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NEW CONCEPT

A New Protocol for Venous Thromboembolism Prophylaxis in Bariatric Surgery

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Abstract

Background Morbidly obese patients are at high risk for developing venous thromboembolism (VTE). The aim of this study was to evaluate the effect of a new VTE prophylaxis protocol (low dosage, low-molecular-weight heparin [LMWH]) with a pneumatic compression device (PCD) in patients undergoing bariatric surgery.

Materials and Methods Between November 2015 and December 2017, 368 patients underwent surgery due to obesity. The patients received 0.2 ml of nadroparin (Fraxiparine, GlaxoSmithKline) 12 h before the operation. A PCD (Kendall SCD Compression System) was applied to the patient during the operation and left on the patient during the subsequent 24 h. Nadroparin 0.4 ml was started subcutaneously after the PCD was removed from the patient and the same dosage of nadroparin was given daily for 15 days following the bariatric operation. Ambulation within 2 h of surgery was encouraged and was performed frequently.

Results A total of 368 patients underwent laparoscopic bariatric surgery. The median age was 34.1 years (range, 18–61), the median weight was 128 kg (range, 90–182), and the median body mass index (BMI) was 47.2 kg/m^2 (range, 36–72). No thrombotic events were observed postoperatively or at the 1-, 3-, and 6-month follow-up visits. Four bleedings occurred requiring transfusions. None of these patients required a re-laparotomy for hemorrhage control. The mortality rate was 0% at 30 and 90 days and during the hospitalization.

Conclusion Low dosage LMWH with PCD is very effective for VTE prophylaxis in bariatric surgery.

Keywords Bariatric surgery · Venous thromboembolism · Chemoprevention · Hemorrhage

Introduction

Thromboembolic events, including deep vein thrombosis (DVT) and pulmonary embolism (PE), are common causes of morbidity and mortality in obesity surgery [1]. Morbid obesity, old age, male gender, previous PE/DVT history, and obstructive sleep apnea are well-known risk factors for venous thromboembolism (VTE) [2]. Obese patients have a moderate to high risk for VTE [2]. The incidence of PE in bariatric surgery ranges from 0–3.4% [3]. Typically, some form of prophylaxis, including mechanical, pharmaceutical, or both, are used [4]. The American College of Chest Physicians (ACCP) suggests the use of low-dose unfractionated heparin (UFH), low-molecular-weight heparin (LMWH), or a factor Xa inhibitor for all moderate-risk patients in the perioperative period [5]. The recommendations for higher-risk patients include combining pharmacologic therapy with graduated compression stockings or intermittent pneumatic compression devices (PCDs) [5].

There is no consensus on the standard of care for prophylactic agents, dosing, timing, or duration in bariatric surgery [6]. Dosing of pharmacologic prophylaxis is challenging in postsurgical bariatric surgery patients because dosing by body weight may lead to excessive anticoagulation and bleeding [6].

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The aim of this study was to give the low-dose LMWH with a PCD as an efficient prophylaxis of VTE and to minimize the risk of bleeding in patients undergoing bariatric surgery.

Materials and Methods

From November 2015 to December 2017, a total of 368 patients underwent a laparoscopic bariatric procedure (i.e., laparoscopic Roux-en-Y gastric bypass, laparoscopic one anastomosis gastric bypass, or laparoscopic sleeve gastrectomy) for morbid obesity. With the approval of the Institutional Review Board, a prospectively collected database was retrospectively analyzed. Demographics, operative data, and clinical follow-up findings were evaluated. We applied a combined protocol for VTE prophylaxis to the patients. The patients received 0.2 ml of nadroparin (Fraxiparine, GlaxoSmithKline) 12 h before the operation. A PCD (Kendall SCD Compression System) was applied to the patient during the operation and was left on the patient during the following 24 h. Nadroparin 0.4 ml was started subcutaneously after PCD and removed. The same dosage of nadroparin was given daily to the patients for 15 days following the bariatric operation. This VTE prophylaxis protocol was applied to every patient who underwent the bariatric operation. The only exclusion criteria were patients with a history of VTE and PE. Ambulation was performed within 2 h of the surgery and was frequently encouraged. Postoperatively, the prothrombin time and partial thromboplastin time were monitored. Active clotting times and factor X levels were not measured. Duplex scans of the calf, femoral, and iliac veins were performed for the exclusion of DVT. PE, when suspected, was evaluated with a multislice computed tomographic scan. Ventilation perfusion scans were not required in any patient.

Statistical Analysis

Descriptive statistics were calculated and included means, medians, and standard deviations for continuous variables. Categorical variables were expressed as frequencies.

