ORIGINAL ARTICLE

Efficacy of Prophylaxis Protocol in Prevention of Venous Thromboembolism in Bariatric Surgery Patients

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Abstract

Background: In patients undergoing bariatric surgery, different techniques have been used to avoid venous thromboembolism (VTE), including pharmacological prophylaxis and mechanical prophylaxis. Our aim was to determine the effectiveness of the prophylaxis procedure (pharmacological and mechanical prophylaxis) to prevent VTE following bariatric surgery.

Patients and methods: We performed the present cross-sectional study on patients with morbid obesity who were scheduled to undergo bariatric surgery. The primary outcome of the present stud was the incidence of VTE. The diagnosis of VTE was based on a duplex ultrasound. Patients were followed up for 1 month after the procedure.

Results: Two patients develop pulmonary embolism (6.1%). The first patient was female aged 40-years-old who underwent a sleeve gastrectomy (SG). Her body mass index (BMI) was 43 kg/m^2 and she had a history of diabetes, hypertension (HTN), and VTE 5 years ago. On the 5th postoperative day, she complained of shortness of breath and chest pain, which was followed by the diagnosis of pulmonary embolism and ICU admission. The second patient was a female aged 49-years-old who underwent one anastomosis gastric bypass (OAGB) operation. Her BMI was 55 kg/m^2 and she had a history of diabetes, HTN, and chronic obstructive pulmonary disease (COPD). Twelve days after operation, she complained of chest pain, palpitations, and shortness of breath, which was followed by the diagnosis of pulmonary embolism and ICU admission.

Conclusion: In conclusion, VTE is associated with an increased risk of morbidity and mortality after bariatric surgery; however, it can be prevented using an extensive course of thromboprophylaxis. For the best regime in VTE prevention after the bariatric operation, more prospective experiments are needed.

Keywords: Bariatric surgery, Obesity, Prophylaxis, Venous thromboembolism.

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Introduction

Venous thromboembolism (VTE) is considered the most prevalent cause of postsurgical morbidity and mortality.[1] About 150,000 individuals die annually from pulmonary embolism (PE) in the United States, most of them due to deep venous thrombosis (DVT).[2] DVT typically has nonspecific symptoms and signs and is usually difficult to detect in patients who are morbidly obese.[3] Physical examination is very difficult in obese patients, and they often have subtle first signs so that minimally symptomatic DVT can quickly progress to fatal PE.

Obesity is an abnormal accumulation of body fat to the extent that it may have a negative effect on health.[4] A strong correlation between obesity and type II diabetes, hypertension (HTN), dyslipidemia, cardiovascular disease, sleep apnea syndrome, and several types of cancer is confirmed by long-term research.[5] Obesity contributes to a deterioration of the quality of life.[6] In both developed and developing countries, the prevalence of obesity is growing rapidly and is considered one of the most severe public health issues.[7,8]

Bariatric surgeries, including sleeve gastrectomy (SG) and gastric bypass surgery (GBS), play a significant and well-established role in the care of obese and morbidly obese patients.[9] In 2013, the number of bariatric surgeries alone in the United States was close to 180,000.[10] Bariatric surgeries are very successful in reducing morbid obese patients' weight and improving obesity and associated complications.[11] Accurate, evidence-based risk evaluation methods for VTE in bariatric patients are currently not available, but many risk factors that need to be addressed are identified in the literature to evaluate a prophylaxis strategy.[12] Higher age, gender, body mass index (BMI), immobility, venous stasis disease, operative time, and type and approach of the procedure can be included in these risk factors.

