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ASMBS updated position statement on prophylactic measures to reduce the risk of venous thromboembolism in bariatric surgery patients

The American Society for Metabolic and Bariatric Surgery Clinical Issues Committee*

Cleveland Clinic, Bariatric and Metabolic Institute, 9500 Euclid Avenue, M61, Cleveland, OH 44194, United States

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The following updated position statement is issued by the American Society for Metabolic and Bariatric Surgery (ASMBS) for the purpose of enhancing quality of care in bariatric surgery. In this statement, suggestions for management are presented that are derived from available knowledge, peer-reviewed scientific literature, and expert opinion regarding reasonable use of anticoagulation therapy for bariatric surgery procedures at this time. 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 may be revised in the future should additional evidence become available.

The issue

Patients undergoing bariatric surgery are at increased risk for venous thromboembolism (VTE) [1–4]. The ASMBS initially issued a position statement on VTE prophylaxis in 2007 that recommended early postoperative ambulation, the use of lower extremity sequential compression devices, and unless contraindicated, the use of chemoprophylaxis [5]. Type, dose, and duration of chemoprophylaxis and the indication for inferior vena cava (IVC) filters for bariatric patients were not clearly defined at that time. Since that time, several studies and systematic reviews have emerged that help clarify some of these issues. The lack of randomized, controlled data persists, however, which limits the ASMBS's ability to provide recommendations based on high-level data. This updated position statement is intended to provide a current review of the literature with respect to VTE prophylaxis in the bariatric surgery patient and provide recommendations based on this evidence.

The data

Scope of the problem

In the modern era of bariatric surgery with a majority of programs having VTE prophylaxis protocols in place, the incidence of symptomatic deep venous thrombosis (DVT) and pulmonary embolism (PE) ranges from 0%–5.4% [6,7] and 0%–6.4% [8,9], respectively. Most large series, though, report VTE rates $<1\%$ for the average risk bariatric patients [10–12], and this is comparable to rates for many other elective operations performed today [13]. A recent systematic review of 19 studies evaluating VTE after laparoscopic bariatric surgery reported an incidence of pulmonary embolism of .5%, and the Michigan Bariatric Surgery Collaborative published 2 large series from their quality collaborative registry that showed overall VTE rates less than .5% in average risk bariatric patients [10–12]. Accurate evidence-based risk assessment tools for VTE in bariatric patients are not currently available, but the literature highlights several risk factors that must be taken into consideration when determining a prophylaxis strategy. These risk factors may include prior VTE, higher body mass index (BMI), age, gender, immobility, use of hormone therapy, obesity hypoventilation syndrome, pulmonary hypertension, venous stasis disease, operative time, and procedure type and approach [10,12,14–16].

Data published in 2009 from the multicenter prospective Longitudinal Assessment of Bariatric Surgery (LABS) study reported a 30-day incidence of VTE complications of .4% and the risk increased with increasing weight [17]. More recently, LABS data were used to determine whether prophylactic anticoagulation added to compression devices

*Corresponding author: Dr. Stacy Alan Brethauer, Cleveland Clinic, Bariatric and Metabolic Institute, 9500 Euclid Avenue, M61, Cleveland, OH 44194, United States. Tel.: +1 216 444 4794; fax: +1 216 445 1586.
E-mail: brethas@ccf.org

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prevents VTE. The overall 30-day VTE rate among 4416 patients was low (.25% among patients receiving sequential compression alone [n = 396] and .47% when anticoagulation was added [n = 4020]). This study concluded that there was insufficient evidence to make a specific recommendation regarding VTE prophylaxis after bariatric surgery and that a sufficiently powered trial to answer this question is impractical [18]. Prospectively obtained data from nearly 74,000 bariatric surgery patients in the Bariatric Outcomes Longitudinal Database revealed a VTE incidence of .42% in the first 90 days after surgery. Ninety-three percent of patients registered in this database received VTE prophylaxis, and chemoprophylaxis was used in >70% of patients. The majority of VTE events (73%) occurred after discharge from the hospital, and most occurred within the first 30 days [14]. This is consistent with other studies that have reported the risk of VTE complications several weeks after surgery after the patient is discharged from the hospital [14,19–22].

