The impact of extended antithrombotic regimen after bariatric surgery on venous thromboembolism

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ABSTRACT

BACKGROUND: Although the risks associated with bariatric surgery are generally minimal, precautions are still necessary because of the possibility of potentially fatal complications such as venous thromboembolism (VTE) and deep vein thrombosis (DVT).

OBJECTIVE: In this study, we aimed to demonstrate the efficacy of an extended antithrombotic regimen in reducing the risk of VTE.

METHODS: We conducted a retrospective, single-center, observational study between January 2018 and January 2020 at the Jordanian Royal Medical Services. This study included 724 patients who underwent bariatric surgery. All patients underwent a 14-day course of enoxaparin sodium. The collected data included patient demographics, procedure types, and postoperative complications. Follow-up was conducted at 2, 4, and 12 weeks postoperatively.

RESULTS: All the 724 patients who underwent laparoscopic bariatric surgery received enoxaparin sodium for 14 days. Over 12 (1.65%) patients experienced postoperative complications, with only one patient experiencing DVT, resulting in an incidence of 0.14% postoperative VTE.

CONCLUSION: This study demonstrated a notable absence of post-bariatric DVT, emphasizing the efficacy of a 2-week enoxaparin sodium treatment in preventing thromboembolic events. These findings underscore the importance of extended antithrombotic strategies in enhancing patient safety after bariatric surgery.

KEYWORDS: Venous thromboembolism, deep vein thrombosis, sleeve gastrectomy, enoxaparin sodium, postoperative complications.

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INTRODUCTION

The global surge in the prevalence of obsity and associated comorbidities has resulted in a significant increase in the frequency of bariatric procedures (1). Bariatric surgery, recognized as the primary intervention for addressing severe obesity and achieving sustained weight loss, has emerged as a rapidly expanding surgical specialty (2). With this expansion, distinctive complications have occurred within the patient population, necessitating a specialized knowledge base for effective management. Thus, it is imperative for bariatric surgeons to cultivate a foundational understanding of surgical instruments, techniques, and potential complications such as venous thromboembolism (VTE) and surgical anatomy to ensure optimal outcomes in patient care (3,4).

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VTE, which presents as pulmonary embolism (PE) or deep vein thrombosis (DVT), is a significant contributor to postoperative morbidity and mortality. Several obesity- and non-obesity-related factors (e.g., prolonged surgery duration) increase the risk of VTE in patients undergoing bariatric surgery. DVT is the leading cause of postoperative mortality in morbidly obese patients, progressing swiftly and unexpectedly to fatal PE, despite being clinically asymptomatic (5,6). A study conducted by Gambhir et al. in 369,032 bariatric cases found that prolonged operative length is associated with a higher risk of DVT and PE after bariatric surgery. Transfusion and a history of DVT are the primary risk factors for DVT and PE (7). As these fatalities can be avoided, it is crucial to prioritize primary prevention to effectively decrease the incidence and fatality rates of VTE. Current thromboprophylaxis methods include administration of unfractionated or low-molecular-weight heparin (LMWH) via subcutaneous injection, pneumatic compression devices, the use of elastic stockings, and inferior vena cava filters (8). Traditionally, the practice has been to discontinue prophylaxis once the patient regains mobility or is discharged from a healthcare facility. However, the risk of VTE persists for a considerable period after surgery. Consequently, prolonged thromboprophylactic regimens have been implemented to address this concern (9).

We hypothesized that utilizing an extended VTE prevention regimen might yield positive outcomes by mitigating the occurrence of VTE following laparoscopic bariatric surgery. Multiple studies have shown that extended post-discharge thromboprophylaxis is effective in preventing VTE after bariatric surgery (10,11). A study conducted by Rottenstreich et al. recommended the use of anticoagulation for at least 1 week after discharge (12). Since the establishment of o ur. bariatric facility, we have implemented a protocol involving the subcutaneous administration of enoxaparin sodium, which is continued for 14 days throughout the postoperative phase of recuperation at home. Thus, this study aimed to clarify the advantages of an extended antithrombotic regimen for reducing VTE after bariatric surgery at our institution.

MATERIALS AND METHODS:

Study Design This retrospective, single-center, observational study was conducted at King Hussein Medical Center in Jordan from January 2018 to January 2020.

