Guidelines for the Use of Optional (Retrievable and Convertible) Vena Cava Filters

A summary of the SIR multidisciplinary consensus statement.

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In 2003 and 2004, the FDA approved changes to the instructions for use (IFU) of three existing permanent filters to allow percutaneous retrieval. A convertible filter may become available in the near future. Although non-permanent filters were available outside of the US for many years prior to 2003, and the use of these devices is increasing globally, clearly defined indications for the placement and removal of these devices have never been elucidated. To address this deficit, the Society of Interventional Radiology (SIR) convened a multidisciplinary conference on January 14 and 15, 2005. Representatives from interventional radiology, trauma surgery, vascular surgery, and internal medicine participated.* The goal of the consensus conference was to develop a document that would provide guidelines for all physicians who use optional vena cava filters. The discussion focused on optional filters (retrievable or convertible) as a general class of devices, rather than individual filters. The consensus panel defined the indications for placement of optional filters, recommended follow-up while filters are in place, the evaluation of patients before discontinuation of filtration, and management of patients after the procedure. The completed document was published in March 2006 in the *Journal of Vascular and Interventional Radiology* with the endorsement by the SIR and the American Venous Forum.[1]

WHY OPTIONAL FILTERS?

Anticoagulant medications are the current first-line treatment and prevention of venous thromboembolism (VTE).[2] In general, when a patient is considered to be at high risk of pulmonary embolism (PE) and anticoagulants are contraindicated or have failed, a filter is placed. Vena cava filters have only one function: to prevent PE. Filters are not a treatment for established PE or deep vein thrombosis (DVT), nor do they prevent the development of VTE. Permanent vena cava filters are strongly believed by some physicians to increase the long-term risk of DVT without influencing overall mortality from VTE.[3,4] Permanent filters are considered of questionable value and possibly detrimental by many physicians who manage patients with VTE.[2,5,6]

The risk factors for VTE are diverse. Certain risk factors, such as trauma or surgery, are transient, whereas others, such as inherited hypercoaguable states, are life-long.[7] Similarly, contraindications to anticoagulation in patients with or at risk of VTE may be temporary in some patients. It seems reasonable that patients who are transiently at high risk for clinically significant PE, and who have transient contraindications to anticoagulation, do not necessarily need permanent vena cava filters. Although data are lacking to prove a clinical benefit of filter removal after the risk of PE and/or anticoagulation has passed, the use of optional devices is driven by concern over complications of permanent filters.[8]

INDICATIONS FOR OPTIONAL FILTERS

All optional filters are approved for permanent placement, and can be used as such. Optional and permanent fil-

TABLE 1. INDICATIONS FOR ALL VENA CAVA FILTERS

Absolute Indications (Proven VTE)

- Recurrent VTE (acute or chronic) despite adequate AC
- Contraindication to AC
- Complication of AC
- Inability to achieve/maintain therapeutic AC

Relative Indications (Proven VTE)

- Iliocaval DVT
- Large, free-floating proximal DVT
- Difficulty establishing therapeutic AC
- Massive PE treated with thrombolysis/thrombectomy
- Chronic PE treated with pulmonary artery thromboendarterectomy
- Thrombolysis for iliocaval DVT
- VTE with limited cardiopulmonary reserve
- Recurrent PE with filter in place
- Poor compliance with AC medications
- High risk of complication of AC (such as ataxia, frequent falls)

Prophylactic Indications (No VTE, primary prophylaxis not feasible*)

- Trauma patient with a high risk of VTE
- Surgical procedure in patient at a high risk of VTE
- Medical condition with high risk of VTE

AC, anticoagulation.

**Primary prophylaxis not feasible due to high bleeding risk, inability to monitor the patient for VTE, etc.*

ters, as classes of devices, have similar efficacy and safety profiles.[9] Furthermore, any optional filter may become permanent due to unpredictable reasons, such as a change in the patient's clinical status, loss of patient to follow-up, or inability to technically retrieve or convert the device. In other words, no optional filter can be placed with an absolute guarantee of removal or conversion. In this context, the existing indications for permanent filters are wholly applicable to optional filters (Table 1). There are no patient populations for whom permanent filters are absolutely contraindicated and optional filters are indicated. How then to decide when to use an optional filter?