Results

A total of 368 patients underwent laparoscopic bariatric surgery (30 laparoscopic Roux-en-Y gastric bypass, 36 laparoscopic one anastomosis gastric bypass, and 302 laparoscopic sleeve gastrectomy) for morbid obesity in our clinic (Fig. 1). Among the 368 patients, 68% were women. The median age was 34.1 years (range, 18–61), the weight was 128 kg (range, 90–182), and the body mass index was 47.2 kg/m^2 (range, 36–72). The mean American Society of Anesthesiology (ASA) score was 2.7 ± 1.3 (Table 1). The mean operation time for a sleeve gastrectomy was 72 ± 8 min, 166 ± 21 min for a Roux-en-Y gastric bypass, and 114 ± 18 min for a mini-gastric bypass (Table 2).

All patients followed the VTE prophylaxis regimen as described. The median length of stay was 3 days (range, 2–7). Duplex scan and multislice computed tomographic scan were performed for patients suspected with DVT and PE. The overall incidence of symptomatic postoperative DVT and PE was 0%. There were four (1.1%) bleedings in the postoperative period (three staple lines and one gastric remnant bleeding), which all required blood transfusions (Table 2). All patients the prothrombin time and partial thromboplastin time results were within *normal* limits. None of these patients required a repeat laparotomy for hemorrhage control. The mortality rate at 30 and 90 days and during the inpatient stay was 0%. During the subsequent follow-up period (12–36 months), no episodes of VTE were identified.

Discussion

Obesity is an important risk factor for the development of thromboembolic disease [7, 8]. Venous thromboembolism is a preventable cause of mortality [9]. The ideal method of prophylaxis for VTE in bariatric surgery has yet to be elucidated [10]. Patients undergoing bariatric surgery have a moderate to high risk for thrombotic events. There is no generally accepted guidance regarding the type, dose, or duration of prophylactic method in bariatric surgery. Any specific prophylactic method can reduce, but not totally eliminate, VTE in bariatric surgery. As a relatively natural method, the beneficial effect of intermittent PCD in the prevention of VTE has been documented [10].

Its antithrombotic effect is associated with both the reduction of venous stasis and enhanced fibrinolysis [11]. Most series reporting prophylactic methods for obese patients include some form of mechanical prophylaxis [10]. Bleeding complications associated with chemoprophylaxis (2% incidence of bleeding complications in a recent systematic review when a standardized definition of hemorrhage was used) [12] are an important problem. Some authors have used mechanical compression as the only prevention method for VTE in bariatric surgery patients.

Clements et al. studied 957 patients without a history of VTE who underwent a laparoscopic Roux-en-Y gastric bypass [13]. The PCD was connected before the induction of anesthesia. Preoperative and postoperative pharmacologic anticoagulation values were not given. Patients were mobilized on postoperative day 0. The incidence of DVT and PE was 0.31 and 0.10%, respectively, on postoperative day 30. The bleeding complication rate was 0.73%. Gonzalez et al.

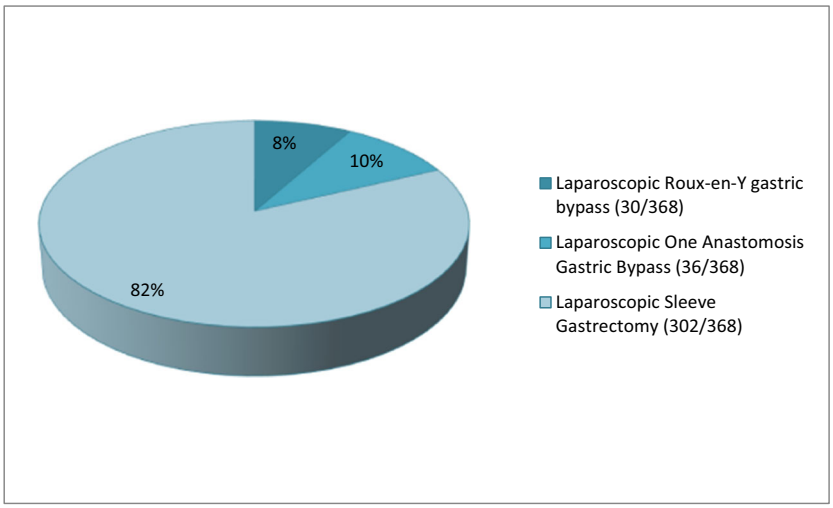

Fig. 1 Surgical procedures type ($n = 368$)

studied 380 patients who also underwent a Roux-en-Y gastric bypass. Nine patients had a severe chronic venous insufficiency [14]. For the VTE prophylaxis, calf-length pneumatic compression stockings were used before surgery and continued until the patient was mobilized. No pharmacological anticoagulant agents were given to the patients. Patients were encouraged to be mobilized on the evening of the operation. The incidence of DVT was 0.8%.

