

Inferior Vena Cava Filters

Current and Future Concepts



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KEYWORDS

• Inferior vena cava filter • IVC filter • Caval filter

KEY POINTS

- There is substantial controversy about inferior vena cava filters because of the lack of data supporting effectiveness and increased awareness of complications.
- Overall filter use is decreasing, especially in patients with prophylactic indications.
- Newer devices are being designed to address concerns about low retrieval rates and long-term complications of the devices.

INTRODUCTION

Interruption of the inferior vena cava (IVC) to prevent pulmonary embolism (PE) has been successfully performed since at least 1910, when Fredrick Trendelenburg,¹ MD ligated the IVC of a patient with postpartum septic pelvic thrombophlebitis. Caval interruption to prevent PE did not become widely available or applied until the development of successful intravascular devices, IVC filters, in the 1970s.^{2,3} The first generation of IVC filters was designed to be placed through surgical exposure of the femoral or jugular veins because of the large size of the introducers. The clinical utilization of IVC filters subsequently increased as the development of percutaneous insertion techniques and smaller introducers decreased the risk and complexity of the procedure, allowing practitioners without surgical skills to place the devices.⁴ Utilization increased in both patients with documented venous thromboembolism (VTE) and those without but who were considered at risk of PE.⁴ With the Food and Drug Administration (FDA) approval of the first retrievable IVC filters in 2003, utilization increased dramatically.⁵ However, this increase was associated with a relaxation of indications, low rates of retrieval of implanted devices, increased reports of IVC filter-related

complications, and the filing of major lawsuits against manufacturers of these devices.⁶⁻⁹ In 2010 the FDA issued an advisory urging removal of retrievable IVC filters and in 2012 Medicare reimbursement for filter placement was lowered, events that coincided with an observed decrease in IVC filter placements.^{10,11} Currently, the use of IVC filters in almost any situation is being questioned in the absence of large randomized clinical trials proving efficacy or benefit but large numbers of publications stressing complications of the devices.¹²

In this review, major trends impacting IVC filters are discussed, including changes in utilization, skepticism about the clinical benefit of filters in general, efforts to increase removal of retrievable devices, and new devices that are designed to meet still-unmet needs and address concerns with current devices. This list is not an exhaustive list of topics related to IVC filters but rather a selection of those that reflect some of the major themes of interest to the medical community and the public.

NOMENCLATURE

Vena cava filters are described using many terms, some of which can confuse the conversation. In this review, the following terms are

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used: *permanent* indicates a filter that was not designed to be removed; *retrievable* indicates a filter that was designed to be removed using percutaneous techniques but can remain permanently; *convertible* indicates a filter that was designed to remain in place but has the capability of opening so that trapping of emboli is no longer possible; lastly, *temporary* indicates a filter that must be removed, as it is usually tethered to an externalized catheter or wire. In the United States, all retrievable and convertible filters are approved by the FDA as permanent implants. The one temporary filter is approved for a 30-day indwell time.

CHANGES IN UTILIZATION

The United States has always placed disproportionately more IVC filters than any other country and experienced far greater growth in filter utilization.¹³ The explanation for this has never been clear, although the observed rate of placement in Medicare patients with PE has remained stable over time even as the absolute number of PE diagnoses has increased.¹⁴ Nationwide, filter utilization varies state by state, and within states from one hospital to another.¹⁵ Nevertheless, filter utilization rates are now decreasing this country, with the inflection point generally accepted as having occurred in 2012.^{10,11}

This decrease in utilization overall is appropriate, but there is likely not one explanation for this change. The increased awareness of IVC filter complications has clearly influenced referrals for IVC filter placements. These complications include filter penetration of local structures, filter migration, filter fracture, and embolization of filter fragments to the heart and pulmonary artery circulation.¹⁶ The impact of reporting bias is always speculative; but published IVC filter articles have increasingly focused on complications of the devices, whereas the total number of articles overall has increased dramatically. A simple PubMed search of the terms *IVC filter* and *IVC filter complications* between January 1, 2000 and June 16, 2017 showed that 57% of articles included the term *complications* compared with only 43% of articles between 1985 and 2000. The absolute number of articles on filters increased almost 600% in this same time period. Whether the actual incidence of IVC filter complications has increased or the interest in reporting has increased is not clear. Analyses of the self-reported FDA Manufacturer and User Facility Device Experience (MAUDE) data on device complications demonstrates a

disproportion representation of retrievable IVC filters compared with permanent devices and variations between the devices themselves.⁷ Unfortunately, the actual denominators are not known, so evidence-based conclusions are difficult.

Over the past 2 decades, one of the drivers of increased filter utilization was the implantation of these devices in patients who did not have VTE but were considered at risk of developing PE and could not have medical prophylaxis (referred to as *prophylactic filters*). The largest group of patients in this category was trauma patients. The use of IVC filters in this patient population in this manner was based on favorable observational series in the 1990s.¹⁷ As data accumulated, the benefits in terms of protection from PE seemed more modest but still positive.¹⁸

More recently, the benefit of prophylactic IVC filters in this population has been questioned and utilization has decreased.^{19,20} Sarosiek and colleagues²⁰ found no survival benefit in trauma patients receiving IVC filters at a major urban trauma center between 2003 and 2012, with only 8% ultimately being retrieved. In an analysis of several large databases containing 272,391 trauma patients with IVC filters, of which 93% were placed prophylactically, Cook and colleagues²¹ found no change in PE rates despite declining utilization of IVC filters between 2003 and 2015. Hemmila and colleagues¹⁹ found no benefit in terms of reduction of mortality but a significantly increased risk of DVT in these patients. The lack of convincing evidence of clinical benefit, the concern that DVT may be increased in patients with filters, and the low retrieval rates have resulted in decreased utilization of prophylactic filters in trauma patients.

The publicity surrounding IVC filters and their complications increased the awareness of both patients and physicians about the potential complications of these devices. The public is exposed to television advertisements, Internet advertisements, news media reports, and direct mail marketing from law firms stressing the complications from these devices. In this environment, there is a disincentive to recommend IVC filter placement and patients are reluctant to agree to placement.

The utilization of IVC filters has decreased simultaneously with a decrease in reimbursement for the procedure.¹¹ Whether the change in reimbursement was coincidental with the decline in procedures or causative cannot be determined from the data, but volumes of other procedures have been shown to be correlated

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