American College of Radiology
ACR Appropriateness Criteria®

Clinical Condition: **Radiologic Management of Inferior Vena Cava Filters**

Variant 1: **Acute pulmonary embolism with negative lower-extremity Doppler ultrasound.**

Treatment/Procedure	Rating	Comments
Anticoagulation	9	
Permanent IVC filter	4	
Retrievable IVC filter	5	
Observation/conservative management	1	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 2: **Acute pulmonary embolism and/or iliofemoral deep-vein thrombosis.**

Treatment/Procedure	Rating	Comments
Anticoagulation	9	
Permanent IVC filter	5	
Retrievable IVC filter	6	
Observation/conservative management	1	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 3: **Symptomatic chronic pulmonary embolism.**

Treatment/Procedure	Rating	Comments
Anticoagulation	9	
Permanent IVC filter	5	Depends strongly on the clinical factors such as lifelong risk, age, etc.
Retrievable IVC filter	5	
Pulmonary thromboendarterectomy	7	Clinical presentation (eg, hemodynamic instability and right-sided heart failure) and anatomic factors are important considerations. Should be performed at center of excellence.
Observation/conservative management	2	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Clinical Condition: **Radiologic Management of Inferior Vena Cava Filters**

Variant 4: **Calf deep-vein thrombosis**.

Treatment/Procedure	Rating	Comments
Anticoagulation	7	Particularly in high-risk patients or if there is evidence of propagation.
Permanent IVC filter	2	
Retrievable IVC filter	3	If neither anticoagulation nor observation is possible or if there is evidence of propagation, this may be an option.
Observation/conservative management	6	For patients who have a contraindication to anticoagulation.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 5: **Prophylactic IVC filter placement in high-risk patients without documented deep-vein thrombosis/pulmonary embolism.**

Treatment/Procedure	Rating	Comments
Anticoagulation	8	This assumes the patient is a candidate for anticoagulation.
Permanent IVC filter	2	
Retrievable IVC filter	5	
Observation/conservative management	5	
Intermittent pneumatic compression devices	8	
Surveillance US for deep vein thrombosis	4	Usually not necessary unless the patient becomes symptomatic.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 6: **Phlegmasia cerulea dolens undergoing endovascular treatment.**

Treatment/Procedure	Rating	Comments
Anticoagulation	9	
Permanent IVC filter	4	If patient has lifelong risk and cannot be anticoagulated.
Retrievable IVC filter	5	
Observation/conservative management	1	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Clinical Condition: **Radiologic Management of Inferior Vena Cava Filters**

Variant 7: **Upper-extremity deep-vein thrombosis**.

Treatment/Procedure	Rating	Comments
Anticoagulation	8	
Observation/conservative management	2	
Permanent SVC filter	3	
Retrievable SVC filter	5	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 8: **Free-floating iliofemoral thrombus.**

Treatment/Procedure	Rating	Comments
Anticoagulation	9	
Permanent IVC filter	6	Depends strongly on the clinical factors such as lifelong risk, age, etc.
Retrievable IVC filter	7	
Observation/conservative management	1	
Endovascular therapy	5	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 9: **Retrieval of a filter placed for prophylaxis.**

Treatment/Procedure	Rating	Comments
Automatically schedule for retrieval consultation at time of placement	9	
Clinic visit prior to retrieval	8	
Duplex of the lower extremities prior to retrieval	6	Depends on clinical presentation and new symptoms in examination interval.
CT venogram prior to retrieval	2	
KUB prior to retrieval	2	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Clinical Condition: **Radiologic Management of Inferior Vena Cava Filters**

Variant 10: **Retrieval of a filter placed for deep-vein thrombosis/pulmonary embolism. Patient is now anticoagulated.**

