What Strategies Would Encourage Appropriate Utilization of IVC Filters?

The co-primary investigators of the PRESERVE trial offer their opinions on how an alternate payment model would affect filter use and if evidence gaps or lags are to blame for overuse.

How Would IVC Use Be Affected if Payment Were Only Offered for Removal, Not Placement?

MATTHEW S. JOHNSON, MD, FSIR

Offering no payment for filter placement would decrease the number of filters that are placed, because there's no guarantee that the physician who placed the filter would be the one removing it or that the removal would be performed in the same institution where the filter was placed. Additionally, many filters are not removed because they shouldn't be (eg, in a person with recurrent venous thromboembolism [VTE] and a persistent contraindication to anticoagulation). Under a reimbursement model with no payment for placement, the institution where the placement procedure occurs would incur costs that would only be recouped if (1) the filter were indeed removed, (2) the removal procedure occurred at that institution, and (3) the payment were sufficient to cover two interventional procedures. In reality, procedures don't often occur under that scenario.

The result of this type of reimbursement model would be far fewer inferior vena cava (IVC) filters placed. The money-driven (rather than patient-driven) scarcity of filters wouldn't necessarily align utilization with patient benefit, unless we believe that it would be to all patients' benefit to avoid filters entirely. Most physicians who treat patients with VTE in the United States do not believe that all filters are bad. Society of Interventional Radiology guidelines outline several scenarios in which filters are indicated, as do the stricter American College of Chest Physicians guidelines. For example, both agree that filters are indicated for patients with above-the-knee deep vein thrombosis (DVT) and/or pulmonary embolism (PE) and a contraindication to or failure of anticoagulation. Those who developed those guidelines and others involved in the treatment of patients with VTE agree that the data supporting filter use are inadequate. Further, the visible complications associated with filters (including tragic complications such as embolization to the heart or thrombosis of the entire IVC, as well as less severe but more frequent complications such as filter fracture and penetration) and a perceived increased incidence of DVT in patients with filters contribute to the current opinions on their use. There is a need for better understanding of when IVC filters are beneficial, which patients would benefit from which type of IVC filter, and if and when the filter should be removed.

One such attempt to address these questions is the PRESERVE trial, which began in October 2015. The trial is a joint effort of the Society of Interventional Radiology, the Society for Vascular Surgery, the US Food and Drug Administration, and manufacturers of the majority of filters available in the United States. Over 200 of the 1,800 planned subjects in that trial have already been enrolled. The PRESERVE trial's primary endpoints are safety (a composite of the incidences of multiple complications) and efficacy (the prevention of clinically significant PE). Demographic data, clinical data, the indication for the filter, procedural data, and retrieval data will be recorded for each subject enrolled in that trial. Clinical data will be recorded at intervals up to 2 years. Abdominal x-rays will be obtained at 3 months or prior to removal (if the

filter is removed earlier than that time), and abdominal CTs will be obtained at 1 and 2 years after IVC filter placement, if the filter is still in place. PRESERVE should provide data that will allow us to answer many of the questions about filter use, as well as align filter use with patient benefit on clinical grounds.

Are Problems Associated With IVC Use Due to Evidence Gaps or a Lack of Exact Guidelines? Can Consensus Guidelines Influence IVC Filter Utilization, and What Trials Are Needed to Help Guide Appropriate Use?

BY DAVID L. GILLESPIE, MD, RVT, FACS

I don't think that overuse of IVC filters is a matter of the lack of evidence. In fact, there is reasonable evidence that IVC filters have no survival benefit over standard anticoagulation alone. This exists for both permanent filters as well as temporary/retrievable IVC filters. In the PREPIC trial, the findings at 2 and 8 years of follow-up suggest that permanent IVC filters increase the risk of insertion site DVT, reduce the risk of PE, do not alter the combined frequency of DVT and PE (ie, recurrent VTE), do not increase the risk of postthrombotic syndrome, and do not alter mortality.

With regard to temporary/retrievable IVC filters, a recent article by Hemmila et al echoes these same points. They analyzed quality collaborative data on trauma from 2010 to 2014 and found that the rates of prophylactic IVC filter placement have no effect on reducing mortality in trauma patients and are associated with an increase in DVT events. We know that the bleeding risk after trauma is approximately 72 hours. After this time, 95% of patients can be safely anticoagulated. Temporary IVC filters are placed under the assumption that they will be removed when it is safe to anticoagulate the patient; however, this is not being done in the majority of cases. In fact, many of my patients have now become their own advocates and have refused placement of temporary IVC filters in lieu of anticoagulation.

On the other hand, I think that the overuse of IVC filters is partly due to a lack of clear guidance from existing guidelines. We have published guidelines, but they contradict each other. To date, there is no level 1 evidence to support insertion of an IVC filter in a trauma patient without an established DVT or PE. However, at this time, the Eastern Association for the Surgery of Trauma guidelines recommend considering IVC filter insertion in patients without a documented DVT or PE who meet high-risk criteria and cannot be anticoagulated. In contrast, according to the American College of Chest Physicians, "if an IVC filter is indicated in a patient with acute DVT or PE because anticoagulant therapy is temporarily contraindicated (eg, active bleeding), there is the option of inserting a retrievable filter and removing it when it is safe to start anticoagulant therapy. However, most retrievable filters are not removed; retrievable filters that are not removed may have a higher long-term complication rate than permanent filters, and there currently is no good evidence that retrievable IVC filters improve patient outcomes."

Certainly, consensus guidelines on when an IVC filter should not be placed could be helpful, as this is confusing for most practitioners. As such, practitioners often default to IVC filter placement. Common indications for IVC filter insertion include patients who have documented VTE and have failed anticoagulation or who have contraindications to anticoagulation, such as active bleeding, recent intracranial hemorrhage, or severe pulmonary hypertension. Level 1 evidence supporting widespread use of IVC filters outside of these indications is scant.

Given the potential severe consequences of filter fracture, filter embolization, pathologic IVC penetration, and the marked growth in IVC filter use despite no change in disease incidence, a head-to-head comparison of IVC filter placement to anticoagulation would be useful. In response to this lack of evidence, the Society for Vascular Surgery and the Society of Interventional Radiology have collaborated to develop a physician-initiated investigational device exemption study to better understand the current use of IVC filters and the associated adverse events. The PRESERVE study is a multicenter, prospective, open-label, nonrandomized investigation of commercially available IVC filters from six manufacturers placed in patients for the prevention of PE. This study will enroll approximately 1,800 IVC filter patients at up to 60 sites in the United States. All treated patients will be evaluated at procedure and at 3, 6 (phone), 12, 18 (phone), and 24 months after the procedure. The primary objective of this investigational device exemption clinical investigation is to evaluate the safety and effectiveness of the commercially available IVC filters (retrievable and permanent) in subjects with clinical need for mechanical prophylaxis of PE with an IVC filter.

In my opinion, because of the lack of contemporary use of pharmacologic prophylaxis across studies, we cannot make firm conclusions either for or against the routine use of prophylactic IVC filters. Prospective randomized trials are needed to determine the role of prophylactic IVC filters, especially in trauma patients. ■

Matthew S. Johnson, MD, FSIR
Professor of Radiology and Surgery
Indiana University School of Medicine
Director, Interventional Oncology
Indiana University Health
Indianapolis, Indiana
matjohns@iupui.edu
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David L. Gillespie, MD, RVT, FACS
Chief of Vascular and Endovascular Surgery
Cardiovascular Care Center
Southcoast Health System
Fall River, Massachusetts
(508) 973-2213; gillespied@southcoast.org
Disclosures: Consultant and speaker, Volcano/Philips.