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The use of intravascular ultrasound imaging to improve use of inferior vena cava filters in a high-risk bariatric population

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Objective: **Pulmonary embolism is the leading cause of death after gastric bypass procedures for obesity, approximating 0.5% to 4%. All bariatric patients, but especially the super-obese, which have a body mass index (BMI) >50 kg/m^2, are at significant risk for postoperative venous thromboembolism (VTE). Visualization and weight limitations of fluoroscopy tables exclude most bariatric and all super-obese patients from inferior vena cava (IVC) filter placement using fluoroscopy. Intravascular ultrasound (IVUS)-guided IVC filter placement is the only modality that allows these high-risk patients to have an IVC filter placed.**

Methods: **Hospital and outpatient records of the 494 patients who underwent gastric bypass procedures from January 1, 2004, to May 31, 2006, were reviewed. All patients who had concurrent IVC filter placement with the use of IVUS guidance were selected. Comorbidities, outcomes, and complications were recorded.**

Results: **We identified 27 patients with mean BMI of 70 ± 3 kg/m^2; of these, 25 were super-obese (BMI >50 kg/m^2). Procedures included five laparoscopic and 22 open gastric bypass operations. All patients underwent concurrent IVC filter placement using IVUS guidance. In addition to super-obesity, indications for IVC filter placement included history of VTE (n = 4), known hypercoagulable state (n = 2), and profound immobility (n = 21). Mean follow up was 293 ± 40 days. Technical success rate was 96.3%. There were no catheter site complications. In one surviving patient, a nonfatal pulmonary embolism was detected by computed tomography 2 months postoperatively. Two patients died, and autopsy excluded VTE as the cause of death in both.**

Conclusion: **This study suggests efficacy of IVUS-guided IVC filter placement in preventing mortality from pulmonary embolism in high-risk bariatric patients, including the super-obese. IVUS-guided IVC filter placement can be safely performed with an excellent success rate in all bariatric patients, including the super-obese, who otherwise would not be candidates for IVC filter placement due to the limitations imposed by their large body habitus. (J Vasc Surg 2007;46: 1248-52.)**

Postoperative pulmonary embolism (PE) is the leading cause of death after gastric bypass procedures for obesity, with an incidence of 0.5% to 4%.[1-7] Super-obese patients, defined as having a body mass index (BMI) > 50 kg/m^2, are at increased risk for venous thromboembolism (VTE) due to multiple physical and physiologic factors, with PE rates as high as 28%.[1,25,6,8-12] The mortality from PE in super-obese patients is reported to be 27% to 75%.[4,6] Current techniques for deep venous thrombosis (DVT) prophylaxis include sequential compression devices, early ambulation, and medical prophylaxis with heparin or low-molecular-weight heparin (LMWH).[4,5,13-15] The success of these protocols in PE prevention continues to be mixed.[4] Inferior vena cava (IVC) filters have previously been shown to decrease the incidence of and mortality from PE in bariatric surgery patients.[1,4,6,9,13-21]

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IVC filters are recommended for those patients with super-obesity, decreased mobility, venous insufficiency, previous thromboembolic event, or hypercoagulability. As BMI increases, visualization of the vena cava becomes more difficult fluoroscopically and eventually becomes suboptimal. Some super-obese patients may be excluded from IVC filter placement with fluoroscopy due to table weight limits and inadequate fluoroscopic penetration. Transabdominal ultrasound imaging has been used for IVC filter placement but is limited in all obese patients by increased abdominal girth and overlying bowel gas.[22-24] Intravascular ultrasound (IVUS) imaging offers a technique for IVC filter placement for bariatric patients, including those who are super-obese, which is unaffected by body habitus.[3,9,17,22-29] This study examined a contemporary series of IVUS-guided IVC filter placement in a high-risk population of bariatric patients. This study was approved and performed in accordance with the regulations of the Institutional Review Board of East Carolina University.