Treatment/Procedure	Rating	Comments
Retrieve filter with patient anticoagulated	8	
Clinic visit prior to retrieval	8	
Duplex of the lower extremities prior to retrieval	7	To check for propagation.
CT venogram prior to retrieval	2	
KUB prior to retrieval	2	
Reverse anticoagulation prior to retrieval	2	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 11: **Failed first retrieval attempt.**

Treatment/Procedure	Rating	Comments
Consider the filter permanent with scheduled follow-up (imaging, clinic visit, operator choice)	5	
Consider the filter permanent without any follow-up	4	
Consider the filter permanent with lifelong anticoagulation	5	
Re-attempt retrieval with more aggressive measures	8	Consider referral to a center of excellence.
Refer for surgical evaluation for surgical retrieval	2	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

RADIOLOGIC MANAGEMENT OF INFERIOR VENA CAVA FILTERS

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Summary of Literature Review

Introduction/Background

Pulmonary embolus (PE) and deep venous thrombosis (DVT) represent the clinical spectrum of venous thromboembolism (VTE), which remains a major cause of morbidity and mortality in hospitalized patients. VTE occurs spontaneously or as a common complication during and after hospitalization for acute medical or surgical illness. PE accounts for 5%-10% of deaths in hospitalized patients and is the most common preventable cause of in-hospital death [1-4]. Recent studies have emphasized that a significant number of medicine and surgery patients are not receiving adequate prophylaxis against VTE. More than 50% are at risk of VTE, and only half of those patients are receiving prophylaxis [5].

The primary prophylaxis and therapy for VTE are pharmacologic, including intravenous (IV) heparin, oral warfarin, subcutaneous low-dose heparin (LDH), or low-molecular-weight heparin (LMWH) [6]. Newer commercially available oral anticoagulation pharmacologic agents such as dabigatran are also gaining popularity. This agent does not require frequent hematologic tests to assess anticoagulation effect, and it has been shown to be as effective as warfarin in clinical trials for atrial fibrillation (Randomized Evaluation of Long-Term Anticoagulation Therapy [RE-LY] trial) [7]. Lower-extremity graduated compression stockings (GCS) and intermittent pneumatic compression (IPC) devices have been found to be effective as well. Surveillance ultrasound studies in lieu of anticoagulation have also been proposed [8].

Vena cava filters do not prevent or treat DVT [9,10]. The sole function of inferior vena cava (IVC) filters is prevention of clinically significant and potentially life-threatening PE by preventing the passage of emboli into the pulmonary arterial circulation by trapping the embolus as it passes from the iliofemoral venous system through the IVC. They are placed percutaneously with relatively low risk to even severely ill patients [11].

Permanent IVC filters have been used clinically for over 35 years, and studies show that the use of IVC filters has dramatically increased in the past 20 years [12,13]. Despite this fact, there is a striking lack of rigorously performed clinical studies. The vast majority of the literature includes retrospective nonrandomized case series. Of 586 studies evaluated in a recent review, two-thirds were retrospective, and the heterogeneous study design of the few large prospective series precludes relevant comparison and analysis [14].

Filters were initially intended to be used in the small group of patients who had VTE and a contraindication to anticoagulation, a complication of anticoagulation, inability to achieve adequate anticoagulation, or recurrent embolus despite anticoagulation [15].

The indications have been expanded by many authors to include a substantial proportion of patients with high risk of developing VTE but no evidence of it [16]. The availability of retrievable/optional filter designs extends the clinical utility of filters. Proposed indications now include prophylactic use in patients with major trauma; in those who will undergo hip or knee replacement; in patients with compromised cardiopulmonary reserve such as cor pulmonale or pulmonary hypertension; in pregnant women with DVT; in burn patients; in patients undergoing

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thrombectomy, embolectomy or thrombolysis; and in patients with free-floating iliofemoral thrombus [17]. Additionally, new indications that have been proposed lack significant data to support their use, such as prophylactic filter use for patients undergoing bariatric surgery [18].