The easy answer is that every filter placed should be optional. With this approach, no prospective consideration regarding future patient management is necessary. This strategy may not be economically acceptable because some permanent filters are significantly less expensive than optional devices. More importantly, this approach delays or defers management decisions regarding treatment or prophylaxis of VTE, possibly leading to missed opportunities for filter retrieval or conversion.

The decision to use an optional device should be made after the patient has demonstrated a genuine indication for a filter. Once the need for a filter is established, consideration of a patient's long-term risks for VTE and complications of anticoagulation, ability to comply with medications and medical care, and life expectancy will determine which type of filter is most appropriate. The consensus panel recommends that patients with short-term risk of VTE and/or PE, short-term contraindication to anticoagulants, a life expectancy greater than 6 months, and the ability to comply with medications and follow-up requirements should be considered for optional filters (Table 2). The life-expectancy recommendation was arrived at by consensus and is intended to ensure that patients live long enough to realize a benefit from filter removal or conversion. When uncertainty exists about one of these criteria, placement of an optional filter and re-evaluation within 2 weeks is recommended.

MANAGEMENT OF PATIENTS WITH FILTERS IN PLACE

Patients with optional vena cava filters require tracking and routine follow-up. The "window of retrievability" varies for each device; patient conditions may change such that discontinuation of the filter is no longer desired or safe, and physicians may require guidance on timing of the procedure. The panel recommends that the physician placing the filter perform the follow-up.

Patients with VTE should be managed with primary (anticoagulant) therapy at the first safe opportunity, regardless of the presence of a vena cava filter. This concept is essential because the filter will not impact existing VTE or prevent recurrent disease. There are several published guidelines for treatment of VTE.[2,10-12]

Patients with filters placed for prophylactic indications should be assessed frequently for suitability for initiation of medical prophylaxis because the filter will not prevent development of DVT.[6,13] This assessment should be made by the patient-care team on a daily basis with the goal to institute appropriate anticoagulant and mechanical VTE prophylaxis. In the event that the patient with a filter placed for prophylactic indications develops VTE, appropriate primary therapy should be initiated as soon as it is safe to do so.

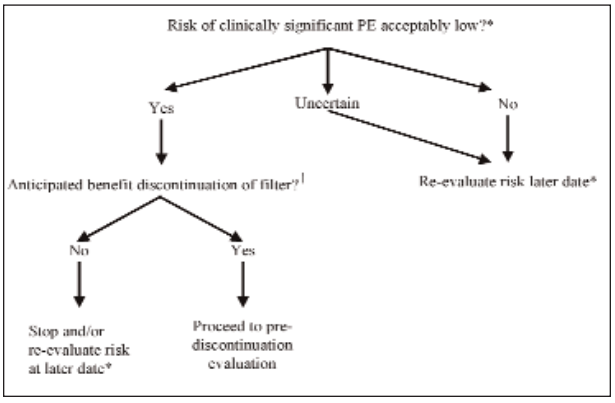

Figure 1. Patient selection for discontinuation of filtration. *Risk of PE determined by the patient's current venous thromboembolic disease status, underlying conditions, and tolerance of primary therapy or prophylaxis. †Requires consideration of life expectancy and need for caval filtration in the near future. Reprinted with permission from Kaufman J, Kinney T, Streiff M, et al. Guidelines for the use of retrievable and convertible vena cava filters: report from the society of interventional radiology multidisciplinary consensus conference. J Vasc Interv Radiol. 2006;17:449-459.

PATIENT SELECTION AND EVALUATION FOR FILTER REMOVAL OR CONVERSION

The decision to discontinue filtration by either retrieval or conversion of a functioning filter is the most important part of management of a patient with an optional device (Figure 1). The bulk of the consensus panel's discussions centered on this issue. The fundamental clinical criterion for discontinuation of caval filtration is when the risk of clinically significant PE is acceptably low. Usually, this will be when the patient is satisfactorily managed with anticoagulant therapy, or has passed the period of risk for VTE (Table 3). In these cases, the presumed risks of leaving the filter in place must be weighed against the estimated future risk of recurrent PE. The panel concluded that, due to the inadequacy of published data on filters and the complexity of real clinical situations, the decision to discontinue filtration must be individualized in each case.

