

POINT:

Do the Benefits Outweigh the Risks for Most Patients Under Consideration for Inferior Vena Cava Filters? Yes



CrossMark

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ABBREVIATIONS: IVC = inferior vena cava; PE = pulmonary embolism; PREPIC = Prevention du Risque d'Embolie Pulmonaire par Interruption Cave

It is logical that an inferior vena cava (IVC) filter can catch clots—like a pasta chef draining noodles through a colander. We have seen them catch these clots, thank goodness. Studies have characterized the comparative clot trapping efficacies of caval filters; however, there are few randomized prospective studies comparing caval filtration with no therapy. Given decades of research, would a patient with DVT and a contraindication to anticoagulation wish to be randomized to the nonfilter group? “Sir, begin your skydive. You may have a parachute in your pack...or a pair of shoes. Pull the ripcord and see.” Therefore, the paucity of controlled trials of filter vs no filter is not surprising. Withholding a relatively benign acute intervention—having a filter placed, is challenging. That said, we readily acknowledge the need to remove filters when this protective value

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fades. The better question is not, “do filters work?” but rather, “whom do they best help—and for how long?”

The first randomized study on caval filtration was performed in 1973 in 100 patients with femur fractures and no DVT; none received anticoagulation.¹ Forty-one patients were randomized to receive prophylactic filters, and 59 patients served as a control group. Only 10% of the filter group, compared with 32% of the control group, had definite, probable, or possible pulmonary emboli. Mortality was also lower in the filter group, 10% vs 24% in the control group. Most of the deaths in the control group (8/14) were related to pulmonary emboli compared with a single death in the filter group. Interestingly, this patient suffered a fatal pulmonary emboli 2 hours before a filter could be inserted but was included in the filter group anyway.

Clinicians who argue that there is little evidence of filters efficacy² cite the Prevention du Risque d'Embolie Pulmonaire par Interruption Cave (PREPIC) studies^{3,4} (ie, the only recent randomized trials), while ignoring the aforementioned study and a large body of evidence accumulated over decades. Both PREPIC trials found that filters provided no significant benefit in terms of mortality or symptomatic pulmonary emboli. The major problem with these trials were that both were designed to determine whether or not filters were beneficial to patients in addition to unfractionated heparin or low molecular weight heparin, not as a second-line therapy in patients who were not candidates for anticoagulation. Although this is an interesting question, it is not the 90% indication for which filters are placed. In some respects, this was a trial of redundancy, like “Does putting on sunscreen prevent skin cancer if you walk around with a beach umbrella?” or “We have randomized you to skydiving with only one parachute vs a main canopy and a reserve.”

The PREPIC 1 trial supported filter efficacy. At day 12, the incidence of pulmonary emboli in the control group was > fourfold greater than the filter group (1.1% vs 4.8%, respectively). At 8-year follow-up, symptomatic pulmonary emboli occurred in 6.2% of the filter group vs 15.1% of the nonfilter group. However, there was no change in survival, and the decrease in nonfatal pulmonary emboli was offset by an increased incidence of DVT (20.8% vs 11.6%, respectively). What

does this mean? It shows that filters reduce the rate of pulmonary emboli, but even without caval filtration, anticoagulation effectively limits clots that embolize to the lungs from enlarging and causing significant symptoms. Moreover, in some people, the presence of a foreign object in their veins increases risk of forming a clot. The take home point is that filters work, but so does anticoagulation, and there is no reason that most people need both—and if you get your filter, you gain real benefit early, but need to have it removed thereafter.

Any metal implant can cause complications. Presumably, the longer the dwell time, the more likely complications might develop—this has proven true of caval filters. Major complications include IVC thrombosis, embolization and migration, perforation, and element fractures. Permanent filters tend to have fewer problems than early versions of retrievable devices. These issues have gained rightful attention in the medical literature, and also in lay press and in medicolegal circles. Confounding this risk is the liberalization of insertion indications without methodical efforts to reach patients for their removal. Studies have shown notable disparities in physician compliance rates for placement indications by national guidelines⁵ and removal rates.^{6,7} Further, not all filters are created equal for both efficacy and risk: some designs may be more prone to complications, and others may be more prone to difficult retrieval. As mandated by the US Food and Drug Administration, patients receiving retrievable filters must be tracked longitudinally, and filters should be removed when there is no longer an ongoing indication for caval filtration. Practiced within guidelines and with programs for tracking and retrieval, the absolute risk is modest, and most complications are minor allowing clinicians to focus on the advantage of clot capture. In the PREPIC 1 trial, the only major complication associated with filters was filter thrombosis (8.9%); in the PREPIC 2 trial, the complications related to filter insertion were access site hematoma (2.6%) and filter thrombosis (1.6%).

Clearly, more trials are needed. The Predicting the Safety and Effectiveness of Inferior Vena Cava Filters (PRESERVE) trial, which is jointly sponsored by the Society of Interventional Radiology and the Society for Vascular Surgery, in collaboration with the US Food and Drug Administration, is the first large-scale, multispecialty, prospective trial to evaluate the safety and efficacy of IVC filters and includes long-term follow-up. Answers and information will be forthcoming.

In summary, there are three questions worth asking when addressing the question of “Do the benefits

outweigh the risks for most patients under consideration for IVC filters?” First, can large venous clots travel to your lungs and kill you? Second, can IVC filters catch clots before they do? Finally, if you were at high risk for developing blood clots and could not receive anticoagulation, would you want an IVC filter? The answer to all three questions is unequivocally “Yes.”

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COUNTERPOINT:

Do the Benefits Outweigh the Risks for Most Patients Under Consideration for Inferior Vena Cava Filters? No



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Since the Mobin-Uddin umbrella launched in the late 1960s, the implantation of inferior vena cava (IVC) filters has vastly outpaced the quality evidence for their use. In 2012, approximately 250,000 IVC filters were

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