Pulmonary Embolus with a Contraindication to Anticoagulation

There are certain absolute contraindications to anticoagulation in which filters are used to prevent PE. These include unsecured intracranial aneurysm after subarachnoid hemorrhage, acute intracerebral hemorrhage, or hematomyelia and current or recent major gastrointestinal hemorrhage or lesions at high risk of bleeding (eg, esophageal varices). Relative contraindications include recent (within two weeks) major surgery; major trauma, including cardiopulmonary resuscitation (CPR) or deep biopsy; uncontrolled hypertension; renal or hepatic disease; current guaiac-positive stools; and known bleeding diatheses [19]. Neither stable peptic ulcer disease with no history of bleeding nor a history of guaiac-positive stools is a contraindication to anticoagulation. Anticoagulation is safe in most trauma and neurosurgical patients after the first or second postoperative week and in most stroke patients without hemorrhage. Patients with spinal cord injury without hematomyelia may still be considered for anticoagulation [20].

Major Complication of Anticoagulation

Major bleeding is the most significant complication of anticoagulation. It is defined as intracranial or retroperitoneal bleeding or bleeding that requires hospitalization or transfusion while the patient is on therapeutic levels of anticoagulants. When anticoagulation therapy for VTE must be stopped because of major bleeding, placement of an IVC filter should be considered. Heparin-induced thrombocytopenia — defined as platelet count below 50,000/uL, with or without arterial thrombosis — is also considered to be a complication of heparin therapy, and placement of an IVC filter should be considered after heparin therapy is discontinued.

Inability to Adequately Anticoagulate

Progression or Recurrence of Venous Thromboembolism despite Adequate Anticoagulation

Although VTE can progress during adequate anticoagulation, it is unusual and therefore it is critical to fully evaluate whether therapeutic levels have been consistently achieved. Raising the target INR (international normalized ratio) is preferable to placing a filter in the setting of inadequate anticoagulation. Hypercoagulable states such as antiphospholipid antibody or Trousseau's syndrome must be excluded prior to filter placement in order to avoid significant morbidity [17].

Patient Factors Affecting Anticoagulation

Elderly patients and patients who are unable to reliably comply with anticoagulation regimen or have a history of falls are at increased risk of hemorrhage and complication, and filters have been used in these patients [19]. Other factors that may affect anticoagulation status can include vitamin K-rich diets or other concurrent medications. Discomfort from frequent blood draws and/or self-injections may also cause patient compliance issues with currently available medications.

Pulmonary Thromboendarterectomy

Patients (3.8% or more) who experience initial symptomatic PE go on to chronic thromboembolic pulmonary hypertension (CTEPH) [21]. Permanent filters are routinely placed in these patients prior to thromboendarterectomy, and they are given lifelong anticoagulation as well [22].

Patients with Poor Cardiopulmonary Reserve

Among patients at high risk for death or severe morbidity from PE are those who have severe pulmonary hypertension and a history of PE. There are no data to support the use of prophylactic filters in this setting. When a patient has had multiple prior episodes of VTE and any additional embolization might result in severe morbidity or mortality, a filter may be indicated. Similarly, in a patient who has had cardiovascular collapse as the result of a PE and/or who has undergone pulmonary thrombolysis/embolectomy, the use of a filter may be warranted given the potential effects of re-embolization [23].

Free-Floating Iliofemoral Thrombus

There has been much speculation about PE risk due to free-floating iliofemoral or IVC thrombus. A prospective study demonstrated no increased risk of PE [24]. Although no study has demonstrated improved outcomes with IVC filters in addition to or in place of anticoagulation [17], this condition is still considered a relative indication in many consensus statements [15].

Prior to Thrombolysis
In the setting of proximal DVT, catheter-directed thrombolysis appears to result in fewer PEs than systemic thrombolysis. Filters are sometimes used but have not been shown to be more effective than thrombolysis alone. Retrievable filters may be a viable option in this situation [17].

