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Risk of venous thromboembolism, use of enoxaparin and clinical outcomes in obese patients undergoing laparoscopic adjustable gastric band surgery
A retrospective study

Zahid Hussain, PhD[a,b,*] , Gregory M. Peterson, PhD[a,b], Corinne Mirkazemi, PhD[a], Colin Curtain, PhD[a], Syed Tabish R. Zaidi, PhD[a,c]

Abstract
There is a lack of clear guidance for the prophylactic use of anticoagulants for patients undergoing laparoscopic adjustable gastric banding (LAGB) surgery.

This study aimed to evaluate the risk of venous thromboembolism (VTE), prophylactic use of enoxaparin and clinical outcomes in patients undergoing primary and revisional LAGB procedures.

A retrospective study evaluated the prophylactic use of enoxaparin in adult patients who underwent primary and revisional (band and port) LAGB procedures. The incidence of VTE and major bleeding was investigated during a 90-day follow-up period. Descriptive and inferential statistics were used for data analysis.

We included 112 and 100 patients who had undergone primary and revisional (24 band procedures and 76 port procedures) LAGB surgery, respectively. The majority of patients (97%) had a mild risk of VTE development using a post-discharge VTE risk calculator tool published from the Cleveland Clinic. All primary procedure patients received prophylactic enoxaparin, compared to 79% and 20% of revisional patients who underwent band and port procedures, respectively ($P < .001$). The overall VTE incidence was 0.9%, with no significant difference between patients who did or did not receive chemoprophylaxis (0.7% and 1.5%, respectively; $P = .58$). No major bleeding events were observed.

Chemoprophylaxis may not be required in all patients undergoing low-risk LAGB surgery unless there are additional risk factors, such as the presence of super-super-morbid obesity or concomitant hormone replacement therapy. More studies are needed on the prophylactic use and dosing of enoxaparin in patients undergoing LAGB procedures to provide high-level evidence.

Abbreviations: ACS-NSQIP = American College of Surgeons-National Surgical Quality Improvement Programme, ASA = American Society of Anaesthesiologists, ASMBS = American Society for Metabolic and Bariatric Surgery, BMI = body mass index, CHEST = American College of Chest Physicians, HRT = hormone replacement therapy, LAGB = laparoscopic adjustable gastric banding, LMWH = low molecular weight heparin, LOS = length of hospital stay, NICE = National Institute for Health and Care Excellence, SNIIRM = French National Health Care System, UFH = unfractionated heparin, VTE = venous thromboembolism.

Keywords: dose, enoxaparin, laparoscopic adjustable gastric banding, obese, prophylaxis, surgery

1. Introduction

Bariatric surgery is considered the most effective treatment in the management of morbid obesity and prevention of obesity-related complications.[1] The number of obese patients undergoing bariatric surgery has increased more than 10-fold in the past 2 decades.[2] One of the main reasons for this increase has been the development of laparoscopic techniques, which offer an excellent safety profile.[1] However, venous thromboembolism (VTE)

remains a significant cause of morbidity and mortality during the post-operative period.[3] The incidence of VTE ranges from 0.2% to 3.5% in bariatric patients undergoing laparoscopic surgery.[3]

Mechanical prophylaxis methods, such as thromboembolic deterrent stockings and sequential compression devices, and chemoprophylaxis, such as unfractionated heparin (UFH) or low molecular weight heparin (LMWH), are often used to prevent VTE in patients undergoing bariatric surgery. The routine use of mechanical prophylaxis is recommended by various guidelines, such as those of the American Society for Metabolic and Bariatric Surgery (ASMBS), the American College of Chest Physicians (CHEST) and the National Institute for Health and Care Excellence (NICE).[4–6] However, studies have reported inconsistent findings regarding the potential need, choice of drug, dosing regimen, and duration for VTE chemoprophylaxis. Generally, there is consensus that enoxaparin is more effective in VTE prevention compared to UFH, without increasing the bleeding risk in bariatric surgical patients.[7] Yet, controversy regarding the use and dose of enoxaparin exists in the literature; recommendations have ranged from its use not being essential (mechanical prophylaxis alone is enough)[8,9] to the use of high-dose enoxaparin (60 mg twice daily).[10,11] Similarly, some studies have reported that an extended duration of chemoprophylaxis for 10 days or 2 weeks post-discharge resulted in less VTE complications compared to in-hospital use only.[11–13]

