Viewpoints on the Nuances of IVC Filter Usage

Three physicians differing in practice location and specialty discuss placement indications, follow-up and retrieval, current and next-generation devices, and geographical usage disparities.

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Do you follow any particular guidelines for placement of inferior vena cava (IVC) filters?

Dr. Goh: We follow our local guidelines, which are based on the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) quality improvement guidelines for percutaneous IVC filter placement for the prevention of pulmonary embolism (PE). The guidelines state that patients with PE or deep vein thrombosis (DVT) who have a contraindication to anticoagulation, complication of anticoagulation, or in whom there is failure of anticoagulation (such as recurrent PE despite adequate therapy) are indicated for IVC filter placement. There are several other additional indications such as severe trauma, poor compliance with anticoagulation medications, and free-floating iliofemoral or IVC thrombus.

Dr. Arko: We tend to follow a rather strict guideline for placement of IVC filters in our practice. Indications include patients in whom anticoagulation is either an absolute or relative contraindication, complication of anticoagulation therapy, or when there is failure of anticoagulation with recurrent PE, an inability to maintain anticoagulation, or propagation/progression of DVT while on therapeutic anticoagulation. This closely follows the Society of Interventional Radiology (SIR) guidelines. Although we do not place IVC filters in trauma patients at our center, there is prophylactic use of the filters in those with severe trauma with a closed head injury, spinal cord injury, and those with long bone fractures or pelvic fractures.

Dr. Kuo: Over the years, several society and multidisciplinary guidelines have been published, including those from the American College of Chest Physicians (ACCP),[1] the American Heart Association (AHA),[2] the Eastern Association for the Surgery of Trauma (EAST),[3] and SIR.[4] The most recent and routinely updated are the ACCP's guidelines on antithrombotic therapy for venous thromboembolism (VTE) disease.[1] Regardless of the guidelines used, the strongest recommendation for filter placement is primarily based on the landmark randomized PREPIC

trial,[5] and we acknowledge that there is a need for more data supporting filter use, especially for the relative and prophylactic indications.

Currently, the guidelines offer no good recommendations on managing filter-related anticoagulation in those patients with indwelling or permanent filters, and there is little discussion on indications for filter removal. Although we lack large-scale studies showing the benefits of prompt filter retrieval, we have observed an abundance of complications from indwelling filters reported in the literature.[6-12] and in the US Food and Drug Administration's (FDA) MAUDE database.[13] Consequently, it is important to heed the FDA's Safety Alert for IVC filters, which recommends 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.[14] In 2014, the alert was updated with a Safety Communication stating that the risk-to-benefit ratio begins to favor IVC filter removal within 29 to 54 days after implantation if the patient's risk for PE has passed (see the *IVC Filter Retrieval-Assistance Programs* sidebar on page 28).[15]

What are the indications for IVC filter placement in your practice?

Dr. Arko: In addition to those I previously listed, there are certainly some other patients who may receive a filter, such as a patient with a massive PE with residual DVT, those with potentially free-floating IVC thrombus, and those with severe cardiopulmonary disease and DVT. Within the last year, we started a program called Code PE, in which we evaluate patients with submassive and massive DVT for thrombolysis, and in some of those patients with the previous risk factors, IVC filters are placed.

Dr. Kuo: If inpatient filter placement is desired in our hospital, our clinicians must electronically request a consultation with the Interventional Radiology service. We take responsibility for determining whether filter placement is truly indicated based on the aforementioned guidelines. We evaluate the patient with two key questions in mind: (1) does the patient have proven VTE? and (2) does the patient have contraindications to therapeutic anticoagulation or anticoagulation failure? If the answer is yes to both, then the patient is scheduled for filter placement. If the answer is no to either question, it does not mean we automatically refuse to place the filter, but we then perform a more in-depth review of the patient's VTE risk factors and overall condition before rendering a decision.

Dr. Goh: We place filters in patients with DVT or PE and in whom there is a contraindication to anticoagulant therapy, or have breakthrough PE or extension of DVT while on therapeutic anticoagulants. We also routinely place IVC filters in severe trauma patients, and we are currently running a registry examining this.

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What is your protocol for follow-up and retrieval?

Dr. Kuo: Several years ago, we initiated a dedicated protocol to follow our filter patients for prompt retrieval. After filter placement in patients who only need temporary filtration, we automatically schedule them for filter removal within a few months after successful therapeutic anticoagulation has been achieved and once the risk of PE has diminished. If the desired filter duration is unclear, we have dedicated resources to follow our patients on a routine basis with the help of trained clinic staff. This requires a concerted effort to routinely monitor the electronic chart and/or contact patients directly for a clinic visit if necessary, to assess the need for ongoing filtration versus prompt filter removal.

