Indications for and Management of Inferior Vena Cava Filters

ABSTRACT

Inferior vena cava (IVC) filters are devices implanted in patients at risk for life-threatening pulmonary embolism (PE) who cannot tolerate anticoagulation therapy or for whom the anticoagulation therapy is ineffective. The filters are implanted either permanently (i.e., permanent filter) or with the intent to remove them (i.e., retrievable filters) when the risk of PE has passed or when anticoagulation therapy can be initiated. In 2010, the U.S. Food and Drug Administration (FDA) issued a device safety alert regarding retrievable IVC filters that described several types of adverse events involving filters, some with serious patient outcomes, and suggested that these events may be related to retrievable filters being left in patients longer than clinically necessary. Between June 2004 and November 2010, the Pennsylvania Patient Safety Authority received 35 reports describing adverse events related to implanted IVC filters. FDA and other literature on IVC filters suggest that managing patients with filters, especially continued follow-up visits after filter implantation or removal, is an important part of the process in reducing complications from filters. Careful consideration of the indications for placing IVC filters, the indications for removing filters, as well as follow-up care and evaluation of patients with retrievable filters, can all help reduce the likelihood of complications following filter implantation. (Pa Patient Saf Advis 2011 Mar;8[1]:8-11.)

Deep vein thrombosis (DVT)—a blood clot formed in a vein, most often the femoral or pelvic veins, can result in significant life-threatening consequences if it travels to the lungs, a condition referred to as pulmonary embolism (PE). Pharmacologic therapy—low molecular weight heparin/heparin for short-term anticoagulation and warfarin for long-term anticoagulation—is typically the primary treatment for patients with or at risk for DVT; however, patients with a contraindication to anticoagulation therapy (e.g., major trauma, pregnancy) or in which the therapy is ineffective may be candidates for inferior vena cava (IVC) filters.

IVC filters are implanted into the vena cava to trap blood clots, preventing or reducing the likelihood of a PE (IVC filters do not prevent or treat the formation of blood clots). IVC filters are typically collapsible cone-shaped arrays of six struts (wires) of stainless steel, titanium, or nickel-titanium (nitinol), with hooks (barbs) on the wire ends to secure the filter to the vena cava wall. Other filter shapes are also used–for example, the bird's nest IVC filter, which is a random array of wires extending in various directions; the shape is reminiscent of a bird's nest. There are basically two types of IVC filters, permanent and optional, commonly referred to as retrievable. Permanent filters are designed to remain in the patient without the ability to be removed. Permanent filter design should permit significant fixation to the vena cava wall to prevent migration over the patient's life. Optional (retrievable) filters are designed to remain permanently in the patient or to be removed when it is no longer warranted, such as when the risk of PE has subsided or when the patient no longer has a contraindication to anticoagulation therapy. Retrievable filters should also achieve fixation to the vena cava wall, but their structure must have the ability to be altered (e.g., collapsible) at the time of removal with catheter-based retrieval devices to facilitate safe removal. Often, retrievable filters become permanent filters due to changes in a patient's clinical status, loss of a patient to follow-up, or the inability to technically retrieve the filter.[1] However, in practice, many physicians decide to use retrievable filters rather than permanent filters.[2] From 1979 through 1999, the number of implanted IVC filters rose from 2,000 to 49,000. In 2007, 167,000 filters were implanted, with a projection of approximately 259,000 filters being implanted in patients in 2012.[3] This growth may be linked to the introduction of retrievable filters.[3]

In August 2010, the U.S. Food and Drug Administration (FDA) issued a medical device safety alert regarding retrievable IVC filters describing filter-related adverse events and recommendations on reducing complications related to their use.[4] Based on the FDA alert, Pennsylvania Patient Safety Authority analysts reviewed IVC filter-related reports submitted to the Authority correlating the adverse event types with FDA data. This discussion focuses on some of the indications for implanting IVC filters, some of the complications associated with implanted filters, and some suggestions on patient management. The focus is on retrievable filters more than permanent filters; however, the principles described can apply to both filter types.

