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Incidence of Silent Deep Venous Thrombosis after Laparoscopic Bariatric Surgery in Patients Who Received Combined Mechanical and Chemical Thromboprophylaxis Compared to Patients Who Received Mechanical Thromboprophylaxis Only Surgical Innovation 2020, Vol. 0(0) 1–7 © The Author(s) 2020 Article reuse guidelines: sagepub.com/journals-permissions DOI: 10.1177/1553350620965812 journals.sagepub.com/home/sri SAGE

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Abstract

Background. This prospective randomized study compares the incidence of silent deep venous thrombosis (DVT) among 2 groups of patients who underwent laparoscopic bariatric surgery. The first group received mechanical thromboprophylaxis only, while the second group received a combination of mechanical and chemical thromboprophylaxis. Methods. This study included 150 morbidly obese patients who underwent primary one-stage laparoscopic bariatric surgery (sleeve gastrectomy and mini-gastric bypass) over a 6-month period. Patients were randomly assigned to 2 groups: group A (n = 75) was subjected to mechanical thromboprophylaxis in the form of perioperative elastic stockings on both lower limbs and early postoperative ambulation, and group B (n = 75) was subjected to combined mechanical thromboprophylaxis and chemical thromboprophylaxis in the form of 40 mg subcutaneous enoxaparin 12 hours before surgery and postoperative enoxaparin (40 mg subcutaneous every 24 hours) for 2 weeks. Bilateral lower limb venous duplex was done for all patients before discharge, on the second and fourth weeks postoperatively, to detect silent DVT. Results. Nine patients out of 150 patients developed silent DVT (6%). All patients among group A were subjected to mechanical thromboprophylaxis only (12%) [P = .247, relative risk: .45, 95% confidence interval; .37-.62]. There was no silent DVT among group B who received combined mechanical and chemical thromboprophylaxis. No bleeding complications were reported in both groups. Conclusion. Combined mechanical and mechanical thromboprophylaxis is effective and safe in the prevention of silent DVT after laparoscopic bariatric surgery. Trial registration: The trial was registered in the Thai Clinical Trials Registry (TCTR20200127002) on January 20, 2020 retrospectively.

Keywords

silent deep venous thrombosis, bariatric surgery, mechanical thromboprophylaxis, chemical thromboprophylaxis

Background

Deep venous thrombosis (DVT) is defined as an acute formation of thrombus inside deep veins. Silent DVT is deep venous thrombosis without clinical manifestation such as tenderness and pain. 50% of patients with image-proved DVT are asymptomatic.¹ Thrombus that does not lead to complete venous obstruction is silent. Many clinical and surgical circumstances not only lead to the development of DVT but also can occur in healthy individuals. Patients treated surgically could develop thrombosis of the deep venous system complicated by pulmonary embolism (PE),

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Khaled S. Ahmad, Department of General Surgery, Prince Mohammed Bin Abdulaziz Hospital, Riyadh 14214, Saudia Arabia. Email: khaled.ahmad.md@gmail.com which is considered 1 of the major factors that increase morbidity and mortality in these patients.²

The incidence of PE is greater than 1 case/1000/year in the overall population, which leads to sudden death in approximately 25% of patients.³ Surgically treated patients are at significant risk of venous thromboembolism (VTE); the extent of the risk is based mainly on the type of operation. Elderly and cancer patients are other factors that may affect the incidence of VTE.⁴ The overall incidence of VTE detected by fibrinogen testing mark 125I in patients undergoing general surgery operations without DVT prophylaxis is 25%.⁵

One of the major risk factors for VTE is obesity. Body mass index (BMI) ≥ 25 kg/m² was associated with a higher risk of DVT and PE after arthroplasty of the hip joint.⁶ Complications of VTE in the postoperative period are common among morbidly obese patients, especially with prolonged surgery, which also can occur after weight loss surgery. There are several factors responsible for DVT development in morbidly obese patients, including limited mobility and fibrinolytic activity reduction in these patients.⁷ Because VTE is a potentially preventable cause of death, primary prevention is essential to reduce VTE's morbidity and mortality.⁸

To this date, there is no agreement regarding the ideal VTE prophylaxis for this type of patients. Also, the incidence of lower extremities of DVT in obese patients submitted to surgical management is still high in the literature.⁹ Our study aimed to detect the incidence of lower limb DVT in patients who underwent laparoscopic weight loss surgery, and evaluate the efficacy and safety of combined prophylaxis in the prevention of DVT.