Although the overall incidence is low, VTE events remain a leading cause of mortality after bariatric surgery [15,23,24]. A review of 10 autopsies performed after bariatric surgery revealed PE was the direct cause of death in 30% of patients; however, 80% were found to have PEs [25].

Prophylaxis options

The ideal method of prophylaxis for VTE complications in bariatric surgery has yet to be elucidated. Patients undergoing bariatric surgery are considered at moderate to high risk for having thrombotic complications. Published literature varies widely on optimal guidelines for the prevention of perioperative VTE events. The major accepted forms of prophylaxis range from mechanical compression devices with early ambulation alone, to the addition of chemoprophylaxis and the use of IVC filters.

Mechanical prophylaxis

Most series evaluating prophylactic strategies for bariatric patients include some form of mechanical prophylaxis. Because of concerns of bleeding complications associated with chemoprophylaxis (2% incidence of bleeding complications in a recent systematic review when a standardized definition of hemorrhage was used) [10], several studies have examined the use of mechanical compression only in bariatric surgery patients. A retrospective study of 1692 patients evaluated VTE rates comparing low-molecular-weight heparin (LMWH) 40 mg twice daily and sequential compression devices (SCD) (N = 435) with patients who received SCDs and early ambulation (within 2 hours of arrival to ward) only (N = 1257). This study represented a change in the authors' practice protocol over time and was not a randomized trial. These authors reported DVT and PE rates of 1.6% and 1.1%, respectively, in patients who received LMWH and SCD compared with a .4% DVT rate and no PEs in the patients who receive mechanical prophylaxis and early ambulation. Bleeding complications were higher in the LMWH group (4.8%) compared with the mechanical prophylaxis group (.4%) [26]. The ability to generalize these results is limited, because it is a single practice's experience with fewer complications over time and a higher mean BMI and longer operative times in the group that received chemoprophylaxis.

Another study reported a retrospective analysis of 957 consecutive patients undergoing laparoscopic Roux-en-Y gastric bypass surgery who received no pharmacologic treatment for VTE prevention [27]. Calf-length SCDs were placed before surgery, and early, frequent ambulation was encouraged. The authors reported 30-day DVT and PE rates of .31% and .10%, respectively, and a bleeding complication rate of .73%.

Both of the preceding studies excluded patients who were at high risk for VTE. 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.

Chemoprophylaxis

The benefit of routine anticoagulation prophylaxis has been described in other surgical populations at increased risk but without high-level evidence or 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 again there is no class I evidence to guide specific recommendations regarding dosing or duration.

Both unfractionated heparin (UFH) and LMWH have been used extensively in bariatric surgery [19,23,28–32]. Currently, there are no direct comparative studies evaluating the relative risks and benefits of chemoprophylaxis for bariatric surgery, and the published data evaluating chemoprophylaxis are heterogeneous and generally not high-level evidence.

A systematic review that included 30 publications of open and laparoscopic bariatric procedures reported various combinations of UFH and LMWH with or without mechanical prophylaxis and IVC filters. That review concluded that it is reasonable to use UFH 5000 IU subcutaneously every 8 hours or LMWH 30–40 mg every 12 hours starting before surgery and in combination with sequential compression devices [33].

A review of VTE prophylaxis for laparoscopic bariatric procedures included only 19 studies and found a relatively low (.5% weighted mean incidence) rate of VTE using "standard regimens" that included either UFH 5000 IU 2 or 3 times daily, enoxaparin 30 mg twice daily, 40 mg once daily,

or weight-adjusted LMWH. Given the overall low incidence of VTE and the relatively low quality of the data analyzed, no difference in VTE rates was reported among different regimens, but the authors did conclude that weight-adjusted dosing of heparin increased the incidence of major bleeding without an advantage in terms of VTE reduction [10].

