

Retrievable Vena Cava Filters: A Clinical Review

Marianne Tschoe, MD¹
Hyun S. Kim, MD²
Daniel J. Brotman, MD³
Michael B. Streiff, MD⁴

¹ Division of Hospital Medicine, Feinberg School of Medicine, Northwestern University, Chicago, Illinois.

² Russell H. Morgan Department of Radiology and Radiological Science, School of Medicine, Johns Hopkins University, Baltimore, Maryland.

³ Hospitalist Program, Department of Medicine, School of Medicine, Johns Hopkins University, Baltimore, Maryland.

⁴ Division of Hematology, Department of Medicine, School of Medicine, Johns Hopkins University, Baltimore, Maryland.

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Vena cava filters were developed as a method of preventing pulmonary embolism (PE) in patients with venous thromboembolism (VTE) at risk for bleeding from therapeutic anticoagulation. However, the long-term complications of filter placement, such as caval thrombosis, have mitigated some of the benefits, particularly in those patients with only a temporary contraindication to anticoagulation. Retrievable filters were designed to avoid the long-term risks of a permanent filter while still providing short-term protection against PE. As a result, their use has expanded from patients with known thrombosis to those without VTE who are at high risk for developing PE. In this review, we discuss the different types of retrievable filters, indications for their placement, complications that can occur during and after placement, and their use as prophylaxis in surgical patients. Although the use of retrievable filters in patients with known VTE is clear, further studies are needed to establish their prophylactic efficacy in the surgical patient. Until this evidence is available, we recommend that retrievable filters should be used only in patients with acute VTE who are at risk for recurrent thromboembolism and have a transient risk for bleeding. *Journal of Hospital Medicine* 2009;4:441–448. © 2009 Society of Hospital Medicine.

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Vena cava filters were introduced in the 1960s as a mechanical means to prevent pulmonary embolism (PE).¹ Since that time, the number of filters placed has grown steadily, to over 49,000 annually in the United States alone.² However, patients with vena cava filters can develop complications from the filter itself, which can lead to significant morbidity and, rarely, mortality. In particular, the interruption of venous flow caused by the filter can precipitate lower extremity deep vein thrombosis (DVT),³ as well as vena caval thrombosis involving the filter itself. This has led some experts to recommend indefinite anticoagulation in patients with vena caval filters,^{4,5} potentially exposing many patients to the risks of anticoagulation. Given these long-term safety concerns, there has been recent enthusiasm for the development of optional filters. Optional vena cava filters can be classified into 2 types: temporary and retrievable. Temporary filters, which are not currently available in the United States, are held in place by a tether or catheter⁵ and cannot be used as permanent devices. Retrievable filters, on the other hand, maintain their position by hooks, radial pressure, or barbs and can either be removed within a prescribed time period after placement or remain in place permanently. In this way, optional filters offer the possibility of avoiding long-term filter complications in patients with temporary contraindications to anticoagulation. Not surprisingly, the use of retrievable filters has increased dramatically, with many filters being placed for prophylactic indications in

patients without known venous thromboembolism (VTE).⁶ In this work we review the different types of retrievable vena cava filters, current indications for placement, complications, and areas for future research.

Filter Design and Efficacy

Currently, there are 5 U.S. Food and Drug Administration (FDA)-approved filters in the United States that can be used as retrievable filters: ALN (ALN Implants Chirurgicaux, Ghisonaccia, France); Celect (Cook Medical Incorporated, Bloomington, IN); Gunther-Tulip (Cook Medical Incorporated, Bloomington, IN); G2 (Bard Peripheral Vascular, Tempe, AZ); and OptEase (Cordis Corporation, Miami Lakes, FL) (Table 1). Three more devices are in U.S. clinical trials: SafeFlo (Rafael Medical Technologies, Hasselt, Belgium); Crux (Crux Biomedical, Portola Valley, CA); and Option (Rex Medical, Conshohocken, PA). Filters are constructed from magnetic resonance imaging (MRI)-compatible, nonferromagnetic alloys and are produced in either a hexagonal or conical shape. There are potential advantages and disadvantages to both designs. A hexagonal design is thought to be better for trapping small thrombi, but conical filters may have a decreased propensity toward thrombosis.⁷ When a hexagonal filter becomes partially occluded in vitro, flow disturbances can lead to turbulence, stasis, and progressive clot formation.⁷ Some clinical studies have demonstrated an increased incidence of thrombosis with hexagonal filters,⁸

