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Prescribing patterns of thromboprophylaxis post-bariatric surgeries: no additional benefits of extended prophylaxis

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Abstract

Background Venous thromboembolism is one of the critical complications of bariatric surgeries resulting in life-threatening outcomes. The benefits and duration of appropriate thromboprophylaxis in the morbidly obese patients stay unclear. The study aims to compare the benefits of in-hospital thromboprophylaxis versus extended thromboprophylaxis post-bariatric surgery among a cohort with a high prevalence of morbid obesity.

Results A retrospective observational cohort study was conducted on 229 morbidly obese patients who had undergone bariatric surgery in a tertiary care teaching hospital in Saudi Arabia. Upon discharge, the patients were split either to receive no thromboprophylaxis or enoxaparin 40 mg once or twice daily for 14–21 days post-discharge. Primary outcomes were the clinical difference between the study groups in the percentage of patients who developed a symptomatic venous thromboembolic event during postoperative hospitalization or after discharge. Among patients who received no thromboprophylaxis ($n = 119$), no one developed a venous thromboembolic event, while, in the extended prophylaxis group ($n = 110$), 1.82% developed a non-fatal one ($P = 0.23$). Additionally, no significant difference in percentages of bleeding events occurred in both groups ($p = 0.054$).

Conclusions The incidence of venous thromboembolism and bleeding events that occurred with extended thromboprophylaxis were deemed comparable and non-significant to the conventional in-hospital thromboprophylaxis. However, portal thrombosis stays an enigmatic complication despite its documented sparsity in literature.

Keywords Morbid obesity, Bariatric surgery, Thromboprophylaxis, Extended therapy, Adverse effects

Background

The development of venous thromboembolism (VTE) stands for one of the most critical clinical complications of bariatric surgeries. The incidence rates of reported VTE events range between 0.3 and 2.0% and up to one third resulting in life-threatening outcomes. [1, 2] Despite the vast evidence reported on the beneficial outcomes of VTE prophylaxis via either early ambulation or the routine use of inter pneumatic compression devices in morbidly obese patients, sporadic data addressed other prophylactic measures, such as thromboprophylaxis and inferior vena cava (IVC) filters [3, 4].

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The 2013 position paper published by the American Society for Metabolic and Bariatric Surgery (ASMBS) illustrated this enigmatic topic but did not delve into robust recommendations [1]. Furthermore, most bariatric surgeons follow their own established practice patterns and are unlikely to change their current practices in absence of a robust scientific evidence. However, the 2013 ASMBS position paper and the 2012 American College of Chest Physicians (ACCP) CHEST guidelines supported the rational use of thromboprophylaxis during bariatric surgery if there are no clinical contraindications [1, 3–8]. In a large survey of the ASMBS members in 2009, 95% of bariatric surgeons reported their preference of low molecular weight heparins (LMWH) over the unfractionated heparins (UFH) [9]. Theoretically, LMWH may provide greatest prophylaxis with lower rates of both bleeding and heparin-induced thrombocytopenia (HIT). The main pharmacological action of LMWH depends on its inhibition of both factor Xa (aFXa) and thrombin, while the UFH must bind to both thrombin and antithrombin, which requires a larger molecular bulk. Therefore, LMWH has a greater effect against Factor Xa, hence, its superior effects and higher safety profile [10, 11].

CHEST guidelines endorsed the use of in-hospital thromboprophylaxis (IHTP) but did not define any detailed recommendations about the extended thromboprophylaxis (ETP) [12] post-bariatric surgery [1, 6]. Evidence is still controversial regarding the appropriate regimens and timescales of thromboprophylaxis [13]. For instance, the currently available published literature varies on the optimal type, dose, and treatment timescale of thromboprophylaxis [1, 6]. In Saudi Arabia, the prevalence of obesity ranged from 29.0 to 35.5% which stands for a serious threatening to life expectancy [14, 15]. Bariatric surgery is a relatively evolving and effective intervention in morbid obese patients for more than a decade [16]. However, it is sometimes complicated by VTE events which are clinically associated with morbidity and mortality after the recommended bariatric surgery [2, 17, 18]. Therefore, this study aimed to differentiate the benefits of IHTP and ETP in terms of their safety profiles as VTE and bleeding events in a cohort of morbidly obese patients.

Methods

Study design and study settings:

According to Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines, a retrospective observational cohort study was conducted at a 360-bed tertiary care teaching hospital in Saudi Arabia [19].