Dr. Goh: We use an in-house IVC filter registry, which records all placements and follow-up dates for retrievals. A removal date 6 weeks from placement is routinely booked, and the referring physicians are asked to cancel the appointment if it is no longer required, such as earlier removal or a decision to keep the filter permanently. In the vast majority of cases, the patients have their filters removed at this time or at least have rescheduling of the removal, and we have a very high rate of filter retrieval. Instances when patients do not attend the retrieval appointment are followed up with phone calls. Whenever possible, we educate patients to tell them that the filter needs to be retrieved. Before filter removal, a cavogram is obtained to exclude the presence of a large amount of residual clot within the filter.

Dr. Kuo: If retrieval is needed after a prolonged implantation, we are fortunate to have the expertise to remove the filters regardless of dwell time. We also enroll patients into our own FILTER registry (NCT01158482) to gather data on our filter usage and to help ensure good follow-

up. Moving beyond these objectives, we established the Stanford IVC Filter Clinic to help patients outside our institution. We soon realized that there were many patients around the country who lacked good filter follow-up, and they were being referred to us after developing filter-related complications or after their filters had become embedded and refractory to standard retrieval methods. These patients inspired us to develop better endovascular methods to retrieve a variety of embedded IVC filters, and we evolved into a quaternary referral center dedicated to complex filter retrieval. Today, regardless of when or where a filter has been placed in the United States or globally, any patient or referring physician can consult us to remove an embedded filter.

Dr. Arko: Our protocol for retrieval is to have the patients follow up in 4 weeks to assess their current thromboembolic state. We have very good follow-up in our patient population, but this is due to the fact that we really do not have any trauma patients in our practice. Certainly, a number of patients who receive a filter require it to be implanted permanently. If we think that patients are past their risk of PE, then we will recommend filter removal.

Do you think there is a benefit to prophylactic use of IVC filters?

Dr. Goh: There have only been two randomized controlled trials on IVC filter usage, with a third, the PREPIC 2 trial, ongoing. There was no survival advantage found by either RCT with the use of IVC filters;[5,16] in the 8-year PREPIC trial follow-up, it was found that IVC filter patients had a lower incidence of PE, however, also a higher rate of DVT. At retrieval, we find that some filters have a small amount of clot within them, but it's impossible to know if this is a "caught clot" or clot formed around the filter.

Dr. Arko: I am not sure that there is benefit to the prophylactic use of IVC filters. Certainly, there is benefit for patients who require a filter, but I personally try to limit the use of prophylactic filters.

Dr. Kuo: This is a controversial subject. There may be a benefit in some patients, but the answer is not clear, and current guidelines conflict over this issue. EAST guidelines originally recommended the use of prophylactic filters in certain high-risk trauma patients with no proven VTE,[3] and this was listed as a relative indication by the SIR guidelines.[4] The current ACCP guidelines do not favor prophylactic filter use.[1] In our practice, we currently do not place prophylactic filters in trauma patients with no proven VTE, but this remains a complicated issue. A recent meta-analysis showed an association between IVC filter placement and a lower incidence of fatal PE in trauma patients; however, most trauma patients have not been followed for prompt filter removal, and they may be subjected to a higher risk of filter-related complications down the road.[17]

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> —Dr. Arko

For patients undergoing thrombolysis or thrombectomy, the use of IVC filters is considered a relative indication in the ACCP[1] and SIR guidelines,[4] but this is not indicated according to the AHA guidelines.[2] In our practice, we do not routinely place prophylactic filters before catheter-directed thrombolysis for DVT unless there is a large, free-floating iliocaval thrombus.

For patients scheduled to undergo gastric bypass surgery, our bariatric surgeons still favor preoperative placement of a prophylactic filter. So far, we have obliged their requests, but we are reevaluating this indication in light of meta-analytic data[18] in combination with new data suggesting little benefit and perhaps significant risks associated with prophylactic IVC filters among bariatric surgery patients.[19]

Why do you think there is such a large geographic discrepancy in IVC filter utilization (around the world and in the United States)?