TABLE 1. Currently Available Retrievable Filters

Filter	Image	Insertion Site	Retrieval Site	Maximum Successful Documented Dwell Time
Gunther-Tulip (photo courtesy of Cook Medical Incorporated, Bloomington, IN)		Femoral or jugular	Jugular	204 days ⁴²
Optease (photo courtesy of Cordis Corporation, Miami Lakes, FL)		Femoral or jugular	Femoral	48 days ⁴³
ALN (photo courtesy of ALN Implants Chirurgicaux, Ghisonaccia, France)		Femoral, jugular, or brachial	Jugular	352 days ⁴⁴
Celect (photo courtesy of Cook Medical Incorporated, Bloomington, IN)		Femoral or jugular	Jugular	357 days ⁴⁵
G2 (photo courtesy of Bard Peripheral Vascular, Tempe, AZ)		Femoral or jugular	Jugular	300 days ⁴⁶

but further investigation is needed to determine if a true correlation exists. Comparisons of the 2 types of filter design are limited but have shown no difference in their efficacy in the prevention of PE.⁹ Therefore, filter choice is usually dependent upon the physician performing the procedure, although other factors, such as caval size, clot extent, available venous access, and route of retrieval also may affect this decision. Furthermore, retrospective reviews have shown no difference in efficacy between retrievable and permanent filters.¹⁰

Insertion of filters is typically performed under fluoroscopy in the operating room or interventional radiology suite. Placement can also occur at the bedside using intravascular ultrasound. This option is particularly useful for critically ill patients who are not stable enough to leave the intensive care unit (ICU) for insertion. The safety of this approach

has been documented for both retrievable and permanent filters.^{11,12} Duplex ultrasonography has been used to allow bedside placement of permanent filters, but published experience with this modality in placement of retrievable filters is lacking.^{13,14}

There are no set time limits for retrieving filters, although the retrieval success rate decreases as the time postplacement increases. Rather, the decision to remove them is based on the clinical situation. Table 1 shows data on some of the longest documented successful dwell times for the various retrievable filters. Prior to filter retrieval, a venogram is performed to ensure that there is no clot in the inferior vena cava (IVC) or common iliac veins (Figure 1). Removal of a retrievable filter involves snaring one end of the filter with a hook and then slipping a sheath over the filter, which retracts the filter from the vessel wall as it is being pulled