Cancer Patients
Although cancer has been considered a contraindication to IVC filters in some instances, it is a prothrombotic state and independent risk factor for VTE [25]. Filters have been recommended [26], but pharmacologic approaches such as LMWH are preferred over filters or oral anticoagulation in cancer patients [27].

Pregnancy
Pregnancy produces a hypercoagulable state, and VTE complicates 0.5%-1% of pregnancies. Anticoagulation with heparin products is the mainstay of treatment, while warfarin is contraindicated due to its teratogenicity. Filters are indicated in selected patients with contraindications to anticoagulation, progression of VTE while anticoagulated, and inability to tolerate a subsequent PE [28,29].

Patients without Venous Thromboembolic Disease

Prophylaxis in High-Risk Trauma and Spinal Cord Injury Patients
Patients recovering from trauma, especially spinal cord injury, have the highest risk of VTE of all hospitalized patients [30,31]. There is great controversy regarding the use of IVC filters in trauma patients, with some authors believing that there is no benefit to filters in these patients [8] and that as soon as hemostasis is achieved (within 36 hours in most patients), pharmacologic prophylaxis should begin [32]. Others believe that filters are safe and effective [33], though prospective randomized trials are severely lacking in this area.

Prophylaxis in High-Risk Surgery Patients
Patients undergoing orthopedic procedures such as total knee and total hip arthroplasty are at high risk for VTE. Although retrievable filters are sometimes used in the perioperative period, pharmacologic therapies are safe and effective once the immediate risk of hemorrhage is past [34].

Prophylaxis in Burn Patients
Filter use in burn patients was found to be safe in a small series [35] but is not an established indication for filter placement.

Prophylaxis in Bariatric Surgery Patients
PE is a leading cause of perioperative death in bariatric patients due to their many comorbidities. However, there is little evidence to support routine use of filters in place of adequate prophylaxis, such as anticoagulation [36].

Other Clinical Conditions
Patients with chronic obstructive pulmonary disease (COPD), pediatric patients, and organ transplant recipients have also been proposed as potential recipients of IVC filters. However, none of these conditions preclude anticoagulation, and filters are suggested only after the accepted indications are met.

Septic Emboli
The proposed use of IVC filters in the patients with septic emboli is based on a single animal study and, given the risks of filter infection, is not recommended [37]. Candida infection of filters has also been reported [38]. Retrievable filters, if they become infected, can often be removed.

Filters

Permanent and Retrievable Filter Designs
Permanent and retrievable filter designs are available. There are much more robust data on permanent filter designs, starting with the Greenfield in 1973 and including over 9,500 filter placements. To date, only 1,000 placements of retrievable designs are described in case series [39]. Six permanent options currently available include the Gianturco-Roehm Bird's Nest filter, titanium and stainless steel Greenfield, Simon Nitinol, Vena Tech, and Trap Ease filters [40,41].

Retrievable designs were originally approved in 2003 and have recommended dwell times from 10-100 days. Six designs available in the U.S. include the Opt Ease, Gunther Tulip, Celect, Recovery, G2, and now the Option. Although retrieval is associated with relatively low complication rates [42], in one prospective observational study longer dwell times decreased the rate of successful retrieval from 100% to 50% [43]. Thrombus in a retrievable filter may prevent removal until a period of anticoagulation is possible [44]. .

Superior Vena Cava Filter Placement
Filter placement in the superior vena cava (SVC) is considered for patients with upper-extremity DVT. The decision is complicated by the short length of the available SVC and the associated increased risk of problematic migration or thrombosis [45]. In addition, no filter is specifically designed for the SVC, and such use is considered off-label.

Temporary Inferior Vena Cava Filters (Externally Anchored)
Temporary filter designs in which the filter is anchored externally risk infection and have waned in popularity, given more appealing retrievable alternatives. Currently, there are no FDA-approved IVC filters of this type in the United States.