METHODS

A retrospective review of all bariatric patients who underwent IVUS-guided IVC filter placement at the time of their gastric bypass procedure was performed. Recorded data included history of DVT, PE, hypercoagulable disorder, arthritis, pain in weight bearing joints, chronic obstructive pulmonary disease, asthma, obstructive sleep apnea, lower extremity edema, venous insufficiency, age, BMI, complications, postoperative PE or DVT, and time of follow-up. Venous insufficiency was defined by ankle edema without associated foot edema for a CEAP clinical score of at least 3.[30] Sleep apnea was defined by a sleep study with a positive result. Results were reported as mean and standard error. History and physical exams were performed in the bariatric clinic and in the vascular surgery clinic within the same university practice.

Super-obese patients and patients with a history of venous insufficiency, hypercoagulable disorder, profound immobility, and a history of VTE were considered for IVC filter placement. There was no specific BMI threshold at which all bariatric patients had IVC filter placement; however, those with BMI >50 kg/m^2 were considered for filter placement on the basis of BMI alone.

Adjunctive DVT prophylaxis in this study included sequential compression devices or foot pumps placed before operation and 5000 U of heparin given subcutaneously in preoperative holding. Patients ambulated the day of surgery if they were not in the intensive care unit. They received 5000 U of heparin three times daily and continued to have sequential compression devices in place while in bed. Patients with BMI >60 kg/m^2 were treated with Enoxaparin (Sanofi-Aventis, Paris, France) for 2 weeks postoperatively. They were given 40 mg of Enoxaparin twice a day rather than the standard daily dose of 40 mg.

Follow-up abdominal radiographs were performed the day of the operation to confirm filter placement. Patients were followed up in the bariatric surgery clinic at 2 weeks; 2, 4, 6, and 9 months, 1 year, and then annually. Insertion site exams and complaints related to filter thrombosis or VTE were recorded. Any filter-related problems or complaints were referred to the vascular surgeons within the same university practice.

Technique of filter insertion. Each patient was supine under general anesthesia. Both groins were prepared. The femoral vein, most frequently the right, was cannulated with an 18-gauge needle. The Seldinger technique was used to place an 8F sheath. A second percutaneous access was obtained immediately cephalad to the first, and a 12F sheath was placed.

Imaging was performed with a Galaxy 1 (Boston Scientific Corp, Natick, Mass). The 8F, 12.5-Mhz IVUS probe was passed through the femoral vein cephalad to the IVC and to the right atrium. The catheter was pulled back, visualizing in sequence the hepatic veins, the right renal artery, renal veins, and finally the iliac confluence before being returned to the level of the renal veins. The IVC was measured at the level of the renal veins to ensure its size was between 20 and 28 mm in greatest diameter. With concurrent IVUS imaging, a stainless steel over-the-wire Greenfield Vena Cava Filter (Boston Scientific Corp) was inserted through the 12F sheath and placed so that the filter's tip rested at or below the middle portion of the renal veins (Fig 1).

The filter was deployed and IVUS was used to view the struts of the filter to ensure appropriate strut spacing and apposition to the vena cava (Fig 2). The sheaths were removed and pressure held for 5 minutes. The location of the filter was verified with a postoperative abdominal radiograph.[23]

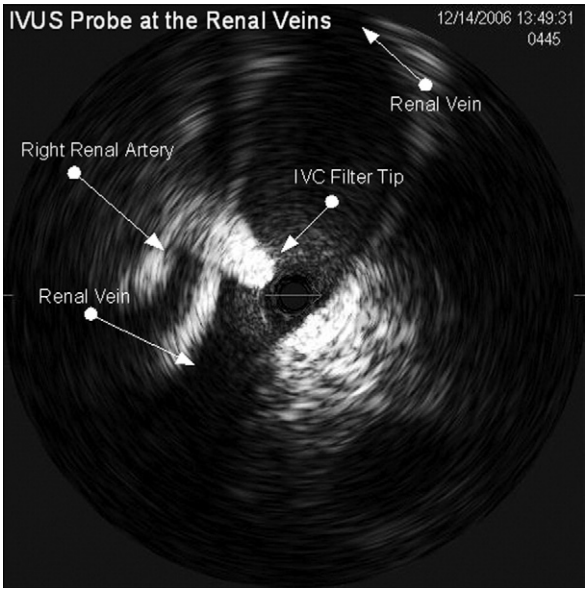

Fig 1. Intravascular ultrasound probe at the renal veins.

