

Risk-Group Targeted Inferior Vena Cava Filter Placement in Gastric Bypass Patients

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Abstract

Background Despite a growing body of evidence guiding appropriate perioperative thromboprophylaxis in the general population, few data direct strategies to reduce deep venous thrombosis (DVT) and pulmonary embolism (PE) in the morbidly obese. We have implemented a novel protocol for venous thromboembolism (VTE) risk stratification in Roux-en-Y gastric bypass (RYGB) candidates at our institution, which augments clinical assessment with screening for thrombophilias, to guide retrievable inferior vena cava (IVC) filter utilization.

Methods A retrospective review of prospectively collected data from patients who underwent primary RYGB between 2001 and 2008 at the University of North Carolina at Chapel Hill was completed. During that time, clinical assessment of VTE risk was amplified by focused plasma screening for common thrombophilias (factors VIII, IX, and XI, d-dimer, fibrinogen). Preoperative prophylactic IVC filters were offered to high-risk patients. The database was reviewed for perioperative DVTs, PEs, and filter-related complications.

Results Of 330 patients, in 162 attempts, 160 had prophylactic IVC filters placed with four complications overall (2.47%). No patient had symptoms of PE during the planned 6-week filter period, though one had a PE occur immediately after filter removal (0.63%); in contrast, five of 170 patients (2.94%) without prophylactic IVC filters presented with symptomatic PE ($p=0.216$). In total, 147 (91.88%) prophylactic filters were removed.

Conclusions Risk-group targeted prophylactic inferior vena cava filter placement prior to RYGB is safe with a trend towards reduced occurrence of PE.

Keywords Morbid obesity · Bariatric surgery · Gastric bypass · Vena cava filters · Pulmonary embolism · CT venography · Thrombophilia

Introduction

Obesity has reached epidemic proportions in many countries. Recent US National Health and Nutrition Examination Surveys data found 32.2% of American adults to be obese (body mass index (BMI) ≥ 30 kg/m²) and 4.8% extremely obese (BMI ≥ 40 kg/m²) [1].

Mounting evidence for the superior efficacy and durability of weight-loss surgery over medical and behavioral therapies for obesity [2–4] has led to a four to sixfold increase in the population-based rate of bariatric surgery and improved societal acceptance [5]. According to the American Society for Metabolic and Bariatric Surgery, the most commonly performed procedure in the US is the Roux-en-Y gastric bypass (RYGB), with an estimated 140,000 such operations performed in 2005 [6].

Consistent with other types of major surgery, RYGB carries a significant mortality risk of 0.3–1.0% [3];

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pulmonary embolism (PE) accounts for up to 50% of these postoperative deaths [7]. While up to 80% of post-bariatric-surgery patients have “silent” PEs found at autopsy following death from other causes [8]; postoperative PE is diagnosed in only 0.41–1.2% of laparoscopic and open RYGB patients [7, 9].

Thromboprophylaxis reduces deep venous thrombosis (DVT), PE, and fatal PE [10]. Despite a large body of literature on the topic from studies of a variety of surgical procedures and in the general population, there are few trials to guide bariatric surgeons’ decision making where thromboprophylaxis in the morbidly obese is concerned [11]. In the absence of clear guidelines, we have implemented a novel protocol for venous thromboembolism risk stratification in patients presenting for bariatric surgery at our institution; this includes a detailed history focusing on history of venous thromboembolism (VTE) and assessment of ambulatory impairment, followed by routine plasma screening for thrombophilias. Selective placement of retrievable inferior vena cava (IVC) filters is utilized for patients deemed to be at high risk by any of these parameters. In this manuscript, we report our experience using prophylactic retrievable IVC filters in patients undergoing RYGB surgery.

Materials and Methods

After institutional review board approval, we retrospectively reviewed prospectively collected bariatric surgery data maintained by the Division of Gastrointestinal Surgery at the University of North Carolina at Chapel Hill, NC, USA, to identify all morbidly obese patients who underwent primary RYGB between January 2001 and February 2008. Patients undergoing revisional surgery were excluded. Data were stored in a purpose-designed Microsoft Access database (Microsoft Corporation, Redmond, WA, USA) and were analyzed with GraphPad Software (La Jolla, CA, USA).

