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Guidance for Sponsors
Volume 6, Issue 10 · 2026 Edition

Inferior Vena Cava Filters: Medical Imaging in Clinical Trials

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Venous thromboembolism affects as many as 900,000 Americans each year and causes an estimated 60,000 to 100,000 deaths.[1] Anticoagulation is the treatment, but for patients who cannot be anticoagulated, an inferior vena cava (IVC) filter offers mechanical protection against pulmonary embolism. Filter use expanded dramatically with the introduction of retrievable devices, then came under scrutiny when the FDA warned of fractures, migration and perforation and when randomized evidence failed to show benefit in patients who could receive anticoagulation. Since then a large prospective trial has defined the safety of modern filters, professional societies have issued evidence-based guidelines and imaging has become central to both the indication for a filter and its follow-up. This issue reviews the evidence and the imaging a filter trial requires.

From Permanent to Retrievable, and the FDA Warnings

Permanent IVC filters were introduced in the 1970s and retrievable designs in the early 2000s. Because filters are Class II devices cleared through the 510(k) pathway, most reached the market on the basis of equivalence to earlier designs rather than clinical trials. Use grew far faster than the evidence. In 2010 the FDA issued a safety communication after receiving more than 900 adverse event reports describing migration, embolization of fractured components, perforation and filter fracture, and recommended that retrievable filters be removed as soon as protection from pulmonary embolism is no longer needed. A 2014 update, informed by a decision analysis, suggested that the risk-benefit balance favors removal between 29 and 54 days after implantation if the risk of PE has passed.[2]

What the Randomized and Prospective Evidence Shows

The PREPIC2 trial randomized 399 patients hospitalized with acute pulmonary embolism and a high risk of recurrence to a retrievable filter plus anticoagulation or anticoagulation alone. At three months, recurrent PE occurred in 3.0 percent of the filter group and 1.5 percent of the control group, a difference that was not significant and that argued against routine filter placement in patients who can be anticoagulated.[3]

The PRESERVE trial answered a different question: how safe and effective are modern filters when used for accepted indications? This prospective, multicenter study, sponsored jointly by the Society of Interventional Radiology and the Society for Vascular Surgery, enrolled more than 1,400 patients receiving commercially available filters at 54 sites. At 12 months the trial met its primary safety and effectiveness objectives: clinically significant PE occurred in 1.6 percent of patients, caval occlusion in 1.1 percent and clinically significant perforation in 0.2 percent, and retrieval was successful in 98.8 percent of attempts.[4] PRESERVE established that contemporary filters are safe when used appropriately, while reinforcing that retrieval should be planned from the moment of placement.

Current Guidelines

The 2020 Society of Interventional Radiology clinical practice guideline, developed with multiple partner societies, recommends IVC filters for patients with acute VTE who have a contraindication to anticoagulation, recommends against routine placement in patients who can be anticoagulated, and advises against prophylactic filters in most trauma and surgical patients. It also recommends that retrievable filters be removed when no longer indicated and that patients with indwelling filters be followed systemat-

ically.[5] Registry analyses continue to show that retrieval rates remain well below what guidelines call for, and that structured follow-up programs improve them.[6] Recent guidance from cardiovascular societies has reinforced the same positions.[7]

Imaging for Placement, Follow-up and Complications

Imaging defines every stage of filter use. Before placement, duplex ultrasound or CT venography documents the thrombus burden and anatomy; at placement, fluoroscopic cavography confirms caval diameter, renal vein position and the absence of anomalies such as a duplicated or megacava that change device choice. During follow-up, abdominal radiography is adequate to detect gross migration or fracture, but CT with venous-phase contrast is the reference standard for the complications that matter: strut penetration beyond the caval wall, tilt greater than 15 degrees that complicates retrieval, filter fracture with component embolization, caval thrombosis and the ingrowth of tissue that makes retrieval difficult. Standardized measurement of these features, including filter position relative to the renal veins and tilt angle relative to the caval axis, is what a trial endpoint requires.

Complex retrieval has become its own discipline, with advanced endovascular techniques able to remove filters after years in place, and imaging is used to plan these procedures and to document outcomes. Trials of new filters, of retrieval devices and of strategies to improve retrieval rates all depend on consistent, centrally read imaging.

Designing an IVC Filter Trial

Device trials in this space are typically single-arm with objective performance criteria, as PRESERVE was, or randomized strategy trials. In either case the imaging charter should define the modality and timing of follow-up imaging, the measurements to be made, the definitions of penetration, tilt, fracture, migration and occlusion, and the reading procedure. Because many complications are asymptomatic and found only on imaging, the completeness of imaging follow-up is itself an outcome. The FDA's guidance on imaging endpoint process standards applies to device studies as much as to drug trials.[8]

Guidance for Sponsors

Imaging an IVC filter trial

- **Document the indication.** Baseline imaging of thrombus burden and anatomy supports the eligibility criterion.[5]
- **Standardize placement imaging.** Record caval diameter, renal vein level and filter position at deployment.
- **Define complication measurements.** Penetration depth, tilt angle, fracture, migration distance and caval patency, each with a stated method.[4]
- **Use CT venography as the reference.** Radiography for gross surveillance, CT for the endpoints.
- **Plan retrieval from day one.** Track retrieval attempts, success and the imaging that supports each decision.[2,5]
- **Read centrally.** Blinded independent review with device-experienced radiologists and adjudication.[8]

Summary

IVC filters have traveled a full arc from unregulated growth through regulatory warning to evidence-based use. PREPIC2 showed where filters do not help, PRESERVE showed that modern devices are safe when used properly, and guidelines now define the indications. For sponsors, the lesson is that imaging is not an afterthought in a filter trial but the means by which safety, performance and retrieval are measured.

About the Author

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