The benefit of routine anticoagulation prophylaxis has been shown in many surgical procedures [10]. There are also significant findings in the literature regarding the safety and efficacy of pharmacologic prophylaxis of VTE in the bariatric surgery setting. However, there is no sufficient evidence to guide specific recommendations for dosing or duration. Recent data suggest that LMWH is a better VTE prophylactic agent than UFH without increasing the bleeding risk [10].

Table 1 Characteristics and preoperative comorbidities of patients

Demographics	Value
Age[a]	34.1 (16–81)
Gender	
Female[b]	250 (68)
Male[b]	118 (32)
Previous abdominal surgery[b]	35 (9.5)
American Society of Anesthesiology (ASA) score[c]	2.7 ± 1.3
Body mass index (kg/m2)[a]	47.2 (36–72)
Comorbid conditions	
Diabetes mellitus[b]	91(24.7)
Arterial hypertension[b]	86 (23.3)
Hyperlipidemia[b]	78 (21.1)
Obstructive sleep apnea[b]	41 (11.1)

[a] Median

[b] *n* (%)

[c] Mean ± standard deviation, or percentage

Magee et al. used pharmacological prophylaxis in 735 patients who underwent laparoscopic bariatric surgery (2,500 IU/day dalteparin preoperatively and 5,000 IU/day dalteparin for 3 weeks postoperatively) [15]. The postoperative VTE incidence and mortality were both reported as 0%. Bleeding occurred in three patients in the postoperative period. The pharmacological prophylactic regimen that we used in our study has some similarities with Magee's regimen. Nadroparin (0.2 ml) was administered 12 hours before the surgery. LMWH was not given on day 0. On postoperative day 1, 0.4 ml nadroparin was started and continued for 15 days. In our four patients, bleeding occurred on postoperative day 1 and thereafter. Hemorrhage was controlled by

Table 2 Postoperative outcomes

	Value
Operative time (min)[a]	
Roux-en-Y gastric bypass[a]	166 ± 21
One anastomosis gastric bypass[a]	114 ± 18
Sleeve gastrectomy[a]	72 ± 8
Hospital stay (day)[b]	3 (2–7)
Complications	
Bleeding[c]	4 (1.1)
Leakage and/or fistulas	–
Stricture	–
Twist	–
Pulmonary emboli	–
Re-operation	–
Re-admission	–
Mortality	–
Follow-up period (months)	12–36

[a] Mean ± standard deviation

[b] Median

[c] *n* (%)

Table 3 Comparison of the latest literature for venous thromboembolism prophylaxis in bariatric surgery

Study/year	BMI	Prophylactic anticoagulant regime	PCD	DVT (%)	PE (%)	Bleeding (%)	Post-operative transfusion (%)	Re-operation for bleeding (%)	Mortality (%)	Operation
Gonzales et al. [14] 2004	48.5 ± 6.6	No	Yes	0.8	0	0	0	0	0	LGB
Clements et al. [13] 2009	49.1 ± 0.2	No	Yes	0.31	0.1	0.73	0.42	0.21	0.10	LGB
Frantzides et al. [17] 2012	45.3 ± 3	No	Yes	0,48	0	0,4	0,4	0	0	LGB
	51.6 ± 4	Enoxaparin 40 mg	Yes	1.6	1.1	4.8	4.8	0	0.12	LGB
Brasileiroet al. [18] 2008	43 ± 5	Enoxaparin 40 mg	No	0.79	0	3.17	0.79	NM	0.79	Open/LGB
Hamad et al. [19] 2005	49.6 ± 8.4	Enoxaparin 30 or 40 mg	No	0.1	0.9	0.9	0.9	NM	0.3	Open/LGB/VBG
Magee et al. [15] 2010	47.9	Deltaparine 2500 IU (preoperative) Deltaparine 5000 IU (postoperative)	No	0	0	0.4	0.1	0.3	0	LGB/VBG/ LSG/DS/RS
Cotter et al. [20] 2005	51.3	Heparin	Yes	0.99	0	1.9	0	0	0	Open/LGB
Miller et al [21] 2004	50	Heparin	Yes	0.4	1.2	2.4	2	0	0	LGB
Abuoglu et al. (current)	47.2	Nadroparine 0.2 ml (preoperative) Nadroparine 0.4 ml (postoperative)	Yes	0	0	1.1	1.1	0	0	LGB/LSG
Kothari et al. [22] 2007	48.7 ± 6	Enoxaparin 40 mg	Yes	0	0	5.9	5.9	1.7	0	LGB
	47 ± 6.2	Heparin	Yes	0	0.42	1.3	1.3	0	0	LGB
Javanainen et al. [16] 2015	49.0	Enoxaparin 40 mg 1 × 2*	Yes	0	0	15	NM	2	NM	LSG/LGB
	48.9	Enoxaparin 40 mg 1 × 2**	Yes	0	0	6	NM	0	NM	LSG/LGB/DS/BR
	48.4	Enoxaparin 40 mg 1 × 1**	Yes	0	0	4.5	NM	1	NM	LSG/LGB/BR