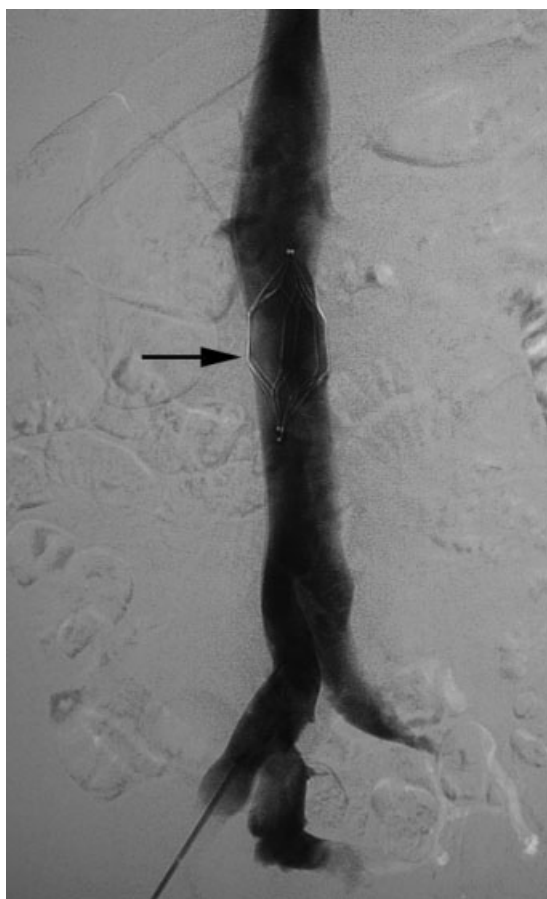


FIGURE 1. IVC venogram prior to filter retrieval confirms no thrombus in IVC or common iliac veins. Note the OptEase filter in the infrarenal IVC (arrow).

into the sheath (Figure 2). Retrieval rates from various studies are listed in Table 2. Common reasons for nonretrieval include loss to follow up,¹⁵ ongoing contraindications to anticoagulation,^{11,16–18} presence of large thrombi in the filter,^{16,18–20} poor patient prognosis,^{16,18} unrelated death,^{16–18} and filter tilting or embedment.^{19,21}

Indications for Filter Placement

Patients with Known VTE

Suggested indications for the use of vena cava filters in patients with proven VTE are listed in Table 3. For patients at risk for either recurrent or severe bleeding (eg, multiple falls, recurrent gastrointestinal or intracranial hemorrhage) or most patients who have failed treatment with therapeutic anticoagulation, a permanent filter is usually the preferred mechanical option. However, for certain conditions (such as Trousseau's syndrome, heparin-induced thrombocytopenia, antiphospholipid syndrome, or anatomic abnormalities such as thoracic outlet syndrome-Paget-von Schroetter syndrome, or May-Thurner syndrome-iliac vein compression syndrome), vena cava filters have been shown either to be ineffective or to worsen thrombosis. In these cases, alternative

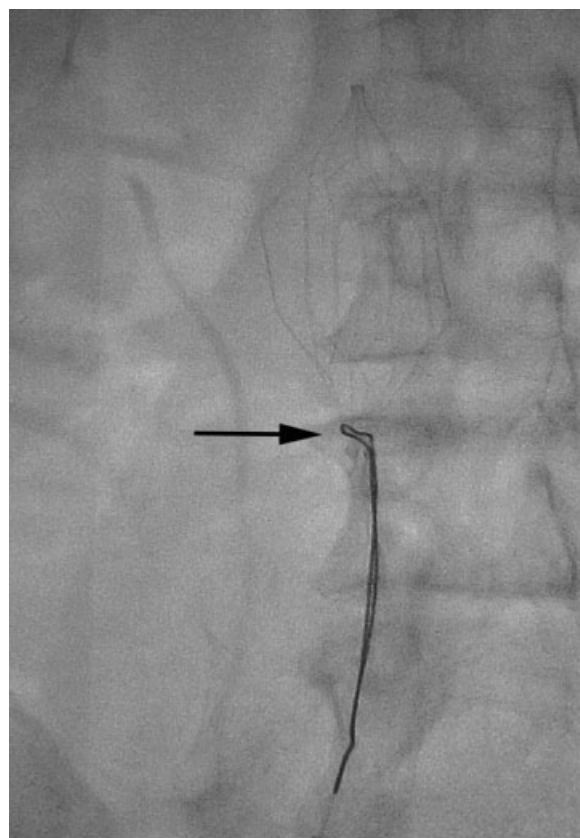


FIGURE 2. During the filter retrieval, a gooseneck snare is advanced and secured the hook (arrow) at the caudal end of the OptEase filter prior to sheath advancement to collapse and retrieve the filter.

therapies must be used, based on the underlying disorder and the clinical situation.