The ASMBS position statement published in 2013 reported there was no level 1 evidence regarding the type, dose and duration of chemoprophylaxis to be used in bariatric surgical patients.[4] The CHEST guidelines published in 2012 recommended the use of LMWH or UFH in bariatric surgical patients who have moderate (grade 2B) or high (grade 1B) VTE risk; however, no information regarding the dose and duration of chemoprophylaxis was provided.[5] The NICE guidelines published in 2018 suggested the use of chemoprophylaxis (LMWH or fondaparinux sodium) in all patients with low bleeding risk, and for it to be continued while the patient had significantly reduced mobility.[6] Importantly, these guidelines did not distinguish between types of bariatric procedure (gastric bypass, sleeve gastrectomy, gastric banding) and surgical techniques (open vs laparoscopic) in regard to VTE prophylaxis.

In light of this variation and uncertainty, we retrospectively examined current local practice for chemoprophylaxis in patients undergoing primary and revisional bariatric surgery (laparoscopic adjustable gastric banding; LAGB). We estimated the risk of VTE in each patient using a post-discharge VTE risk assessment tool published by the Cleveland Clinic.[14] We determined the use (dose and duration) of chemoprophylaxis and the incidence of adverse outcomes (VTE and bleeding events). Finally, we identified the factors associated with the use of chemoprophylaxis.

2. Methods

Ethical approval for this study was obtained from the Tasmanian Health and Human Research Ethics Committee (H0015795). The need for consent from patients was waived by the committee due to the retrospective nature of the study and the collection of non-identifiable patient information.

A retrospective study was conducted of adult (age ≥ 18 years) obese patients (body mass index (BMI) ≥ 30 kg/m^2) who underwent primary and revisional bariatric surgery at the Royal Hobart Hospital and the Hobart Private Hospital, from January

1, 2013, to December 31, 2017. The sole primary bariatric procedure at our study sites was LAGB. Revisional procedures were done for adjustment, replacement, or removal of bands, as well as adjustment, replacement, or removal of ports. Patients were excluded from the study if they were on regular anticoagulant or vitamin K therapy, underwent a concurrent surgical procedure (e.g., hysterectomy), or had an established congenital or acquired bleeding disorder, varicose veins, renal impairment with an estimated glomerular filtration rate < 60 mL/min/1.73m^2, prior heparin-induced thrombocytopaenia, haemorrhagic stroke within the previous 3 months, other surgery within the previous 3 months, or if relevant information was missing. Patients had been advised to stop taking any non-steroidal anti-inflammatory drugs and aspirin 5 days preoperatively.

A list of patients who had undergone primary and revisional LAGB during the study period was obtained from hospital coding databases. Patients' medical records were reviewed to confirm eligibility and to collect demographic and clinical information, including age, gender, body mass index, length of hospital stay, duration of surgical procedure, American Society of Anaesthesiologists score,[15] return to operating room, incidents of dyspnoea at rest, smoking status, presence of diabetes mellitus, hypertension, congestive heart failure, paraplegia, or obstructive sleep apnoea, history of VTE, oral contraceptive, or hormone replacement therapy (HRT) use, details of mechanical prophylaxis, use of prophylactic anticoagulant (including dose and duration), and the occurrence of VTE (deep vein thrombosis and/or pulmonary embolism; deep vein thrombosis , and/or pulmonary embolism), or major bleeding complications within 90 days following the procedure. Colour Doppler ultrasound and CT pulmonary angiography techniques were used for diagnosis of VTE at our study sites. To define major bleeding, we used the criteria of the International Society on Thrombosis and Haemostasis: fatal bleeding; bleeding in vital organs (intracranial, intraspinal, retroperitoneal, intra-articular, pericardial, intraocular); bleeding at a surgical site requiring reoperation; and bleeding associated with a reduction in haemoglobin of at least 2 g/dL or requiring transfusion of at least 2 units of packed red cells/whole blood.[16]

Categorical variables were expressed as count (percentage) and continuous variables as median (range). Fischer exact test and Pearson X^2 test were used for categorical variables to compare primary and revisional procedures. The Kruskal–Wallis test was used for continuous variables to compare demographic and clinical variables and prophylactic anticoagulant usage for primary and revisional procedures. Univariate logistic regressions were used to identify variables associated with enoxaparin use. Subsequently, variables with a P-value < .15 in the univariate analyses, procedure type, and VTE risk were considered in a multivariate regression analysis.