Effectiveness
There has been only one randomized clinical trial on caval filters, the PREPIC study [46]. In this study, 400 patients with iliofemoral DVT at high risk for PE were anticoagulated and assigned to either receive a permanent filter or not. Patients in both groups were checked for PE at 2 days and again at 8-12 days by ventilation-perfusion scan. Patients receiving filters had fewer PEs initially (as well as at 2- and 8-year follow-up periods), but over 2 years experienced more frequent DVT and no decrease in mortality. It is important to note that the PREPIC patients were all anticoagulated, while a typical patient receiving an IVC filter has a contraindication to anticoagulation. Therefore, the population of this study is not representative of patients in whom filters are routinely placed [46,47].

A single large population-based observational study involving nearly 75,000 patients in California showed that in patients with prior VTE, those with filters were readmitted to the hospital for PE as often as those without filters. Among patients who had presented with initial PE, a filter was associated with double the relative risk of DVT. Time to recurrent PE was similar, and among those who had never been hospitalized for VTE, patients with filters had a higher mortality rate — a finding that may represent unidentified comorbidities given the limitations of the observational nature of this study [48].

These studies have placed an emphasis on the retrievable filter concept, in which the embolic risk appears to be highest early on, while the thrombotic complications, including recurrent DVT and caval thrombosis, appear later. This controversy has caused much confusion in the medical community, as many physicians feel that life-long anticoagulation may be necessary in any patient with an IVC filter [49]. A 2008 meta-analysis by Ray and Prochazka [50] finds a non-statistically-significant trend toward decreased VTE rates in patients undergoing postfilter anticoagulation, suggesting that patients without anticoagulation are not at dramatically increased risk. Additionally, as also indicated by Kaufman et al [51] a 2001 study by Greenfield and Proctor published results from a prospective registry of filter patients in Michigan showing a similar rate of IVC occlusion and recurrent DVT in patients with filters regardless of the use of anticoagulation [52]. This suggests that patients with permanent filters may not require indefinite anticoagulation after completion of an appropriate duration of anticoagulant therapy for the thromboembolic event that prompted filter insertion.

Risks and Complications
Filter designs as well as indications continue to evolve. No ideal filter exists [53]. Although filters are effective at reducing the incidence of PE, there is a 3%-5% PE recurrence rate [54,55]. In a 26-year single-institution study of 1,765 filters, rates of major complication associated with placement were 0.3% and postinsertion migration, fracture, and caval perforation ranged from 0.1%-0.2%. The rate of caval thrombosis was 2.7% (3.2% if the Mobin-Uddin device is included) [12]. Other authors cite a 2%-10% caval thrombosis rate, and up to 30% may thrombose over the long term [40,56]. Another study shows 4%-11% complication rates after filter insertion, and death in 0.12% of these patients [54]. As above, filters appear to increase the incidence of recurrent DVT and have not been shown to increase overall survival in the long term. Cross-sectional imaging findings of complications such as maldeployment, malpositioning, tilt, migration, perforation, fragmentation, caval thrombosis, and recurrent PE are described by Cina et al [57].

A 2010 article from Nicholson et al [58] evaluating the Bard Recovery and G2 filters demonstrated alarmingly high rates of strut fractures and complications. In this retrospective, single-center, cross-sectional study, it was found that the Bard Recovery had a 25% strut fracture rate (7 out of 28) with 71% fragment embolization to the heart. The Bard G2 was found to have a 12% strut fracture rate (6 out of 52), with two of the six patients having asymptomatic end-organ embolization. In total, a 16% strut fracture was noted for the Bard filters. This prompted an FDA warning on 8/9/2010: “Since 2005, the FDA has received 921 device adverse event reports involving

IVC filters, of which 328 involved device migration, 146 involved embolizations (detachment of device components), 70 involved perforation of the IVC, and 56 involved filter fracture." It goes on to recommend that "implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed" [59]. It stops short of any direct recommendations against use of filters or their indications, although the need for additional research is indicated.

