with a *p* < 0.05 were considered statistically significant. Statistical analyses were performed using the software package PASW, version 22.0, for Windows (SAS Institute, Cary, NC).

Results

From January 2005 to January 2013, 4,293 patients underwent bariatric surgery at the two institutions. VTE events were identified in 57 patients (1.3 %). The mean age was 49.0 ± 10.5, and the mean BMI was 52.0 ± 11.7. The bariatric procedures for these patients are summarized in Table 1. Fourteen patients (24.6 %) had postoperative complications in addition to VTE within 30 days of surgery, including four leaks and two hemorrhages. Of VTE patients, 39 had pulmonary embolism (PE) and 18 had deep venous thrombosis only. Of PE patients, massive PE was identified in 3 (7.7 %) and negative duplex studies of the lower extremities in 15 (38.5 %). Eight patients (14.0 %) had VTE diagnosed during their inpatient stay. The mean time to VTE diagnosis after surgery was 24 days (range 2–124). Seventeen patients who developed VTE had been prescribed extended prophylaxis for 2–4 weeks after discharge. There was only one VTE-related mortality from PE reported in this cohort (0.02 %).

Table 2 Type of operation in the VTE group

Procedure	Patients (<i>n</i>)	Percentage (%)
Lap RYGB	30	52.6
Lap SG	12	21.1
Lap revisional RYGB	7	12.3
Lap gastric banding	1	1.8
Lap DS	1	1.8
Open RYGB	2	3.5
Open revisional RYGB	3	5.3
Open reversal	1	1.8

VTE venous thromboembolic, Lap Laparoscopic, RYGB gastric bypass, SG sleeve gastrectomy, DS duodenal switch

VTE rates for gastric bypass (*n* = 2,945), sleeve gastrectomy (*n* = 709), gastric banding (*n* = 467) and revisional procedures (*n* = 171) were 1.1, 2.9, 0.2 and 6.4 %, respectively. VTE patients had higher age and preoperative BMI compared to non-VTE patients. Univariate and multivariate analyses revealed age, preoperative BMI, open and revisional surgery as predictive of VTE (Tables 2, 3).

Discussion

In this study, we reported our VTE and PE rates from a large cohort of patients who underwent mostly laparoscopic bariatric surgery and were provided mechanical and chemoprophylaxis. The VTE rate in this cohort was 1.3 %, with a PE rate of 0.9 % and a fatal PE rate of 0.02 % for all patients undergoing bariatric surgery corresponding to one mortality only. For those patients experiencing a VTE event, the mortality rate was 1/57 or 1.8 %. Our incidence of VTE is similar to other large cohorts. Stein et al. [10] analyzed the Nationwide Inpatient Sample database, for patients who underwent bariatric surgery from 2007 to 2009 and found a PE prevalence of 4,500 of 508,230 (0.9 %), and a VTE prevalence of 2.2 % (10,980 of 508,230).

Demaria et al. evaluated PE rates in 3,861 patients who underwent open and laparoscopic bariatric procedures from 1980 to 2004, prior to wide adoption of routine chemoprophylaxis [5]. They reported a PE rate of 0.85 % (33 patients) with a PE-related mortality risk of 27 %. They found no difference in the rates of PE, when comparing open and laparoscopic cases. They also found no difference in the rates of PE when comparing incidence of PE in patients in the chemoprophylaxis era when compared to those who had their operations prior to the institution of routine chemoprophylaxis protocol.

There are no randomized trials in the bariatric surgery population to support the use of a specific

Table 3 Univariate and multivariate analyses

	VTE	Non-VTE	Univariate <i>p</i> value	Multivariate <i>p</i> value
Female gender (%)	73.9	68.40	0.6	0.2
Age (year)	49 ± 10.5	46.1 ± 9.8	0.04	0.001
Preoperative BMI	52.0 ± 11.7	48.4 ± 12.7	0.03	0.01
Open procedure	6	11	0.0001 ^a	0.0001 ^a
Revisional surgery	11	160	0.0001 ^b	0.004 ^b

VTE venous thromboembolic,
^a versus non-open, ^b versus non-revision

chemoprophylaxis protocol. The routine chemoprophylaxis protocol used by Carmody et al. [5] was instituted in 1998 and included a preoperative injection of 5,000 units of subcutaneous heparin and a daily injection of 40 units of LMWH.

Birkmeyer et al. [6] analyzed the Michigan Bariatric Surgery Collaborative (MBSC) database, which is a state-wide database for patients who underwent bariatric surgery from 2007 to 2012 to evaluate the safety and effectiveness of current chemoprophylaxis protocols. They identified three chemoprophylaxis protocols, one using unfractionated heparin (UH) pre- and postoperatively, one using UF heparin preoperatively and LMWH postoperatively UF/LMWH and one using LMWH pre- and postoperatively LMWH/LMWH. They found all these regimens to be safe in terms of the rate of bleeding but determined that the LMWH/LMWH protocol was the most effective in terms of prevention of VTE.