Study population

All patients who underwent bariatric surgery from January 1, 2015, until December 31, 2016, had been included according to the eligibility criteria listed below. All their medical charts had been rigorously and regularly reviewed. Baseline characteristics collected included patient's age, sex, weight, body mass index (BMI), and comorbid conditions. In addition, type and duration of surgery, length of hospital stay, as well as dosage and duration of enoxaparin prescribed at discharge were recorded. Postoperative incidences of deep venous thrombosis (DVT), pulmonary embolism (PE) and all symptomatic bleeding events that occurred during their hospital stay were also recorded.

All patients were treated in the hospital with UFH (5000 IU subcutaneous (SC) one hour before surgery then every eight hours till discharge according to activated partial thromboplastin (aPTT) readings) [20], external compression devices, and mandatory ambulation every 4 h while awake starting on the day of the operation. The medication administration records were reviewed to assess compliance with medications for VTE thromboprophylaxis inside the hospital. Then, the patients were split either to receive no thromboprophylaxis upon discharge or enoxaparin 40 mg once or twice daily for either 14–21 days post-discharge [12] according to the physician's clinical decision.

Eligibility criteria

The inclusion of patients depends on their Body Mass Index (BMI). Patients, who were aged 18 years or above and had a BMI ≥ 50 , were included in the study. All included patients should be free of hepatitis B and C. The excluded patients were all patients with a documented VTE at the time of surgery, past medical history of malignancy or known indications of anticoagulant therapy after discharge. Any medical files with incomplete data were also excluded.

Study outcomes

The primary outcome of the study was to calculate the percentage of patients developed symptomatic DVT or PE during postoperative hospitalization or after discharge in each of the study groups. Patients were regularly monitored for 30 days after surgery during their weekly outpatients' clinic appointments. VTE events were confirmed by Doppler ultrasonography, computed tomography, pulmonary angiogram, or V/Q lung scan and documented by the treating physician. The secondary outcome was to assess the potential incidence of major bleeding, manifested either by hemoglobin drop

from baseline of ≥ 2 g/dL, requiring whole blood or RBCs transfusion of ≥ 2 units and/or hemodynamic instability necessitating reoperation [21].

Statistical analysis

Statistical analysis was done using IBM SPSS® Statistics version 26 (IBM® Corp., Armonk, NY, USA). Numerical data were expressed as mean and standard deviation or median and interquartile range as appropriate. Nominal data were expressed as frequency and percentage. Data were tested for normality using Skewness-Kurtosis test and Shapiro–Wilk test and were found not normally distributed, so the nonparametric tests were used. Comparison between two groups with respect to continuous variables was done using Mann–Whitney test. The Chi-square and Fisher’s exact tests were used to compare between the groups with respect to categorical data. All *p* values were two-sided and values < 0.05 were considered statistically significant.

Results

A total of 729 patients scheduled for elective bariatric surgery were screened for eligibility. As shown in Fig. 1, 229 morbidly obese patients met the inclusion criteria of the study and were accordingly included in the final analysis, of which, 119 patients just received the conventional IHTP only while 110 patients received the ETP.

At baseline, there were no significant differences among the two studied groups of morbidly obese patients in terms of age, weight, BMI, or comorbid conditions, Table 1. In the whole sample studied, age, weight and BMI ranged from 18 to 66 years, 103 to 199 kg, and 50 to 72 kg/m², respectively. No patient had congestive heart failure or suffered from history of ischemic heart disease or atrial fibrillation diagnosis. Dyspnea at rest was experienced in 3 patients (0.8%) who received enoxaparin post-hospital discharge (*P*=0.109). Previous DVT was experienced in four patients (1.75%); two in each of the studied groups (*P*=1.0) and history of stroke was observed in one patient (0.44%) who received no thromboprophylaxis upon discharge (IHTP).

Patient procedure characteristics are shown in Table 2. No significant difference was detected between the two studied groups regarding type of procedure (*P*=0.477), duration of surgery (*P*=0.167) and length of hospital stay (*P*=0.066) where more than 90% of all patients observed, underwent laparoscopic sleeve gastrectomy (LSG). More than 45% of patients were discharged after one day (58.2% in IHTP and 47.1% in ETP), whereas one patient in IHTP group was discharged after 29 days.

Reviewing medication charts on discharge revealed three different regimens prescribed as extended thromboprophylaxis. Enoxaparin 40 mg once daily for 14 days was the most common prescribed regimen (87.3%) as illustrated in Table 3.

