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Longitudinal retrospective review of three-tiered low molecular weight heparin dosing protocol to prevent thromboembolism in low-risk patients undergoing laparoscopic sleeve gastrectomy

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Abstract

Background According to the most recent consensus guidelines from the American Society for Metabolic and Bariatric Surgery (ASMBS), almost all bariatric surgery patients are at least a moderate to high risk for the development of postoperative venous thromboembolism (VTE). The most recent update also concludes that there continues to be a lack of high-quality data on safety, efficacy, dosing, and duration of treatment for pharmacologic thromboprophylaxis in the perioperative period up to discharge. Observational data has reported VTE rate between 1.9 and 5.4% in patients undergoing bariatric surgery, and rates as low as 0.5% in less invasive surgery including laparoscopic sleeve gastrectomy (LSG). In a retrospective study of over 175,000 LSGs performed from 2015 to 2016, 0.6% were complicated by postoperative bleed. This retrospective analysis reviews results from a consistent low molecular weight heparin (LMWH) protocol over a 12-year period for safety and efficacy.

Objective To address the lack of long-term data associated with a consistent LMWH protocol providing long-term safety and efficacy data in bariatric surgery.

Setting The study was conducted at a Community Hospital, United States.

Methods Protocol of enoxaparin 30 mg, 40 mg, or 60 mg every 12 h for patients with a weight of < 300 lbs., 300–400 lbs., or > 400 lbs., respectively, and is initiated at least 2 h before surgery.

Results Of 1936 patients, 4 patients (0.21%) developed VTE while 3 patients (0.15%) had bleeding complications.

Conclusion The thromboprophylaxis regimen utilized in this study demonstrated enoxaparin to be safe and efficacious, with incidences of thromboembolism and bleeding both below reported averages from the national quality databases.

Keywords Venous thromboembolism prophylaxis · Bariatric surgery · Laparoscopic sleeve gastrectomy · Low molecular weight heparin

Background

Adults and adolescents with obesity have reached epidemic proportions, with the incidence tripling between 1975 and 2016 and is progressing at an even higher rate since 1991 [1–5]. As obesity predisposes individuals to a multitude of other medical conditions, patients are often searching for solutions to navigate this condition. Bariatric surgery remains the most effective method of weight loss and can often lead to the complete resolution of multiple medical conditions including diabetes, hypertension, and obstructive sleep apnea [6].

Bariatric surgery patients are at a substantial risk for venous thromboembolism (VTE) given the prevalence of risk factors that promote VTE, including obesity, obstructive sleep apnea/hypoventilation syndrome, and exposure to general anesthesia [7]. In regard to VTE prophylaxis, the current American Society of Bariatric and Metabolic Surgeons (ASMBS) guidelines state that all bariatric patients receive mechanical prophylaxis and are recommended to ambulate early in the postoperative period [7–9]. Additionally, chemical prophylaxis consisting of either low molecular

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weight heparin (LMWH) or unfractionated heparin (UFH) is recommended [9, 10]. Enoxaparin has been shown to be the most prescribed anticoagulant for bariatric surgery [7]. A study conducted by Birkmeyer et al. in 2012 compared the effectiveness of unfractionated and LMWH for prevention of VTE and found that the rates of VTE were significantly lower in patients receiving LMWH with no significant differences in rates of hemorrhage among treatment [11].

Chemoprophylaxis still possesses a risk of hemorrhage, especially in patients with obesity, and LMWH has demonstrated various absorption, particularly with increased adipose tissue, leading to under or over-dosing by 15% [12, 13]. There remains considerable variability in the approach to thromboprophylaxis and appropriate dosing because no best practice has been established or had a consensus guideline recommended for this population [14–19]. A number of different dosing regimens have been compared, but rarely against one another or if they have, a minimum amount of participants were involved [14–19].

Patients who are considered to be at higher risk for VTE, such as patients with hypercoagulable disorders, history of previous VTE, or body mass index greater than 60 kg/m^2, may be considered for extended administration of VTE prophylaxis [20]. There is no consensus regarding indications for extended prophylaxis for patients undergoing bariatric surgery [21–23].

According to the most recent consensus guidelines from the American Society for Metabolic and Bariatric Surgery (ASMBS), almost all bariatric surgery patients are at least a moderate risk and some considered high risk for the development of postoperative VTE [9]. The most recent update also concludes that there continues to be a lack of high-quality evidence regarding safety, efficacy, dosing, and duration of treatment for pharmacologic thromboprophylaxis in the perioperative period [9]. Observational data have reported VTE rate between 1.9 and 5.4% in patients undergoing bariatric surgery [15], and rates as low as 0.5% in laparoscopic surgery including laparoscopic sleeve gastrectomy (LSG) [24]. In a retrospective study of over 175,000 LSGs performed from 2015 to 2016, 0.6% were complicated by postoperative bleed [24].

This retrospective analysis reviews results from a consistent prophylactic protocol over a 12-year period for safety and efficacy.

Methods

This retrospective chart review consisted of patients undergoing LSG from January 2013 to December 2024. The dosing protocol of enoxaparin 30 mg (mg), 40 mg, or 60 mg every 12 h for patients with a weight of < 300 pounds (lbs.), 300–400 lbs., or > 400 lbs., respectively, and is initiated at least 2 h before surgery (Table 1). Prophylaxis is typically continued until hospital discharge and can be extended for up to six weeks depending on risk factors, though no patients extended their dosing past admission. The incidence of a thrombus was determined by using positive results of a D-dimer test, imaging (X-ray, computed tomography scan imaging (CT), magnetic resonance imaging (MRI), ultrasound or Doppler), and the clinical assessment of imaging as stated in the patient's progress notes and admission history. Bleeding was defined as hemoglobin less than 7 g/dL, a drop of hemoglobin from baseline of greater than 2 g/dL, and/or hemodynamic compromise consisting of a blood pressure less than 90/60 mmHg [25].