Dr. Arko: I think that this is an interesting question that is most likely multifactorial. I believe that IVC filters save lives by preventing PE in patients in whom there is a clear need. However, I would say that controversy remains with the prophylactic use of these filters. This appears to be more prevalent within the United States than outside the country. Certainly, the fact that IVC filter placement reimburses so well for such a simple, straightforward procedure needs to be considered.

Dr. Kuo: This is a fascinating issue that may relate to insurance coverage, our litigious climate, and other factors. In 2012, the estimated number of filter placements in the United States was 25 times higher than an equivalent population in Europe (224,700 vs 9,070).[20] Within the United States, there are striking geographic differences with higher filter placement rates along the Eastern versus Western

states, and this may relate to variations in local medicolegal environments.[21] Overall, there is likely insufficient awareness of current guidelines resulting in overutilization. In a recent single-center study on filter usage,[22] there was poor compliance with any published guidelines, and the authors concluded there must be harmonization of current guidelines among the professional societies.

Dr. Goh: I believe this is mostly due to a lack of firm evidence, but also due to funding differences in various countries and litigation issues for unretrieved filters. Forming a robust follow-up strategy to track patients with filters for retrieval is quite time- and resource-consuming, which may discourage some centers from placing them.

In your opinion, is there any difference between the various filters currently on the market?

Dr. Goh: I think there are some differences. Filter design has changed over the years, with some designs experiencing problems such as irretrievability, filter fracture, and migration. Modern designs are evolving to tackle the issues from the past. We have performed a meta-analysis of the prospective trials of IVC filters (unpublished at this stage) and found that there were some differences between the filter types. The differences seem to be in filter complications (eg, tilt seems to be an issue with many filters) and retrievability, which is more of an issue with some than with others.

Dr. Arko: I believe that there is a difference in the various filters on the market. We see a number of patients referred to us with an OptEase filter (Cordis Corporation) that became occluded, which I believe is one of the greatest problems with this filter. It becomes a difficult problem to deal with when trying to recanalize this filter and/or stent it. Otherwise, I believe most of the conical filters to be relatively similar.

Dr. Kuo: Differences certainly exist among permanent and among retrievable filters, as well as between these groups. In 2003, there were only three FDA-cleared retrievable filters in the United States. Over a decade later, more than a dozen retrievable filters are available, and that number is growing every year. There are unique pros and cons with each device that go beyond the scope of this discussion. Although a variety of models are cleared by the FDA, we know there are unique risks associated with each model.[6-12] Currently, we are working on a filter identification algorithm to help clinicians recognize various filter types, device differences, and reported risks associated with each model. The algorithm will require routine updates to keep up with this evolving landscape.

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—Dr. Goh

Have you seen a new, innovative filter design? What would you most like to see from a next-generation device?

Dr. Arko: Certainly, the Crux vena cava filter (Volcano Corporation—please note my disclosure related to this device.) offers a new design with its helical backbone and netting. The backbone acts more like a capacitance spring, which will hopefully avoid some of the complications of filter erosion through the vena cava. Its bidirectionality and self-centering also eliminate the risk of tilting and complex retrievals.

Dr. Goh: In next-generation devices, I would like to see: (1) some ability to deliver a filter with less tilt via both the femoral and jugular approach (tilt with femoral-placed umbrella filters is a recurring issue), (2) reduced limb perforation, (3) ease of retrieval, and (4) femoral retrieval options. Bioabsorable filters are currently being investigated.

Dr. Kuo: Newer designs have emerged over the years, but other than improved retrievability, we have not seen any substantial improvements over some devices that were developed 10 to 20 years ago. Among some newer platforms, there seems to have been an overemphasis on features that increase retrievability at the inadvertent expense of higher complication rates with device penetration, fracture risk, and component embolization.

The in vivo caval environment is harsh on an implanted filter because the vena cava contracts and expands cyclically with each respiration. The FDA recommends that a filter's response to vena caval respiratory stress should demonstrate sufficient fatigue resistance,[23] and according to the FDA and American Society for Testing and Materials (ASTM), all filters should demonstrate durability over a 10-year equivalent of real-time use under simulated respiratory cycles and physiologic loading.[24,25] Given an estimated respiratory rate of 28,800 breaths per day,[26] the IVC filter should be designed to withstand at least 100 million respiratory cycles or 10 years of physiologic stress. Nevertheless, we have seen many current devices fracture well before this

10-year threshold, sometimes with life-threatening consequences. Much more should be done to regulate and prevent this aspect of device failure. Manufacturers must get back to the basics and create removable filters that never penetrate, fracture, or embolize. ■

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