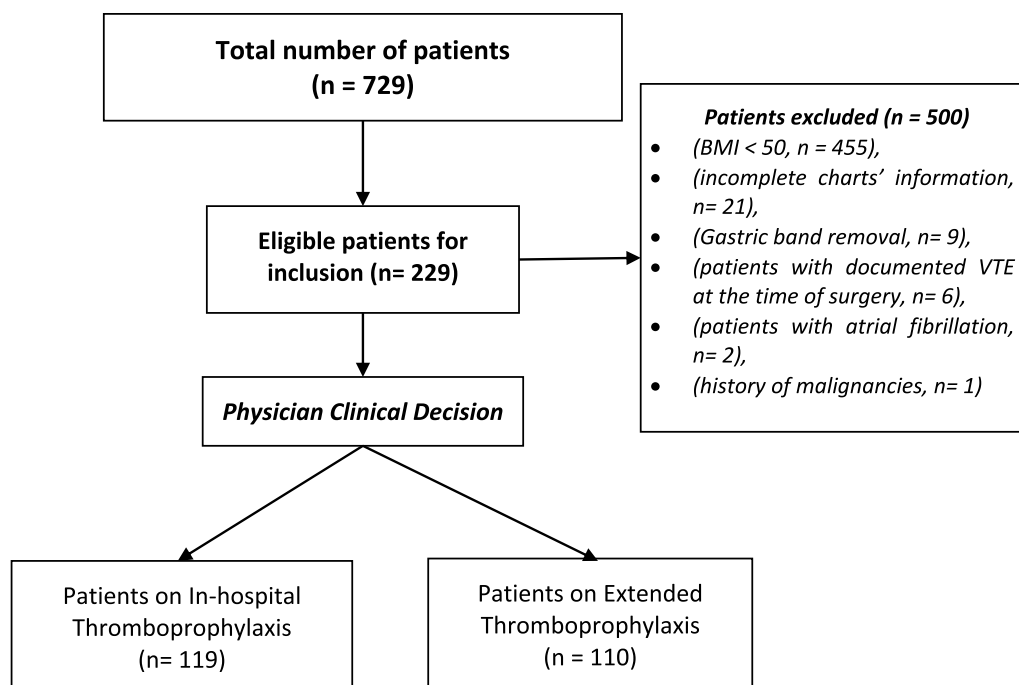


Fig. 1 Eligibility of patients for inclusion

Table 1 Baseline demographic and clinical characteristics of patients who received either in-hospital (IHTP) or extended thromboprophylaxis (ETP), $N = 229$

Characteristics	Total ($n = 229$)	IHTP ($n = 119$)	ETP ($n = 110$)	P value
Age (Mean \pm SD)	35.48 \pm 11.44	35.82 \pm 12.07	35.11 \pm 10.75	0.665
Female (%)	128 (55.9%)	83 (69.7%)	45 (40.9%)	0.0001
Weight (kg) (Mean \pm SD)	145.22 \pm 19.90	143.72 \pm 18.51	146.85 \pm 21.28	0.172
BMI (kg/m ²) (Mean \pm SD)	55.24 \pm 4.00	54.97 \pm 4.23	55.54 \pm 3.73	0.158
<i>Most common Comorbid Conditions, n (%)</i>				
Hypertension	66 (28.8%)	33 (27.7%)	33 (30.0%)	0.705
Diabetes	50 (21.8%)	27 (22.7%)	23 (20.9%)	0.772
Hypothyroidism	34 (14.8%)	21 (17.6%)	13 (11.8%)	0.215
Dyslipidemia	21 (9.2%)	11 (9.2%)	10 (9.1%)	0.968
Mild obstructive sleep apnea	35 (15.3%)	15 (12.6%)	20 (18.2%)	0.241

BMI Body mass index, n number of patients, chi-square, or Mann–Whitney test were used to compare between data at level of significance < 0.05

Table 2 Procedure characteristics in the two studied groups, $N = 229$

	Total ($n = 229$)	IHTP ($n = 119$)	ETP ($n = 110$)	P value
Length of hospital Stay, median (IQR)		2 (1–2)	1 (1–2)	0.066
Type of Procedure, n (%)				0.477
LSG	216 (94.3%)	111 (93.3%)	105 (95.5%)	
RYGB	13 (5.7%)	8 (6.7%)	5 (4.5)	
Range of duration of surgery (min)	40–325	45–325	40–259	
Duration of Surgery (min), mean \pm SD	93.4 \pm 41.0	98.3 \pm 45.7	88.0 \pm 34.7	0.167
LSG (min), mean \pm SD		91.1 \pm 31.6	84.5 \pm 27.9	0.208
RYGB (min), mean \pm SD		210.6 \pm 81.1	159.8 \pm 75.3	0.372

