The use of enoxaparin as venous thromboembolism prophylaxis in bariatric surgery: A retrospective cohort study

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A B S T R A C T
Introduction: Venous thromboembolism (VTE) is one of the major causes of morbidity and mortality in bariatric patients. The use of low-molecular-weight heparin (LMWH), as enoxaparin, is considered one of the mainstay thromboprophylaxis regimens in postoperative bariatric patients. Despite the universal agreement on the importance of thromboprophylaxis in these patients, there are inadequate strong recommendations for its dosing and duration. The aim of our study is to explore the current practice on using enoxaparin in bariatric patients, as well as to assess both the efficacy and safety of varying dosing regimens.

Material and methods: This is a retrospective cohort study of morbidly obese patients who underwent bariatric procedure at a tertiary care hospital between 2016 and 2019. All adult patients who met the eligibility criteria for bariatric surgery and received enoxaparin with a minimum follow-up period of one month were included in our study. Participants with a history of coagulopathy, renal or hepatic insufficiency were excluded from the study. Data collected include patient demographics, VTE risk factors, and co-morbidities. The outcome of treatment failure was defined as the composite of either VTE or major bleeding.

Results: A total of 1,169 patients who underwent bariatric surgery were included in the study. The mean age was 35.54 years, with mean body mass index (BMI) of 45.78 kg/m². The mean duration of enoxaparin use was 9 days, and the majority of patients (78%) received a prophylaxis dose of 40 mg subcutaneously (SC) once daily. The overall rate of VTE at 90 days was 1.4% while only 0.1% of patients developed major bleeding. There was no statistically significant difference in patients’ age, gender, BMI, or various enoxaparin dosing regimens between patients who developed VTE or bleeding versus patients who did not develop. Patient’s weight was the only statistically significant risk factor that directly correlated to higher risk of complications (P = 0.006). In the multivariable logistic regression model, higher BMI was significantly associated with treatment failure, either VTE or major bleeding [OR 1.05 (95% CI 1.0–1.09); P = 0.038].

Conclusions: The rate of VTE or major bleeding did not differ in patients who received various enoxaparin regimens. Patients undergoing bariatric surgery may benefit from enoxaparin thromboprophylaxis at a dose of 40 mg SC daily for a total duration of 14 days, with higher doses may be needed for extremely obese patients. We recommend standardizing the current practice of VTE prophylaxis post bariatric surgery and unifying the optimal dose and duration.

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1. Introduction

Obesity is a global epidemic with significant public health and economic consequences, which is becoming more common in all populations and age groups around the world (Björntor, 2001; World Health Organization, 2021). Its prevalence among adult males and females in Saudi Arabia is 24.1% and 33.5%, respectively (Memish et al., 2013). Bariatric surgery has proven to be the most effective treatment in achieving weight loss for morbidly obese people, with an estimated 15,000 bariatric operations performed in Saudi Arabia each year (Al-Khaldi, 2016). Obesity-related complications such as type 2 diabetes, hypertension, hyperlipidemia, and obstructive sleep apnea, can all be improved with bariatric surgery.

Venous thromboembolism (VTE), which includes deep vein thrombosis (DVT) and pulmonary embolism (PE), is a substantial cause of morbidity and mortality in bariatric patients. Furthermore, it has an incidence rate of 3% of symptomatic DVT and a 2% incidence rate of symptomatic PE after bariatric surgery (Froehling, 2013). Various preventive measures to reduce the incidence rate of VTE complications in bariatric surgical patients are available. The American Society for Metabolic and Bariatric Surgery (ASMB) currently recommends pharmacological prophylaxis, in the absence of contraindications, to all bariatric surgery patients (ASMB, 2013). Current VTE prophylaxis regimens for post-bariatric surgery patients vary depending on expert preference. Despite conflicting evidence, evidence show that low-molecular-weight heparin (LMWH) provides better VTE prophylaxis than unfractionated heparin (UFH) in bariatric surgery patients without increasing the risk of bleeding (Birkmeyer et al., 2012).

Despite widespread agreement on the importance of thromboprophylaxis, there is insufficient data to make solid recommendations on its dose and duration in obese patients (ASMB, 2013). In bariatric surgery, there is no consensus on the standard of care for prophylactic agents, dosing, timing, or duration. Therefore, the purpose of this study was to obtain information on current enoxaparin regimens used for VTE thromboprophylaxis in patients undergoing bariatric surgery, as well as to evaluate the safety and efficacy of different enoxaparin doses used in the prevention of postoperative VTE.