Obesity also interferes with the mechanisms of anticoagulants, leading to a hyper coagulating state.[13] In obese patients, plasma concentrations of von Willebrand, fibrinogen, and factor VII are substantially elevated, while platelet aggregation due to leptin is promoted.[14] There is evidence that some of the above abnormalities may be partly reversed by the treatment of morbid obesity, as weight loss is associated with a substantial decrease in fibrinogen, plasminogen activator inhibitor-1, and an increase in antithrombin III deficiency.[15]

In patients undergoing bariatric surgery, different techniques have been used to avoid VTE, including pharmacological prophylaxis and mechanical prophylaxis; pharmacological prophylaxis involves

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low-molecular-weight heparin (LMWH), and mechanical prophylaxis includes intermittent compression devices, elastic stockings, and early ambulation after surgery.[16,17] Our aim was to determine the effectiveness of the prophylaxis procedure (pharmacological and mechanical prophylaxis) to prevent VTE following bariatric surgery. Moreover, to demonstrate that the regimen of prophylaxis played a significant role in preventing VTE following bariatric surgery.

Patients and Methods

Study Design and Patients

We performed the present cross-sectional study at the Department of Surgery, Faculty of Medicine, Suez Canal University from January 2019 to February 2020. Patients aged more than 16-years-old were deemed eligible if they had documented morbid obesity, defined as BMI ≥40 kg/m^2 or ≥35 kg/m^2 with comorbidities, and were scheduled to undergo bariatric surgery. Patients were excluded if they aged more than 65-years-old, had documented coronary artery disease, malignancy, chronic hepatic or renal impairments, mental or cognitive illness, history of VTE, history of heparin-induced thrombocytopenia, coagulation defects, and/or history of concomitant anticoagulant/antiplatelet therapy for other risk factors. We excluded pregnant women as well.

Our protocol was approved by the institutional review board at Suez Canal University and all participants signed informed written consent before the procedure.

Sampling

The required sample size was calculated based on the following equation.

$$n = \left[\frac{Z_{\propto/2}}{E}\right]^2 * P(1-P)$$

where n = required sample size; $Z_{(\propto/2)} = 1.96$; P = prevalence of the outcome (estimated to be 2%);[15] and E = margin of error determined to be 0.05.

Thus, the calculated sample size was 30 participants. By calculating the nonresponse rate which is 10% based on previous studies, the required sample size was 33 participants.

Data Collection and Prophylaxis Protocol

We collected the following routine preoperative characteristics of the patients: demographics, BMI, comorbidities, and risk factors for VTE. Besides, we collected the type of procedure, operative time, postoperative complications, hospital stay, and the incidence of VTE. The VTE prophylaxis protocol in our institution consists of mechanical modalities (such as lower extremity compression and early mobilization) and pharmacological modalities in the form of Enoxaparin 40 mg once daily the day before surgery (preoperative) and continued 15 days after the procedure.

Outcome Measures

The primary outcome of the present stud was the incidence of VTE. The diagnosis of VTE clinically was based on painful, tender calf muscles, sudden shortness of breath, chest pain, and cough and radiologically by duplex ultrasound and CT chest angiography if needed. Patients were followed up for 1 month after the procedure.

Statistical Analysis

For descriptive statistics, we used the mean ± standard deviation, while for categorical parameters, we used the count (%). To analyze the association between baseline data and outcomes, we used Chi-square or Fisher's exact tests (for categorical) and *t*-test (for numerical data) depending on data normality. All statistical analyzes were performed using the *SPSS* (version 22 for Windows, IBM, Armonk, New York). A two-sided *p*-values <0.05 were considered statistically significant.

Results

Baseline Characteristics

A total of 33 patients were included with a mean age of 32.6 ± 6.1 years and female predominance (66.7%). Our patients had a mean BMI of 47 ± 5.9 kg/m^2. All patients had hyperlipidemia (100%), 66.6% had diabetes mellitus, and 51.5% had hypertension. Besides, 12.2% of the patients had a previous history of DVT. Most of the patients did laparoscopic sleeve gastrectomy (LSG) operation (81.8%) and 18.2% did one anastomosis gastric bypass (OAGB). Concerning the risk factors for VTE, 33.3% of patients were smokers, 30.3% had varicose vein, 27.3% on contraceptive therapy, 9.1% did major surgery in the last 3 months, 12.1% had previous DVT, and 6.1% had previous CVS disease (Table 1).