Patients and Methods

Study Design and Setting

This study is a single-centered, prospective, blind, randomized, controlled study conducted at the general surgery department, Benha University Hospital between June 2019 and December 2019.

Inclusion Criteria

- 1. Age: 18-60 years
- BMI ≥35 kg/m2 associated with comorbidities (hypertension, dyslipidemia, type 2 diabetes mellitus (DM), and sleep apnea)
- 3. BMI \geq 40 with or without comorbidities
- 4. No history of recent or old thromboembolism

Exclusion Criteria

- 1. History of congenital or acquired coagulation defects
- History of anticoagulant or antiplatelet medications for other diseases

- 3. Allergy to heparin and its derivatives
- 4. History of heparin-induced thrombocytopenia
- 5. History of recent or old thromboembolism
- 6. Postoperative complications such as bleeding and leak
- 7. Symptomatic thromboembolism postoperatively

Methods of Randomization and Blinding

An Excel sheet was used to create a randomization sequence with a 1:1 allocation using random block sizes of 2 and 4 by an independent doctor. A researcher who was not included with the clinical trial determined the allocation of treatment by sequentially opening numbered, opaque, sealed envelopes. The same person was also responsible after the assignment to the interventions. No patient was withdrawn from the study after randomization in addition to no changes to methods and outcomes after the commencement of the trial (Figure 1).

Eligible Cases

Group A. This group was subjected to mechanical thromboprophylaxis in the form of perioperative elastic stockings on both lower limbs and early ambulation.

Group B. This group was subjected to combined mechanical thromboprophylaxis and chemical thromboprophylaxis in the form of enoxaparin (40 mg) every 12 hours subcutaneously (SC) and postoperative enoxaparin (40 mg SC every 24 hours) for 2 weeks.

Approval of the study was obtained by the Ethical Committee of the Faculty of Medicine, Benha University. This prospective randomized controlled study includes 150 morbidly obese patients randomly assigned into 2 groups: group A, subjected to mechanical thromboprophylaxis, and group B, subjected to combined mechanical and chemical thromboprophylaxis. The sample size of the study was calculated using online software (https:// clincalc.com/stats/samplesize.aspx). All patients had repeated failure of weight loss after multidisciplinary medical treatment. Routine laboratory investigations were done for all patients, including pulmonary function tests and abdominal pelvic ultrasound scan.

On the first postoperative day, all patients underwent a routine upper gastrointestinal gastrografin contrast study to evaluate the gastric volume and exclude postoperative leaks before discharge from the hospital. An oral liquid diet was introduced if the results were normal.

Duplex on the bilateral lower limb venous system was done for all patients before hospital discharge. It was repeated 2 and 4 weeks during the follow-up visit. The examination was done using a 3-7.5 -MHz transducer using a Voluson E8 Machine (General Electric, Boston, Massachusetts, USA) by an experienced operator. All



Figure 1. Consolidated standards of reporting trials flowchart demonstrating patient recruitment and exclusion.

venous systems, including iliac, femoral, popliteal, peroneal, post-tibial, and soleal veins, were examined. Examination for both iliac and femoral veins was done in a supine position, while other parts of the venous system were evaluated in an upright position. Positive signs of DVT include noncompressible vessels, loss of spontaneous flow, phasic flow during respiration, presence of the hypoechogenic image, and distal compression of the examined vessel resulting in nonincrease in the flow.

Outcomes

Primary outcome. Detection of silent DVT using duplex ultrasonography, 2 and 4 weeks after surgery; if there is no evidence of DVT, the patient is discharged from the outpatient clinic.

