

ASMBS Guidelines

# The American Society for Metabolic and Bariatric Surgery (ASMBS) updated position statement on perioperative venous thromboembolism prophylaxis in bariatric surgery

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The following position statement is the second update by the American Society for Metabolic and Bariatric Surgery (ASMBS) on prophylactic measures for reducing the risk of venous thromboembolism (VTE) in bariatric surgery patients, after the previous update in 2013 [1]. The purpose of this statement is to enhance the quality of care in bariatric surgery by reviewing the available evidence on VTE prophylaxis. Since there is limited high-quality data, these practice guidelines suggest some recommendations that are based on available knowledge, peer-reviewed scientific literature, and expert opinion regarding reasonable use of prophylactic measures for VTE in bariatric surgery patients. The intent of issuing such a statement is to provide objective information regarding the use of VTE prophylaxis and its possible role in the prevention of such complications. The statement will be revised in the future when additional evidence becomes available.

## The Issue

Patients undergoing bariatric surgery are at an increased risk for VTE [2–4]. The initial ASMBS position statement on VTE prophylaxis in 2007 recommended early postoperative ambulation, the use of lower extremity sequential compression devices (SCDs), and pharmacoprophylaxis if not contraindicated [5]. Type, dose, and duration of pharmacoprophylaxis and the indication for inferior vena cava (IVC) filters for bariatric patients were not clearly defined at that time. Since then, several studies and systematic reviews have been published that add to the body of evidence that contributes to these clinical practice guidelines. The lack of randomized controlled data persists which limits the ASMBS's ability to provide recommendations based on a high level of evidence. This updated position statement is intended to provide a current review of the literature regarding VTE prophylaxis in bariatric surgery patients and provide recommendations based on the available evidence.

## Scope of the Problem

The importance of VTE prophylaxis in the perioperative period has been well explained. The incidence of symptomatic deep venous thrombosis (DVT) and pulmonary embolism (PE) after bariatric surgery ranges from 0.2% to 3%

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and 0.1% to 2%, respectively [6–10]. With the majority of bariatric programs having a protocol in place for VTE prophylaxis [11], VTE rates have been <1% for the average risk bariatric patients based on large database studies [6,12–14]. This is comparable to rates for many other elective operations [15]. A systematic review of 19 studies from 2000 to 2010 evaluating VTE after laparoscopic bariatric surgery reported an incidence of PE of 0.5% [16]. The Michigan Bariatric Surgery Collaborative published 2 large series from their quality collaborative registry from 2006 to 2012 that showed overall VTE rates less than 0.5% in average-risk bariatric patients [13,14]. Based on the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database from 2015 to 2017, the incidence of DVT was 0.2% after both laparoscopic sleeve gastrectomy (SG) and laparoscopic Roux-en-Y gastric bypass (RYGB), and the incidence of PE was 0.1% after SG and 0.2% after RYGB [12].

VTE after bariatric surgery can be associated with a 30-day mortality rate of 2.6% to 8.6% comparing to an average of 0.1% to 0.2% in the absence of these complications [6,14,17]. A study on the Bariatric Outcomes Longitudinal Database (BOLD) data from 2008 to 2012 showed that PE within 30 days of surgery is the strongest independent predictor of 1-year mortality after laparoscopic bariatric surgery (adjusted odds ratio of 34.5 for RYGB and 252 for SG) [18].

Most VTE events after bariatric surgery occur after discharge. Based on a study using the American College of Surgeons–National Surgical Quality Improvement Program with 91,963 patients who had bariatric surgery from 2007 to 2012, 83% of VTEs occurred after hospital discharge [6]. This is compatible with the previous data from the BOLD which revealed that 74% of VTE events occurred after discharged from the hospital [19].

An analysis of the MBSAQIP database suggests that initiatives targeting a reduction of postbariatric surgery VTE would have the greatest potential to reduce mortality and readmission rates in the national level [20].

### High-Risk Patients

Almost all bariatric surgery patients are considered to be at least at moderate risk for VTE events due to presence of moderate to severe obesity, undergoing laparoscopic surgery, and perioperative immobility. Depending on the characteristics of every patient and operation, some bariatric surgery patients are high risk or extremely high risk for the development of postoperative VTE [6].

