Patient Selection for Retrievable IVC Filters

Proper candidate evaluation guidelines can prevent nightmarish complications.

BY NICHOLAS J. GARGIULO, III, MD

The advent of the 21st century has ushered an explosion of technological advancements that far exceed our ability as clinicians to evaluate their application to the treatment of patients. Our patients are more confused than we are, which has resulted in the loss of control of what was once a dignified and honorable profession—the care of our fellow human beings. And, yet, at times with industry-driven healthcare, and precise application of new technology, today's clinician has the ability to positively impact, prolong, or even save a human life—far beyond what some of our mentors ever professed.

The application of externally applied inferior vena cava (IVC) clips expanded our treatment of patients having massive pulmonary embolism (PE) after surgery. This often required a laparotomy incision to facilitate the exposure, and eventual clip ligation of what some of us refer to as "big blue." The percutaneous deployment of IVC filters (credited to Dr. Lazar Greenfield) revolutionized our treatment of PE prevention.

The Greenfield filter has a distinct history with excellent long-term results. The development of several other IVC filters, and now the development of retrievable filters, has taken fairly straightforward clinical decision making and made it much more complex. The discussion with our patients not only includes whether an IVC filter will be placed, but also includes the type of filter and whether it will be removed in the future.

The concept of the retrievable IVC filter evolved from some of the adverse events associated with permanent IVC filters, including caval thrombosis, filter migration, and insertion site deep venous thrombosis (DVT), which depends on the type of filter used and patient selection. Many of us have vivid memories and recurrent night sweats of the 70-year-old colon cancer patient 3 years out from IVC filter placement presenting with phlegmasia cerulea dolens, in whom all attempts at caval lysis failed, and who ultimately required bilateral leg amputations. Far fewer of us have horrid memories of the 36-year-old patient 3 months out from gastric bypass surgery demanding immediate IVC removal because of chronic back pain. And yet, only a very elite group of us have the everlasting memory of witnessing that retrievable filter embolize into the pulmonary artery and immediately kill an 18-year-old trauma victim who was going to return home and finish his last year in high school—and the despair of the family who was at the bedside for 3 months.

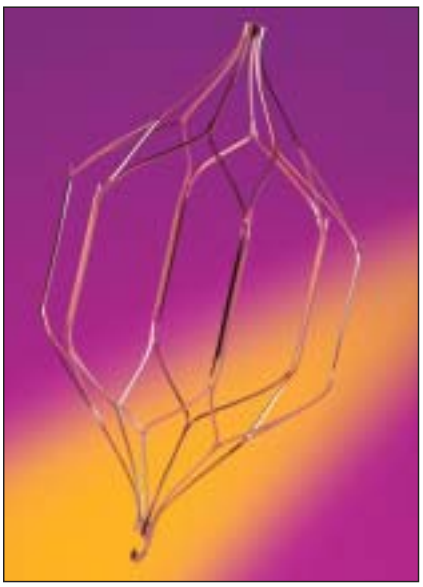

Figure 1. The Optease vena cava filter.

Historically, two classes of retrievable filters were marketed: the temporary tethered filter, which requires

almost immediate removal, and an optional retrievable filter, which may be maintained as a permanent filter. These marketing strategies were stimulated by observations made in France and reported in 1998 by Decousus demonstrating immediate (12 days) benefit of IVC filter insertion in preventing PE for proximal DVT, but late (2-year) complications of insertion site DVT and caval thrombosis thought to be related to this innocuous procedure. Few report on the unpublished observations by Decousus, which demonstrate almost no significant difference in insertion site DVT whether or not IVC filters were placed.

CURRENTLY APPROVED RETRIEVABLE DEVICES

In the US, there are currently three FDA-approved retrievable filters: (1) Optease (Cordis Endovascular, Warren, NJ) (Figure 1), (2) Bard Recovery Filter (C.R. Bard, Inc., Tempe, AZ) (Figure 2), and (3) Günther Tulip (Cook, Inc., Bloomington, IN) (Figure 3). Each of the filters may be deployed via a 6-F or 7-F sheath and retrieved via a 12-F or 13-F sheath system. Indications for use may include (1) prophylactic insertion for a trauma or pregnant patient at high risk for PE with or without DVT who may be anticoagulated within 2 to 4 weeks of the injury or pregnancy; (2) a patient with iliofemoral DVT requiring temporary thrombolysis; (3) a patient with DVT with a temporary contraindication to anticoagulation that may be resolved in 2 to 4 weeks; (4) patients with hypercoagulable disorders and DVT requiring temporary protection during high-risk surgery, pregnancy, or trauma; or (5) patients with morbid obesity requiring temporary PE protection. It would be fair to say that none of these indications have been sorted out in any scientific or prospective, randomized study except for our existing study comparing a permanent and retrievable IVC filter in PE prevention for those patients undergoing open gastric bypass.