STUDY PARTICIPANTS :This study aimed to enroll patients who had undergone bariatric procedures to investigate the clinical, demographic, and prognostic features associated with the immediate administration of antithrombotic medication following bariatric surgery. We identified all patients with a minimum of 2 weeks of follow-up who had undergone a laparoscopic bariatric procedure (i.e., laparoscopic adjustable gastric banding, laparoscopic Roux-en-Y gastric bypass, or laparoscopic sleeve gastrectomy). A standardized protocol for thromboprophylaxis was followed. Patients received subcutaneous enoxaparin sodium (40 mg) once daily for 14 postoperative days following all procedures. Our inclusion criteria were all patients who had undergone bariatric surgery and received enoxaparin sodium for 2 weeks after surgery. We excluded any patients with a history of DVT, PE, or any family history of coagulopathy or bleeding disorders. Follow-up was conducted at the clinic at 2, 4, and 12 weeks postoperatively.

ETHICAL APPROVAL: This study was approved by our Institutional Review Board (IRB) and was conducted in accordance with the principles of the Declaration of Helsinki, 1975. The requirement of obtaining informed consent was waived by the IRB committee due to the retrospective nature of the study, as the research could not practically proceed without the waiver. In addition, the research

involves minimal risk to patients and will not adversely affect the rights or privacy of the participants, given the importance of the knowledge to be gained. Patient data were anonymized, and confidentiality was maintained.

DATA COLLECTION: Retrospective data collection was performed by reviewing patients' hospital records.

The following demographic and clinical variables were retrieved as the study outcomes: age at the time of the operation, sex, body mass index (BMI), height (in cm), weight (in kg), packed cell volume levels (PCV) at 6 h and 24 h after surgery, white blood cell (WBC) levels at 6 h and 24 h after surgery, use of drains, type of surgery (gastric band, Roux-en-Y gastric bypass, or sleeve gastrectomy), and postoperative bleeding.

STATISTICAL ANALYSIS: Continuous variables are presented as means and their corresponding standard deviations (SDs), while categorical variables are summarized using frequencies and percentages. To explore the connection between demographic, and clinical variables with a category count of <5, we used either the chi-squared (X2) test or Fisher's exact test. Statistical significance was established when the p-value was <0.05. All statistical analyses were performed using R software (version 4.2.3, Vienna, Austria).

RESULTS:

A total of 724 patients who underwent bariatric surgery at the King Hussein Medical Center were included in this study. The mean age of the sample was 34.7 (8.9), and the mean age at operation was 33.5 (8.9). The majority of patients (92.1%, n=667/724) were females, with a mean BMI of 43.6 (4.6) kg/m^2, mean height of 164.4 (8.2) cm, and mean weight of 117.2 (16.2) Kg. Six hours postoperatively, the mean PCV and WBC values were 39.6 (4.9) and 10.3 (3.3), respectively, whereas at 24 h postoperatively, these values were 38.4 (5.2) and 12.6 (3.8), respectively. **Table 1** shows the demographic and clinical characteristics of patients. Most patients (94.3%, n=683) underwent sleeve gastrectomy, 39 (5.4%) underwent Roux-en-Y gastric bypass, and only two (0.3%) underwent gastric bypass. Postoperative complications were observed in only 12 (1.7%) patients: three (0.4%) experienced postoperative bleeding, two (0.3%) experienced general weakness, two (0.3%) experienced hiatal hernia, two (0.3%) experienced intestinal obstruction, and only one (0.14%) experienced DVT. **Table 2** presents the surgical and postoperative characteristics of all the included patients. When comparing postoperative characteristics between the types of bariatric surgery (sleeve gastrectomy vs. Roux-en-Y gastric bypass), we performed propensity score matching based on age and sex to obtain balanced data between surgery type, there was a significant association between drains and the type of surgery (p=0.009): 37/39 (95%) patients who underwent Roux-en-Y gastric bypass had drains. There were no significant differences in postoperative complications or type of surgery as shown in **Table 3**.

DISCUSSION:

Obesity, as evidenced by various studies, constitutes a significant risk factor for VTE (13,14). The American College of Chest Physicians categorizes all bariatric patients as having moderate to high risk of VTE, prompting a recommendation for pharmacological thromboprophylaxis (15). This guidance primarily stems from the evaluation of relative risks associated with obese patients undergoing diverse surgical procedures. Notably, data from the 2009 Longitudinal Assessment of Bariatric Surgery indicates an escalating risk of VTE corresponding to weight (16). However, a comprehensive review of 19 studies in 2012 found limited advantages of weight-adjusted dosing regimens and an elevated bleeding risk (17). Consequently, this study only

considered non–weight-adjusted regimens. The present investigation of individuals who underwent bariatric surgery provides evidence supporting the efficacy of prolonged thromboprophylaxis in reducing the incidence of VTE after surgical intervention. A total of 724 individuals with a median age of 34 years and a female-to-male ratio of 11.7:1 (667 females and 57 males) were treated with a standardized dosage of subcutaneous enoxaparin 40 mg administered once daily for 14 days. At follow-ups at 2, 4, and 12 weeks, there were no instances of bleeding or VTE, except for one case of DVT. The findings of our study align