Several risk factors for VTE after bariatric surgery have been identified in the literature. Three studies have developed evidence-based risk assessment tools for VTE after bariatric surgery based on large databases. These studies have found independent predictors for VTE after bariatric surgery including prior VTE events, higher body mass index

(BMI), older age, male sex, longer operative time ( $\geq 3$  hr), more complex procedures (duodenal switch > RYGB > SG > adjustable gastric band), history of congestive heart failure, paraplegia, poor preoperative functional status, return to the operating room, dyspnea at rest, length of stay  $\geq 3$  days, and race (black > white) [6,14,17].

Postoperative complications including bleeding and subsequent transfusion have been shown to be risk factors for VTE after bariatric surgery [21,22]. Other factors that may place patients into a high-risk category include immobility, hypercoagulable conditions, genetic risk factors, venous stasis disease, and hormonal therapy [6]. Hormonal therapy after menopause, for contraception (in the forms of combined estrogen-progestin or estrogen-only pills, injectable, patch, implants, or vaginal ring), and selective estrogen-receptor modulators may also increase the risk of VTE [23].

### Mechanical Prophylaxis

Mechanical prophylaxis options include intermittent pneumatic compression, graduated compression stockings, and venous foot pumps. These devices serve to enhance the blood flow in the deep veins of the lower extremities to prevent venous stasis and are commonly used as adjuncts to pharmacoprophylaxis [1].

Due to the possible risk of bleeding complications from pharmacoprophylaxis, several studies have examined the use of mechanical compression alone in bariatric surgery patients. A retrospective study of 1692 patients evaluated VTE rates comparing low-molecular-weight heparin (LMWH; enoxaparin 40 mg twice daily) and SCDs ( $n = 435$ ) with patients who received SCDs and early ambulation (within 2 hr of arrival to the ward) and selective pharmacoprophylaxis in high-risk patients only ( $n = 1257$ ). This study represented a change in the authors' practice protocol over time and was not a clinical trial. These authors reported DVT and PE rates of 1.7% and 1.1%, respectively, in patients who received LMWH and SCDs compared with a 0.5% DVT rate and no PE in the patients who received mechanical prophylaxis, early ambulation, and selective pharmacoprophylaxis. Bleeding complications were higher in the LMWH group (4.8%) compared with the second group (0.9%). The study concluded that adequate VTE prophylaxis can be achieved using SCDs, early ambulation, emphasis on hydration, and shorter operating times without need for pharmacologic VTE prophylaxis in all but the high-risk population [24]. The ability to generalize these results is limited, because it is a single practice's retrospective study with fewer complications over time and a higher mean BMI and longer operative times in the group that received pharmacoprophylaxis [1].

Another study reported a retrospective analysis of 957 consecutive patients without a history of VTE undergoing RYGB who received no pharmacologic agent for VTE prevention [25]. Calf-length SCDs were placed before surgery,

and early, frequent ambulation was encouraged. The authors reported 30-day DVT and PE rates of 0.3% and 0.1%, respectively, and a bleeding complication rate of 0.7%. In the aforementioned studies, the authors suggest that mechanical prophylaxis is sufficient for patients without a personal or strong family history of VTE events or known hypercoagulable state. It should also be noted that the VTE rates reported were based on symptomatic patients who underwent diagnostic testing, and no routine imaging or screening was performed [1].

A more recent prospective randomized study comparing mechanical prophylaxis with elastic stockings alone with combined mechanical and pharmacoprophylaxis found that the rate of silent DVT with mechanical prophylaxis was higher than when pharmacoprophylaxis was administered, 6% compared to 0%, respectively [26]. In this study, each patient underwent a postoperative ultrasound and mechanical prophylaxis did not include pneumatic devices, both of which could account for a higher DVT rate [1].

In the ninth edition of the American College of Chest Physicians Evidence-Based Clinical Practice Guidelines, pharmacologic prophylaxis or mechanical prophylaxis is recommended in moderate-risk patients (Caprini score 3–4). This would include lower-risk bariatric patients. For higher-risk patients (Caprini score >5), a combination of mechanical and pharmacologic prophylaxis is recommended. For patients with a higher risk of bleeding, mechanical prophylaxis is recommended over no prophylaxis [27].

## Pharmacoprophylaxis

### *Pharmacological agents*

There continues to be a lack of high quality and class I evidence in regard to safety, efficacy, dosing, and duration of treatment regarding pharmacologic thromboprophylaxis for the perioperative period. Strategies have been presented that use single-agent and combinations of unfractionated heparin (UFH) and LMWH.