Secondary endpoints. Measuring the side effects of chemical prophylaxis (bleeding complications) in the immediate postoperative period and during duration of chemical thromboprophylaxis (2 weeks).

Statistical Analysis

Measurement data were expressed as mean \pm SD ($x \pm s$) and analyzed with Student's *t*-test. Comparisons between quantitative variables were made using the nonparametric Mann-Whitney test. For comparing categorical data, chi-square (c2) test was performed. The exact test was used when the expected frequency was less than 5. All data were processed with an SPSS 17.0 software package. A P < .05 was defined as statistically significant.

Clinical Characteristic		Group A (n = 75)	Group B (n = 75)	P Value
Age (years)	Range Mean ± SD	21-54 37.6 ± 8.7	18-57 41.8 ± 9.4	.249
Sex, n (%)	Female Male	70 (93.3) 5 (6.67)	65 (86.7) 10 (13.3)	.353
BMI (kg/m ²)	Range Mean ± SD	38.7-51.5 45.6 ± 5.2	39.4-60.3 46.4 ± 8.7	.238
Comorbidity, n (%)	DM Hypertension	3 (17.3) 9 (25.3)	8 (10.7) 17 (22.7)	.619 .516
Type of surgery, n (%)	LSG MGB	68 (90.7) 13 (17.3)	49 (65.3) 20 (26.7)	.325 .613
Operative time		149 ± 29	163 ± 43	.314

Table I. Demographic and Clinical Characteristics of the Patients.

Abbreviations: SD = standard deviation; BMI = body mass index; LSG = laparoscopic sleeve gastrectomy; MGB = mini-gastric bypass; DM = diabetes mellitus.

Table 2. Clinical Variables of Patients with silent DVT vs Patients without DVT.

		Silent DVT			
Variables		Positive (n = 9)	Negative (n = 141)	P Value	
Age, mean ± SD (years)		44.2 ± 5.0	36.6 ± 8.4	.244	
BMI , mean $\pm SD$ (kg/m ²)		46.6 ± 4.3	45.3 ± 3.6	.465	
Operative time, mean \pm SD (min)		161 ± 57	157 ± 28	.527	
DM, n (%)		0 (0)	21 (14.9)	1.000	
Hypertension, n (%)		3 (33.3)	33 (23.4)	.891	
Type of surgery, n (%)	LSG MGB	9 (100) 0 (0)	108 (76.6) 33 (23.4)	.923 1.000	

Abbreviations: SD = standard deviation; BMI = body mass index; LSG = laparoscopic sleeve gastrectomy; MGB = mini-gastric bypass; DM = diabetes mellitus; DVT = deep venous thrombosis.

Results

This study included 150 morbidly obese patients admitted for a primary one-stage laparoscopic bariatric surgery procedure over a 6 -month period. 90% of patients were females, and 10% were males. 117 patients (78%) out of 150 underwent laparoscopic sleeve gastrectomy (LSG), while 33 patients (22%) out of 150 underwent laparoscopic mini-gastric bypass (MGB). Patients' characteristics are summarized in (Table 1). Nine patients (6%) out of 150 patients developed silent DVT (6%) 2 weeks after surgery. It was noticed that the 9 patients (12%) who developed silent DVT were among the 75 patients who received mechanical thromboprophylaxis (P = .247), while the 75 patients who received combined chemical and mechanical thromboprophylaxis had no silent DVT. Relative risk (RR) of combined methods was 0.47, and 95% confidence interval, .37-.62. The 9 patients who developed silent DVT were admitted and treated initially with low molecular weight heparin (LMWH) (enoxaparin) and warfarin until targeted international normalized ratio (INR) reached 2-3, after which warfarin was

continued alone for 6 months with an INR between 2 and 3, with follow-up duplex ultrasonography every 2 weeks to assess canalization of deep venous system. There were no reported postoperative complications in both groups in the form of bleeding, hematoma, leak, wound infection, or cardiopulmonary complications.

Analysis of the Factors Associated with Silent DVT

Univariate analysis of the factors related to the development of DVT was undertaken. There was no statistically significant difference between patients with silent DVT and those without DVT regarding age, BMI, operative duration, co-morbidities, or type of surgery (Table 2).

