IVC Filters: Do Current Data Support the Indications?

The increasing use of IVC filters has increased scrutiny of the indications.

BY JOHN A. KAUFMAN, MD

he number of inferior vena cava (IVC) filters placed increases steadily each year. The overall incidence of venous thromboembolism (VTE) is increasing as well but not as fast as IVC filter utilization. This suggests that the indications for IVC filters are in flux. How well-founded are these indications?

WHAT IS THE PURPOSE OF AN IVC FILTER?

Before proceeding to a discussion of IVC filter indications, it is important to establish the purpose of a filter. IVC filters are placed to prevent venous emboli from reaching the central cardiopulmonary circulation. The ideal filter does this efficiently, reliably, and without impeding the return of blood. IVC filters do not prevent VTE, nor do they have any effect on resolution of peripheral or central venous thrombus, or potentiate the effect of pharmaceutical treatment of VTE.

INDICATIONS FOR IVC FILTERS

The currently described indications for IVC filters are listed in Table 1. The indications for IVC filters are generally divided into three main categories.²⁻⁴ This is a convention based on consensus rather than scientific validation. However, with time, these categories have become widely adopted within the scientific literature.

The first category refers to patients with VTE and an obvious need for interruption of the IVC. For example, a hypotensive patient with a massive pulmonary embolism (PE) and ongoing gastrointestinal bleeding would generally be considered to have a "classic" or "absolute" indication for an IVC filter. There has never been a randomized trial comparing the efficacy and outcomes of IVC filter placement and no treatment, or IVC filter placement and anticoagulation, in this group

of patients. However, based on the current state of knowledge about the risks of anticoagulation and massive PE, these indications are accepted by even the most ardent critics of IVC filters.⁵⁻⁹ The original indications approved by the Food and Drug Administration all fall into the category of "absolute" or "accepted."

The second category encompasses patients also with VTE but with a contraindication to anticoagulation or risk from PE that is open to interpretation. For example, an elderly, mildly demented patient with a history of a fall 3 months ago and acute single extremity deep venous thrombosis (DVT) to the level of the femoral vein would, in some clinicians' eyes, have a contraindication to anticoagulation and therefore an "extended" or "relative" indication for a filter. Other physicians may choose to anticoagulate the patient and not place a filter. 10,11 Often, patients in this category might receive both a filter and undergo anticoagulation, such as the patient with large iliofemoral thrombus undergoing catheter-directed thrombolysis. 12 One patient population that may benefit from both anticoagulation and a filter are patients with massive PE (arterial hypotension, evidence of right heart strain on imaging or laboratory studies). These patients have a high early in-hospital morality rate from recurrent PE and may be suitable for filters that can provide short-term protection from PE. 13,14

The third category of indications are filters placed in the absence of documented VTE but in patients considered at high risk for developing VTE. This is generally termed a prophylactic indication and has been proportionally the most rapidly growing indication. ^{10,15-17} This is also one of the most controversial indications, because the determination of risk for VTE with subse-

TABLE 1. REPORTED INDICATIONS FOR VENA CAVA FILTERS

Classic Indications (Proven VTE)

- · Contraindication to AC
- · Complication of AC
- · Inability to achieve/maintain therapeutic AC
- · Massive PE treated with thrombolysis/thrombectomy
- Chronic recurrent PE refractory to anticoagulant therapy

Extended Indications (Proven VTE)

- Recurrent VTE (acute or chronic) despite adequate AC
- · Iliocaval DVT
- · Large, free-floating proximal DVT
- · Difficulty establishing therapeutic AC
- · Chronic PE treated with thromboendarterectomy
- · Thrombolysis for iliocaval DVT
- · VTE with limited cardiopulmonary reserve
- · Recurrent PE with filter in place
- · Poor compliance with AC medications
- High risk of complication of AC (such as ataxia, frequent falls)

Prophylactic Indications (No VTE^a)

- · Trauma patient with high risk of VTE
- · Surgical procedure in patients at high risk of VTE
- · Medical condition with high risk of VTE

Abbreviations: AC, anticoagulation; DVT, deep vein thrombosis; PE, pulmonary embolism; VTE, venous thromboembolism (eg, DVT and/or PE).