2. Material and methods

2.1. Study design

This is a retrospective cohort study of morbidly obese patients who underwent bariatric procedure at a tertiary care hospital between 2016 and 2019. This study included all adult (age ≥ 18 years) obese patients (BMI ≥ 30 kg/m²) who met the eligibility criteria for bariatric surgery and received enoxaparin with a minimum follow-up period of one month. Participants with a history of coagulopathy, renal or hepatic insufficiency, were excluded from the study. Data collected include patient demographics, VTE risk factors and comorbidities (diabetes mellitus (DM), obstructive sleep apnea (OSA), hypertension (HTN), other cardiovascular diseases (CVD), use of hormone replacement therapy, smoking, gastroesophageal reflux, asthma, renal insufficiency, liver disease, cancer, dosage and duration of enoxaparin use. In addition, we collected information on study outcomes including VTE and major bleeding. Approval of the study protocol was obtained from the King Saud University Medical City (KSUMC) Institutional Review Board (IRB) before the commencement of the study, and it was conducted in accordance with the Declaration of Helsinki.

2.2. Definitions

2.2.1. Complications post hospital discharge

Complications post-hospital discharge defines as the composite of either VTE or major bleeding. Major bleeding was defined as overt bleeding, acute anemia associated with a 2 g/dL decrease in hemoglobin from the preoperative value, or bleeding requiring reoperation or transfusion (Schulman and Kearon, 2005). Thrombosis is defined based on the presence of new leg pain or edema, chest pain, dysrhythmia, unexplained hypoxemia, or dyspnea, underwent lower extremity venous ultrasonography, helical computed chest tomography or ventilation-perfusion lung scanning (Borkgren-Okonek et al., 2008).

2.2.2. Treatment duration

We categorized treatment duration based on the number of days the patients received thromboprophylaxis, to those who received enoxaparin for < 14 days, or those who received therapy for 14 days or more.

2.2.3. Statistical analysis

Descriptive statistics were used to summarize demographic and clinical characteristics for all study subjects. Continuous variables were expressed as mean and standard deviation, while categorical variables as number and percentages. Data were also summarized based on the study outcome (i.e., those who developed complications post-discharge versus those who did not). In addition, data were categorized based on the duration of thromboprophylaxis therapy (i.e., those who received thromboprophylaxis for < 14 days versus for 14 days or more). Paired t-test was used to compare continuous variables, and chi-square test to compare categorical variables. Univariable and multivariable logistic regression models were used to measure the association between clinical characteristics and complications post hospital discharge, and with thromboprophylaxis duration. We conducted the statistical analysis using “R” version 4.1.2.

3. Results

A total of 1,169 patients who underwent bariatric surgery and met inclusion criteria were included in the study. The mean age was 35.54 ± 10.95 years, with the majority being females (59%). The pre-operative mean BMI was 45.78 ± 8.57 kg/m². The mean duration of enoxaparin use was 9 days, and the postoperative mean follow-up duration was 2.5 months. The majority of patients (78%) received a prothrombin dose of 40 mg SC once daily, followed by 60 mg SC once daily (19.5%). These results are summarized in Table 1.

The overall rate of VTE at 90 days was 1.4% while only 0.1% of patients developed major bleeding. Other common complications were anastomotic leak in 22 patients (1.9%), pancreatitis in 9 patients (0.8%), hypertensive crises in 8 patients (0.7%), and trocar site infection in 5 patients (0.4%). In terms of VTE risk factors in this cohort, >356 (30.5%) patients were > 40 years of age, 62 patients (5.3 %) had a BMI > 60 kg/m2, 11 (0.94%) had a previous history of VTE, 10 (0.9 %) had cancer, 9 (0.8%) patients reported estrogen use, 4 (0.3 %) patients had varicose veins, 3 (0.8%) patients had undergone general surgery, 3 (0.3 %) had previous fractures, 2 (0.2 %) had a history of stroke, 2 (0.2%) had restricted ambulation, and 1 (0.1%) had a family history of VTE. In terms of co-morbidities in this population, 218 (18.6%) of the patients had been diagnosed with type 2 diabetes mellitus, 222 (19%) patients are hypertensive, 196 (16.8%) of the patients reported a current and history of smoking, 155 (13.3%) diagnosed with gastroesophageal reflux, 135...
(11.5%) patients were asthmatic, and 123 (10.5%) of the patients had osteoarthritis. These results are summarized in Table 1.