with those of other studies, indicating that prolonged thromboprophylaxis is effective in reducing the incidence of postoperative VTE in individuals who have undergone bariatric surgery. In one retrospective study, 374 individuals underwent bariatric surgery, and enoxaparin was administered enoxaparin for 14 days. This study aimed to assess the occurrence of symptomatic postoperative VTE at the end of 3 months. The findings revealed an incidence of 0.64% for symptomatic postoperative VTE (14). Furthermore, in a retrospective analysis, 735 patients underwent laparoscopic bariatric surgery and received a VTE regimen involving extended postoperative administration of LMWH. Specifically, the regimen consisted of a postoperative dalteparin dose of 2500 IU, followed by a daily dose of 5000 IU for 1 week. The incidence of VTE following the surgical procedure was observed to be 0% (15). Additionally, an interesting study conducted by Magee et al. reported results similar to ours, demonstrating that extended VTE prophylaxis using LMWH after bariatric surgery resulted in a postoperative VTE incidence of 0% and a low incidence of bleeding complications. However, Aminian et al. proposed a risk assessment tool to guide indications for post-discharge thromboprophylaxis, suggesting that it can only be considered for high-risk patients (i.e., those with heart failure, paraplegia, and reoperation) (18). This

study has several strengths, particularly its efficiency in terms of time and budget. This efficiency stems from the fact that the outcome of interest has either already transpired or is anticipated, aligning seamlessly with the investigative goal of the study. Furthermore, the acquisition of patient data from our comprehensive database enhanced the robustness of this study. However, our investigation has inherent limitations. First, it was conducted in a single bariatric center, which resulted in a constrained sample size. The retrospective nature of our study precluded the recruitment of a control group. Furthermore, the near absence of VTE outcomes in our study limited the ability to identify additional risk variables associated with the occurrence of VTE after laparoscopic bariatric surgery. In conclusion, this study demonstrated that the implementation of a prolonged antithrombotic regimen, specifically incorporating enoxaparin sodium, after bariatric surgery significantly mitigated the occurrence of VTE in this particular patient population.

Table 1: Demographic and clinical characteristics of all included patients.

Characteristic (N = 724)	Mean (SD)	Median (IQR)
Age (years)	34.7 (8.9)	34.0 (15.0)
Age at operation (years)	33.5 (8.9)	33.0 (15.0)
Sex, no. (%)		

Female		667 (92.1%)
Male		57 (7.9%)
BMI (Kg/m^2)	43.6 (4.6)	43.0 (6.0)
Height (cm)	164.4 (8.2)	163.0 (9.0)
Weight (Kg)	117.2 (16.2)	114.0 (19.5)
Postoperative blood tests		
6-hours PCV (%)	39.6 (4.9)	39.0 (6.0)
24-hours PCV (%)	38.4 (5.2)	38.0 (6.9)
6-hours WBC (*10^3)	10.3 (3.3)	10.0 (4.0)
24-hours WBC (*10^3)	12.6 (3.8)	12.0 (5.0)

Abbreviations: BMI: body-mass index, PCV: packed cell volume, WBC: white blood cells.

Table 2: Surgical and post-operative characteristics of all included patients.

Characteristic, n (%)	N = 724
Drains	569 (78.59%)
Surgery Type	
Gastric band	2 (0.3%)
Roux-en-Y Gastric Bypass	39 (5.4%)
Sleeve Gastrectomy	683 (94.3%)
Complications	12 (1.65%)
Type of Complication	
Bleeding	3 (0.41%)
DVT	1 (0.14%)
General Weakness	2 (0.27%)
Hiatal Hernia	2 (0.27%)
Intestinal Obstruction	2 (0.27%)
Intra-abdominal Abscess	1 (0.14%)
Multiple	1 (0.14%)

Abbreviations: DVT, deep venous thrombosis

Table 3: Comparison of post-operative characteristics between bariatric surgery types after propensity score matching.

Characteristic	Sleeve gastrectomy, N = 39[1]	Roux-en-Y Gastric Bypass, N = 39[1]	p-value[2]
Drains	27 (73%)	37 (95%)	0.009
Unknown	2	0	
Complications	1 (17%)	1 (17%)	>0.9
Unknown	33	33	
Type of Complication			>0.9
Bleeding	1 (2.6%)	0 (0%)	
Multiple	0 (0%)	1 (2.6%)	
no	38 (97%)	38 (97%)	

[1] n (%), [2] Pearson's Chi-squared test; Fisher's exact test Abbreviations: DVT, deep venous thrombosis

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