FDA ISSUES SAFETY ALERT FOR IVC FILTERS

Since 2005, FDA received 921 adverse event reports involving IVC filters, some of which led to adverse patient outcomes. According to FDA, of the 921 reports, 328 involved filter migration, 146 involved embolization, 70 involved perforation of the IVC, and 56 involved filter fracture[4] (see "IVC Filter Adverse Event Types Defined"). FDA's alert does not specify whether the 921 reported events are specific to retrievable filters only or retrievable and permanent filters, nor does it indicate event types for the remaining 321 reports. In the alert, FDA suggested that these events may be linked to retrievable IVC filters being left in patients after the risk for PE abates, which may increase the chance

IVC FILTER ADVERSE EVENT TYPES DEFINED

The general-consensus definitions for the inferior vena cava (IVC) filter adverse event types referenced in the U.S. Food and Drug Administration's retrievable IVC filter medical device safety alert[1] are as follows:

Filter migration. The entire IVC filter breaks free from the vena cava wall and travels to another part of the body (e.g., lungs, heart).

Filter embolization. A part of the filter (e.g., strut) breaks free from the filter and travels to another part of the body (e.g., lungs, heart).

IVC wall perforation. A part of the filter (e.g., strut, hook) pierces through the vena cava wall.

Filter fracture. A part of the filter (e.g., strut) breaks free from the filter but does not travel through the body.

NOTE

1. U.S. Food and Drug Administration. Removing retrievable inferior vena cava filters: initial communication [online]. 2010 Aug 9 [cited 2010 Nov 1]. Available from Internet: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm221676.htm.

of complication associated with long-term implantation of retrievable filters.[4] FDA recommends that physicians who implant them and clinicians who are responsible for ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed.[4] Additionally, FDA recommends that all physicians involved in the treatment and follow-up care of IVC filter patients consider the risks and benefits of removing filters on an individualized patient basis and remove the filter when clinically feasible.[4]

AUTHORITY DATA

From June 2004 through November 2010, the Authority received 35 reports describing adverse events related to implanted IVC filters (Not all the reports submitted to the Authority indicated the type of filter used: permanent or retrievable) during the events. Analogous to the FDA event types, of the 35 reports to the Authority (see the event breakdown by category in the chart in the Figure), 12 involved filter migration, 2 involved embolization, 4 involved perforation of the vena cava, and 1 involved filter fracture. However, reports to the Authority also included 10 reports of filter deployment problems and 3 reports of filters dislodging from the vena cava wall after implantation. Several reports to the Authority discussed filters implanted upside-down, filters implanted in the incorrect location, and unsuccessful attempts (several surgeries) to remove the filter.

Of the 35 reports, 24 were classified by reporting facilities as unsafe conditions or no harm, 8 reports were classified as causing patient harm, and 3 were classified as causing patient death. In the three deaths, two involved the filter migrating to the patient's right atrium of the heart and one involved the filter dislodging (the filter tilted), allowing clots to reach the patient's lung.

The Authority and FDA adverse event IVC filter data appear to corroborate much of the literature discussion on the complications associated with the use of IVC filters and suggest the need for better understanding of the complications and management of filter use. None of the analyzed data suggested that the clinical need for placing the filters was in question; however, the indications for placing IVC filters must also be understood.

INDICATIONS FOR PLACING IVC FILTERS

The availability of retrievable IVC filters has led to a change in clinical practice of the indications for filter implantation.[1] Retrievable filters cannot be implanted with the assumption that they will always be removed.[1] As such, the indications to implant a permanent filter are applicable to a retrievable filter. The decision to use a retrievable filter rather than a permanent filter is based on the anticipated length of time that protection against a clinically significant PE is warranted and/or based on the risks associated with the use of anticoagulation therapy. For example, one decision algorithm might consist of the following:[5]