Discussion

Obesity has been considered a risk factor for the development of VTE diseases. The risk increases after major abdominal surgeries, such as in bariatric surgery. Such a predisposition is due to the difficulty in the mobilization of morbidly obese patients and the reduction in fibrinolytic activity in those patients. According to the published studies, the risk of P.E. following bariatric operations ranges from .1% to 1.3%.¹⁰

Our study compared the efficacy and safety of 2 different modalities of VTE prophylaxis. When using mechanical thromboprophylaxis only, there were 9 established cases of silent DVT. In contrast, when using combined mechanical and chemical thromboprophylaxis regimen, it was noted that there were no silent DVT cases among this group of patients, implementing a high protective effect of chemical thromboprophylaxis. Also, chemical thromboprophylaxis extended to 2 weeks, which is the same period in which the positive cases of silent DVT were detected, highlighting the importance and the effective value of chemical thromboprophylaxis postoperatively for 2 weeks or a furthermore extended period. There were no attacks of bleeding, demonstrating that the regimen employed was safe. While the incidence of DVT is high (12%) without thromboprophylaxis, postoperative bleeding after surgery has been an obstacle in applying more aggressive regimens.

A retrospective analysis of 225 obese patients who underwent a primary bariatric surgery was done at the surgery department in Lehigh Valley Hospital, Allentown, USA. Patients received preoperative subcutaneous heparin (5000-7500 international unit (IU)) and then every 8 hours postoperatively during the admission period. The application of intermittent pneumatic compression (IPC) devices was done during surgery and postoperatively. Early postoperative ambulation was encouraged. DVT/PE was developed in 3 patients within 30 days after surgery. The incidence of DVT/PE was 1.2%. There were 6 postoperative bleeding attacks (2.4%). This study concluded that this regimen provided excellent VTE prophylaxis in the hospital setting, and the result of this study matches our results. Still, we compared 2 methods of VTE prophylaxis in 2 groups of patients.^{11,12}

Cotter et al conducted a study including 107 patients who underwent bariatric operations. All patients received prophylaxis against VTE during hospitalization, composed of medical treatment, external compression devices, and postoperative early ambulation orders, and they were screened for VTE development. During the hospitalization period, there were no documented VTE cases, and only 1 patient developed symptomatic DVT after hospital discharge. This study concluded that combined medical treatment, early postoperative ambulation, and external compression devices significantly prevent DVT development in obese patients after bariatric operations.¹³

In 2006, a systemic review was done to evaluate the effect of various VTE prophylaxis methods at the Federal University of Bahia, Salvador, Brazil. Of the 124 studies, prophylactic methods [unfractionated heparin (UFH), LMWH, and IPC] were evaluated in morbidly obese

patients in 6 studies only. Although these studies have some methodological bias, they suppose the efficacy of combined prophylaxis regimens against VTE in weight loss surgery. The limited number of prospective trials in morbidly obese patients prohibits a conclusion regarding the safest and effective VTE prophylaxis regimens for morbidly obese patients. This review concluded that randomized clinical trials are still highly warranted to compare VTE prophylaxis methods in morbidly obese patients.^{14,15}

Retrospective analysis of 668 obese patients who underwent primary laparoscopic bariatric surgery at 5 different centers was analyzed at the University of Pittsburgh Medical Centre. Patient's demographics data, established cases of VTE, and bleeding attacks were reported. Patients received mechanical prophylaxis in addition to preoperative enoxaparin (30 mg), postoperative enoxaparin (40 mg every 12 hours or 24 hours), and on discharge (30 mg every 24 hours for 10 days). The results were PE in 6 patients (.9%) and DVT in 1 patient (.1%); all happened after the discontinuation of chemical prophylaxis. The incidence of VTE was highest at a center that did not give perioperative VTE prophylaxis. The complications were bleeding in 6 patients (.9%), and 2 deaths were reported (.3%), 1 because of sepsis and the other due to bleeding; both mortalities occurred after chemical thromboprophylaxis was stopped. This study concluded that combined chemical and mechanical thromboprophylaxis regimens are effective and safe in morbidly obese patients who underwent weight loss procedures. With perioperative chemical thromboprophylaxis, fewer VTE incidents were developed during hospitalization. Extended VTE prophylaxis may be of value because most of the thromboembolic events happened after discontinuation of chemical thromboprophylaxis.¹⁶

