Permanent versus Retrievable Inferior Vena Cava Filters: Rethinking the "One-Filter-for-All" Approach to Mechanical Thromboembolic Prophylaxis

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Abstract

Inferior vena cava (IVC) filtration for thromboembolic protection is not without risks, and there are important differences among commercially available IVC filters. While retrievable filters are approved for permanent implantation, they may be associated with higher device-related complications in the long term when compared with permanent filters. Prospective patient selection in determining which patients might be better served by permanent or retrievable filter devices is central to resource optimization, in addition to improved clinical follow-up and a concerted effort to retrieve filters when no longer needed. This article highlights the differences between permanent and retrievable devices, describes the interplay between these differences and the clinical indications for IVC filtration, advises against a "one-filter-for-all" approach to mechanical thromboembolic prophylaxis, and discusses strategies for optimizing personalized device selection.

Keywords
- inferior vena cava filters
- optional filter
- retrievable filter
- complications
- patient selection
- interventional radiology

Objectives: Upon completion of this article, the reader will be able to identify the differences between permanent and retrievable filters, the indications for filter placement, the complications associated with filters, and strategies for optimizing personalized device selection.

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The introduction of the retrievable inferior vena cava (IVC) filter in the late 1990s had a profound impact on the practice of mechanical thromboembolic prophylaxis in the decades that have followed. More filters were placed as the indications for placement relaxed,[1] while a lack of emphasis on retrieval led to retrieval rates as low as 5% in some practices.[2] Reports of complications grew, prompting intense scrutiny of IVC filter use, and today whether and when to place a filter remains a topic of controversy in facilities across the United States. Decision making by the interventional radiologist is complicated by a relative paucity of level I data,[3,4] the rapidity with which technologies change, and the many filter designs that are commercially available. All IVC filters are not created equal, nor are the clinical scenarios for which placement of a filter is entertained.

Types of Filters

In broad terms, modern IVC filters can be divided into two categories: permanent IVC filters (pIVCFs) and retrievable IVC filters (rIVCFs). pIVCFs are percutaneously placed intracaval filtration devices that trap migrating venous thromboemboli

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and prevent pulmonary emboli (PE) while allowing caval flow-through. These filters are not designed with any mechanism to permit ready removal from a percutaneous approach; however, there are reports of successful removal of such devices using advanced retrieval techniques.[5,6] Examples of pIVCF currently in use include Vena Tech LP (B. Braun IS, Bethlehem, PA), titanium Greenfield (Boston Scientific, Watertown, MA), Trap Ease (Cordis, Bridgewater, NJ), Simon Nitinol (Bard Peripheral Vascular Inc., Tempe AZ), and Bird's Nest (Cook Group, Bloomington, IN) filters. Retrievable filters function on similar principles as pIVCF. These devices are maintained in place in the IVC by hooks, barbs, or radial pressure,[7] and are designed with features that permit percutaneous removal if and when the risk of PE resolves. It is important to note that all rIVCFs have Federal Drug Administration (FDA) approval for permanent use. A few of many current-day examples include Celect (Cook Medical Inc, Bloomington, IN), Günther-Tulip (Cook Medical Inc), Option (Argon Medical Devices, Athens, TX), ALN (ALN Implants Chirurgicaux, Ghisonaccia, France), Denali (and predecessors Meridian, Eclipse, and G2) (Bard Peripheral Vascular Inc.), and Crux (Volcano Corp, San Diego, CA). The VenaTech Convertible filter (B. Braun IS) is in its own category, and is based on the existing VenaTech LP filter design; it has been structurally altered such that the filter can be percutaneously placed but converted into an IVC stent when mechanical prophylaxis for PE is no longer indicated. FDA approval is anticipated in 2016.