Lovenox (enoxaparin) continues to be the most commonly prescribed medication for postdischarge pharmacoprophylaxis. Clark et al. reported in 2019 on 104,421 patients from a claims database that was made up of procedure diagnoses and prescription filling data; 55% of the patients underwent RYGB and 44% underwent SG. Postdischarge pharmacoprophylaxis was used in a total of 11% of patients. Enoxaparin was the most commonly used medication in these patients, accounting for 88% of prescriptions [28]. LMWH is recommended over UFH in perioperative VTE chemoprophylaxis by the European Society of Anesthesiology VTE Guideline Task Force [29].

The optimal dosing of postoperative LMWH remains unanswered. Standardized dosing schedules have been postulated to underestimate the dosing required in patients with obesity. A 2017 French study looked at questionnaires sent to 37 French obesity specialized care centers. Surveys

asked about perioperative thromboprophylaxis usage. Data revealed that 90% of centers used LMWH. Half of respondents reported standardized dosing, and 50% reported adjusting dose based on total body weight or BMI [30].

A Canadian study looked at 30-day outcomes in 819 bariatric surgery patients. Patients had an average BMI of 48 kg/m<sup>2</sup> and received UFH just before surgery. Some patients received it on the evening of surgery as well. On postoperative day 1, patients were started on weight-adjusted LMWH (tinzaparin), which was continued for 10 days. VTE occurred in 0.5% of patients (4/819), and major bleeding occurred in 1.6% of patients (13/819). Trough anti-factor Xa activity (AFXa) was measured in 187 patients on day 6 (median) after surgery. No differences were seen in trough levels for patients on weight-based prophylaxis (tinzaparin 4500 IU for <110 kg, 10,000 IU for 110–159 kg vs 14,000 IU for >160 kg). All patients had AFXa levels of ≤4 IU/mL, indicating relative safety of weight-based administration of higher doses of LMWH [31].

One alternative that has been suggested to LMWH for VTE pharmacoprophylaxis is rivaroxaban (Xarelto; Bayer Pharma AG). This direct oral anticoagulant is a factor Xa inhibitor with high (80%–100%) oral bioavailability, meaning patients are not required to self-administer injections such as LMWH and UFH. Maximum plasma levels of rivaroxaban are achieved in 2 to 4 hours after dosing. It has been approved for VTE prophylaxis in certain orthopedic procedures. A phase 1 clinical trial looking at pharmacokinetic (PK) and pharmacodynamic parameters of rivaroxaban in bariatric patients took place in 2017. Twelve primary bariatric surgery patients (6 RYGB with mean BMI of 38 kg/m<sup>2</sup> and 6 SG with mean BMI 45 kg/m<sup>2</sup>) received 1 dose (10 mg) of rivaroxaban 1 day prior to and 3 days after bariatric surgery. Patients were treated with LMWH on postoperative day 0 to 3. PK and pharmacodynamic parameters were assessed at baseline and 24 hours after ingestion and were found to be unchanged in the postoperative setting. There were no thrombotic events or clinically relevant bleeding issues in this small series of patients at 30 days (30 ± 7 d) [32]. The potential use of direct oral anticoagulants for VTE prophylaxis requires more studies to evaluate safety and efficacy of these oral agents in bariatric surgical patients.

### *In-hospital pharmacoprophylaxis*

The benefit of routine in-hospital pharmacoprophylaxis has been described in other surgical populations at increased risk, but without high-level evidence or randomized clinical trials. Similarly, a significant body of literature exists regarding the safety and efficacy of pharmacologic prophylaxis of VTE in the setting of bariatric surgery, but there is no high-level evidence to guide specific recommendations regarding dosing or duration. Many proposed regimens of thromboprophylaxis have been reported perioperatively in

bariatric surgery patients; however, the optimal dose and duration remain uncertain.

A study highlighting the varied practices shows that among 11,860 patients, 5% had only preoperative pharmacoprophylaxis, 39% had only postoperative pharmacoprophylaxis, 22% had both pre- and postoperative pharmacoprophylaxis, and 34% had no in-hospital pharmacoprophylaxis [7]. Another study in the French population also describes significant discrepancies in perioperative pharmacoprophylaxis administration [30]. This is further complicated by the various agents, dosages, and regimens of prophylaxis, as pharmacoprophylaxis can be used preoperatively, postoperatively, or both.