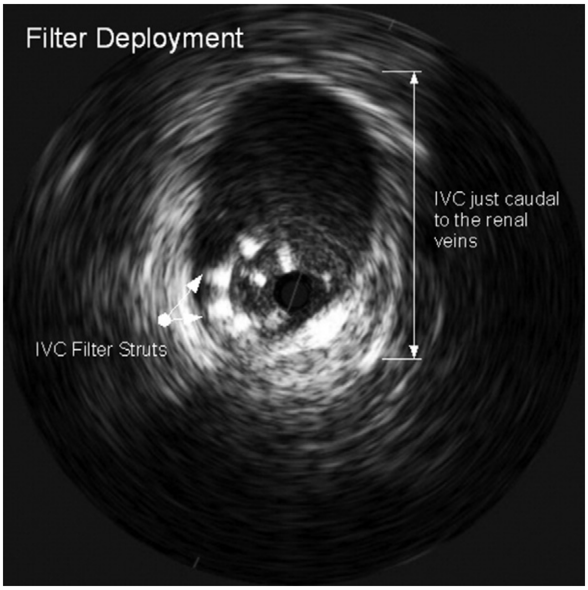

Fig 2. Intravascular ultrasound imaging shows that the struts of the inferior vena cava filter (*IVC*) are appropriately spaced and in apposition to the vena cava.

RESULTS

From January 2004 to April 2006, 27 patients underwent IVUS-directed IVC filter placement at the time of their gastric bypass procedure. Their mean age was 42 ± 1.8 years (range, 20 to 59 years), their mean BMI was 70 ±

Table I. Demographic data of the study population

Demographics	
Age, y, mean ± SE (range)	43 ± 1.8 (20-59)
Gender	
Male	11
Female	16
BMI, kg/m^2, mean ± SE (range)	70 ± 3 (38-107)
Surgical technique	
Open	22
Laparoscopic	5

SE, Standard error; *BMI,* body mass index.

Table II. Comorbidities

Comorbidity	*No.*	*Percentage*
History of PE	3	11
History of VTE	4	15
Factory V Leiden	2	7
COPD	1	4
Asthma	4	15
Obstructive sleep apnea	16	52
Venous insufficiency	4	15
Bilateral	4	15
CEAP C3	3	11
CEAP C5	1	4
Lower extremity edema	9	35
Pain in weight-bearing joints	12	44
Arthritis	5	19
BMI >50 kg/m^2	25	93

PE, Pulmonary embolism; *VTE,* venous thromboembolism; *COPD,* chronic obstructive pulmonary disease; *BMI,* body mass index.

3.0 kg/m^2 (range, 38 to 107 kg/m^2; Table I), and 25 patients were super-obese (BMI >50 kg/m^2). Of the two patients who were not super-obese, one had a history of DVT and the second had obstructive sleep apnea and venous insufficiency. All procedures were Roux-en-Y gastric bypass performed by open (n = 22) or laparoscopic technique (n = 5). The most common comorbidities and risk factors were obstructive sleep apnea (n = 16), pain in weight bearing joints (n = 12), and lower extremity edema (n = 9; Table II). A postoperative abdominal radiograph was used to verify filter position in all patients. Filter placement could not be verified owing to inadequate x-ray penetration in 5 patients (19%).

Patients were followed up regularly in the bariatric clinic for the first year and then annually indefinitely. Mean follow up was 293 ± 40 days (median, 213 days). One patient was lost to follow up after 79 days, 22 patients remained in follow-up at 3 months, and nine patients remained in follow-up after 1 year. Two patients (7%) died postoperatively, 1 on day 8 and 1 on day 15. Autopsy confirmed that neither death was related to VTE or filter-related complications. One patient died from bowel necrosis and another died from a tracheoinnominate fistula at her tracheostomy site. One of these two patients had filter placement in the right iliac vein and did not have an opportunity for filter repositioning. An upper extremity DVT developed in 1 surviving patient, and a PE developed in another patient (4%), which was discovered 41 days postoperatively by spiral computed tomography (CT). Lower extremity duplex ultrasound imaging did not demonstrate DVT in this patient (Table III.) No insertion site hematoma or infection occurred. There were no arterial injuries requiring any secondary intervention. No nerve injuries were noted during follow-up. Symptoms of venous insufficiency were not significantly improved during follow-up.