Retrievable IVC filters first became available at our institution in late 2002; in early 2003, we began stratifying preoperative patients into groups based on estimated risk for developing VTE. All patients were screened for acquired thrombophilias by comparing baseline levels of common procoagulant plasma markers against laboratory standards, namely coagulation factors VIII (62–222% of normal), IX (79–150% of normal), XI (66–187% of normal), d-dimer (0–229 ng/ml), and fibrinogen (208–409 mg/dl).

Also, during this period, we screened patients for other thrombophilias, namely antithrombin III deficiency, protein C deficiency, protein S deficiency, homocysteine elevation, factor V Leiden mutation, presence of anticardiolipin antibodies (immunoglobulins G and M), and presence of lupus anticoagulant (by lupus anticoagulant-sensitive acti-

vated partial thromboplastin time and Dilute Russell Viper Venom Time with appropriate phospholipid mixing studies when screening tests were prolonged). In the first 180 consecutive patients, the incidence for these thrombophilias was in most cases similar to that of the general population; given the high incidence of abnormalities of the procoagulant factors VIII, IX, XI, d-dimer, and fibrinogen, we found that the majority patients were likely to meet our criteria for temporary caval interruption prompting us to cease routine measurement of these other thrombophilias based on cost-effectiveness considerations.

We offered selective preoperative prophylactic IVC filter placement to all patients with elevation above the normal range of any of the aforementioned variables associated with thrombophilia and to those who had strong clinical indicators of high VTE risk including poor ambulation, history of severe venous stasis disease, pulmonary hypertension, severe sleep apnea with obesity hypoventilation syndrome, and patients with central obesity and a BMI greater than 60 or patients with a history of DVT or PE.

All filters were placed as outpatients in the 24 h prior to operation by an appropriately credentialed radiologist or vascular surgeon using fluoroscopic guidance and local anesthesia with conscious sedation in the Interventional Radiology suite. Preplacement inferior vena cagrams were performed in the anterior–posterior plane in order to determine renal vein anatomy and IVC diameter. All filters were placed in an infrarenal location. Types of retrievable IVC filters utilized were: the Celect filter (10), Günther-Tulip filter (136; Cook Medical, Bloomington, IN, USA), Bard Recovery filter (3; Bard Peripheral Vascular, Tempe, AZ, USA), and Optease retrievable filter (2; Cordis Endovascular, Warren, NJ, USA). Early in the study, a single non-retrievable Venatech filter (B. Braun Medical, Bethlehem, PA, USA) was used because of radiologist preference. Also, eight Bard G2 permanent filters (Bard Peripheral Vascular, Tempe, AZ, USA) were used off-label as prophylactic filters with intent to retrieve them using the Bard Cone Retrieval device.

A right internal jugular vein approach was used for the insertion of most filters, and the removal of all. A triple lumen central venous catheter was left in place at the completion of filter placement to facilitate perioperative vascular access.

All patients received VTE prophylaxis in the form of pneumatic sequential calf compression devices and subcutaneous heparin (5,000 to 7,500 U² every 8 h) from before surgery until hospital discharge, usually on the second or third postoperative day, unless bleeding concerns prompted heparin avoidance.

Patients were reviewed in an outpatient clinic 2–3 weeks after discharge. Approximately 6 weeks postoperatively, the majority of patients who had received retrievable IVC

filters underwent computed tomographic venography from the diaphragmatic domes to the popliteal veins (111 patients) or lower extremity venous duplex ultrasonography (38 patients). If these studies showed absence of thrombus, contrast cavography was done for confirmation and filter retrieval was initiated. If these studies or preremoval cavography showed presence of thrombus below or within the filter, the device was left in place and anticoagulation with low-molecular-weight heparin and then warfarin was initiated. Four to 6 weeks after the first attempted retrieval, the patient was reimaged and, if there was no evidence of residual thrombus, filter retrieval was attempted. Whether or not the thrombus resolved and the filter was successfully retrieved, all patients with thrombus completed a total course of 3–6 months of anticoagulation.

The database was reviewed for any DVTs, PEs, and filter-related complications. Patients with and without retrievable IVC filters were compared for demographics and for occurrence of VTE events using the two-tailed Fisher's exact test.