### Indication

The American College of Chest Physicians Evidence-Based Clinical Practice Guidelines have suggested patients undergoing bariatric procedures as high risk for VTE events. Their recommendations for high-risk patients for VTE (who are not at high risk for major bleeding complications) are pharmacologic prophylaxis with LMWH or low-dose UFH over no prophylaxis, in addition to mechanical prophylaxis. For patients at high risk for major bleeding complications or for those in whom the consequences of bleeding are thought to be particularly severe, mechanical prophylaxis is recommended until the risk of bleeding diminishes and pharmacologic prophylaxis may be initiated [27].

### Agents

There are several studies examining various thromboprophylactic agents. A prospective, double-blind, randomized controlled trial in 198 consecutive bariatric patients compared pre- and postoperative subcutaneous injection of enoxaparin 40 mg twice daily with postoperative 5 mg fondaparinux sodium once daily. At 2 weeks postoperatively, patients underwent magnetic resonance venography (MRV) to detect DVT. The primary outcome was the attainment of therapeutic AFXa levels, whereas the secondary outcome was DVT, as detected by MRV. In addition, safety outcomes including perioperative bleeding, perioperative complications, and death were examined. Adequate AFXa levels were more common with fondaparinux compared with enoxaparin (74% versus 32%, respectively). Four of the 175 patients who underwent MRV developed DVT, with an equal number in each arm. No major adverse events occurred in each arm. Bleeding complications were 5% in the enoxaparin group compared to 3% in the fondaparinux group. The authors concluded that fondaparinux was more likely to produce target prophylactic AFXa levels compared to enoxaparin, while both regimens were equally effective at reducing the risk of DVT [33].

The Michigan Collaborative examined 3 regimens: UFH pre- and postoperatively (UFH/UFH), UFH preoperatively and LMWH postoperatively (UFH/LMWH), and LMWH

pre- and postoperatively (LMWH/LMWH). Overall, adjusted rates of VTE were significantly lower for the LMWH/LMWH group (.25%,  $P < .001$ ) and UFH/LMWH group (0.29%,  $P = .03$ ) compared to the UFH/UFH group (.68%). The study concluded that LMWH would be more effective compared with UFH among patients undergoing bariatric surgery, without any effect on increased rates of bleeding. However, exact dosages of these regimens were not reported [13].

Kothari et al., in a nonrandomized study, compared LMWH and UFH. The LMWH group received 40 mg of enoxaparin administered subcutaneously preoperatively and on the day of surgery and then twice daily until discharge. The UFH group received 5000 IU preoperatively, nothing else on the day of surgery, and then 5000 IU 3 times per day until discharge. Bleeding episodes were significantly higher in the LMWH group as 14 patients (5.9%) required transfusion compared to 3 patients (1.3%) in the UFH group. There were no DVT events in either group and 1 PE in the UFH cohort. The study concluded that the UFH would be potentially superior due to the lower rate of bleeding events [34].

Another trial examined LMWH given 12 hours before surgery and restarted 24 hours following surgery and then for 15 days. They examined the incidence of symptomatic DVTs, which was 0 for 36 months [35].

European guidelines, published in 2018, recommend using both pharmaco- and mechanical prophylaxis together for patients with obesity who are high risk for VTE, as they recommend the use of LMWH over UFH [29]. Similarly, LMWH is recommended by others [10].

### Dosage and timing and duration

Dosage and timing add another layer of complexity to providing guidelines, as there is a lot of variation. Pharmacoprophylaxis has not been well studied in the obese population; thus, the PK of these agents is uncertain. The American College of Chest Physicians Guidelines recommend AFXa monitoring for LMWH when body weight exceeds 150 kg [27]. However, others have questioned whether following AFXa levels correlate well with VTE or bleeding in the obese population, as there are no studies providing level 1 evidence to date [36,37].

Two randomized clinical trials comparing dosages of LMWH had similar results with no differences in terms of VTE events. Imberti et al. found no significant differences in bleeding events, while Kalfarentzos et al. showed that bleeding was associated with administration of higher dose of LMWH (nadroparin) [38,39]. A retrospective study at 5 centers examined different doses and timing in 668 patients. Patients received enoxaparin preoperatively (30 mg) or postoperatively (40 mg) every 12 or 24 hours or upon discharge (30 mg every 24 hr for 10 d). Fewer VTE events were seen when perioperative prophylaxis was initiated in the hospital [40].