DVT, deep vein thrombosis; *LGB*, laparoscopic gastric bypass; *LSG*, laparoscopic sleeve gastrectomy; *DS*, duodenal switch; *RS*, revisional surgery; *BR*, band remove; *PE*, pulmonary embolism; *VBG*, vertical banded gastroplasty; *PCD*, pneumatic compression device; *NM*, not mentioned

*Starting one day before the operation. Patients received a dose in the operation morning and one after the operation

**Starting one day before the operation, and no dose in the operation morning

blood transfusions throughout the hemorrhage and no surgical intervention was required. This suggests that the risk of bleeding after the onset of LMWH may arise and that we should be careful during this period.

Javanainen et al. evaluated 400 bariatric surgical patients (sleeve gastrectomy or Roux-en-Y gastric bypass) using LMWH at different doses in a non-randomized prospective study [16]. The first 100 patients (high-dose group) were treated with enoxaparin 40 mg twice daily that started 1 day prior to surgery. The next 100 patients (intermediate-dose group) were treated with enoxaparin 40 mg twice daily provided that they were not taken the morning of the operation. The last 200 patients (low-dose group) were given a single dose of enoxaparin 40 mg daily without taking the morning dosing that started one day prior to the operation. No thromboembolic complications occurred in the study. The difference in bleeding complications between the high-dose and low-dose group was − 10.5% (95% CI from − 18.1 to − 3.0%) and between the high-dose and intermediate group was -9% (95% CI from − 17.4 to − 0.6%). (P = 0.01, 95% CI from 1.55 to 29.7%) and significantly increased the amount of bleeding complications (Table 3).

The use of mechanical prophylaxis and chemoprophylaxis should be considered based on the clinical judgment and the risk of bleeding for each patient [10]. There is some evidence that mechanical prophylaxis alone in a low-risk patient is associated with low VTE rates (0.4%). But many bariatric data suggest the combination of chemoprophylaxis and mechanical prophylaxis with overall VTE rates of 0.5% [10].

The American Association of Clinical Endocrinologists, the Obesity Society, and the American Society for Metabolic and Bariatric Surgery Medical Guidelines for Clinical Practice for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient (AACE/TOS/ASMBS guidelines) recommend prophylaxis against DVT for all bariatric surgery patients (grade B; best evidence level [BEL] 2) [23]. Chemoprophylaxis after a hospital discharge should be advised for high-risk patients, including those with a history of DVT (grade C; BEL 3). Early ambulation is encouraged in all patients (grade C; BEL 3). Most VTE complications occur within the first 30 days after surgery.

In this study, all patients were informed about the VTE prophylaxis prior to surgery and were encouraged to mobilize postoperatively at 2 h. On postoperative day 0, PCD use was continued throughout the patient's stay in bed, while pharmacologic prophylaxis was not used. Extended pharmacologic prophylaxis was continued postoperatively from day 1 to day 21. Our postoperative VTE incidence was 0% at the end of 1, 3, and 6 months, and 0% at the end of 0, 30, and 90 days (Table 3). The aim of the combined treatment was to avoid the higher dose of heparin prophylaxis and thus the risk of serious bleeding.

There are some limitations to this study. First, it was not a prospective randomized controlled study. Second, only the clinical complaints regarding VTE were evaluated, and the lack of radiological examinations could be misleading in determining the actual incidence of VTE.

Conclusion

The results of this study showed that low doses of LMWH with PCD are highly effective in VTE prophylaxis with very low bleeding risk in laparoscopic bariatric surgical procedures.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Studies with Human Participants All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Ethical consideration An approval from the local ethics committee of Haydarpaşa Numune Training and Research Hospital (HNTARH) was obtained for this study, and written informed consent was obtained in accordance with the Declaration of Helsinki from all patients. Privacy rights of the patients have been observed.

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