A retrievable filter should only be considered in patients who have a transient contraindication to anticoagulation (Table 5). Such contraindications include isolated but treatable episodes of hemorrhage, urgent surgeries, or procedures associated with a high risk of bleeding, and trauma. The risk of recurrent VTE in the absence of anticoagulation has been estimated at 40% in the first month after VTE and then 10% during the second and third months.²² Therefore, it is reasonable to place a retrievable filter in perioperative patients who cannot be treated with therapeutic anticoagulation during the first 30 days after an acute VTE. If more than 30 days have passed since the thrombotic event, a filter is probably not necessary for patients who will have temporary interruptions in anticoagulation therapy. Instead, bridging anticoagulation (eg, unfractionated heparin [UFH] or low molecular weight heparin [LMWH]) can be given while warfarin is being held prior to surgery. Then, the patient can be transitioned back to warfarin therapy with prophylactic and then therapeutic LMWH or UFH in the postoperative period.

Controversy remains regarding the use of retrievable filters in patients with calf vein DVT. It also exists for patients

TABLE 2. Selected Published Experience with Different Retrievable Filters Currently Available in the United States

Study	Total Number of Patients	Study Type	Filter Type	Follow-Up Duration (months)	PE [number (%)]	IVC Thrombosis [number (%)]	DVT [number (%)]	Retrieval Attempted/Successful Retrieval [number (%)]	Mean Duration Between Filter Placement and Retrieval (days)
Millward et al., 2001 ¹⁶	90	RO/PO	G	3.4	0	1/39 (2.6)	1/39 (2.6)	53 (59)/52 (98)	9
de Gregorio et al., 2003 ¹⁹	87	RO	G	N/R	0	0	0	69 (79)/68 (99)	13
Wicky et al., 2003 ¹⁷	71	RO	G	30	0	0	0	47 (66)/33 (70)	8.2
Rosenthal et al., 2004 ¹¹	94	PO	O	N/R	0	0	1 (1.1)	34 (36)/31 (91)	19
Grande et al., 2005 ¹⁵	106	RO	R	N/R	3 (2.8)	0	0	15 (14)/14 (93)	150
Oliva et al., 2005 ⁴⁷	27	PO	O	N/R	0	0	1/27 (3.7)	21 (78)/21 (100)	11.1
Hoppe et al., 2006 ¹⁸	41	PO	G	3	1 (2.4)	1 (2.4)	1 (2.4)	23 (57)/23 (100)	11.1
Kalva et al., 2006 ⁴⁸	96	RO	R	5.3	1 (1.0)	0	10/53 (18)	11 (12)/9 (82)	117
Meier et al., 2006 ³⁵	37	PO	O	5	0	1/5 (20)	1/5 (20)	32 (86)/32 (100)	16
Ray et al., 2006 ⁴⁹	197	RO	G, R	N/R	1 (0.5)-G	2 (1.0)-G	0	94 (48)/80 (85)	11 (G)/28 (R)
Rosenthal et al., 2006 ⁵⁰	127	RO	G, R, O	N/R	0	0	0	70 (52)/66 (94)	71
Looby et al., 2007 ²¹	147	RO	G	N/R	1 (0.7)	0	0	45 (31)/36 (80)	33.6
Yamagami et al., 2007 ⁵¹	86	RO	G	N/R	0	N/R	N/R	80 (93)/77 (96)	13.4
Kim et al., 2008 ⁵²	427	RO	G, P, R, G2	10.4	20 (4.7)	2 (0.5)	54 (12.6)	60 (15.5)/46 (69.7)	20.4

Abbreviations: DVT, deep vein thrombosis; G, Günther Tulip; IVC, inferior vena cava; N/R, not reported; O, OptEase; PE, pulmonary embolism; PO, prospective observation; R, recovery; RO, retrospective observation.

TABLE 3. Suggested Filter Indications for Patients with Proven VTE

	Anticipated Transient Need for Anticoagulation	Anticipated Long-Term Need for Anticoagulation*
Transient bleeding risk in a patient at high risk for recurrent thromboembolism	Retrieval filter appropriate	Retrieval filter appropriate
Permanent, or likely recurrent, bleeding risk	Retrieval filter with extended dwell time	Permanent filter appropriate
No unusual bleeding risk	No filter indicated	No filter indicated

* See Table 4.