Dose stratification by BMI has also been examined by several studies, which have shown such strategies are safe and effective [41–43]. A prospective cohort study examining enoxaparin 40 mg every 12 hours for BMI  $\leq 50$  kg/m<sup>2</sup> and enoxaparin 60 mg every 12 hours for BMI  $>50$  kg/m<sup>2</sup> showed that BMI-stratified enoxaparin dosing regimen would be effective in preventing VTE without increasing bleeding risks [41].

The majority of VTE events (80%) in bariatric surgical patients occur after discharge [6]. Clark et al. showed that postdischarge pharmacoprophylaxis was highly variable and was used only 11% of the time following laparoscopic bariatric procedures [28]. Moaad et al. demonstrated that altered coagulation profiles were present 2 weeks postoperatively and recommended prophylaxis to be continued at least for 2 weeks following surgery [44]. The data again are not high-level evidence, as several prospective studies and review articles include studies with follow-up between 10 and 15 days after the procedure [30,45–49]. These studies showed that postdischarge administration of pharmacoprophylaxis was well tolerated without any significant postoperative bleeding [31,50].

#### *Extended postdischarge pharmacoprophylaxis*

PE is a major cause of postdischarge mortality after bariatric surgery [51,52]. Winegar et al. evaluated the 90-day VTE events after bariatric surgery using the BOLD database and found that greater than 70% of VTE events occurred after the patient was discharged; furthermore, the majority of the events occurred within a 30-day period [19]. In a Cleveland Clinic study based on the American College of Surgeons–National Surgical Quality Improvement Program database, 83% of postbariatric surgery VTE events occurred after hospital discharge. The mortality rate was 25 times higher in patients who developed a postdischarge VTE compared with patients who did not develop VTE [6].

It is important to identify risk factors for VTE following discharge so patients with a higher risk profile could theoretically benefit from more aggressive prophylaxis. In an observational study based on the 110,824 bariatric surgical patients (56% SG cases) in the French National Health Insurance database, 75% of patients received postdischarge pharmacoprophylaxis. No use of postdischarge pharmacoprophylaxis was an independent predictive factor of VTE during the first 90 days after surgery (odds ratio 1.27, 95% confidence interval 1.01–1.61) [53]. Nonetheless, the effectiveness of extended pharmacoprophylaxis to decrease the risk of VTE events in clinical practice has not been well studied in clinical trials and prospective studies [28,54,55].

#### *Indication*

In considering extended pharmacoprophylaxis, predicted risk of VTE, potential benefits and possible complications

(including the risk of bleeding) of available medications, and associated cost should be considered [6].

There are a few VTE risk assessment tools, including models created by Kucher et al., Rogers et al., Caprini, Panucci et al., Scarborough et al., Dang et al., and Fink et al [14,17,56–60]. However, the accuracy and clinical usefulness for bariatric surgery patients have not been examined for most of these models. A Cleveland Clinic study found 10 major independent risk factors for postdischarge VTE after bariatric surgery, all of which increased the risk of VTE by at least 1.5-fold and subsequently were used to generate a risk calculator that can assist in risk assessment and decision-making [6,61–63].

Once the higher-risk patients for postdischarge VTE are identified, the question remains as to how to adequately carry out VTE prophylaxis beyond their hospital stay [6]. No clear consensus exists on the choice, dosing, and duration of pharmacoprophylaxis following bariatric surgery in these patients [3,4,10].

#### *Agents*

A large literature review showed that LMWH was efficacious, associated with low rates of clinically relevant bleeding complications, and cost-effective in patients at high risk for VTE [64]. Results of a cohort study from Michigan Bariatric Surgery Collaborative indicated that LMWH was more effective ( $>50\%$ ) than UFH for the prevention of postoperative VTE among patients undergoing bariatric surgery. This difference was more pronounced in patients at high risk of postbariatric surgery VTE. In addition, the rate of postoperative hemorrhage was similar in patients who were taking either prophylactic doses of LMWH or UFH (1.6%) [13]. Although UFH is much less expensive than LMWH, there is a trend toward the use of LMWH over UFH for prophylaxis [10]. LMWHs bind specifically to antithrombin III and have a better bioavailability through easier subcutaneous absorption (which may be important in patients with severe obesity). The half-life of LMWHs is longer than that for UFH, which translates into less frequent injections [6]. In addition, heparin-induced thrombocytopenia and osteoporosis are less common in LMWH-treated patients [58,65,66].