We also compared outcomes for our primary procedure cohort with the American College of Surgeons-National Surgical Quality Improvement Programme (ACS-NSQIP) and the French National Health Care System (SNIIRM).[14,17] Only the primary LAGB procedure cohort was compared because the published data do not include revisional procedures. The one proportion sample test was used to compare our incidence of VTE and major bleeding with these data.

3. Results

Out of 262 screened patients, 212 met the inclusion criteria (Fig. 1). One hundred twelve underwent primary LAGB and 100
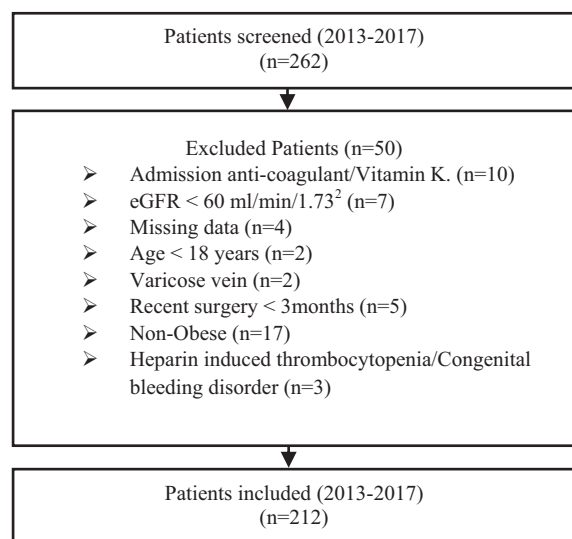
Figure 1. Flow diagram of patient inclusion.

had revisional (24 band and 76 port) procedures. Socio-demographic and clinical characteristics of the patients are presented in Table 1. Patients in both cohorts were predominantly female. The primary procedure cohort had a significantly higher mean weight and BMI. Primary and revisional band procedure patients had longer hospital lengths of stay (median of 1 day vs 0 days, $P < .001$) compared to the port procedure patients. Almost all patients in the primary (95%), revisional band (100%) and revisional port procedures (99%) categories had mild risk of VTE.[14]

Mechanical prophylaxis was used during hospital stay in 100% of patients undergoing primary procedures compared to 96% and 84% for revisional band and port procedures, respectively. All patients in the primary procedure cohort were given the combination of thromboembolic deterrent, sequential compression devices and enoxaparin, compared to 75% in the revisional band procedures and just 18% of patients in the revisional port procedures cohorts ($P < 0.001$). Overall, 69% of patients received chemoprophylaxis. The use of prophylactic enoxaparin was significantly higher in the primary and revisional band procedure cohorts compared to the revisional port

Table 1

Socio-demographic and clinical variables (N = 212).