There was no statistically significant difference in patients’ age, gender, BMI, VTE risk factors, or various enoxaparin dosing regimens between patients who developed VTE or bleeding versus patients who did not develop VTE. Patient’s weight was found to be the only statistically significant risk factor that is directly correlated to higher risk of complications (P = 0.006) for VTE (Table 2). When comparing study variables based on treatment duration, patients’ weight, BMI, and Enoxaparin dose post discharge were found to be significantly different (P < 0.001) in patients who received thromboprophylaxis for short duration versus long term duration (i.e., < 14 days, or ≥ 14 days) (Table 3).

In the multivariable logistics regression model, BMI was significantly associated with treatment failure, either VTE or major bleeding [OR 1.05 (95% CI 1.0–1.09); P = 0.038] (Table 4). Furthermore, when analyzing the relationship between factors associated with longer VTE duration, both BMI (P < 0.001) and GERD (P = 0.022) were found to be statistically related to the duration of VTE prophylaxis in both univariable and multivariable regression models. (Table 5).

4. Discussion

Bariatric surgery is considered an appropriate intervention for morbidly obese individuals in the face of increasing obesity in the global population. Obesity has become more common because of poor dietary habits and a lack of physical activity. It is estimated that between 280,000 and 325,000 deaths occur annually because of obesity-related complications and comorbidities such as ischemic heart disease, stroke, and congestive heart failure (Franz, 2007). Therefore, bariatric surgery has been recommended as a therapeutic option for people with BMI > 35 kg/m². Weight loss after bariatric surgery has been linked to lower risk factors for type 2 diabetes, hypertension, and other obesity-related comorbidities (Alfarhan, 2022). However, one of the most difficult challenges in the successful management of bariatric patients is reducing the risk of VTE complications, which can increase the risk of morbidity and mortality.

This retrospective study aimed to investigate the efficacy and safety of various enoxaparin dosing regimens in obese patients who had undergone bariatric surgery. According to the study findings, the patients in the study cohort be classified high risk for complications based on their clinical characteristics, as the mean age was 35 years and the mean BMI was 45 kg/m². There were no significant differences between the patients’ age and gender and the risk of developing VTE. However, the patients’ BMI and weight were the only significant risk factors that predicted complications including VTE or major bleeding. When looking at the relationship between complications post-discharge and the VTE prophylaxis regimen, we found no relationship with either enoxaparin dose or duration. Other studies have shown a benefit of extended thromboprophylaxis (>14 days) with enoxaparin post bariatric surgery (O’Connor et al., 2021). Several randomized controlled clinical trials have been conducted to determine the optimal enoxaparin dosing regimen for patients who have undergone bariatric surgery. According to the ASMBS, extensive thromboprophylaxis with enoxaparin to prevent VTE in patients who have undergone bariatric surgery is recommended. It is also recommended that patients continue VTE prophylaxis after being discharged from the hospital. Several randomized controlled trials aimed at determining the maximum tolerable dose of enoxaparin for the treatment of VTE have revealed that 40 mg subcutaneous daily is the recommended standard dose in patients who have undergone bariatric surgery (ASMBS, 2013).

The findings of this retrospective study validate the findings from previous clinical trials that were conducted to determine the efficacy and safety of enoxaparin after bariatric surgery. Scholten et al. compared the efficacy of two different doses of enoxaparin in patients who had undergone bariatric surgery (Scholten et al., 2002). He concluded that the use of a higher dose of enoxaparin, 40 mg every 12 h, may reduce the incidence of DVT complications in patients following bariatric surgery without an increase in bleeding complications (Scholten et al., 2002). However, in the present study, the overall rate of VTE at 90 days was 1.4%, while only 0.1% of patients developed significant bleeding. These results were concordant with previous results on the rates of haemorrhage that have been reported in other bariatric surgery studies.

Similar findings were demonstrated in a multicentre retrospective study that sought to evaluate enoxaparin’s efficacy and safety...
in patients who had undergone bariatric surgery. Hamad et al. demonstrated that enoxaparin should also be administered perioperatively for adequate prophylaxis in bariatric surgery (Hamad and Choban, 2005). Furthermore, extended postoperative prophylaxis may be beneficial in lowering the rate of postoperative VTE after bariatric surgery (Hamad and Choban, 2005).