Results

In this series, 330 morbidly obese patients underwent primary RYGB, with 314 (95.15%) being laparoscopic and 16 (4.85%) being open. The mean BMI was 51.42 kg/m² (range 32.00–86.40 kg/m²); 282 patients were female (85.45%; Table 1).

Of the 330 patients, 162 had attempted prophylactic filter placement, with 160 placed successfully. Of the two patients who had failed insertions (1.24% insertion failure rate), one was due to an inability to advance a Günther-Tulip device through the introducer sheath and one was due to migration of a Günther-Tulip filter after IVC deployment to the right atrium with immediate successful retrieval. Of these 162 patients, only one suffered a complication at placement (0.62%), a pneumothorax resulting from a jugular venous cannulation attempt.

Of the 160 patients who received prophylactic IVC filters, 147 (91.88%) had successful removal and 13 did not (8.13%; Table 2). Of these 13, seven (4.38%) were deemed technically irretrievable; one (0.63%) was left in place due to persistent thrombus despite anticoagulation; one (0.63%) was removed nonthrombosed at autopsy in a patient who

Table 1 Patient demographics

	Female	Male	Total
Laparoscopic gastric bypass	269	45	314
Open gastric bypass	13	3	16
Total	282	48	330

Table 2 Number of prophylactic IVC filters placed and removed

	Number	Percentage of total
Filter placements attempted	162 of 330	49.09%
Filters successfully inserted	160 of 162	98.77%
Filters retrieved	147 of 160	91.88%
Filters not retrieved	13 of 160	8.13%
Technically irretrievable	7 of 160	4.38%
Persistent thrombus	1 of 160	0.63%
Lost to follow-up	4 of 160	2.50%
Death with filter in place	1 of 160	0.63%
Retrieval attempted	155 of 160	96.88%
Retrieved on first attempt	142 of 155	91.61%
Retrieved on second attempt	5 of 155	3.23%
Technically irretrievable	7 of 155	4.52%
Persistent thrombus	1 of 155	0.65%

died from a cardiac dysrhythmia, and four (2.50%) were lost to follow-up.

Of 155 initial retrieval attempts, there were 13 failures (8.39%); most failed primary attempts were delayed by a prolonged or complicated perioperative recovery (mean 79.85 days after implantation). There were two immediate complications related to removal (1.29%; Table 3); one a presumed guidewire injury with hemopericardium which was treated by needle pericardiocentesis and one a PE immediately after prophylactic filter removal despite the absence of detectable IVC thrombus on preretrieval cava-gram. Secondary retrieval was successful in five of 13 cases. One failed filter retrieval (0.67%) later precluded transvenous accessory pathway ablation in a patient who developed supraventricular tachycardia.

There were three deaths in 330 patients within 30 days of operation (0.91%). One (0.30%) was attributed to PE which occurred 5 days after discharge in a patient who underwent surgery prior to the implementation of our prophylactic IVC filter protocol; one was an in-hospital

Table 3 Complications of prophylactic IVC filters

	Number	Percentage of Total
Filters attempted	162	
Insertion complications (Pneumothorax)	1 of 162	0.62%
Initial removal attempts	155	
Early removal complications (hemopericardium, PE)	2 of 155	1.29%
Delayed removal complications (unable to perform transvenous accessory pathway ablation)	1 of 155	0.65%
Total complication rate	4 of 162	2.47%

death from leak-related sepsis, and one was from the previously mentioned arrhythmia.

During clinical follow-up, the overall PE rate for the 330 patients studied was 1.82% ($n=6$; Table 4), and the overall DVT rate was 2.73% ($n=9$). None of the 160 patients with a prophylactic IVC filter in place had symptoms of PE, although one developed a small PE shortly after a complicated filter removal putting the total PE rate in the prophylactic IVC filter group at 0.63%. In comparison, five of 170 patients (2.94%) without a prophylactic IVC filter had PE ($p=0.216$; Table 3). Four of 170 patients (2.35%) without a prophylactic IVC filter developed symptoms and had evidence of DVT by imaging, whereas five of 160 (3.13%) with a prophylactic IVC filter had incidentally found DVTs on routine imaging as noted above ($p=0.744$).

