

IVC Filter Use: What's Next?

Matthew Johnson, MD, FSIR, discusses the current issues surrounding IVC filter use and retrieval.



How would you summarize the nature and scope of the issues currently surrounding the use of inferior vena cava (IVC) filters?

Hundreds of thousands of people in the United States suffer from venous thromboembolic disease (VTE) each year. The majority of these patients are treated appropriately with anticoagulation. However, many cannot be anticoagulated because of a contraindication to, or failure or complication of, that therapy. Since the late 1960s, when the Mobin-Uddin and original Greenfield filters were first introduced, many of those patients have been treated with IVC filters. It was recognized (eg, the 1998 study by Decousus et al^{1,2}) that there was an increased rate of lower extremity deep venous thrombosis (DVT) in patients with permanent IVC filters. The potential to reduce the risk for DVT and other less frequent complications, such as IVC thrombosis, provided the rationale for the development of retrievable IVC filters.

Theoretically, removing the filter decreases its risk to the patient. The first of those potentially retrievable filters was cleared by the US Food and Drug Administration (FDA) in 2002. Although all of the IVC filters that are available today in the United States were approved by the FDA for permanent placement, the majority are potentially retrievable. That potential and its concomitant promise of increased safety has likely contributed to the increase in IVC filter usage of the last several years: More than 200,000 IVC filters were placed in the United States in 2010. However, many of those filters were placed in patients without VTE; rather, they were placed prophylactically (eg, before bariatric or spinal surgery) or in those who have suffered trauma and were thus considered to be at risk for VTE. Concomitant to that increased use of IVC filters—off-label use because those patients do not have VTE—there has been an increase in the number of recognized IVC filter-related complications, such as filter migration, perforation, fracture, or IVC thrombosis.

When and how did these issues first come to light?

It has been recognized since the introduction of retrievable filters that design modifications that were necessary to allow filter retrievability might lead to complications that are not seen, or are less frequently seen, with permanent filters. The extent of those complications and whether they are more common with permanent or retrievable IVC filters, or perhaps with one or a few of the retrievable filters, is not known. That possibility led the FDA to publish an advisory letter to physicians in August 2010, recommending removal of retrievable filters as soon as possible after the risk of pulmonary embolus has abated.

Is a postmarket study or registry of some kind necessary to answer the questions about optimal applications, follow-up, and retrieval protocols?

Yes. The current level of data regarding IVC filter usage—safety and efficacy, device-specific complication rates, even why and when physicians are implanting filters—is poor. As a result of the Society of Interventional Radiology's (SIR's) response to the FDA's advisory letter and multiple discussions that followed that response, a multispecialty task force (comprised predominantly of physicians and staff from SIR and the Society for Vascular Surgery, as well as representatives from the FDA) was formed to provide answers to questions about filter use. David Gillespie, MD, a member of the Society for Vascular Surgery, and I are co-chairs of the task force. More details about this IVC filter project will be released soon.

What are some of the difficulties inherent in designing and implementing such a study?

Optimally, we would perform a prospective, randomized controlled trial that is designed to answer a specific question, such as "What is the rate of pulmonary embolus after filter placement?" However, filters are the last line of defense for patients who cannot be anticoagulated. Would it be appropriate to have a control group comprised of patients with DVT or pulmonary embolism

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who cannot be anticoagulated? Most clinicians in the United States would have a difficult time merely observing those patients.

Conversely, were we to choose to study only prophylactic filter use, given the very low rate of pulmonary embolism in that population, the numbers of subjects involved and the time that would be required to perform the study would preclude it. Further, such a study would answer only one or two questions about a single filter type. Additionally, if the study was able to answer those questions about a single filter type, it would only be able to answer them in one particular setting, such as prophylactic filter use in trauma patients. We need a study that can answer questions about all of the available filters within a reasonable period of time.

The completion and analysis of any such prospective study would not take place for some time. Is there an interim plan for any guidance to be issued to physicians or industry regarding the use and monitoring of IVC filters?

The SIR published guidelines for filter usage in 2003 and is currently working on an updated revision of those guidelines. Implanting physicians should be aware of the guidelines and adhere to them. Additionally, it is very important that physicians implanting IVC filters, especially retrievable filters, follow the patients in whom those filters are placed. Devoted follow-up would increase awareness of complications, as well as assist in removing filters when they are no longer clinically necessary, if such removal is deemed appropriate.

Moving away from the task force and into your own practice, what is your protocol for selecting between permanent and retrievable filters? What is your follow-up and retrieval protocol?

All of the filters that are cleared by the FDA for retrieval are also cleared for permanent placement. We predominantly use the same retrievable filter in all patients. I was involved in the design and evaluation of that filter and am thus familiar with its safety and efficacy. If we believe that there is a chance that the filter might be removed, we discuss that potential with the referring physician, as well as with the patient and his or her family, and make an interventional radiology clinic

follow-up appointment at what we believe to be an appropriate interval, usually between 1 and 3 months, depending on indication and clinical scenario.

Has your decision-making process when placing a filter changed at all in recent months or years? Has your follow-up protocol?

My decision-making process has not changed; I evaluate the indication for filter placement at the time of its request, and if it is not clear, I discuss it with the referring physician. If there is not a clear indication, I do not place the filter. Although that may seem problematic, it has not been; patients seem to appreciate the consideration. To that end, we have placed very few prophylactic filters at our center—only occasionally before bariatric or spinal surgery in patients with a history of VTD or a greatly increased risk of VTD (eg, a very high body mass index)—and then only after a discussion with the patient in which I note that the filter may end up being permanent. My follow-up protocol has changed by becoming more standardized, as I previously described.

With the understanding that the task force's work has essentially just begun, do you personally have any guidance to offer vascular practitioners regarding the placement, monitoring, and retrieval of IVC filters?

I think that there are several important things to consider: Is the indication for filter placement appropriate? Do you have a plan for retrieval, or is the device intended to be permanent? Do you know, to the best extent possible, the risks and benefits of the device that you are implanting? Are you using what you believe to be the best device available? If you are asking yourself these questions and following your patients after you place the filters and removing them if/when appropriate, I think that you are doing the best you can for your patients. ■

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