In our current retrospective study, the patients' weight was the only statistically significant risk factor directly correlated to an

Table 2

| Variables                  | Overall     | No complications | With Complications | p-value |
|----------------------------|-------------|------------------|--------------------|---------|
| Age, years, mean (SD)      | N = 1169    | N = 1152         | N = 17             | 0.759   |
| Gender, male, n (%)        | 35.54 (10.95)| 35.53 (10.97)    | 36.35 (9.59)       | 0.197   |
| Weight, kg, mean (SD)      | 475 (40.6)  | 465 (40.4)       | 10 (58.8)          | 0.006*  |
| Height, cm, mean (SD)      | 123.04 (25.78)| 122.79 (25.35)  | 140.04 (44.62)     | 0.216   |
| BMI, kg/m², mean (SD)      | 163.81 (13.76)| 163.75 (13.80)  | 167.92 (9.93)      | 0.052   |
| SCr, μmol/L, mean (SD)     | 45.78 (8.57) | 45.72 (8.41)     | 49.78 (15.93)      | 0.06    |
| Enoxaparin dose post discharge, n (%) | 62.86 (15.28)| 62.75 (15.23)    | 69.76 (17.02)      | 0.832   |

Table 3

| Variables                  | Overall     | Thromboprophylaxis < 14 days | Thromboprophylaxis ≥ 14 days | p-value |
|----------------------------|-------------|------------------------------|------------------------------|---------|
| N                          | N = 1169    | N = 1,001                    | N = 168                      |         |
| Age, years, mean (SD)      | 35.54 (10.95)| 35.46 (10.93)               | 36.00 (11.11)                | 0.552   |
| Gender, male, n (%)        | 475 (40.6)  | 400 (40.2)                  | 75 (43.4)                    | 0.481   |
| Weight, kg, mean (SD)      | 123.04 (25.78)| 121.93 (25.16)             | 129.41 (28.35)               | <0.001* |
| Height, cm, mean (SD)      | 163.81 (13.76)| 163.89 (14.20)             | 163.36 (10.92)               | 0.64    |
| BMI, kg/m², mean (SD)      | 45.78 (8.57) | 45.35 (8.41)                | 48.23 (9.11)                 | <0.001* |
| SCr, μmol/L, mean (SD)     | 62.86 (15.28)| 62.72 (15.02)               | 63.66 (16.71)                | 0.454   |

Note: *Statistical significance was set at the level of P value < 0.05.

Abbreviations: BMI, body mass index; SC, subcutaneous; SD, standard deviation; SCr, serum creatinine; VTE, venous thromboembolism.

Note: *Statistical significance was set at the level of P value < 0.05.

Abbreviations: BMI, body mass index; SC, subcutaneous; SD, standard deviation; SCr, serum creatinine; VTE, venous thromboembolism.
increased risk for complications. An increased BMI was directly correlated to treatment failure, the increased onset of VTE, and or significant bleeding. The findings highlight the leading risk factor during patient assessment for bariatric surgery. The compounding negative impacts of weight on the development of VTE complications in study participants indicate that bariatric surgery should incorporate BMI stratification in management pre and post-operatively. A study detailing the effect of a patient’s BMI and prevention of PE after a regimen for managing VTE complications is documented (Beenen et al., 2020). After completing a clinical trial in the use of enoxaparin, a posthoc study explored the development of PE during patient assessment for bariatric surgery. The compounding negative impacts of weight on the development of VTE complications and recurrence. The study’s implications are in concurrence with trials indicating the significance of weight over prevailing comorbidities (El-Menyar et al., 2018). The role of BMI in extending the thromboprophylactic duration when patients undergo post-discharge prophylaxis and poor treatment outcomes were also noted. Patients with a BMI > 60 kg/m² had longer than the nine days mean duration of prophylaxis, extending up to fourteen days. Poor treatment outcomes also depended on BMI, which increased the odds ratios for concerned patients. Gender and age did not significantly impact the VTE outcomes, such as duration of prophylaxis and treatment failure (El-Menyar et al., 2018). In addition to the previous reports of the impact of BMI on VTE management, duration of therapy, and other treatment failures, including bleeding in patients require attention. Enoxaparin used in the current study was found to be adequate supports a similar finding where its single usage also reduced bleeding in the patients.