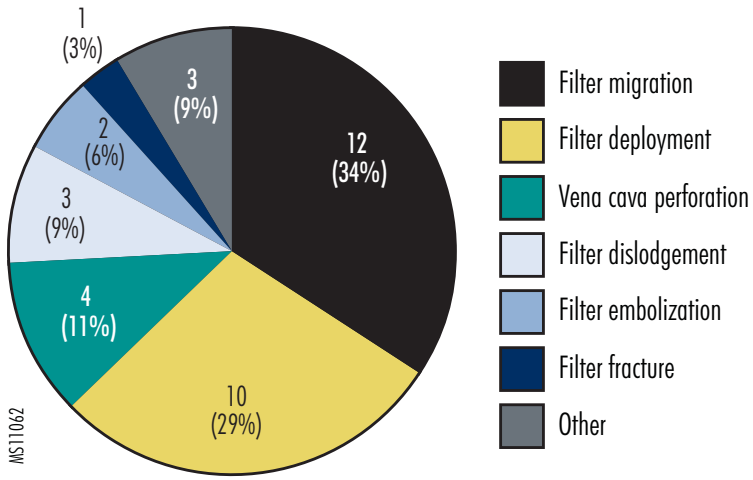
- Short-term risk of PE and/or a short-term contraindication to anticoagulation therapy: retrievable filter
- Uncertain risk of PE and/or contraindication to anticoagulation therapy: retrievable or permanent filter
- Long-term risk of PE: permanent filter

Long-term risk factors to consider with regard to retrievable filters include patient life expectancy of more than six months following implantation (long enough to realize any benefits of a filter removal procedure) and the patient's ability to comply with medications and follow-up physician visits.[5]

The indications for placing all IVC filters can be categorized as follows[1] (not intended to be comprehensive):

- Absolute indications
  - ☐ Proven venous thromboembolism (VTE) and contraindication or complication to anticoagulation therapy
  - ☐ Recurrent VTE despite adequate anticoagulation therapy

Figure. Pennsylvania Patient Safety Authority Inferior Vena Cava Filter Reports, June 2004 through November 2010



— Relative indications
  - ☐ Proven VTE and contraindication or complication to anticoagulation therapy
  - ☐ Large, free-floating proximal DVT
  - ☐ Poor compliance with anticoagulation therapy
  - ☐ Thrombolysis for iliocaval DVT
— Prophylactic indications
  - ☐ No VTE, but anticoagulation therapy is not possible (e.g., high risk of bleeding)
  - ☐ Transient risk of VTE (e.g., trauma, surgical procedure, medical condition)

Implanting filters for prophylactic indications is a controversial and varied practice. It is difficult to identify the risk of VTE with subsequent PE in patients without previously documented VTE.[2]

Bariatric patients undergoing surgery are at a significant risk of developing DVT[6] and PE after hospital discharge. The indications for placing IVC filters in patients undergoing bariatric surgery vary slightly from the general indications above and include the following:[6]

— BMI greater than 55
— Previous history of DVT/PE
— Hypercoagulable state (increased risk of blood clot)
— Chronic venous insufficiency
— Truncal obesity
— Contraindication to anticoagulation therapy

INDICATIONS FOR REMOVING RETRIEVABLE IVC FILTERS

The fundamental reason to remove a retrievable IVC filter is that the patient has an acceptably low risk of PE. Typically, a physician would remove a retrievable filter when the patient is responding well to anticoagulation therapy or when the transient risk of PE has passed.[5] However, before removing the filter, the physician would consider the risk of future PE compared to the risk of leaving the filter in place.[5] When patients with filters no longer require treatment for VTE, but life-long anticoagulation therapy is prescribed only because a filter is in place, removal may be considered.[5] Long-term use of anticoagulation therapy to prevent recurrent DVT for patients with IVC filters can be associated with complications (e.g., hemorrhage).[5]

Currently, there is little published data confirming the benefit of removing IVC filters.[5] In response to the lack of data, in January 2005, the Society of Interventional Radiology (SIR) established a multidisciplinary panel that developed the following patient conditions to be met before considering retrieving filters:[5]

— No current indication for implanting a permanent filter
— Acceptably low risk of clinically significant PE because of continued anticoagulation therapy or change in clinical status
— No expected near-term, recurrent high risk of PE (e.g., stopping anticoagulation therapy for a planned surgery)
— Life expectancy of more than six months following implantation to appreciate the potential benefits of filter retrieval
— Ability to retrieve the filter without causing unacceptable patient injury
— Patient or consenting guardian agrees to filter removal