Operative and Postoperative Characteristics

The mean operative time was 71.67 ± 23.61 minutes; OAGB operation had a significantly longer mean operative duration of 120.0 ± 9.49 minutes than SG operation 60.93 ± 3.11 minute

Table 1: Preoperative characteristics

Variables	*(N = 33)*	
Age	(Mean ± SD) Range	32.6 ± 6.1 (23–55)
Gender		
Male	11	33.3
Female	22	66.7
BMI	(Mean ± SD) Range	47 ± 5.9 (38–60)
Comorbidities	*N*	%
Hypertension	17	51.5
Diabetes mellitus	21	66.6
Dyslipidemia	33	100
Previous history of VTE	4	12.2
Heart failure	0	0
COPD	2	6.1
Operation type	*N*	%
Sleeve	27	81.8
Mini gastric bypass	6	18.2
Roux-en-Y operation	0	0
Others	0	0
Risk factors for DVT		
Varicose vein	10	30.3
Previous DVT	4	12.1
Previous pulmonary embolism	0	0
Major surgery in last 3 months	3	9.1
Previous MI	0	0
Previous CVS disease	2	6.1
Smoking	11	33.3
Heart failure	0	0
Contraceptive therapy	9	27.3

Table 2: Operative data of surgeries

		(N = 33)
Operative time (minute)	Mean ± SD	71.67 ± 23.61
Complications	Bleeding	0 (0%)
	Leakage and/or fistulas	0 (0%)
	Stricture	0 (0%)
	Twist	0 (0%)
	Pulmonary emboli	2 (6.1%)
	DVT	0 (0%)
	Re-operation	0 (0%)
	Re-admission	0 (0%)
	Mortality	2 (6.1%)
Hospital stay (days)	(Mean ± SD) Range	2.0 ± 0.0 (2–2)

Table 3: Criteria of patient develop in PE regarding different parameters

		(N = 2)
Age	Mean ± SD Range	44.50 ± 5.36 40–49
Sex	Male	0 (0%)
	Female	2 (100%)
Type of surgery	Sleeve	1 (50%)
	Mini gastric bypass	1 (50%)
BMI	Mean ± SD Range	49.0 ± 8.49 43–55
Type of prophylaxis	Mechanical pharmacological	2 (100%)
Time of incidence PE after surgery (days)	Mean ± SD Range	8.50 ± 4.95 5–12

(p <0.001). The mean hospital stay was 2 days. Regarding postoperative complications, 6.1% of patients had PE as a postoperative complication and two patients (6.1%) died (Table 2).

Incidence of VTE at the End of Follow-up

Two patients developed PE (6.1%). The first patient was female aged 40-years-old who underwent (SG). Her BMI was 43 kg/m^2 and she had a history of diabetes, hypertension, and VTE 5 years ago. On the 5th postoperative day, she complained of shortness of breath and chest pain, which was followed by the diagnosis of PE and ICU admission. The second patient was a female aged 49-years-old who underwent OAGB operation. Her BMI was 55 kg/m^2 and she had a history of diabetes, HTN, and chronic obstructive pulmonary disease (COPD). Twelve days after the operation, she complained of chest pain, palpitations, shortness of breath, which was followed by the diagnosis of PE and ICU admission (Table 3).

Discussion

VTE is a disease that can be prevented, and thromboprophylaxis is a key strategy to minimize post-bariatric VTE mortality and morbidity.[18] The reverse placement of Trendelenburg and pneumoperitoneum use during laparoscopy reduces the venous return to the heart, further increasing the prothrombotic state.[17,19] VTE risk is also increased by postoperative pain and poor ambulation.[20] Even with the challenges of preventing these complications, rates of VTE incidents after bariatric surgery range from 0.3 to 2.2%. The optimal dose or duration of thromboprophylaxis is still debatable. Since most VTE complications occur posthospital discharge, a comprehensive approach to thromboprophylaxis is necessary, particularly in patients at high risk.[21] After bariatric surgery, LMWH was confirmed to be superior to unfractionated heparin (UFH) for thromboprophylaxis, with a comparable risk of bleeding.