TABLE 4. Situations That May Require Long-Term Anticoagulation

Recurrent VTE
 Idiopathic VTE
 Near-fatal thrombosis
 Thrombosis at an unusual site (eg, mesenteric vein)
 VTE in high-risk thrombophilic disorders:
 Antiphospholipid antibody syndrome
 Protein C or S deficiency
 Antithrombin III deficiency
 Heterozygous mutations for both the Factor V Leiden and the Prothrombin gene mutation (compound heterozygosity)
 Homozygous Factor V Leiden mutation
 Cancer-associated VTE

Abbreviation: VTE, venous thromboembolism.

TABLE 5. Transient Contraindications to Anticoagulation That May Require Filter Placement

Major trauma
 Peripartum
 Isolated and treatable causes of hemorrhage (eg, peptic ulcer)
 Bleeding complications after procedures or surgeries⁵³
 Liver or kidney biopsy
 Urgent surgery associated with a high bleeding risk⁵⁴
 Cardiac (coronary artery bypass or valve replacement)
 Vascular (aortic aneurysm repair, peripheral artery bypass)
 Neurosurgical (intracranial or spinal)
 Urologic (prostate and bladder)
 Major cancer surgery

with massive or submassive PE who are receiving anticoagulation therapy but are at high risk for poor outcomes should another PE—even if small—occur while they are on anticoagulation therapy. Vena cava filters are generally not recom-

mended for patients with distal VTE unless they have a persistent contraindication to anticoagulation therapy and have shown clot propagation on serial duplex studies. At least 1 institution, however, has noted an increased use of filter placement in this population since the advent of retrievable filters.²³ Randomized controlled trials and practice

guidelines are still lacking in this area. Therefore, there is currently insufficient evidence to recommend retrievable filters for distal VTE.

There is also insufficient evidence to recommend filters for patients with massive or submassive PE who can tolerate anticoagulation therapy. Only 1 registry study has compared patients with massive PE (defined by a systolic blood pressure <90 mmHg at presentation) who were treated with vena cava filters to those who were not.²⁴ Though there was a reduction in recurrent PE and mortality at 90 days in patients who received filters, this result requires further confirmation due to the small number of patients who received filters (11 patients) and a possible selection bias (patients who received filters were, on average, 16 years younger than those who did not). More evidence will be needed to weigh not only the cost but the risks of filter insertion (such as insertion site hematoma, increased incidence of DVT, or contrast nephropathy) against any benefit. Until then, routine filter use in patients with massive or submassive PE cannot be routinely recommended, but may be considered in those with massive PE and impending hemodynamic collapse.

Prophylaxis in High-Risk Patients

Controversy also exists in the use of retrievable filters in patients without VTE who are at high risk for thromboembolic events. Currently, there are no randomized controlled trials that have established the efficacy of retrievable filters as prophylaxis in these patients. However, there are a number of prospective and retrospective studies that examine this topic, particularly in trauma patients.

Trauma

The Eastern Association for the Surgery of Trauma currently recommends that prophylactic filters be considered in trauma patients who are at increased risk for bleeding and prolonged immobilization (level III).²⁵ These patients include those with severe closed head injury, incomplete spinal cord injury with paraplegia or quadriplegia, multiple long bone fractures, and complex pelvic fractures with multiple long bone fractures. The largest study to date on retrievable filters in trauma patients was done by the American Association for the Surgery of Trauma.²⁶ The incidence of new PE after filter placement was 0.5%, which compares favorably with permanent filter recipients (PE 0.7%) and historical controls (2.1%).²⁷ OptEase filters were more commonly associated with caval thrombosis. The majority of filters (78%) were not retrieved, primarily because patients were lost to follow up. Failure to retrieve filters has become a major issue as these devices grow in popularity.^{28,29} In this situation, the benefit of using retrievable filters could be mitigated by the same long-term complications associated with permanent filters. Therefore, well-coordinated patient follow-up is essential to ensure optimal use of retrievable filters. Furthermore, randomized studies of retrievable filters

are urgently needed to confirm that vena cava filters are associated with net benefit compared with conventional approaches to VTE prophylaxis (enoxaparin, sequential compression devices) in trauma patients.