The only randomized trial currently available compared 2 different doses of LMWH (nadroparin) and had no control group. The study was small (n = 30 in each group) and reported no VTE events in either group postoperatively but did report 2 major bleeding events in the higher-dose group [34].

The Michigan Bariatric Surgery Collaborative (MBSC), a state-wide quality improvement consortium that includes all 32 bariatric programs in the state of Michigan, recently published data comparing the efficacy and bleeding risk associated with the 3 dominant VTE prophylaxis strategies used by its members [11]. The analysis included 24,775 patients who underwent bariatric surgery between 2007 and 2012. The 3 dominant prophylaxis strategies used were UFH preoperatively and postoperatively (UFH/UFH), UFH preoperatively and LMWH postoperatively (UFH/LMWH), and LMWH pre and postoperatively (LMWH/LMWH). These 3 groups accounted for 79% of the total patients in the registry for that time period. Rates of VTE, hemorrhage, and serious hemorrhage (>4 units of blood products or reoperation) occurring within 30 days of surgery were evaluated.

Overall, adjusted rates of VTE were significantly lower for LMWH/LMWH (0.25%; $P < .001$) and UFH/LMWH (.29%; $P = .03$) compared with the UFH/UFH group (.68%). For high-risk VTE groups (predicted risk >1%), the VTE rate for LMWH/LMWH (1.46%) was less than the UFH/LMWH rate (2.36%), but this was not statistically different than that of the UFH/UFH high-risk group (2.12%). There were no significant differences in rates of hemorrhage or serious hemorrhage among the treatment strategies. The authors conclude that LMWH is more effective than UFH for prevention of VTE among patients undergoing bariatric surgery and does not increase the risk of bleeding. Although this study does not provide class I evidence and does not include dosing and duration data, it is the largest study evaluating different VTE prophylaxis regimens in the bariatric surgery populations and provides some guidance. It should be noted that 98% of the patients included in this study also received mechanical prophylaxis with sequential compression devices, and 3.2% of the patients had a prophylactic IVC filter placed [11].

IVC filters

The use of temporary IVC has been reported for bariatric patients who are at high risk for VTE [35–40]. Although there is no consensus on what constitutes a high-risk patient, there is general agreement in the published literature that patients with higher BMIs (>55 kg/m^2), immobility, venous stasis, pulmonary hypertension, obesity hypoventilation syndrome, hypercoagulable state, and a history of VTE place patients in a higher risk category for VTE. Some evidence supports a decreased rate of PE and death resulting from VTE in this group of patients when prophylactic IVC filters are used [37,39]. Other reports, however, show a higher complication rate and risk of death [41] that, in one series, was primarily attributable to device-related complications [35]. Additionally, data from the Bariatric Outcomes Longitudinal Database showed that IVC filters resulted in a higher incidence of VTE [14]. However, none of these studies specifically evaluated patients who had obesity hypoventilation syndrome with associated elevated pulmonary artery pressure or those with congenital hypercoagulability, both of whom may have benefited from an IVC filter.

Although IVC filters can usually be inserted safely with a low short-term complication rate [38], insertion-related complications have been described and insertion and removal of IVC filters in super-obese patients can pose a technical challenge for the interventionalist. Finally, there are no data on the long-term safety of IVC filters and no strong data comparing permanent versus retrievable filters.