Table III. Complications

Complication	*No.*	*Percentage*
Insertion site	0	0
Pulmonary embolism	1	4
Deep venous thrombosis	0	0
Filter malposition	1	4

DISCUSSION

Several metabolic and mechanical factors contribute to the hypercoagulable state of the obese patient. High levels of leptin are frequently seen in these patients. This is associated with increased C-reactive protein formation, which has procoagulant and antithrombolytic properties. Tumor necrosis factor-α, serum amyloid A (SAA), plasminogen activator inhibitor-1 (PAI-1), adipsin (complement D), adipocyte complement-related protein (Acrp30), and interleukin 6 are all elevated in obese patients contribute to inflammation and hypercoagulability.[31,32] Obesity has been shown to increase intra-abdominal pressure. This increased pressure is transmitted to the femoral venous system, contributing to obesity-associated venous insufficiency. These mechanical and physical factors lead to increased incidence of VTE.[4,32-34]

Super-obesity (BMI >50 kg/m^2) has been found to be an independent risk factor for perioperative mortality in bariatric patients.[4,9] Carmody et al[4] demonstrated from a 24-year review of more than 3800 bariatric patients that BMI >50 kg/m^2, venous stasis disease, and obesity hypoperfusion syndrome were all independent risk factors for PE. Widespread use of DVT prophylaxis and the increased frequency of laparoscopic gastric bypass have not decreased the rate of PE. The inadequacy of non-weight-based regimens of heparin and Enoxaparin may contribute to this limited success.[4] For this reason, study patients were given 40 mg of Enoxaparin twice a day rather than the standard 40 mg daily dose. In the super-obese bariatric population, there is less consensus about PE prophylaxis compared with recommendations for the general population. Many recommendations are based on adaptations of recommendations for the general populations rather than on trials of super-obese bariatric patients.[5,13-15,35]

In one study by Gargiulo et al,[6] patients with a BMI >55 kg/m^2 undergoing open gastric bypass demonstrated a tenfold increase in relative risk of PE. PEs were fatal in 75% of those with a BMI >55 kg/m^2. By changing their practice and placing an IVC filter in all patients with a BMI

>55 kg/m^2, they decreased the overall PE rate from 2.1% to 0% and their PE related mortality from 1.6% to 0%. In patients with a BMI >55 kg/m^2 who refused an IVC filter, the incidence of PE was 22.5%, and 56% of those patients died of heir PEs.[6]

The mean BMI of >70 kg/m^2 in our study is 40% higher than the previously stated threshold of 50 kg/m^2 for increased risk of PE. It can be assumed that these patients would be at significantly greater risk for PE than those populations with a mean BMI of <50 kg/m^2. The PE rate of 4% in our study was on the high end of published PE rates, which range from 0.5% to 4% across bariatric populations with no stratification by BMI.[5,6,8-12] This is likely due to bias in our study because we selected patients for IVC filter placement because they were at high risk. The one PE that that did occur in our study was nonfatal and noted to be small on spiral CT. This patient had a BMI of 69 kg/m^2 in addition to factor V Leiden mutation. This patient was not restarted on Warfarin therapy before discharge. At our facility, patients with a history of VTE or hypercoagulable disorder are now started on Warfarin therapy in addition to Enoxaparin before discharge, with a therapeutic international normalized ratio target range of 2 to 3.