Variable	Primary Procedures (n = 112)	Revisional procedures (n = 100) Band Procedures (n = 24)	Port Procedures (n = 76)	P-value
Gender				.003
Female, n (%)	86 (76.8)	16 (66.7)	70 (92.1)	
Age (yr), median (range)	47.0 (18.0–69.0)	49.5 (25.0–71.0)	46.0 (24.0–67.0)	
Weight (kg), median (range)	135.5 (87.0–210.0)	112.0 (88.0–178.0)	120.0 (79.0–181.0)	<.001
BMI (kg/m²), median (range)	48.9 (36.2–75.3)	38.6 (34.5–62.5)	45.0 (32.4–64.9)	<.001
TED/SCD				
Yes, n (%)	112 (100.0)	23 (96.0)	64 (84.2)	<.001
Length of hospital stay, n (%)				<.001
Day procedure only	0 (0.0)	7 (29.7)	62 (81.6)	
1 day	103 (92.0)	10 (41.7)	11 (14.5)	
2 days	6 (5.4)	5 (20.8)	1 (1.3)	
3 days	3 (2.7)	0 (0.0)	2 (2.6)	
4 days	0 (0.0)	2 (8.3)	0 (0.0)	
Days, median (range)	1 (1–3)	1 (0–4)	0 (0–3)	
Duration of surgery (min), median (range)	48.5 (30.0–113.0)	64.0 (25.0–145.0)	45.0 (20.0–92.0)	<.001
ASA score				
1, n (%)	0 (0.0)	1 (4.2)	1 (1.3)	
2, n (%)	36 (32.1)	9 (37.5)	22 (28.9)	
3, n (%)	76 (67.9)	13 (54.2)	53 (69.7)	
4, n (%)	0 (0.0)	1 (4.2)	0 (0.0)	
Congestive heart failure				
Yes, n (%)	2 (1.8)	1 (4.2)	0 (0.0)	
Paraplegia				
Yes, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	
Return to operating room				
Yes, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	
Dyspnoea at rest				
Yes, n (%)	6 (5.4)	1 (4.2)	0 (0.0)	
Smoker				
Yes, n (%)	26 (23.2)	7 (29.2)	19 (25.0)	
Diabetes mellitus				.004
Yes, n (%)	43 (38.4)	9 (37.5)	13 (17.1)	
Hypertension				
Yes, n (%)	50 (44.6)	7 (29.2)	22 (29.0)	
VTE history				
Yes, n (%)	3 (2.7)	1 (4.2)	0 (0.0)	
Obstructive sleep apnoea				
Yes, n (%)	32 (28.6)	4 (16.7)	18 (23.7)	
Oral contraceptive/hormone replacement therapy				
Yes, n (%)	7 (6.2)	1 (4.2)	2 (2.6)	
VTE risk				
Mild, n (%)	107 (95.5)	24 (100.0)	75 (98.7)	
Moderate, n (%)	4 (3.6)	0 (0.0)	1 (1.3)	
High, n (%)	1 (0.9)	0 (0.0)	0 (0.0)	

Only statistically significant values ($P < .05$) are shown under the P-value column.

Table 2

Thromboprophylaxis practices and outcomes (N = 212).

| Regimen | Primary procedures (n = 112) | Revisional procedures (n = 100) | | P-value |
		Band adjustment/ replacement/ removal (n = 24)	Port adjustment/ replacement/ removal (n = 76)	
TED/SCD only, n (%)	0 (0.0)	5 (20.8)	50 (65.8)	*<.001*
Enoxaparin only, n (%)	0 (0.0)	1 (4.2)	1 (1.3)	
TED/SCD and Enoxaparin, n (%)	112 (100.0)	18 (75.0)	14 (18.4)	
None, n (%)	0 (0.0)	0 (0.0)	11 (14.5)	
Peri-operative anticoagulant				*<.001*
Enoxaparin 40 mg daily, n (%)	111 (99.1)	17 (70.8)	7 (9.2)	
Enoxaparin 60 mg daily, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	
Enoxaparin 80 mg daily, n (%)	1 (0.9)	0 (0.0)	1 (1.3)	
None, n (%)	0 (0.0)	7 (29.2)	68 (89.5)	
Post-operative anticoagulant				*<.001*
Enoxaparin 40 mg daily, n (%)	110 (98.2)	16 (66.7)	11 (14.5)	
Enoxaparin 60 mg daily, n (%)	1 (0.9)	0 (0.0)	0 (0.0)	
Enoxaparin 80 mg daily, n (%)	1 (0.9)	0 (0.0)	0 (0.0)	
None, n (%)	0 (0.0)	8 (33.3)	65 (85.5)	
Duration of chemoprophylaxis				*<.001*
Peri-op only, n (%)	0 (0.0)	3 (12.5)	4 (5.3)	
Peri-op until discharge, n (%)	0 (0.0)	1 (4.2)	0 (0.0)	
Post-op until discharge, n (%)	0 (0.0)	2 (8.3)	7 (9.2)	
10 d post-discharge, n (%)	110 (98.2)	13 (54.2)	4 (5.3)	
30 d post-discharge, n (%)	2 (1.8)	0 (0.0)	0 (0.0)	
None, n (%)	0 (0.0)	5 (20.8)	61 (80.3)	
Enoxaparin use[*]				*<.001*
Yes, n (%)	112 (100)	19 (79.2)	15 (19.7)	
VTE within 90-d, n (%)	1 (0.9)	0 (0.0)	1 (1.0)	1.000
Major bleed within 90 d, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	1.000

Statistically significant values (P < .05) are shown in italics under the P-value column to highlight such significance.