Study design

All patients having undergone LSG during the defined period of January 2013 through December 2024 were included. The only exclusions were patients who did not qualify for the standard prophylactic protocol, i.e., a history of hypercoagulable state or higher risk for VTE given other medical conditions such as active atrial fibrillation or recent VTE requiring therapeutic anticoagulation pre and post-surgery. Any patients lost to follow-up within 30 days of surgery were also not included. A total of 5 patients were lost to follow-up over the study period and were not included in the data.

Data abstraction

This retrospective data collection was performed by manual chart review of the electronic medical record. Baseline characteristics of age, sex, ethnicity, weight, and BMI were collected (Table 2). Additional data collected from charts will include number of readmissions within 30 days post-discharge, length of stay during readmissions, hemoglobin, hematocrit, platelets, and D-dimer. Evidence of bleeding or thrombus will be assessed using imaging collected through CT scan imaging, MRI, venous duplex ultrasound, Doppler ultrasound, and angiography.

Table 1 Thromboprophylaxis protocol

Weight (lbs.)	Weight (kg)	Enoxaparin dose (mg)
< 300	< 136	30
300–400	136–181	40
> 400	> 181	60

Initiated 2 h prior to and every 12 h after operation until discharge

Table 2 Demographic information

Female (%)	1611 (83.2%)
Male (%)	325 (16.8%)
Mean weight	288.1 lbs (131.0 kg)
Mean BMI	48.9
Age	44.0 years
Caucasian (%)	1471 (76.0%)
African American (%)	383 (19.8%)
Asian (%)	5 (0.2%)
Hispanic/Latino (%)	66 (3.4%)
Other (%)	11 (0.6%)

Results

Of the 1936 patients abstracted, it was found that at day 30, 4 patients (0.21%) had developed a VTE, including one portal vein thrombosis and three DVTs while 3 patients (0.15%) had bleeding complications while on the enoxaparin standardized prophylactic regimen (Table 3). The average time to event post-discharge was 4.65 days. Specific regimen data revealed the 30 mg every 12 h group with 1224 patients each had 1 incidence of VTE and bleeding, respectively (0.08%). Of the 636 patients in the 40 mg every 12 h group, 2 (0.31%) had bleeding incidents and 1 (0.15%) a VTE. Correspondingly, 2 of 68 (2.94%) patients in the 60 mg LMWH group developed VTE within 30 days. The secondary outcome showed the average length of stay for all patients was 35 h.

Discussion

This is one of the largest collections of standardized LMWH prophylaxis regimens to be reported and tracked over twelve years and nearly 2,000 patients. This retrospective review addresses the lack of long-term data with a consistent protocol providing long-term safety and efficacy data. It also establishes a large enough sample size to really compare against database averages that range from mechanical to aggressive chemical prophylaxis. The thromboprophylaxis regimen utilized in this study demonstrated enoxaparin to be safe and efficacious, with incidences of thromboembolism and bleeding both below reported averages from the national quality databases [9, 26, 27]. Interestingly, the most aggressive LMWH protocol with patients averaging a BMI of greater than 60 led to VTEs, and no bleeding incidents. This finding illustrates the high-risk nature of obesity and surgery for VTE but also shows we should be aggressive in dosing compared to a normal prophylactic regimen of 40 mg daily as listed in the enoxaparin package insert [13].

Limitations

Despite the robust data and favorable safety profile, our study had several limitations. First, our study was a single-center retrospective study, limiting the applicability of the results and introducing the risk for selection bias. In an attempt to eliminate this limitation, all patients undergoing LSG were included unless they had a significant history of bleeding or risk of thromboembolism secondary to atrial fibrillation or any other condition, a history of VTE within the last six months, or a history or recurrent VTE. Second, the protocol utilized consisted of stratifying patients in pounds. It is important to note that this is a surgeon derived protocol that has been utilized by the hospital for the last ten years. While it proved to be helpful in dosing patients appropriately, a protocol translated to kilograms would have allowed for better applicability worldwide. Third, this study only evaluated the effects of enoxaparin in laparoscopic sleeve gastrectomy which were performed by a single surgeon. While this allowed for standardization within the study to help reduce confounding factors, it would be beneficial to evaluate how this protocol performs in different gastric surgeries with various surgeons. Lastly, most patients included in the study were Caucasian and female, limiting the applicability and variability in the patient population.

Conclusions

In conclusion, an aggressive enoxaparin protocol compared to package insert data of 40 mg daily or even 30 mg every 12 h intended to lower the risk of thromboembolism for high-risk bariatric patients demonstrated to be safe and efficacious in patients undergoing a LSG.

Table 3 Results by group

Group	< 300 lbs. (136 kg)	300–400 lbs. (136–181 kg)	> 400 lbs. (> 181 kg)
Number	1224	636	68
Mean weight	254.9 lbs. (115.9 kg)	336.8 lbs. (153.1 kg)	432.3 lbs. (196.5 kg)
Mean BMI	46.4	52.4	60.8
VTE	1 (0.08%)	1 (0.31%)	2 (2.94%)
Bleeding	1(0.08%)	2 (0.15%)	0 (0%)

Declarations

Disclosures Mohamed Dahman, Craig Ratermann, and Lein Ghuniem have no conflicts of interest or financial ties to disclose.

Ethical approval This study was approved by the Institutional Review Board (IRB) on September 8, 2023, and is in accordance with the ethical standards of the research committee.

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