A study was also conducted by Maggee et al on 735 patients with laparoscopic bariatric surgery. This study aimed to detect the incidence of symptomatic VTE in extended prophylaxis regimens using dalteparin at an independent hospital in England. Retrospective analysis of a prospective database of all patients who underwent laparoscopic bariatric operations was done. Combined regimens of DVT prophylaxis in the form of LMWH, IPC, and early ambulation were applied for each patient in perioperative and for an extended postoperative period (dalteparin 2500 IU preoperatively, followed by 5000 I.U. every 24 hours postoperatively). The duration of VTE prophylaxis ranged from 1 to 3 weeks. Inferior vena cava (IVC) filters were inserted in selected patients. The endpoint was symptomatic VTE incidence. The incidence of postoperative VTE and all-cause mortality was zero%. Bleeding events occurred in 3 patients, in contrast to our study, where there are no bleeding events. This study concluded that an extended thromboprophylaxis using combined LMWH and mechanical thromboprophylaxis regimens is safe, simple, and effective and was associated with a low incidence of hemorrhage complications.¹⁷

A large cohort in the Bariatric Outcomes Longitudinal Database analyzed by Winegar et al showed that VTE after laparoscopic bariatric surgery was .42% within 90 days postoperative. These morbidly obese patients were at higher risk of VTE. Their hospitalization was short, and they were advised to wear elastic compression devices, and they were able to ambulate early. It was noted that VTE's risk was higher in patients who continued their postoperative period without any form of chemical VTE prophylaxis.¹⁸ The American College of Chest Physicians guidelines recommends higher doses of low-dose UFH, LMWH, or fondaparinux for patients undergoing bariatric surgery.¹⁹

The American Association of Clinical Endocrinologists (2013), 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 and obesity society (American Association of Clinical Endocrinologists/American Society for Metabolic & Bariatric Surgery/the Obesity Society recommendations) recommend combined therapy of prophylaxis against DVT after weight loss surgery in the form of IPC, in addition, LMWH, or UFH. The extended prophylactic regimen is indicated for highrisk patients, such as patients with a previous history of DVT.²⁰

A survey among bariatric surgeons noted that most of the surgeons prefer using prophylactic medications. Approximately 60% of bariatric surgeons preferred LMWH for prophylaxis, but many were uncertain about the best regimens, timing, and duration for VTE prophylaxis. Therefore, there is much variation in clinical practice, ranging from no prophylaxis to combined thromboprophylaxis regimens that might include preoperative placement of an IVC filter.^{21,22}

An important observation in the current study is that the 9 patients who developed silent DVT did not have any special features to be considered a significant risk factor for VTE development. This confirms our point of view of the necessity of combined prophylaxis regardless of the presence or absence of known risk factors. Our study has some drawbacks: first, a small sample size, which can be avoided in further studies by a larger size of a sample, and second, short-term follow-up, so long-term follow-up is required to assess VTE.

Conclusion

Combined mechanical and chemical thromboprophylaxis has a high protective value in preventing deep venous thrombosis safely.

Author Contributions

All authors have read and approved the manuscript. Khaled S. Ahmad helped in study concept, design, and literature review; Mohamed S. Essa performed study design, literature review, and writing; and Mohamed E. Zayed and Mohamed H. Faheem peformed data collection and interpretation.

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Acquisition of data: Mohamed E. Zayed and Mohamed H. Faheem

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Declaration of Conflicting Interests

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Ethical Approval and Consent to Participate

This data collection was approved by the Ethical Committee of Benha University Hospital (No: Rc.May 1, 2020). Written informed consent was obtained from study participants.

Data Availability Statement

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

Guarantor

The corresponding author is the guarantor of submission.

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