[*] Any of the following regimen of enoxaparin: start at induction until discharge, start post-operatively until discharge, start at induction until post-discharge, or start post-operatively until post-discharge.

procedure cohort (100% and 79%, vs 20%; P < .001). The majority of patients in the primary and revisional (band and port) cohorts received 40 mg enoxaparin once daily (Table 2). All patients in the primary procedure cohort received prophylactic enoxaparin post-discharge, typically for 10 days, compared to 54% of revisional band procedure and just 5% of revisional port procedure patients. The multivariate logistic regression model showed that patients who stayed longer in hospital (typically those who had undergone primary LAGB and band procedures) were more likely to receive chemoprophylaxis (Table 3); that is, enoxaparin use was higher in patients who had an overnight stay in hospital.

Table 3

Logistic regression for variables associated with enoxaparin use (n = 212).

Variable	Unadjusted OR (95% CI)	P-value	Adjusted OR (95% CI)	P-value
Gender				
Female	0.49 (0.21–1.13)	.09	2.09 (0.32–13.64)	.44
Age	0.99 (0.96–1.02)	.86	———	———
Procedure				
Primary	0.00 (0.00–0.00)	.99	0.00 (0.00–0.00)	.99
Duration of surgery (mi)	1.03 (1.01–1.06)	.001	1.02 (0.99–1.06)	.15
BMI	1.08 (1.04–1.12)	<.001	1.03 (0.94–1.12)	.45
Overnight stay[*]				
Day procedure	307.78 (86.92–1089.87)	<.001	33.32 (7.99–130.00)	<.001
ASA score				
1	1.91 (0.11–32.00)	.65	———	———
Smoker				
Yes	1.15 (0.58–2.92)	.68	———	———
VTE risk				
Mild	1.84 (0.20–16.82)	.59	0.00 (0.00–0.00)	.99

ASA = American Society of Anesthesiologist, BMI = body mass index, CI = confidence interval, OR = odds ratio.

Variables with P-value less than .15 and other factors which were associated with anticoagulant use (procedure type and VTE risk) were considered in multivariate regression analysis.

VTE risk is categorised into mild and moderate/severe.

[*] Overnight stay is categorized into ≥ 1 d or day procedure (0 d).

There was 1 VTE occurrence in each of the primary and revisional port procedure cohorts. Both patients were taking HRT. One patient (210 kg; BMI 75.3 kg/m^2) who underwent primary LAGB was diagnosed with a deep vein thrombosis 35 days post-operatively. This patient had received 40 mg enoxaparin at induction and 40 mg enoxaparin daily for 10 days post-discharge. The other patient (118 kg; BMI 49.1 kg/m^2) had undergone a port adjustment and was diagnosed with pulmonary embolism 2 months post-operatively, after reporting 4 weeks of shortness of breath. This patient had received only mechanical prophylaxis during hospital stay and no chemoprophylaxis. Two other primary procedure patients developed possible clinical manifestations of VTE (pain and calf swelling). These patients underwent diagnostic procedures (colour Doppler ultrasound and CT pulmonary angiography) but no VTE was detected in either patient. There was no significant difference in the overall occurrence of VTE between the primary and revisional procedure cohorts (0.9% vs 1.0% respectively; P-value = 1.00). No major bleeding event was observed in either cohort. Similarly, there was no statistically significant difference in the overall 90-day VTE incidence between the cohorts who received and did not receive chemoprophylaxis (0.7% vs 1.5%, respectively; P-value = .58).

The majority of clinical and demographic variables in our primary procedure cohort were similar to those reported in the American College of Surgeons-National Surgical Quality Improvement Programme (ACS-NSQIP) and SNIIRM databases. The reported incidences of VTE in primary LAGB patients in the ACS-NSQIP (30 days) and the SNIIRM databases (90 days) were 0.1% (26/24,650) and 0.2% (31/14,947), respectively.[14,17] Our study's 30-day and 90-day VTE incidences were not significantly different compared to the ACS-NSQIP database (0.0% vs 0.1%, P-value = .63, 95% CI = 0.00–3.24) and the SNIIRM database (0.9% vs 0.2%, P-value = .09, 95% CI = 0.02–4.89), respectively.