*IQR Interquartile range, n number of patients, min: minutes, LSG Laparoscopic sleeve gastrectomy, RYGB Roux-en-Y gastric bypass, chi-square, student's t test, or Mann–Whitney test were used to compare between data at level of significance < 0.05

Table 3 Frequencies of Prescribed Regimens in patients who received extended thromboprophylaxis therapy, $N = 110$

Prescribed Regimen	Frequency (%) $n = 110$
Enoxaparin 40 mg SC once daily for 14 days	96 (87.3%)
Enoxaparin 40 mg SC once daily for 21 days	6 (5.5%)
Enoxaparin 40 mg SC twice daily for 14 days	8 (7.3%)

SC Subcutaneous, n number of patients

In all patient population, there was no development of either DVT or PE during their hospital stay. Upon discharge, 119 patients received no thromboprophylaxis, of whom no one developed VTE while 110 received enoxaparin, of whom two (1.82%) developed non-fatal VTE ($P = 0.23$). The observed two VTE cases developed portal vein thrombosis (Tables 4 and 5).

Table 4 Number of patients experienced VTE and bleeding events among the two studied groups, $N = 229$

Characteristics n (%)	Total ($n = 229$)	IHTP* ($n = 119$)	ETP ($n = 110$)	P value**
VTE	2 (0.87)	0	2 (1.8%)	0.23
Bleeding	4 (1.75)	3 (2.5%)	1 (0.9%)	0.054
Hemoglobin drops from baseline of ≥ 2 g/dL		2 (1.7%)	0	
Blood transfusion of > 2 units		0	1 (0.9%)	
Reoperation		1 (0.8%)	0	

n number of patients, VTE venous thromboembolism, IHTP in-hospital thromboprophylaxis, ETP Extended thromboprophylaxis

*Three missing data in follow-up

**Fischer exact test

Bleeding events were observed in four patients (1.75%) in the whole studied population, with no significant

Table 5 Details of VTE diagnosis on a per-patient basis

Case	Age (yr.)	Sex	BMI	VTE diagnosis	LOS	Time from surgery to diagnosis	Enoxaparin dose-duration	Comorbidities
1	27	male	56	PVT	2	4	40 mg q24h-14 days	None
2	32	male	57	PVT	1	15	40 mg q24h-14 days	Hypertension and dyslipidemia

yr. year, BMI Body mass index, VTE Venous thromboembolism, PVT Portal vein thrombosis, LOS Length of hospital stay, q24h Once daily

difference between percentages occurred in IHTP group (2.52%) and that in ETP group (0.91%) ($P=0.054$).

Discussion

The present study reflected the frequent inappropriate dosing of extended thromboprophylaxis in more than 90% of the morbidly obese patients. Also, the results could not statistically differentiate between the benefits and harms of the in-hospital and the extended thromboprophylaxis therapies post-bariatric surgeries. Despite the relatively large sample and the presence of some numerical differences in clinical complications, however, they were closely comparable and did not reach a statistical difference. Overall, the results may reflect the safety of bariatric surgeries in terms of bleeding and embolic events. Nevertheless, the very few embolic events were the rare but life-threatening PVT events despite extended anticoagulation.

The present results are in line with the findings of the earlier anticoagulation literature. For instance, a study at the University of Tennessee by Arnold and colleagues found no differences in the development rates of VTE or bleeding events among a cohort of 476 trauma patients who had been prescribed either LMWH or UFH [22]. Like our study, Scholten et al. [23] came up with a comparable conclusion in their non-randomized study that enrolled 481 patients. Hence, the LMWH (Enoxaparin 30 mg twice daily) was prescribed to the first ninety-two patients in comparison to the regimen of Enoxaparin 40 mg twice daily in the other cohort of patients. The two groups were matched except for longer surgery duration in the 30 mg group. With similar bleeding events, the rates of VTE were higher in the former group, which led the study authors to weakly recommend the beneficial use of the higher dose regimen.

Magee et al. [24] strongly supported the use of ETP. In a study recruiting 735 bariatric patients, Dalteparin was prescribed perioperatively and postoperatively for three weeks according to the type of the procedure performed. The daily dosing of Dalteparin was adjusted from 2500 IU perioperatively to 5000 IU postoperatively. In contrast to most prophylaxis regimens, pneumatic compression devices were not used in this study.