Other High-Risk Situations

The use of permanent filters has been studied in neurosurgical, bariatric, orthopedic, and pregnant patients. However, there are very few studies that look at the use of retrievable filters specifically in these populations. One such study was done in obese (body mass index [BMI] > 55 kg/m²) patients undergoing gastric bypass surgery.³⁰ Filter retrieval rates were high (87%), and there were no DVTs or PEs prior to or after removal. The authors attributed their high removal rates to a dedicated follow-up program and close collaboration with the interventional radiologists. More research needs to be done comparing outcomes with filters to conventional pharmacologic VTE prophylaxis before these devices can be recommended in these patients.

Filter Complications

During Filter Placement

Complications related to both retrievable and nonretrievable filter placement are rare but have been documented in several studies. Failure of the filter to deploy properly has been reported.²¹ The same study also noted pneumothorax as a complication in some patients whose filters were inserted via the jugular vein.²¹ Therefore, location of access and retrieval should be an important consideration for patients with significant underlying pulmonary disease. Insertion site thrombosis and arteriovenous fistula formation have been reported primarily with permanent filters^{31,32}; that risk could be extrapolated to retrievable filters given that the method of placement is the same. Iodine contrast-induced nephropathy is of concern for high-risk patients, although the procedure can be performed using gadolinium-based contrast, carbon dioxide contrast, or without contrast (under ultrasound guidance).

During Filter Retrieval

Filter tilting and clot trapping under the filter that occurs during the filter removal process are infrequent causes of non-retrieval. Tilting of the filter sometimes can pose problems, but if this occurs, the filter can be repositioned so that the degree of tilt no longer precludes removal. Severe cases of tilting that lead to nonretrieval are very rare. When thrombus is trapped in the filter (Figure 3), retrieval often depends on the amount of thrombus. A visual scale to assist in judgment of thrombus volume has been developed to assist in retrieval decision-making.³³ In some cases, catheter-directed thrombolysis has been used to facilitate thrombus dissolution.³⁴

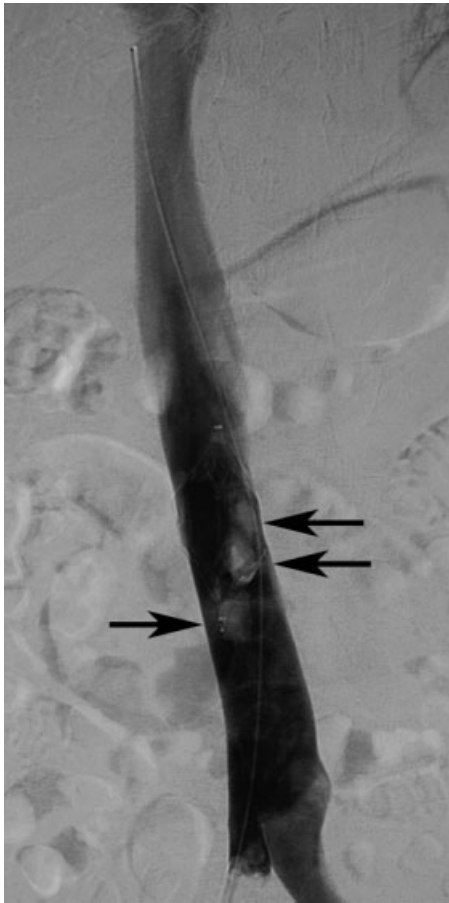


FIGURE 3. IVC cavogram prior to filter retrieval demonstrates trapped thrombus (arrows) under the filter. The filter retrieval procedure was aborted.