THE BEST CANDIDATES

It is our current opinion that patients undergoing open gastric bypass procedures may derive the most benefit from a retrievable IVC filter. During the past 5 years, there has been a resurgence of interest in morbid obesity surgery.[1-4] Morbid obesity is a multisystemic disease and affects every organ system. Surgical weight loss procedures can reverse many if not all of these comorbidities.[6-8] This surgery is typically performed in relatively young, but high-risk, patients who often expect immediate weight loss without any surgical complications. Unfortunately, because of the high-risk nature of the patient population, a significant number of associated complications can occur resulting in significant morbidity and disappointment for the patients and their families and ultimately a host of medicolegal nightmares for the surgeons involved.

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PE is one of the most devastating but preventable complications and has a reported incidence of 2% to 4% in the morbidly obese patient undergoing open gastric bypass.[9] A lower incidence of PE has been observed for those patients undergoing laparoscopic gastric bypass (unpublished results). Currently accepted practices for the prevention of PE include perioperative subcutaneous heparin injections and systemic compression devices with thromboembolic stockings. IVC filter placement has been suggested for patients with a history of DVT, PE, or pulmonary hypertension.[8]

As vascular specialists, we are often called in peripherally as consultants to determine which morbidly obese patients should have perioperative IVC filters placed. Unfortunately, as a group we have not established any published objective guidelines to provide our bariatric surgical colleagues or patients.

Figure 2. The Bard Recovery filter.

COMPLICATIONS OF IVC FILTER PLACEMENT

As we are all aware, IVC filter placement is not a completely benign procedure. In our series of 41 patients undergoing IVC filter placement at the time of open gastric bypass, there have been two patients with postoperative DVT on the side of venous puncture for IVC filter insertion and one IVC thrombosis 4 months postoperatively. Both patients with postoperative DVT presented 3 months after IVC filter placement with lower-extremity pain and edema and were diagnosed with duplex sonography. These patients were both treated with intravenous heparin and subsequent warfarin therapy. Neither patient developed a PE. The patient with IVC

thrombosis presented 1 week after the onset of symptoms and was found to have a compartment syndrome in both lower extremities requiring bilateral fasciotomies. This patient subsequently died after 2 months of hospitalization from septic complications related to the gastric bypass procedure. To date, the other 38 patients have been followed without any documented complications related to IVC filter placement. Despite this, the vascular specialist still needs to discuss these complications with the patient and their support groups.

Figure 3. The Günther Tulip filter

COMPLICATIONS OF IVC REMOVAL

Retrieving an IVC filter requires additional expertise and institutional credentialing. The morbid obese patient proves to be quite challenging and should not be the initial patient to "learn on." Retrieval failure, IVC perforation, PE (captured emboli), and filter embolization are some of the dreaded complications. These risks need to be weighed against the risks of chronic IVC filter implantation.

PERMANENT VERSUS RETRIEVABLE IVC FILTERS AND OPEN/LAPAROSCOPIC GASTRIC BYPASS

Our initial experience with simultaneous IVC filter placement and open gastric bypass was quite revealing. The perioperative PE rate in patients undergoing open gastric bypass surgery was reduced from 17% (4 of 23) to 0% (0 of 33) when a body mass index >55 kg/m2 was used as an indication for IVC filter placement. This constitutes a 72% reduction in the risk of PE (RR, 0.28; 95% CI, 0.05-0.98; P <.05). In addition, the 30-day mortality from PE was reduced from 13% to 0% (Table 1; P=.1). Clearly, IVC filter placement at the time of open gastric bypass is invaluable.

In our series of 213 patients undergoing laparoscopic gastric bypass, there was only one patient that had a PE. This patient also had a history of previous DVT. Despite the theoretical hindrance of venous return and vena caval compression seen with pneumoperitoneum, fewer pulmonary emboli have been observed in the laparoscopic group.

However, the 14% late complication rate (one IVC thrombosis, two insertion-site DVTs) may be reversed with the use of a retrievable IVC filter. This prompted our prospective, randomized study comparing early and late sequelae of IVC filter placement (permanent vs retrievable) in those patients undergoing open gastric bypass. This study will help elucidate the role of retrievable IVC filters in the morbid obese patient undergoing open gastric bypass surgery.

TABLE 1. IVC FILTER PLACEMENT IN PATIENTS WITH BMI >55

Patients BMI >55	IVC Filters	PE Rate	30-Day Mortality
31 (Group I)	8	17%* (4/23)	13% (3/23)
33 (Group II)	33	0%* (0/33)	0% (0/33)

GUIDELINES FOR RETRIEVABLE IVC FILTER PLACEMENT

At our institution, current recommendations for retrievable IVC filter placement are: (1) randomized patients undergoing open gastric bypass; (2) patients (pregnant, trauma) with temporary (2 weeks to 3 months) contraindications to anticoagulation and history of DVT; (3) hypercoagulable patients with DVT undergoing major abdominal surgery; and (4) patients with severe pulmonary hypertension and known DVT undergoing major abdominal surgery. We recommend that before embarking on IVC retrieval, the patient and clinician understand the risks and compare them thoughtfully with the individualized natural history of long-term IVC filter placement in each patient. ■

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