Several techniques are available for IVC filter placement in the bariatric population. Traditionally, IVC filters have been placed under fluoroscopic guidance. Fluoroscopy table weight limits (225 kg at our facility) preclude the use of the fixed equipment in some super-obese bariatric patients. When a bariatric patient does not exceed the fluoroscopy suite's weight limit, a separate procedure outside the operating room adds to the in-hospital time and resource usage. The radiation dose required for adequate penetration is also significant for patient and staff. Within the operating room, portable C-arms may provide suboptimal visualization for IVC filter placement in the some super-obese patients. IVC filter placement guided by transabdominal ultrasound imaging is very difficult in bariatric patients, particularly the super-obese. In contrast, visualization using the IVUS-guided technique is unaffected by body habitus.[3,23-26,28,29]

With IVUS guidance, IVC filters can be placed through the femoral or jugular veins. In our study, the femoral vein was used in all cases. Access to the femoral vein requires retraction of the pannus, and we find the groin regions of most bariatric patients are relatively flat and accessible once the pannus is lifted. Surface ultrasound guidance can be used for femoral vein cannulation if it cannot be obtained with a routine puncture but was not used to aid venous cannulation in any of the patients in this study. Access to the jugular vein is also difficult because patients frequently have short thick necks. Maintenance of sterile technique and organization of the operating room is easier when the equipment is at the foot of the operating table away from anesthesiology equipment at the crowded head of the table.

Complications of IVC filters include strut fracture, migration, caval wall erosion, insertion site thrombosis, risk of DVT, and postphlebitic syndrome. Postphlebitic syndrome is a serious but rare complication of IVC filter placement. Given the exceptionally high mortality of PE in the super-obese and the limited effectiveness of pharmacologic PE prophylaxis in these patients, we consider that the benefits of PE prophylaxis from the IVC filter outweigh the risks in this population.[18,20,21] In our series there were no insertion sight hematomas or infections or clinically apparent filter-related complications. Routine ultrasound surveillance for lower extremity DVT was not performed; however, no patients returned with symptoms of postphlebitic syndrome during the mean follow-up of 293 days.

Another option for PE prophylaxis is placement of removable IVC filters. These filters offer the opportunity for removal under fluoroscopy generally ≤6 months of placement.[17,19,36] Many studies in non-bariatric patients have noted that most of these filters are never removed. In some cases this is due to a lack of follow-up. Other factors leading to failure of removal are inability to collapse the filter, incorporation of the filter into the vessel wall, wall erosion, or clot trapped in within the filter.[17,36] It is our view that many of the patients in the bariatric population would not have lost adequate weight to be eligible for fluoroscopic removal and would still be susceptible to the VTE risk factors associated with morbid obesity. Contrary to this view, there are series reporting successful use of removable IVC filters.[37]

As a retrospective review, the study has several inherent weaknesses. In a prospective study, follow-up ultrasound imaging of the bilateral lower extremities would have been performed to rule out insertion site thrombosis or occult DVT.

Patients received close follow-up by the bariatric surgeons within the same university-based surgical practice. Follow-up by vascular surgeons might have demonstrated more subtle complications. After the postoperative abdominal radiograph, routine radiographic monitoring for filter migration was not performed.

This review would have been stronger had the records of the entirety of the bariatric population been available for review. This would have allowed for evaluation of relative risk reduction from filter placement as well as risk stratification of PE risks at different BMIs. Future study examining the entirety of the bariatric population correlating the improvement in risk factors related to weight loss with VTE incidence in patients receiving and not receiving IVC filters would be illustrative.

CONCLUSION

Bariatric patients are at increased risk for postoperative VTE. Those with a history of hypercoagulability, venous insufficiency, obesity hypoventilation syndrome, profound immobility, or super-obesity are at even greater risk. As BMI increases, IVC filter placement using traditional fluoroscopic techniques ceases to be feasible due to patient size. IVUS-guided IVC filter placement offers the ability to place an IVC filter at the time of bariatric surgery. Our study demonstrates the safety and applicability of this procedure. Complications, although potentially significant, are far less catastrophic than the complications of VTE and PE. IVUS is a safe and effective technology for IVC filter placement in the bariatric population, especially in super-obese patients, who would not be candidates for IVC filter placement by any other modality.

AUTHOR CONTRIBUTIONS

Conception and design: CK, MS
Analysis and interpretation: CK, MS, MM, FP, SP, WB
Data collection: CK, MM
Writing the article: CK
Critical revision of the article: CK, MS, MM, FP, SP, WB
Final approval of the article: CK, MS
Statistical analysis: CK, MS
Obtained funding: Not applicable
Overall responsibility: CK
CK and MS contributed equally to this work.

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