If filter removal is warranted, patients with concurrent VTE are to receive anticoagulation therapy for several weeks before the removal procedure.[1] This practice is warranted because symptomatic PE can occur within two to three weeks of therapy after an acute VTE episode.[1]

While the number of retrievable filters implanted may be increasing, some of the literature suggests that the number of retrievable filters actually removed may be low. In a study of 446 patients receiving retrievable IVC filters (Karmy-Jones et al.) only 90 filters were retrieved.[7] According to the study authors, the main reason retrievable filters were not removed was because many patients were lost to follow-up physician visits. Two main reasons for failure to follow-up with patients were that the implanting facility was not directly responsible to follow-up and patients failed to follow-up despite notification.[7] Other reasons retrievable filters were not removed included risk of DVT, residual DVT and the inability to receive anticoagulation therapy, multiple other recent surgical procedures, and patient refusal.[7] Some of the retrieval attempts failed due

to technical issues during removal or significant thrombus trapped within filters.[7] When a thrombus is encountered in a filter, the decision to retrieve the filter may require reevaluation. During the procedure to remove a filter, imaging (e.g., contrast-enhanced computed tomography, ultrasonography) of the filter and vena cava can be performed to determine whether a thrombus is trapped within the filter. In patients with proven VTE, a thrombus found in a filter necessitates evaluation of the risk of subsequent PE after the filter is removed.[1] A large thrombus within the filter can become a significant embolization risk during filter removal but may be telling of a poorly treated VTE.[1] However, a small thrombus in the filter may present less of a risk of PE during removal and may indicate a previous and resolving embolus.[1] When thrombi are found within filters of patients without known VTE, a new diagnosis of VTE must be made, the retrieval procedure stopped, and anticoagulation therapy begun, if no contraindications are present. After several weeks of anticoagulation therapy has been administered, the patient is to be reevaluated for filter removal.[1]

MANAGEMENT OF PATIENTS WITH RETRIEVABLE IVC FILTERS

As Karmy-Jones et al. demonstrate, one reason many retrievable filters may not be removed is because patients are lost to follow-up often due to the implanting facility's lack of established follow-up protocols or patients failing to return for follow-up physician visits (follow-up visits are not typically the norm for patients with implanted permanent filters).[7] During its guideline development, the SIR panel suggested that responsibility for follow-up patient care lies with the physicians implanting the filters.[8]

Patients with retrievable filters are to be periodically evaluated to determine whether filter removal is warranted.[8] The decision whether to remove the filter involves assessing the risk of the patient experiencing a fatal PE as well as the risk of long-term filter complications;[8] two main assessment criteria are that the risk of clinically significant PE is acceptably low and that the filter can be safely removed.[9] Safe removal of a retrievable filter will depend on the clinical status of the patient and on the filter's time period of retrievability;[5] dwell times (e.g., up to 23 days) for retrievable filters may vary per filter brand.

Patient management is to be continued after the filter removal procedure. After the retrieval procedure, imaging of the vena cava may be prudent to determine evidence of trauma or thrombus, especially following difficult or lengthy procedures or with reports of pain from patients after the procedure.[5] The physician performing the procedure should examine the filter (directly or through imaging) for signs of filter irregularities (e.g., missing strut). If the filter is missing a component, the physician should examine the retrieval catheter and image the patient to locate and document the position of the component.[5] No accepted guidelines exist for treating patients with retained filter components; however, cardiac consultation should be considered for filter fragments within the heart.[5] Patients with VTE after filter removal should be treated with anticoagulation therapy based on local standards of care or best practice guidelines. Patients without VTE after filter removal should receive prophylaxis treatment based on any underlying patient conditions.[5] All patients regardless of whether their filter has been removed should be tracked for new or recurrent DVT and/or PE and, if present, managed accordingly.[5]

CONCLUSIONS

FDA and other literature on IVC filters suggest that managing patients with filters, especially continued follow-up visits after filter implantation or removal, is an important part of the process in reducing complications from filters. Careful consideration of the indications for placing IVC filters, the indications for removing filters, as well as follow-up care and evaluation of patients with retrievable filters, can all help reduce the likelihood of complications following filter implantation.

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