The two centers at our institution used a similar prophylaxis strategy in which patients received 5,000 U of UH intraoperatively and LMWH twice daily of 40 U. We encourage mobilization on the same night of surgery, and we apply a sequential compression device (SCD) at the time of surgery and postoperatively. The two centers differed in their prophylaxis of what is deemed a high-risk patient. At CC, any patient considered to be at high risk of VTE will receive a 2 weeks course postoperatively of a prophylactic dose of LMWH. At CCW, patients who were deemed high risk had an IVC filter placed preoperatively. There were no variations in the VTE prophylaxis regimens in each center during the study period. We observed no difference statistically between the two centers in VTE rates. The definition of high-risk patients varies in the literature. Patients with a BMI > 50, obesity hypoventilation syndrome, pulmonary hypertension, history of previous VTE, venous stasis and immobility are thought to be at high risk of VTE [4].

Factors associated with high risk of VTE in our cohort of patients were age, BMI, open and revisional surgery ($p < 0.05$). The strongest association with VTE was open and revisional procedures, possibly due to the longer operative time and the higher complication rate, but we did not control for these factors in our analysis due to the

retrospective nature of this study. Further, our data cannot suggest the open approach which is necessarily a risk factor for VTE since all patients who underwent the open approach were high risk by definition. Indeed, the rate of complications in our VTE cohort was at 24.6 % which is considered to be a high complication rate. Finks et al. [4] analyzed the MBSC database and identified several high-risk factors for VTE that they included in a VTE risk calculator model. These factors were a prior history of VTE, male gender, high BMI, procedure time longer than 3 h, procedure type with duodenal switch carrying the highest risk followed by open gastric bypass, laparoscopic gastric bypass and sleeve gastrectomy. One of the limitations of the MBSC database is that it captures only events occurring 30 days post-surgery. The mean time to VTE diagnosis after surgery in our cohort was 24 days (range 2–124).

Despite using a prophylactic dose of LMWH post-discharge, 17 patients developed VTE while being on prophylaxis as outpatient. This is an interesting finding as, to our knowledge, no other single institution reports describe a similar protocol with the result of its implementation. The use of IVC filters is still controversial with conflicting reports. In fact a study analyzing VTE among 73,921 bariatric patients from the Bariatric Outcomes Longitudinal database identified the use of IVC filters as an independent risk factor for VTE postoperatively [11]. Other risk factors for VTE in that study were open surgery, previous history of VTE, male gender, older age and high BMI. They also found that the majority of VTE occurs after patients discharge, which is similar to our finding in this study with only 8 patients (14 %) diagnosed with VTE as inpatients.

Birkmeyer et al. [12] analyzed 6,376 patients who underwent gastric bypass between 2006 and 2008 and identified 542 patients who had an IVC filter inserted preoperatively. They used propensity scores to account for the known confounders among different subgroups. They divided the patients into subgroups according to the VTE risk factor present (immobility, BMI > 50, age > 50, open procedure, history of previous VTE) and found that the complication rates were higher among the IVC filter patients in all patients subgroups except the history of previous VTE subgroup where the complication rates were similar to those not receiving an IVC filter.

There are several limitations in this study, which should be considered when interpreting these results. This is a retrospective review of the data with all the inherent limitations associated with retrospective reviews. The degree of adherence to VTE prophylaxis protocols by caregivers and patients at both institutions, which may significantly affect incidence of VTE events, is not known. The reported rates of clinically significant pulmonary embolism and venous thromboembolism in this retrospective study are likely an underestimate of actual rates due to limitations in follow-up, accurate diagnosis and inability to capture follow-up data from other institutions serving our patients, considering that we receive referrals from primary and secondary health centers and hospitals at significant distances away from our tertiary center. The strength of this study is that it is a contemporary series with a large number of patients who underwent laparoscopic bariatric surgery with a mechanical and chemoprophylaxis regimens which takes into account the high-risk group patients.

Given that VTE rates remain at significant levels and lead to major disability and death despite the adoption of evidence-based mechanical and chemoprophylaxis protocols, there is a need for large prospective multi-institutional studies to evaluate various prophylactic regimens for safety and efficacy. Bariatric surgeons should abide by current evidence-based VTE prophylaxis regimens particularly for high-risk groups including patients with advanced age, high BMI and those undergoing open or revisional procedures.

Conclusion

The risk of VTE among morbidly obese patients undergoing bariatric surgery is persistent despite use of laparoscopy and aggressive prophylactic anticoagulation policy. Patients with advanced age, higher BMI and those undergoing open or revisional surgery are at higher risk of postoperative VTE.

Disclosure Mohammad H. Jamal, Ricard Corcelles, Hideharu Shimizu, Mathew Kroh, Fernando M. Safdie, Raul Rosenthal, Stacy A. Brethauer and Philip R. Schauer have no conflicts of interest or financial ties to disclose.

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