#### *Duration*

Many centers worldwide administer a 4-week course of LMWH as extended thromboprophylaxis postdischarge after major cancer operations [67,68]. A single-center study on 308 consecutive patients undergoing bariatric surgery comparing in-hospital-only versus extended 10-day pharmacoprophylaxis using enoxaparin (30 mg administered subcutaneously every 12 hr) showed that the 30-day VTE rate was significantly higher in the group that only received in-hospital prophylaxis (4.5% versus 0%;  $P = .006$ ) [45]. Depending on the estimated VTE risk, extended

pharmacoprophylaxis for 2 to 4 weeks after discharge has been suggested by some studies [6].

### *Dosage*

Multiple studies have shown that using a higher dose of enoxaparin (60 mg versus 40 mg) administered subcutaneously every 12 hours in the perioperative period, especially for patients with higher BMI (e.g., BMI  $\geq 60$  kg/m<sup>2</sup>), was safe and did not lead to an increased risk of clinically significant bleeding [6,43,69]. Moreover, the safety of pharmacoprophylaxis using the extended (10- to 14-d course) high-dose LMWH has also been shown in multiple studies [41,48].

A study on 223 RYGB patients evaluated the safety and efficacy of an extended BMI-stratified enoxaparin thromboprophylaxis regimen. Patients were assigned to receive enoxaparin 40 mg (for BMI  $\leq 50$  kg/m<sup>2</sup>, n = 124) or 60 mg (for BMI  $> 50$  kg/m<sup>2</sup>, n = 99) every 12 hours during hospitalization and once daily for 10 days after discharge. Borkgren-Okonek et al. used serial serum AFXa levels during the hospital stay to adjust the dosage of enoxaparin for results outside the target VTE prophylactic range after the third dose and patients were subsequently discharged with the adjusted dose for a total of 10 days: 21% of patients in the 40-mg group and 31% in the 60-mg group did not reach the target VTE prophylactic range by the third enoxaparin dose and needed adjustments [41]. Similarly, Karas et al. assessed the adequacy of prophylactic dosing of enoxaparin in patients with severe obesity by measuring AFXa levels 3 to 5 hours after the second dose of enoxaparin. The study found that fixed dosing of enoxaparin after bariatric surgery could be suboptimal in 15% of patients with severe obesity [70]. Therefore, concerns have been expressed that fixed prophylactic doses of anticoagulants may be inadequate in patients with severe obesity [71]. Furthermore, in a similar study by Stier et al. around 60% of patients reached the AFXa prophylactic target range. The latter study concluded that measurement of the AFXa level would help to define the real prophylactic thromboprophylaxis status in bariatric surgery patients, especially in those with a weight above 150 kg [72].

Nevertheless, due to the paucity of high-quality literature to guide exact dosing and duration of extended VTE pharmacoprophylaxis, perhaps AFXa levels could be used to monitor and adjust dosing of the LMWH following discharge for those higher-risk patients that would benefit from an extended thromboprophylaxis [6]. Anti-Xa activities measured at the time of peak plasma concentration (4 hr after subcutaneous injection) yield the best correlation with clinical effect. Target AFXa levels for LMWHs are not well defined, but some studies have suggested peak concentrations of 0.2 to 0.4 IU/mL for VTE prophylaxis [41,48,70].

Future studies, ideally randomized controlled trials, are needed to decide which agent, at what dosage and duration,

should be considered for extended VTE pharmacoprophylaxis.

### *Monitoring of pharmacoprophylaxis*

Routine monitoring of pharmacoprophylaxis is not carried out in most patients on LMWH. More evidence has become available that adjustments in LMWH dosing are likely necessary based on weight. It has also been established that dosing adjustments be made in the setting of renal insufficiency especially when creatinine clearance is  $< 30$  mL/min due to LMWH's renal excretion.

LMWH acts on factor Xa, and UFH acts on factor II and Xa. UFH can be monitored using partial thromboplastin time, but LMWH is monitored by checking AFXa activity levels to assess the therapeutic effect. Peak AFXa levels are reached 3 to 5 hours after administration of LMWH. Therapeutic peak levels of AFXa are clearly defined at 0.6 to 1.0 IU/mL for twice-daily dosing and 1.0 to 2.0 IU/mL for once-daily dosing. Target peak levels for prophylactic dosing are not as clearly defined by high-level evidence. Ranges of 0.2 to 0.5 IU/mL and 0.2 to 0.4 IU/mL, respectively, have been generally accepted [73].