VTE After Placement

Table 2 lists the incidence of VTE after retrievable filter placement. The overall incidence of PE is low, but that of DVT varies widely. These data raise the possibility that some filters may not be removed due to the occurrence of a new DVT, thereby becoming permanent filters with the associated risks of recurrent DVT, caval thrombosis, and PE. Only a few studies have investigated the differences in the rate of PE between permanent and retrievable filters and have shown no differences.²⁹ The long-term complication rates of retrievable filters and how they may differ from permanent filters warrants further investigation.

Some studies have also noted the development of PE after filter retrieval.^{35,36} It is possible that a subclinical DVT was present at the time of removal or that the filter was retrieved before the risk of thrombosis had resolved. Therefore, consideration should be given to the use of duplex ultrasound evaluation for DVT prior to filter removal to ensure that patients with active thrombosis receive therapeutic anticoagulation for an appropriate duration.

Because of the concern for DVT and PE associated with retrievable filters, anticoagulation should ideally occur before and after retrieval, once the bleeding risk has become

acceptable. Consensus guidelines support this practice,^{5,37} though one systematic review has found insufficient evidence regarding the use of anticoagulation in patients with vena cava filters.⁴ Retrospective reviews have shown that filters can be both placed and removed without bleeding complications, even in patients who are therapeutically anticoagulated with warfarin and/or LMWH.^{38,39} Further investigation would be useful to confirm whether this is an effective approach to VTE prevention at the time of retrieval.

Other Adverse Events

Other complications that have been associated with retrievable filters include migration, fracture, infection, and perforation. It may be difficult to estimate the true incidence of these complications, as most of the literature on this topic comes from case reports. Vena cava perforation with hooks may be not uncommon but in most cases is not clinically significant.⁴⁰ Filter fracture is more common but rarely reported. Filter migration toward the heart is a very rare but potentially life-threatening complication. The Recovery filter was taken off the market due in part to concerns about migration.²⁶ As the use of retrievable filters increases, complications related to filters will need to be monitored.

Ongoing and Future Research

Other types of removable filters are currently in development. Convertible filters that can be converted into a stent once they are no longer needed are under investigation. Other devices, such as absorbable or drug-eluting filters, are also being studied.⁵ In addition, there is ongoing research to better characterize the safety and efficacy of available filters. The Prevention du Risque d'Embolie Pulmonaire par Interruption Cave (PREPIC) 2 will assess their use in the first prospective, randomized, controlled trial of retrievable filters in patients with acute VTE receiving anticoagulation (<http://www.clinicaltrials.gov>; Identifier: NCT00457158). Other studies include an evaluation of the long-term outcomes of patients with retrievable filters who failed retrieval (<http://www.clinicaltrials.gov>; Identifier: NCT00163956) and a comparison of Günther Tulip and OptEase filters (<http://www.clinicaltrials.gov>; Identifier: NCT00588757). Randomized controlled trials are still needed to evaluate the efficacy of prophylactic filter placement in high-risk patients. Studies that examine intention to retrieve vs. actual and recommended retrieval rates would provide valuable information on practice patterns.

Conclusions

There is growing concern over the increased use of vena caval filters for the prevention of PE.⁴¹ Retrievable filters offer the possibility of protection without the risk of long-term complications attributable to permanent filters. The advent of these devices has led to an increase in overall filter use but also could result in filter placement without

adequate consideration of the potential complications or consequences of nonretrieval. More evidence is needed in order to establish best practice guidelines for retrievable filter use. Until these data are available, these devices should be used only in patients with acute VTE who are at risk for recurrent thromboembolism and have a transient risk for bleeding.

Address for correspondence and reprint requests:

Marianne Tschoe, MD, Division of Hospital Medicine, Northwestern University Feinberg School of Medicine; 251 E. Huron St, Feinberg 16-738, Chicago IL 60611; Telephone: 312-926-5924; Fax: 312-926-6134; E-mail: mtschoe@nmff.org Received 1 June 2008; revision received 5 August 2008; accepted 6 September 2008.

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