The panel recommends that the following conditions be met by all patients prior to discontinuation of caval filtration: (1) The patient does not have an indication for a permanent filter. This requires a careful assessment of the patient's clinical status and original indication for the filter, ongoing risk factors for VTE, ability to comply with medications, and the ability to comply with follow-up care (Figure 2). (2) The risk of clinically significant PE is acceptably low due to achievement of sustained appropriate primary treatment (therapy or prophylaxis), or change in clinical status. Patients should have demonstrated ability to tolerate and sustain primary treatment prior to discontinuation of filtration. (3) The patient is not anticipated to return to a high-risk state for PE, such as interruption of anticoagulant treatment for surgery, change in clinical management, or change in clinical condition. (4) The life expectancy of the patient is long enough that the potential benefits of discontinuation of filtration can be realized. The consensus of the panel was that patients who are not anticipated to survive beyond 6 months are unlikely to have any discernible benefit from filter retrieval or conversion. (5) The filter can be safely retrieved or converted. Filters that, in the judgment of the physician performing the discontinuation procedure, cannot be safely retrieved or converted without causing unacceptable injury to the vena cava should not be manipulated. (6) The patient or consenting guardian agrees to have filter removed or converted. Patients who desire to continue caval filtration permanently should be allowed to so.

Patients who have filters and established VTE should be treated with anticoagulant therapy for several weeks prior to discontinuing the filtration. Symptomatic PE is most likely to occur within the 2 to 3 weeks after initiation of therapy for an acute episode of VTE.[14-16] In addition, patients with established VTE should not have clinical or objective evidence of failure or a complication of primary therapy prior to filter retrieval. In the absence of clinical evidence to suggest recurrent or progressive VTE on anticoagulation, venous or pulmonary imaging is not

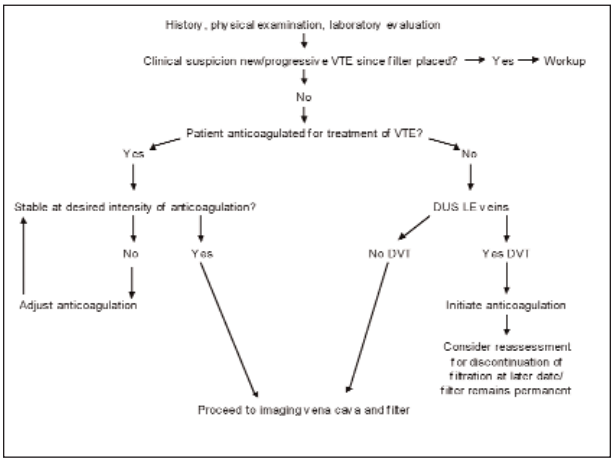

Figure 2. Patient evaluation prior to discontinuation of filtration. DUS, duplex ultrasound; DVT, deep vein thrombosis. Reprinted with permission from Kaufman J, Kinney T, Streiff M, et al. Guidelines for the use of retrievable and convertible vena cava filters: report from the society of interventional radiology multidisciplinary consensus conference. J Vasc Interv Radiol. 2006;17:449-459.

TABLE 2. WHEN TO USE AN OPTIONAL FILTER

A vena cava filter is indicated and:

1. The risk of clinically significant PE is transient
2. The contraindication to anticoagulant medications is transient
3. The risk of recurrent VTE is low
4. Life expectancy of at least 6 months

necessary in patients who have been therapeutically anticoagulated.

Patients who had a filter placed for prophylactic indications should not have clinical or objective evidence of interval development of VTE prior to discontinuation of filtration. The panel recommends that these patients undergo bilateral lower-extremity venous ultrasound to exclude DVT in these patients (Figure 2). A patient who develops VTE while a prophylactic filter is in place should be managed with primary therapy for VTE.

Evaluation prior to filter retrieval/conversion should be aimed at a determination of the patient's risk of clinically significant PE and the retrieval or conversion procedure. A focused history and physical examination should assess for signs of new, progressive, or recurrent VTE. Patients with new findings suspicious for VTE should undergo diagnostic imaging before proceeding. Routine coagulation measurements and complete blood counts are appropriate for patients receiving therapeutic anticoagulation. Renal function tests should be considered in patients at risk for contrast-induced nephropathy.