The incidence of VTE in morbidly obese patients is significantly increased following bariatric surgery. Although VTE is generally decreased in this population pre-bariatric surgery, one of the strategies to prevent this complication is assessing VTE pre-operatively. In addition, establishing a multimodal risk reduction protocol comprises parameters such as the use of compression stocking, promoting early ambulation, and the use of enoxaparin to decrease the incidence in this at-risk population. The conclusion in this study that there were no significant differences during the onset of VTE in patients that received different prophylactic dosages of enoxaparin, supports the fact that a dose of 40 mg administered daily for up to 14 days may be sufficient in decreasing the incidence of VTE, and higher doses might thus be required for morbidly obese patients. Based on the findings of this retrospective study, an alteration of the current guidelines should be carried out in terms of standardizing the current practice of VTE prophylaxis post-bariatric surgery and allowing for the use of a standard optimal dosage and duration of treatment in this patient subgroup. Several authors have confirmed the effectiveness of using enoxaparin pre-and post-operatively in bariatric patients (Alfarhan, 2022).

Further research detailing different enoxaparin regimens and their effects on patient outcomes is warranted in contributing evidence supporting its use as a VTE prophylaxis in bariatric patients. Despite the available evidence, there are still gaps in the VTE prevention guidelines due to a lack of supporting studies elaborating on duration and dosing in obese patients. The results obtained herein reveal an optimal dosage of 40 mg daily for 14 days. Discrepancies in studies overdosing arise due to other patient factors such as age, gender, outcome VTE events, and pre or post-operative prophylaxis used (Borkgren-Okonek et al., 2008; O’Connor et al., 2021; Hamad and Choban, 2005; Altiere et al., 2018). In addition, the patients’ weights must be adjusted during dosage calculation (O’Connor et al., 2021). However, the results are similar in other studies examining dosage of 30 mg to 40 mg twice daily (Hamad and Choban, 2005).

The retrospective nature of the design is the main limitation of this study. For example, the lack of randomization of patients to different dose requirements, given the current study design. In addition, the low number of complications observed may impact the strength of the results. Furthermore, this is a single-center study that may limit the generalizability of the results.

5. Conclusions

The rate of VTE or major bleeding did not differ in patients who received various enoxaparin regimens. Patients undergoing bariatric surgery may benefit from enoxaparin thromboprophylaxis dose of 40 mg SC daily for a total duration of 14 days, with higher doses may be needed for extremely obese patients. We recommend standardizing the current practice of VTE prophylaxis post bariatric surgery and unifying the optimal dose and duration.

| Variable     | Univariable Regression | Multivariable Regression |
|--------------|------------------------|--------------------------|
|              | OR 95% CI p-value      | OR 95% CI p-value        |
| BMI          | 1.04 0.99, 1.08 0.08    | 1.05 1.00, 1.09 0.038*   |
| SCr          | 1.02 1.00, 1.05 0.08    | 1.02 1.00, 1.05 0.068    |
| Age > 40 years | 2.61 0.99, 7.01 0.052  | 2.61 0.98, 7.06 0.052    |

Note: *Statistical significance was set at the level of P value < 0.05.
Abbreviations: BMI, body mass index; SCr, serum creatinine.

Table 5: Univariable and multivariable regression analysis for factors associated with longer VTE prophylaxis duration.

| Variable       | Univariable Regression | Multivariable Regression |
|----------------|------------------------|--------------------------|
|                | OR 95% CI p-value      | OR 95% CI p-value        |
| BMI            | 1.03 1.02, 1.05 <0.001* | 1.03 1.02, 1.05 <0.001*   |
| History of VTE | 3.46 0.90, 11.6 0.069  | 3.45 0.88, 11.8 0.054    |
| HTN            | 1.46 0.98, 2.14 0.06    | 1.38 0.95, 2.04 0.11     |
| GERD           | 1.68 1.08, 2.55 0.222*  | 1.62 1.03, 2.47 0.03*    |

Note: *Statistical significance was set at the level of P value < 0.05.
Abbreviations: BMI, body mass index; GERD, gastroesophageal reflux disease; HTN, hypertension; OR, odds ratio; VTE, venous thromboembolism.
Data Availability
All data analyzed during this study are included in this published article.

Declaration of Competing Interest
The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendixes

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