Indications

For the most part, the indications for IVC filter placement have not significantly changed in the four decades since their introduction. The mainstay of treatment for thromboembolic disease remains anticoagulation, which is well supported in the literature.[8–14] It is important to understand that IVC filters neither treat nor prevent venous thromboembolism (VTE), but that they only prevent the potentially life-threatening complication of PE.[15] Filter indications are divided into three categories: absolute indications, relative indications, and prophylaxis. The only widely accepted indication for IVC filter placement is in patients who "have documented VTE, are at high risk of clinically significant PE, and have a contraindication to or complication or failure of pharmacologic therapy."[4] Relative indications include patients with "VTE and are considered to be at continued high risk of clinically significant PE despite primary therapy, [are] at increased risk of complications of anticoagulation, or [are] noncompliant with medications."[4]

The most controversial category is the placement of IVC filters for prophylaxis: that is, placing a filter in a patient who does not have PE or VTE but may be at risk for developing such diseases. The exponential growth of IVC filters in the last two decades is largely attributed to explosive growth in the use of rIVCFs in the prophylactic patient group.[16] Between 2001 and 2006, the rate of prophylactic filter placement in the United States tripled,[17] with trauma patients comprising much of the prophylactic patient population. These often otherwise healthy patients have acute injuries that place them at high risk for both PE and bleeding complications associated with early anticoagulation. Traditionally, anticoagulation for VTE prophylaxis in trauma patients was considered unsafe,[4,7] which may account for the sharp increase in prophylactic filter placement after rIVCFs were introduced. However, the explosive growth was not appropriately matched with subsequent device retrieval with reports of retrieval attempts in as few as 50% of rIVCFs were reported at large centers.[2,7]

At the same time as the explosive growth of rIVCF placement, reports of filter-related complications increased, so much so that the FDA issued a statement in 2010 calling attention to device-related complications and low retrieval rates.[18] This prompted intense scrutiny of rIVCF placement practices. In addition, attitudes toward early anticoagulation for prophylaxis in high-risk groups began to change around this time. In 2008, the American College of Chest Physicians released clinical practice guidelines for the prevention of VTE, in which the use of early anticoagulation in trauma patients was endorsed as safe and effective.[9] Subsequent reports found that prophylactic filter placement has no effect on reducing trauma patient mortality, and that filter placement is associated with a higher complication rate over anticoagulation.[19] The same appears to hold true in the bariatric surgery patient population.[20] In effect, the indications for IVC filtration that had relaxed following the advent of retrievable filters became more stringent again. Recent estimates report that about one in four rIVCFs is placed for prophylaxis, and that retrieval rates are at a more acceptable level.[21]

Filter Selection

Prospective decision making is a key concept in optimal health care delivery, and is certainly a pertinent issue when selecting one device among the many available for thromboembolic prophylaxis. rIVCFs are appealing because their flexible indications allow providers the opportunity to postpone decision making on a patient's need for permanent prophylaxis. Therefore, it may seem easy to default to rIVCF, but for a patient with a prolonged or lifelong need for protection, pIVCF may be a better choice for several reasons. First, although no randomized controlled trials have been performed comparing the performance of rIVCF and pIVCF over time, there is evidence that rIVCFs have higher complication rates.[22,23] Second, these adverse events (AEs) increase proportionally with prolonged filter dwell time,[24] and that AEs are tied to individual rIVCF designs.[23,25] Reported AEs that have a higher incidence with rIVCF include filter migration, filter fracture, and perforation of the caval wall or adjacent structures by filter components.[3,23,26] Given that routine imaging after filter placement is not typically performed,[7] the actual incidence is not known. Reports of filter migration are largely limited to symptomatic case reports in the literature, and seem to be related to individual filter designs and caval size.[27–29] The incidence of asymptomatic device migration or strut embolization is unknown. Although strut perforation rates are reportedly as high as 95%,[30] these perforations are estimated to be symptomatic in approximately 8% of cases.[31] Regarding caval and deep venous

thrombosis (DVT), the data are more robust, but it is unclear that the risks are any worse with rIVCF than with pIVCF.