MANAGING THROMBUS DISCOVERED IN THE FILTER DURING RETRIEVAL OR CONVERSION

Imaging of the filter and the vena cava can be performed at the time of the discontinuation procedure with catheter-based techniques or within the preceding 24 hours with contrast-enhanced CT, MR venography, or ultrasonography. In patients with known VTE, identification of thrombus in the filter requires an assessment of the risk of clinically significant PE during filter discontinuation or later (Figure 3). An individualized decision

by the physician will be required in each case. For example, substantial filling defects within the filter presents an immediate embolic risk during filter retrieval or conversion, and may indicate active VTE. Conversely, subcentimeter filling defects adherent to filter components pose little risk of PE during filter retrieval or conversion and imply resolving VTE. In some cases, the patient with a thrombus found in a filter can return after a period of weeks for repeat imaging and reconsideration of discontinuation of filtration. The panel generally does not recommend thrombolysis of trapped thrombus immediately prior to filter removal because large amounts of trapped thrombus may indicate an uncontrolled embolic diathesis, which must be addressed.

When a trapped thrombus is discovered in a filter of a patient who previously did not have a diagnosis of VTE, a new diagnosis of VTE must be made. The procedure should be terminated and appropriate primary therapy should be instituted (unless contraindicated). Reassessment for discontinuation of filtration can be considered at a later date.

AFTER FILTER REMOVAL OR CONVERSION

Patients should be managed according to their VTE status after retrieval or conversion of a filter.[2,6,10,12,17-21] There are no specific additional therapies required after removing a vena cava filter. Patients with a diagnosis of VTE should be treated for the full duration suggested in published practice guidelines or according to local standards of care.[2] Patients without VTE but who are still at risk should undergo prophylaxis using standard techniques.[6] After discontinuation of filtration, patients should be monitored for new, recurrent, or progressive DVT and/or PE, and, if diagnosed, managed accordingly.

TABLE 3. WHEN TO DISCONTINUE AN OPTIONAL FILTER

1. Patient is at low risk of clinically significant PE
   a. Patient with VTE
      i. Therapeutic anticoagulation for at least 2 to 3 weeks
      ii. No clinical evidence of recurrent or progressive VTE
   b. Patient without VTE
      i. Prophylactic anticoagulant therapy or risk factors for VTE resolved
      ii. Normal bilateral lower-extremity venous duplex ultrasound
2. Patient is compliant with medications and follow-up care
3. Life expectancy >6 months
4. Return to a high-risk VTE status unlikely
5. Patient desires filter removal or conversion

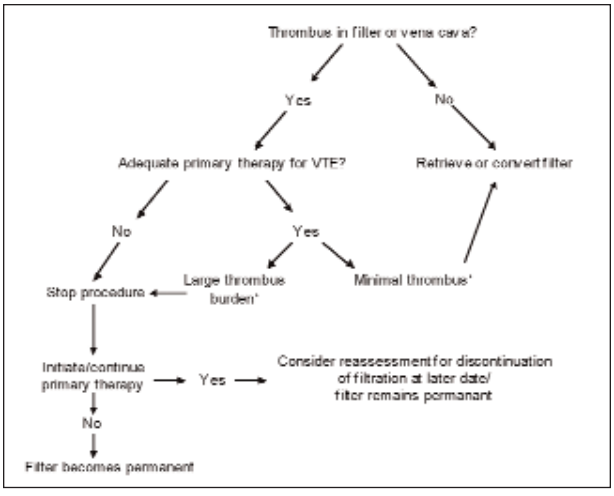

Figure 3. Management of thrombus found in the filter before or during discontinuation procedure. *The determination of the volume and age of thrombus present in a filter is made by the physician performing the retrieval or conversion procedure, as is the clinical significance of this thrombus. Whenever uncertain about the volume, age, or clinical significance of thrombus in the filter, the filter should remain in place. Reprinted with permission from Kaufman J, Kinney T, Streiff M, et al. Guidelines for the use of retrievable and convertible vena cava filters: report from the society of interventional radiology multidisciplinary consensus conference. J Vasc Interv Radiol. 2006;17:449-459.

CONCLUSION

When permanent filters were the only devices available, the decision to place a filter was focused on the immediate risks of PE and anticoagulation. The availability of optional vena cava filters requires continuing attention to these risks after the filter has been placed. The goal of managing patients with vena cava filters should be to resume anticoagulants (therapeutic or prophylactic as indicated clinically) as soon as possible. Once the risk of PE is acceptably low by virtue of medical therapy, medical prophylaxis, or a change in the patient's clinical status, discontinuation of filtration may be considered. Physicians placing optional filters should take an active and informed role in the management of patients with these devices. ■

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