Within a minimum follow-up period of six months, no symptomatic VTE event has been developed, while, bleeding events were recognized in three patients only, however, without the assignment of a comparative group. Elsewhere, McGarry et al. rigorously reviewed a large medical inpatient database comparing the use of enoxaparin versus UFH. The review revealed a lower rate of VTE in the former group (1.7% vs. 6.3%) with similar hospital costs, incidence of bleeding, and HIT events [25]. Similarly, the current study provided a comparative assessment between two cohorts of morbidly obese patients to reflect the real clinical practice in a very special population.

The present study illustrated the inappropriate dosing of ETP in most morbidly obese patients, however, this practice may suggest the unnecessary use of higher dosing of thromboprophylactic agents in obese patients. Also, these results may imply the high safety and quality profile of bariatric surgeries. Nevertheless, the study showed the development of the exceedingly rare but life-threatening portal venous thrombosis events as the only VTE cases among all study subjects despite the extended anticoagulation. These rare events believed to be a clinical complication of the intraoperative manipulation. These events raise the concern of the importance of close follow-up for weeks after surgery day [26]. Elsewhere, Kalfarentzos and colleagues assigned sixty gastric bypass patients to a daily subcutaneous dose of either 5700 IU or 9500 IU of the LMWH Nadroparin, in a randomized parallel trial. All patients had preoperative Doppler studies of their lower extremities as well as at several postoperative checkpoints. The study revealed the absence of VTE episodes as well as the absence of any significant difference in the coagulation parameters in either group. Hemorrhagic complications, however, were reported in only two patients in the 9500 IU group versus zero in the 5700 IU group, supporting the safer prescription of the lower dose of Nadroparin [27]. Upon prescribing a fixed-dose LMWH approach, Borkgren et al. [28] prospectively investigated the outcomes of a total of 223 Roux-en-Y gastric bypass (RYGB) patients who received either a regimen of 40 or 60 mg of enoxaparin twice daily at discharge for 10 days post-discharge. Patients with BMI

higher than 50 kg/m² were assigned to the higher dose of enoxaparin fixed dose. Based on serial measurements of Anti-factor Xa (aFXa) levels dose adjustments were made accordingly. Clinical suspicion of a VTE event was exerted in 7.6% of the patients but only one patient in the cohort of the 40 mg fixed-dose regimen was diagnosed with at least one VTE episode. Also, five patients (2.2%) developed major bleeding event, all but only one patient in the 40 mg cohort. However, no robust relationship has been proved in the medical literature between the levelling of aFXa and LMWH clinical efficacy or bleeding outcome.

Limitation

Few limitations should be acknowledged. First, the single-center design and the low occurrences of VTE and bleeding events in 30 days might have affected the strength of the conclusion. Also, there was no serial measurement of aFXa for guiding the appropriateness of each LMWH dose among the study patient population.

Conclusion

The study found no statistically significant difference in the development rates of VTE and bleeding events with ETP compared to the conventional IHTP. Large randomized clinical trials are highly called for to confirm the safety of either regimen on the long term.

Abbreviations

ACCP	American College of Chest Physicians
aPTT	Activated Partial Thromboplastin
aFXa	Anti-factor Xa
ASMBS	American Society for Metabolic and Bariatric Surgery
ETP	Extended thromboprophylaxis
HIT	Heparin-induced thrombocytopenia
IVC	Inferior vena cava
IHTP	In-hospital thromboprophylaxis
LMWH	Low molecular weight heparins
RYGP	Roux-en-Y gastric bypass
SC	Subcutaneous
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
UFH	Unfractionated heparins
VTE	Venous thromboembolism

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Author contributions

DA, SB and ASA had contributed to study conception and design; ASA, HA and EB had made the data collection; DA, SB and SE had made the data analysis and interpretation; SE and DA wrote the original article draft. Reviewing and editing: ASA, HA, SB and EB had reviewed and edited the final version. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical approval and consent to participate

The study protocol has been approved by King Abdullah Medical City (KAMC) IRB registered at the National BioMedical Ethics Committee, King Abdulaziz City for Science and Technology (Registration number H-02-K-001)—IRB number 17–320. The informed consent had been waived because it is a retrospective study.

Consent for publication

The authors declare no conflict of interest.

Competing interests

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential competing interests.

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