The only definitive indications for vena cava filter placement are as described in the ACCP Conference on Antithrombotic and Thrombolytic Therapy guidelines [60], including the contraindication to, complications from, and failure of anticoagulation. Large, rigorously designed randomized, controlled trials lasting 2 years or more in patients with these indications are required [61]. Anticoagulation should be compared to use of permanent and retrievable filters. Outcomes should include rates of PE and DVT, filter-related complications, mortality, and post-thrombotic syndrome [45]. These recommendations are also echoed in a 2009 consensus statement from Kaufman et al [51].

Filter Retrieval

The successful removal of retrievable filters requires diligent patient follow-up and interdepartmental cooperation, and even so, successful removal is not always possible [62,63]. The many unanswered questions and further study directions regarding retrievable filters are delineated by Sing et al [64], including timing of removal, management of trapped thrombus at the time of removal, effectiveness in reducing PE, and whether filter removal prevents caval thrombosis. Vigilance on the part of the implanting physician is needed to work with referring physicians to improve rates of patient follow-up for retrieval of the filters when indicated. Multiple studies are published that highlight the poor retrieval rates of IVC Filters, despite good follow-up for some populations such as military patients [65]. Additional studies that focus on algorithms to improve retrieval rates have been published, including Minocha et al [66] who demonstrated that a dedicated IVCF clinic resulted in improving retrieval rates from 29% preclinic to 60% postclinic. Similar significantly improved retrieval rates are reported by Ko et al [67] who report an improvement from 42% to 95% retrieval of the eligible patients following implementation of a retrieval algorithm, with the help of the trauma service in their institution.

Retrieval procedures has also evolved over the course of the last 10 years, including the use of multiple new snares from various companies, and more aggressive techniques such as the use of lasers for embedded filters [68].

Summary

- VTE remains an important cause of patient morbidity and mortality. The primary therapy for VTE is pharmacological. In clinical situations where patients with VTE cannot be treated with anticoagulation, IVC filters remain a safe and effective method to prevent fatal PE.
- The clinical application of IVC filters has greatly expanded in the past 20 years. Despite this fact, the limited number of prospective randomized trials of IVC filter patient populations is recognized as a problem when making recommendations about the clinical use of IVC filters. Patients with absolute indications, such as those with VTE and contraindication or complication of anticoagulation, have the highest consensus use for IVC filters. Patients with relative indications for IVC filter insertion may have lower consensus ratings, while prophylactic use of filters such as in trauma populations is still a debated and controversial subject with wide clinical practice variation. The multidisciplinary consensus statement published in the Journal of Vascular and Interventional Radiology in 2009 and other meta-analysis studies highlight the need for funding and research in use of prophylactic filters in trauma patients [51,69].
- For the present, the indications for use of permanent and retrievable IVC filters remain unchanged. Future studies may identify subpopulations of patients with specific clinical indications that may warrant the use of retrievable IVC filters. The present use of retrievable filters is limited in many instances by the small number of filters that are actually removed. Institution-implemented algorithms and more focused attention on IVC filter retrieval such as dedicated clinics have been shown to improve retrieval rates. In view of the recent articles demonstrating higher filter fracture rates than previously realized, other filter complications, and the most recent FDA warning on filters, it is imperative to focus resources on improving retrieval rates.
- Symptomatic chronic PE patients should be treated with pharmacological methods and IVC filtration and referred to specialized centers to determine whether pulmonary thromboendarterectomy is appropriate for them.

- SVC filter use continues to increase but is currently considered off-label use as no current-generation IVC filters are specifically designed or approved for this location.
- While IVC filter complication rates are low, severe complications do occasionally occur. Future research should better define the risk/benefit ratio of IVC filtration for various patient populations.

Supporting Documents

- ACR Appropriateness Criteria® Overview
- Evidence Table

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