Discussion

With as many as 50% of all early postoperative deaths after RYGB attributed to PE [7], many of which occur after cessation of prophylactic measures at hospital discharge, it is clear that efforts to reduce mortality and morbidity after bariatric surgery must focus on improving VTE prevention. A number of studies have suggested IVC filter placement is safe in patients undergoing bariatric procedures [12–14]. Previous studies have focused on demographic and historical predictors of VTE risk, such as super obesity, venous stasis, hypercoagulable states, pulmonary hypertension, severe sleep apnea with obesity hypoventilation syndrome, and poor mobility [13–16]. The current study has implemented profiling of VTE risk through laboratory testing for thrombophilias to increase the objectivity of prophylactic IVC filter utilization. Our safety data support IVC filter use in high-risk bariatric surgery patients, with low morbidity associated with insertion and removal, and a retrieval rate of 91.88%.

Our algorithm for quantifying VTE risk among bariatric patients adds testing for thrombophilias to risk assessment by history and physical examination. Although those patients deemed high-risk who received prophylactic IVC

filters in our study showed a trend towards fewer PEs compared to those earlier in the series without filters, the difference was not statistically significant. Interestingly, the only PE which was attributed to the prophylactic filter group occurred periprocedurally after a difficult filter removal in a patient with a negative preretrieval cavagram. This PE may have been the result of the retrieval procedure itself because of undetected thrombus which dislodged from the device during extraction or because a thrombus which formed and embolized after the patient was no longer protected by the filter. Although this event might have been reported solely as a complication of retrieval instead of both a complication of retrieval and a PE in the prophylactic group, our analysis was performed on an intention-to-treat basis. Prior to this difficult-to-interpret event, we had reported in abstract form a lower PE rate in those high-risk patients protected by prophylactic IVC filters which was statistically significant [17].

There is precedent [14] for interpreting statistically similar PE rates after selective application of a risk-tiered prophylaxis strategy as a measure of success. Although our screening method was designed to select for increased susceptibility to VTE, in the absence of appropriate controls for differences in the true rates of venous thromboembolism and thrombophilias between the groups, the validity of our screening algorithm remains unproven.

A number of circumstantial benefits of prophylactic IVC filter placement have become apparent during our series. Operating room time was saved since patients always had central venous access after IVC filter placement [18]. Patients requiring cessation of pharmacologic anticoagulation because of bleeding had uninterrupted PE prophylaxis. Finally, since filters remained in place after discharge, the duration of prophylaxis included the full period of healing and remobilization in those patients.

Though ours is among the largest reported reviews in the literature, the study is not randomized and is underpowered to confirm a difference in rates of pulmonary embolism with and without prophylactic IVC filters. Since most patients undergoing gastric bypass receive some form of pharmacologic prophylaxis, the incidence of clinically significant PE is low, which necessitates a study much larger than ours to confirm the value of selective utilization of removable IVC filters in bariatric surgery patients. Unfortunately, local and regional differences in laboratory assays and prophylaxis strategies, coupled with uncertainty about the true rates of VTE, will likely limit the utility of aggregated data in support of this protocol outside of a well-funded multi-institutional, prospective study.

Since we began routine screening for thrombophilias, an unexpected paradigm shift has evolved within our program; in the last year of this series, removable IVC filters were placed in 92.16% of bariatric surgery patients. Future cost-

Table 4 Incidence of venous thromboembolism

	With prophylactic filter	Without prophylactic filter	<i>p</i> value	Total
DVT detected	5 (3.13%)	4 (2.35%)	0.744	9 (2.73%)
PE detected	1 (0.63%)	5 (2.94%)	0.216	6 (1.82%)
Total number of patients	160	170		330

effectiveness studies will be important to compare the expense of routine blood laboratory studies and selective filter utilization with the alternative strategy of routine general prophylactic IVC filter utilization.

Conclusion

Protocol-driven use of prophylactic IVC filters is safe and associated with low overall rates of complication (2.47%), irretrievability (4.38%), and loss to follow-up (2.5%). In our series, high-risk bariatric surgery patients with IVC filters had a trend towards fewer overall PEs (0.63% vs. 2.94%) than patients without IVC filters. We believe larger patient numbers will statistically confirm the value of temporary IVC filter utilization in high-risk bariatric patients.

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