In 2018, 50 patients who underwent bariatric surgery were assessed for maximum AFXa levels. LMWH (nadroparin) at a standardized dose was continued for 4 weeks after surgery, and AFXa levels were measured. Mean AFXa concentration was significantly different for patients with a lean body weight of  $< 80$  kg versus patients with a lean body weight  $> 80$  kg. Additionally, mean AFXa levels were found to be subtherapeutic in two thirds of patients in the higher lean body weight group when standard (non-weight-based) dosing was used [74].

In 2018, a report on 122 patients who underwent bariatric surgery (SG and RYGB) and received extended dose LMWH pharmacoprophylaxis was published. LMWH (bemiparin) was started the day before surgery and given daily for 30 days. A standardized dosing strategy was used. Average patient age was 42 years, and BMI was 48 kg/m<sup>2</sup>. There was 1 postoperative mortality included in this series that occurred on day 10 after surgery in a patient who underwent RYGB without identifiable thrombotic cause. There were no thrombotic events in this study. There was a 3.2% rate of mild hemorrhagic events and 5.7% rate of severe hemorrhagic events (4 anastomotic dehiscence, 2 intraluminal bleeds, and 1 rectus sheath hematoma). On the second postoperative day, no patients had supratherapeutic AFXa levels, and only 1 of these patients had an AFXa level above 0.5 IU/mL on postoperative day 3. This study highlights the confounding variables in reporting on postoperative hemorrhage [50].

### **Inferior Vena Cava Filter**

The use of temporary IVC filters has been reported for bariatric patients who are at high risk for VTE [75–80].

The general agreement in the published literature is that higher BMIs (e.g.,  $>55 \text{ kg/m}^2$ ), immobility, venous stasis, pulmonary hypertension, obesity hypoventilation syndrome, hypercoagulable states, and a history of VTE place patients in a higher risk category for VTE. Some early evidence supported a decreased rate of PE and death resulting from VTE in this group of patients when prophylactic IVC filters are used [77,79]. Other reports, however, show a higher complication rate and risk of death that, in one series, was primarily attributable to device-related complications [75,81]. Additionally, data from the BOLD showed that IVC filters resulted in a higher incidence of VTE [19]. Birkmeyer et al. found a statistically higher rate of postoperative DVT, PE, serious complications, and death with prophylactic IVC filter placement [82]. Other more recent studies have also found similar results. A study examining the MBSAQIP data from 2015–2016 found a low ( $<1\%$ ) frequency of IVC filter use in bariatric surgery and no difference in perioperative PE incidence when compared to patients who did not undergo IVC filter placement [83]. Patients with IVC filter placement were also significantly more likely to experience readmission and reintervention within 30 days of surgery. Most of these readmissions and reinterventions were for filter retrieval. Similarly, a propensity score-matched comparison of National Inpatient Sample data from 2005 to 2015 found no reduction in in-hospital PE or mortality with the use of prophylactic IVC filters but did find an increased risk of acute lower extremity and caval VTE [84].

Although these devices can usually be placed safely with a low short-term complication rate, insertion-related complications have been described, and insertion and removal of IVC filters in patients with severe obesity can pose a technical challenge [78]. Studies show that only 20% to 30% of temporary IVC filters are removed. While the data examining the long-term safety in patients with severe obesity are scarce, a recent meta-analysis found that several long-term complications have been reported in the literature that include device fracture, migration, IVC penetration, and thrombus, which all can pose a significant problem when attempting retrieval [85].

Currently, the American College of Chest Physicians recommends that IVC filters should not be used for primary VTE prevention in patients undergoing abdominal and pelvic surgery [27]. Similarly, the most recent European guidelines concluded that these devices should only be considered in rare very high-risk cases of PE and in perioperative situations at very high risk of bleeding, resulting in a prolonged contraindication to pharmacological prophylaxis [86].

### Summary Statements and Recommendations

1. Postoperative VTE, although not a common complication, significantly increases morbidity and mortality of bariatric surgery.