The landmark PREPIC trial (Prévention du Risqué d'Embolie Pulmonaire par Interruption Cave) published in 1998 prospectively compared randomized groups that received filters plus anticoagulation or anticoagulation alone. Over a period of 2 years, the authors found that while filters did prevent more PE over anticoagulation alone, the mortality rate was similar between the two groups and the filter group was statistically more likely to suffer from recurrent DVT.[15] These findings were confirmed at 8-year follow-up.[32] It is important to note that all four types of filters used in the PREPIC trial were permanent filters; several retrospective studies on both permanent and retrievable filters contain widely varying reports of caval or DVT after filter placement, without a clear burden to be placed on either category of filter.[7,33,34] A single-center 2008 retrospective cohort study comparing rIVCF and pIVCF found comparable complication rates and similar protection from PE.[35]

Another consideration when prospectively selecting between rIVCF and pIVCF is cost. Although cost difference between pIVCF and rIVCF may be equalizing, rIVCFs are generally more expensive than pIVCF, while reimbursement by third-party payers is the same for both types of devices. If a rIVCF is placed but ends up being maintained as a permanent filter, greater costs are incurred upon the practice than if a permanent filter were placed instead. It is estimated that 18 to 33% of optional filters placed with the intent of future removal end up being left in place permanently.[22] Modeling by Janne d'Othée et al determined that unilateral use of rIVCF instead of pIVCF is financially favorable only if greater than 41% of those filters are later removed.[36] Therefore, practices with retrieval rates below 41%, whether due to limited follow-up or a high rate of filters being declared permanent due to patients ongoing high risk for PE, may want to consider more careful prospective patient selection based on the anticipated prophylaxis timeline.

Prospective Patient Selection

No physician has a "crystal ball" with which to predict a given patient's future need for long-term mechanical thromboembolic prophylaxis. However, interventional radiologists are well equipped to counsel referring clinicians on appropriate device selection, and can accurately predict which patients will eventually become candidates for retrieval and which will require permanent devices. Prospective consultation with an interventional radiologist prior to filter deployment has been shown to increase rIVCF retrieval rates.[37]

Several conditions measurable at the time of filter placement should prompt the interventional radiologist to consider a pIVCF over a rIVCF. In 2013, analysis of filter data from a single institution reported that four clinical parameters were positively correlated with optional filters being declared permanent: advanced age, male sex, history of underlying malignancy, and history of anticoagulation failure. Parameters negatively associated with filter permanence included a history of VTE and history of a filter being placed for high-risk VTE or for prophylaxis.[22] These data were used to develop a calculator that could be used to analyze prospectively which patients might be better suited to receive a permanent over a retrievable device. The calculator (available at http://ivcfilter.nm.org/calculator.html) uses nine clinical parameters for a given patient and estimates the probability that a rIVCF will not be subsequently retrieved. The calculator is a compelling tool for prospective decision analysis, but it has not been validated outside of the single center at which it was developed. It should be noted that some of the same variables (advanced age, history of malignancy, and indication for placement) were also found to be associated with filter permanence in another institution.[33]

Close clinical follow-up in the postplacement period is also a key concept in optimizing rIVCF utilization. The establishment of dedicated IVC filter clinics has been demonstrated to significantly increase the retrieval rate of rIVCF,[38] as do registry-enhanced institutional follow-up protocols.[39]

Conclusion

Deciding which IVC filters to use, when to use them, and for how long they should remain in place remains a highly complex process with many variables to consider. At a minimum, it is important to recognize that mechanical thromboembolic prophylaxis is not entirely benign: IVC filtration, particularly with retrievable filters, is associated with morbidity risks that increase over time, and filters should be removed when the patient's risk for PE has resolved. Postplacement clinical follow-up is critical to optimizing retrieval rates. Given the increased adverse effects and cost difference when using rIVCF in a permanent manner, an important goal for appropriate IVC filter selection should be selecting those patients best served with a permanent filter due to the patient's unique clinical conditions. Further development and validation of nuanced, large-scale mathematical modeling tools may be helpful in optimizing filter utilization in the future.

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