Other published guidelines

The ninth edition of the guidelines of Antithrombotic Therapy and Prevention of Thrombosis was published by the American College of Chest Physicians in early 2012 [42]. This report states that virtually all bariatric surgery patients are at least at a moderate risk of VTE, with many patients at high risk for VTE complications. Because of the paucity of randomized, controlled trials in the bariatric literature, the recommendations established for the bariatric patient were based on relative risks from randomized, controlled trials in patients who underwent abdominal and pelvic surgery. For the patient at moderate risk of VTE who are not at high risk of having a major bleeding complication, they recommend prophylaxis with LMWH (grade 2B), UFH (grade 2B), or mechanical prophylaxis ideally with SCDs (grade 2C), compared with no prophylaxis. For the high-risk VTE patient who is not at high risk of having a major bleeding complication, they recommend prophylaxis with LMWH or UFH (grade 1B) and mechanical prophylaxis with either SCDs or elastic compression stockings (grade 2C) versus no prophylaxis. Extended prophylaxis (4 weeks of LMWH) recommendations are made only for patients at high risk for VTE who are undergoing abdominal surgery for cancer, but no recommendation for extended prophylaxis for bariatric surgery patients is made in the American College of Chest Physicians guidelines. The American College of Chest Physicians guidelines suggest that, for patients undergoing abdominopelvic surgery, IVC filters not be used for primary VTE prevention (grade 2C).

The updated 2013 American Association of Clinical Endocrinologists, the Obesity Society, and 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 (AACE/TOS/ASMBS guidelines) recommend prophylaxis against DVT for all bariatric surgery patients (grade B; Best Evidence Level [BEL] 2) [43]. Prophylactic regimens after bariatric surgery include sequential compression devices (grade C; BEL 3), as well as subcutaneously administered unfractionated heparin or LMWH after bariatric surgery (grade B; BEL 2). Extended chemoprophylaxis after hospital discharge should be considered for high-risk patients, such as those with history of DVT (grade C; BEL 3). Early ambulation is encouraged (grade C; BEL 3).

Summary recommendations

There is no class I evidence to provide guidance regarding the type, dose, or duration of VTE prophylaxis in the bariatric surgery patient. Based on current evidence available, the following recommendations are made:

1. All bariatric surgery patients are at moderate to high risk for VTE events, and VTE prophylaxis should be used.
2. Factors that place patients into a high-risk category for VTE after bariatric surgery may include high BMI, advanced age, immobility, prior VTE, known hypercoagulable condition, obesity hypoventilation syndrome, pulmonary hypertension, venous stasis disease, hormonal therapy, expected long operative time or open approach, and male gender.
3. Individual practices should develop and adhere to a protocol for VTE prevention. Available evidence suggests that adherence to any specific practice for VTE prevention will reduce but not eliminate VTE as a complication of bariatric surgery.
4. Mechanical prophylaxis is recommended for all bariatric surgery patients. There may be individual circumstances (severe lymphedema) when lower extremity compression devices are not practical and alternative strategies may be needed.
5. Early ambulation is recommended for all bariatric surgery patients.
6. The combination of mechanical prophylaxis and chemoprophylaxis should be considered based on clinical judgment and risk of bleeding. Although there is some low-level evidence that mechanical prophylaxis alone in low-risk patient results in low VTE rates ($<.4\%$), the preponderance of bariatric data supports using a combination of chemoprophylaxis and mechanical prophylaxis with overall VTE rates $<.5\%$.
7. There are conflicting data in the literature regarding the type of chemoprophylaxis to use, but the highest-quality data currently available suggest that LMWH offers better VTE prophylaxis than UFH without increasing the bleeding risk.
8. Most postdischarge VTE events occur within the first 30 days after surgery. Extended VTE prophylaxis should be considered, but there are insufficient data to recommend a specific dose or duration of extended postdischarge VTE prophylaxis for patients deemed to be at high risk for VTE.
9. The use of IVC filters as the only method of prophylaxis before bariatric surgery is not recommended. Filter placement may be considered in combination with chemical and mechanical prophylaxis for selected high-risk patient in whom the risks of VTE are determined to be greater than the risks of filter-related complications.

VTE position statement and standard of care

This position statement is not intended to provide inflexible rules or requirements of practice and is not intended, nor should it 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 this position statement in litigation in which the clinical decisions of a physician are called into question. The ultimate judgment regarding 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 the position statement, 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 position statement 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 this position statement is to assist practitioners in achieving this objective.

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