4. Discussion

We observed low incidences of VTE and no major bleeds in both primary and revisional LAGB procedures. Surgical procedures performed laparoscopically are less likely to result in post-operative VTE compared to open procedures.[18] However, guidelines such as those of ASMBS, CHEST and NICE do not recommend specific VTE prophylaxis for LAGB. These guidelines suggest the same prophylactic chemoprophylactic approach based on the individual patient risk assessment (VTE vs bleeding risk) and clinical judgment of the surgeon for all bariatric procedures regardless of type (gastric banding, gastric bypass, and sleeve gastrectomy) or technique (laparoscopic or open).[4,6] Despite the mild risk of VTE development, all of our primary LAGB procedure patients received chemoprophylaxis.

LAGB is considered the safest bariatric procedure in terms of VTE risk.[19] According to the ACS-NSQIP database, the 30-day prevalence of VTE following LAGB was 0.1% compared to 0.6% and 0.4% in laparoscopic sleeve gastrectomy and laparoscopic gastric reduction patients, respectively.[14] Similarly, according to the SNIIRM database, the reported incidence of 90-day VTE with LAGB was lower (0.2%) compared to laparoscopic sleeve gastrectomy (0.5%) and laparoscopic gastric reduction (0.6%).[17] A German nationwide survey reported a gradually declining trend of chemoprophylaxis in LAGB surgery from 2005 (100%) till 2010 (95%), due to shorter length of hospital stay and less complicated procedures.[20]

A total of 97% of patients who had mild risk of VTE development received chemoprophylaxis. Yet, studies of laparoscopic bariatric surgery have reported that mechanical prophylaxis alone provides sufficient VTE prophylaxis if the operation time is short and the patient becomes ambulatory soon after surgery.[8,9] Our patients fulfilled both of these criteria; the mean operation time was shorter (mean = 49.7 minutes) compared to sleeve gastrectomy (100 minutes) and gastric bypass (135 minutes) patients reported in the ACS-NSQIP database,[14] and the majority of our patients were ambulatory on the day of surgery, likely due to the less complex surgical procedure.

A 10-year longitudinal study reported that LAGB resulted in a higher surgical revision rate compared to gastric bypass and sleeve gastrectomy.[21] This is a possible explanation for the relatively high number of revisional procedures in our study, because LAGB has been the principal bariatric procedure conducted at our study site since the late 1990s. The mean duration from primary to revisional procedures was 7.36 years in our study patients.

This study had some limitations. First, the retrospective study design meant that we had to rely on the notes available in digital medical records, and verbal advice from the principal bariatric surgeon. Secondly, our sample size was relatively small, with limited statistical power when examining relatively rare outcomes. Thirdly, we did not screen all patients for VTE after their surgery, so the incidence may have been under-reported. Lastly, LAGB is now not a first-choice bariatric procedure in many countries, including USA, but this is still widely employed in other countries.

5. Conclusion

A low incidence of VTE was observed in the LAGB surgical cases in this study, which included a heterogenous mix of primary and revisional surgeries, with varying use, dose, and duration of enoxaparin. Because of the low VTE risk associated with LAGB, chemoprophylaxis may not be required in all patients unless there are additional risk factors, such as super-super-morbid obesity (BMI > 60 kg/m^2) or concomitant HRT. As there is no procedure- and technique-specific thromboprophylaxis advice for bariatric surgery, surgeons should follow current recommendations, modifying them as required to suit individual patients' risk. Further research to provide procedure- and technique-specific thromboprophylaxis evidence may improve outcomes.

Author contributions

Zahid Hussain: Study concept and design, data collection and analysis, manuscript drafting and revisions.
Gregory M Peterson: Study design, interpretation of data, manuscript revision.
Corinne Mirkazemi: Study design, manuscript revision.
Colin Curtain: Interpretation of data, manuscript revision.
Syed Tabish R. Zaidi: Study concept, manuscript revision

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