In this descriptive cross-sectional study, 6.1% of patients had PE as a postoperative complication, and two patients (6.1%) died. Moreover, we demonstrated that mini-gastric bypass operation had a significantly longer mean operative duration of 120.0 ± 9.49 minutes than sleeve operation 60.93 ± 3.11 minutes (p <0.001). In terms of the predictors of postoperative VTE, old age (p = 0.013), long duration of peroration (p = 0.005), and previous history of VTE (p = 0.045) were associated with a higher risk of developing postoperative VTE. Magee et al.,[22] reported that among 735 patients who underwent bariatric surgery and received up to 3 weeks of LMWH, the incidence of postoperative VTE and bleeding was 0%. Similarly, in those managed with 10 days of tinzaparin, Tseng et al. reported a 0.5% postoperative VTE.[23] Similarly, the incidence of postoperative bleeding varies from 0 to 6%.[18] On the contrary, Froehling et al.[24] showed that VTE's cumulative incidence ranged between 0.3 and 2.1% in patients who underwent 402 bariatric operations. Furthermore, they highlighted that the patients' age was an independent predictor of postoperative VTE (HR = 1.89, 95% CI: 1.01, 3.55). This variance in the occurrence of postoperative VTE is possibly attributable to variations in patient condition, type of procedure, thromboprophylaxis dose and duration, and assessed outcomes.

In the bariatric surgery population, fatal PE is a common cause of postoperative mortality.[25,26] The previous studies reported that old age, postoperative anastomotic leakage, history of smoking, and previous VTE are associated with a higher risk of VTE following bariatric surgery.[27] In several studies, male sex was associated with an increased VTE risk among patients with bariatric surgery.[26,28] Two studies reported a significant association between patient smoking status and VTE's potential risk.[27,29] The presence of potential hypercoagulability markers among patients in the bariatric procedure has also been evaluated, but there was no observed association with clinical VTE.[30,31]

With regards to procedure-related factors, procedure type, operative time, and postoperative complications are the main risk factors of VTE. Compared to laparoscopic procedures, the open procedure was reported to be associated with a higher risk of VTE.[32] Regarding the duration of the procedure, Finks et al. recorded an increased risk (86%) of VTE with an operative time of more than 3 hours.[28] Chan et al. found that operatives with long-duration excessed 3 hours are associated with an increased risk of postoperative VTE.[33] Regarding the type of surgery, revision surgeries were reported to be correlated with an increased VTE risk.[34] It was also reported that Roux en Y gastric bypass (RYGB) was associated with the postoperative anastomotic leak, which in turn increases the VTE risk.[35] In contrast to adjustable gastric band procedures, Finks et al. found an increased risk of VTE with (SG), laparoscopic gastric bypass, and open RYGB.[28] Masoomi et al. found that in comparison with other bariatric procedures, GBS carries greater VTE risks.[36]

Our study has some limitations, including the cross-sectional nature, which is associated with several risks of bias. Moreover, the

relatively small sample size and short follow-up duration may hinder the generalizability of these findings.

Conclusion

In conclusion, VTE is associated with an increased risk of morbidity and mortality after bariatric surgery; however, it can be prevented using an extensive course of thromboprophylaxis. For the best regime in VTE prevention after the bariatric operation, more prospective experiments are needed.

Criteria for Inclusion in the Authors'/Contributors' List

AS contributed to study's concept, study design, data collection, and manuscript writing; HS contributed to study design, data collection, and manuscript writing; ME contributed to study design, data collection, and manuscript writing; OA contributed to study design, data collection, and statistical analysis; MKE and MA contributed to study design and data collection.

We confirm that the manuscript has been read and approved by all the authors, that the requirements for authorship as stated earlier in this document have been met, and that each author believes that the manuscript represents honest work if that information is not provided in another form.

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