2. Almost all bariatric surgery patients are considered to be at least at moderate risk for VTE events. Depending on the characteristics of every patient and operation, some bariatric surgery patients are high risk or extremely high risk for the development of postoperative VTE.
3. Factors that place patients into a high-risk category for VTE after bariatric surgery may include high BMI, advanced age, male sex, immobility, prior VTE, hypercoagulable conditions, heart failure, pulmonary circulation disorders, venous stasis disease, hormonal therapy, long operative time, open surgery, and occurrence of other postoperative complications such as bleeding and subsequent transfusion.
4. Hormonal therapy after menopause or for contraception (in the forms of estrogen-only or combined estrogen-progestin pills, injectables, implants, patch, and vaginal ring) and selective estrogen-receptor modulators may increase the risk of VTE. Discontinuation of these agents in the perioperative period should be considered and individualized.
5. Individual practices should develop and adhere to a protocol for VTE prevention that should be tailored for patients based on the perioperative risk of thrombosis versus bleeding. Available evidence suggests that adherence to any specific protocol for VTE prophylaxis that integrates early ambulation, mechanical thromboprophylaxis, and pharmacoprophylaxis will reduce but not eliminate VTE as a complication of bariatric surgery.
6. Perioperative VTE prophylaxis is recommended for every bariatric surgical patient.
7. Early ambulation and adequate hydration are recommended for all bariatric surgery patients.
8. Mechanical thromboprophylaxis is recommended for all bariatric surgery patients. There may be individual circumstances (e.g., severe lymphedema) when lower extremity compression devices are not practical and alternative strategies may be needed.
9. A combination of mechanical prophylaxis and pharmacoprophylaxis should be considered for the majority of bariatric surgical patients. In these situations, mechanical prophylaxis and pharmacoprophylaxis should be at least continued throughout the hospital stay.
10. In the current practice of bariatric surgery that postoperative hospital stay has reduced to 1 to 2 days for most patients,  $>80\%$  of postoperative VTE events occur after hospital discharge. Therefore, a selected group of high-risk patients would likely benefit from extended pharmacoprophylaxis after hospital discharge. Although there are scoring systems to identify high-risk patients who are at risk to develop postdischarge VTE, there are insufficient high-quality data to confirm administration of postdischarge

pharmacoprophylaxis meaningfully decreases the risk of VTE events in these patients.

11. Overall, no high-quality data and clear consensus exist on the choice, dosing, and duration of pharmacoprophylaxis after bariatric surgery.
12. There are conflicting data in the literature regarding the type of pharmacoprophylaxis to use, but the highest-quality data currently available suggest that LMWH offers more effective VTE prophylaxis than UFH in patients with severe obesity (with better bioavailability and lower risk of heparin-induced thrombocytopenia without increasing the bleeding risk).
13. For VTE prophylaxis in patients with severe renal insufficiency (creatinine clearance <30 mL/min), a reduction in dose of LMWH, dose adjustment based on AFXa level, or use of UFH are suggested.
14. Administration of LMWH with fixed dosing (e.g., enoxaparin 40 mg bid), BMI-tiered, or weight-tiered dosing (higher dose in patients with higher BMI or weight), and dose adjustment based on AFXa level have been suggested in the literature.
15. Due to the paucity of high-quality literature to guide the exact dosing of LMWH, AFXa levels may be used to monitor and adjust dosing of the LMWH after discharge for certain higher-risk patients (e.g., patients with extremely high BMI, patients with a known hypercoagulable state, or patient with renal insufficiency). Target prophylactic AFXa levels for LMWHs are not well supported by high-level data, but peak concentrations of 0.2 to 0.4 IU/mL for VTE prophylaxis measured 4 hours after administration of the third dose of LMWH has been suggested.
16. Because complications associated with the IVC filters often seem to outweigh a potential benefit, routine use of IVC filters for VTE prophylaxis before bariatric surgery is not recommended. On rare occasions, IVC filter placement may be considered in combination with other prophylactic measures for selected very high-risk patients in whom the risks of VTE are determined to be greater than the risks of filter-related complications.

### VTE Practice Guidelines and Standard of Care

The current practice guidelines are not intended to provide inflexible rules or requirements of practice and are not intended, nor should they be used to state or establish a local, regional, or national legal standard of care. Ultimately, there are various appropriate treatment modalities for each patient, and surgeons must use their judgment in selecting from among the different feasible treatment options.

The ASMBS cautions against the use of these practice guidelines in litigation in which the clinical decisions of a physician are called into question. The ultimate judgment regarding the appropriateness of any specific procedure or course of action must be made by the physician in light of all the circumstances presented. Thus, an approach that differs from these practice guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious physician may responsibly adopt a course of action different from that set forth in the current practice guidelines when, in the reasonable judgment of the physician, such course of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology. All that should be expected is that the physician will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient, to deliver effective and safe medical care. The sole purpose of the current practice guidelines is to assist practitioners in achieving this objective.

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