CHEST

Temporary Inferior Vena Cava Filters
How Do We Move Forward?

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Despite their widespread use, the indications for the selective use of temporary inferior vena cava (IVC) filters remains uncertain with few trials supporting their use. Additionally, the risks of long-term temporary IVC filter insertion are being increasingly discussed amongst the mainstream media and through multiple class action lawsuits. Retrievable IVC filters were specifically designed to have a less secure implantation in order to facilitate retrieval. However, multiple reports have demonstrated significant filter-related complications, most commonly related to duration of implantation. Furthermore, the risk is not isolated to one manufacturer alone. The incidence of filter-related complications is linearly related to its duration of time on the market. Currently, the FDA recommends that IVC filters be removed within 25-54 days of their implantation. Unfortunately, little evidence exists to show that this recommendation is followed routinely. Recently, the PRESERVE Trial (NCT02381509) was initiated as a multicenter non-randomized open label study to determine the safety and effectiveness of commercially available IVC filters (both temporary and permanent) in individuals who require mechanical prophylaxis against pulmonary embolism. Until such evidence is developed, temporary IVC filters should be implanted based on best available evidence and routinely removed within the guidelines of the FDA of 25-54 days. A fair question at this point is whether the design features themselves that are required to manufacture a low profile removable IVC filter can achieve effective prophylaxis against pulmonary embolism at a low rate of short and long-term complications.

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Unlike temporary inferior vena cava (IVC) filters, the safety and effectiveness of the permanent Greenfield filter to reduce the risk of pulmonary embolism (PE) in patients suffering an acute DVT and who cannot be anticoagulated is well-established. In a review of more than 3,000 consecutive patients, the long-term patency of Greenfield IVC filters is 98%.[1]

There are only two randomized controlled trials examining the use of permanent IVC filters.[2,3] Fullen et al[2] randomized patients with hip fracture to either receive a permanent IVC filter or no IVC filter, but none received VTE prophylaxis.[2] The incidence of PE in the nonfilter group was 32%, whereas it was significantly lower in the filter group (10%). The mortality of the filter

ABBREVIATIONS: FDA = US Food and Drug Administration; IVC = inferior vena cava; PE = pulmonary embolism

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group (10%) was substantially lower than the nonfilter group (24%).

The Prevention du Risque d'Embolie Pulmonaire Par Interruption Cave (PREPIC) study showed that permanent IVC filters reduced the long-term incidence of PE by 68%, but had an 8.2% higher incidence of recurrent DVT.[3] The goal of the PREPIC trial was to determine if the addition of a permanent IVC filter to conventional anticoagulation improved VTE outcomes in higher risk patients. However, in the United States, permanent IVC filters are not used routinely in patients with DVT who can tolerate anticoagulation. What is not well-established is the safety and efficacy of selective use of prophylactic, temporary IVC filters in special patient subgroups that are at high risk of VTE, but cannot receive prophylactic anticoagulation.

Despite their widespread use, the indications for the selective use of temporary IVC filters remain uncertain. To address this question, the American College of Chest Physicians has provided indications for the selective use of IVC filters.[4] In addition, a recent publication by the Agency for Healthcare Research and Quality systematically reviewed the comparative effectiveness and safety of pharmacological and mechanical methods of prophylaxis of VTE in patients hospitalized with trauma, traumatic brain injury, burns, or liver disease; patients on antiplatelet therapy; obese or underweight patients; patients having obesity surgery; or patients with acute or chronic renal failure.[5] These special subpopulations have unequal risks for bleeding and thrombosis and may benefit differently from prophylactic therapy. This comprehensive analysis revealed a paucity of high-quality evidence to inform the use of temporary IVC filters in these patients.

This lack of trials to support indications for the selective use of temporary filters only further amplifies the concern about their long-term complication rates. The risks of long-term temporary IVC filter insertion have been recently discussed among the mainstream media as well. Lawsuits, initially against C.R. Bard, have raised the concern that certain temporary IVC filters are more prone to complications than others. Even the development of websites such as www.ivcfilterlawsuit2015.com, has influenced medical decision-making. Are certain temporary IVC filters more prone to complications than others? Does their risk-benefit ratio support their widespread use?

Retrievable, temporary IVC filters began to appear on the market in the early 2000s. They were specifically designed to have a less secure implantation to facilitate retrieval. In 1999, the US Food and Drug Administration (FDA) downgraded the risk of IVC filters from class III to class II, thereby permitting manufacturers to achieve market approval more readily under the assumption that new filters are substantially equivalent to other legally marketed devices.[6] As a consequence, several retrievable IVC filters were submitted to the FDA and approved as permanent filters with an option for retrieval. However, there have since been multiple reports demonstrating significant complications, including vena caval penetration, filter embolization, recurrent VTE, and caval thrombosis. In 2010, the FDA disclosed that retrievable IVC filters had been associated with more than 900 adverse events[7]; therefore, in 2014, the FDA released updated recommendations in which physicians were advised to remove filters within 25 to 54 days of their implantation.[8] Little evidence exists to show that this recommendation is followed routinely.

Recent lawsuits have been directed against the C.R. Bard Recovery and G2 filters. In 2007, a single-institution review of patients with a Bard Recovery filter by noncontrast CT revealed a 21% incidence of filter arm fracture or migration as well as increased incidence of limb perforation of the vena cava over time.[9] Additionally, other studies have continued to show that the risk of temporary IVC filter complications is linearly related to the duration of time on the market.[10,11] A 44-year retrospective review of 9,002 patients with 15 types of filters demonstrated a 19% incidence of caval penetration, of which 19% had significant organ and structural involvement.[12] However, the risks are not isolated to Bard filters alone. A review of 50 Gunther Tulip and 27 Celect filters demonstrated an 86% caval perforation of at least one filter component on CT scan.[12] Additional studies have continued to report that smaller IVC diameters and longer indwell times had higher rates of IVC penetration,[13] regardless of the manufacturer.

In addition to their complication rates, little evidence exists to show that temporary IVC filters are being retrieved routinely. Although a single-center review of the filter retrieval reported a 90.6% success rate,[14] this retrieval rate is not achieved uniformly. Most estimates of temporary IVC filter retrieval hover around 20%, whereas a systematic review found an average retrieval rate of 34%,[15] leaving these patients at risk for late complications, and worse, most of these patients likely become lost to follow-up.

An additional concern is the risk of recurrent VTE in patients after filter retrieval? Two single-institution, retrospective studies have demonstrated a 2.8% to 6.6% risk of recurrent or worsening VTE, and 2.6% risk of PE resulting in death.[16,17] Overall, the risk of VTE was low, but is most prevalent in patients with VTE at the time of filter implantation.

With all of these concerns, how do we move forward? Acknowledging the difficulties of conducting randomized controlled trials of this vulnerable patient population, it is recommended that robust observational studies be undertaken that control for confounding by indication and disease severity. Recently, the Predicting the Safety and Effectiveness of Inferior Vena Cava Filters (PRESERVE) Trial (NCT02381509) was initiated as a multicenter nonrandomized open label study to determine the safety and effectiveness of commercially available IVC filters (both temporary and permanent) in individuals who require mechanical prophylaxis against PE. Until such evidence is developed, use of temporary IVC filters should be implanted based on best available evidence and routinely removed within the guidelines of the FDA (25 to 54 days). At this time, the type and duration of follow-up of the patients in whom the filter could not be removed remains unknown. A fair question at this point is whether the design features themselves that are required to manufacture a low profile removable IVC filter can achieve effective prophylaxis against PE at a low rate of short- and long-term complications.

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