^aPrimary prophylaxis not feasible due to high bleeding risk, inability to monitor the patient for VTE, etc.

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quent PE for individual patients is difficult. There is great variation among institutions and physicians regarding the use of prophylactic filters, particularly in trauma and surgical patients. 18,19

CHOOSING BETWEEN A PERMANENT AND OPTIONAL FILTER

Once the decision to place a filter has been made, there remains a choice (in the United States) between permanent and optional devices. A permanent device is a filter that is designed to remain within the patient for the remainder of his or her life without the ability to be

removed or altered to a nonfiltration state. An optional device can remain permanently or either be removed (percutaneously) or converted to a nonfiltration state. Currently, convertible devices are not available. Optimally, these devices are placed when the anticipated duration of risk of PE is short or within the time-frame during which the filter can be removed. In practice, many physicians use retrievable filters as their default device. ^{10,20}

The inferred benefit of optional filters is avoiding complications related to the presence of the device.²¹ There are only a few retrospective studies that suggest that patients with provoked VTE or prophylactic indications have a low risk of recurrent VTE after removal of a filter, but the data are weak.^{22,23} Thus, the benefit of filter removal remains inferential. This situation is complicated by the low rate of filter retrievals observed in many centers.^{16,24,25}

THE CURRENT STATE OF THE LITERATURE ON FILTER INDICATIONS

Unfortunately, the literature—and therefore the available data on filter indications—remains weak. The first commercial IVC filter was marketed before the Medical Device Amendments so that IVC filters were grandfathered as preamendment devices in 1976.26 There are no randomized prospective studies of filter versus no filter in patients with contraindications to anticoagulation. The only randomized filter study is the PREPIC trial, in which patients with VTE had either a filter in addition to anticoagulation or anticoagulation alone.^{27,28} This is one of the most discussed and most cited filter studies because it is still, after 12 years, the only published, randomized, prospective clinical study of filters. Although there was an early protective effect of IVC filters with respect to recurrent PE, after 2 years, this did not achieve statistical significance. However, there were significantly more symptomatic DVTs in the filter patients (20.8% vs. 11.6%). The follow-up data were reported at 8 years, showing significantly fewer occurrences of symptomatic PE (6.2% vs 15.1%) in the filter group compared to the nonfilter group but significantly more occurrences of symptomatic DVT (35.7% vs 27.5%) in the filter group. Notably, the overall occurrence of VTE was 36.4% in the patients with filters and 35.4% in those without filters (P = .54).²⁸ Postthrombotic syndrome was the same in both groups. There was no survival difference between patients with or without filters at 12 days, 2 years, or 8 years. The findings of this study are variably used either to support or attack the use of IVC filters. However, at the very least, this provides evidence that filters do prevent PE.

The data on prophylactic indications are contradictory and lack scientific rigor. For example, one retrospective single-center study suggested that the increased use of retrievable filters in trauma had no impact on the rate of PE (0.2% in patients with or without filters), and in addition, the majority of filters were not retrieved.²⁹ A subsequent study of similar design positively reported a PE rate of 2.1% in trauma patients receiving permanent prophylactic filters.³⁰ Compounding the situation is the large number of different commercially available filters, which may or may not have different individual rates of complications. 31,32 Furthermore, the low rates of occurrence of VTE in some of these populations will make randomized studies difficult due to the requirement for a large number of patients and long follow-up.4 As a result of this lack of clarity, the use of filters as part of a regimen of prophylaxis for VTE has been discouraged despite its widespread use.33

CONCLUSION

The indications for filters are based largely on custom, historical practice patterns, and physician preferences. Although it may be challenging to defend extended and prophylactic indications, most physicians are confident that they can recognize a bona fide indication for a filter when they see one. The care of patients with or at risk of VTE is as variable and challenging as the range of patients who suffer from venous thrombosis. Careful, individualized decisions regarding IVC filter placement will be required for many years as we strive to learn more about these devices.

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