IVC Filter Use in 2018 and Beyond

Optimizing utility and retrieval to provide appropriate protection.

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Inferior vena cava (IVC) filters are commonly used to prevent pulmonary embolism (PE) in patients with venous thromboembolism (VTE) and a contraindication to anticoagulation. IVC filters are also placed prophylactically in patients at high risk for VTE such as in the trauma or postoperative settings. In 1998, the prospective and randomized PREPIC study demonstrated a significant reduction in the occurrence of PE in patients with proximal deep vein thrombosis (DVT) and IVC filters when compared with those without filters.[1] These favorable results, along with the introduction of retrievable filters in 2003, spurred exponential growth in national IVC filter use during this era.

NATIONAL IVC FILTER UTILIZATION AND RETRIEVAL PATTERNS

Continuing into the early 21st century, the perceived benefits of mechanical IVC filtration combined with a limited knowledge surrounding the risks associated with long-term implantation continued to fuel the rise in IVC filter utilization. In 2010, however, increasing reports of retrievable filter-related complications, concomitant with very low filter retrieval rates, led the FDA to issue a safety communication, placing the responsibility of filter retrieval on implanting physicians once protection from PE was no longer needed. This safety advisory was further renewed in 2014, with added reference to a decision analysis describing the optimal retrieval window for retrievable filters to be between 29 and 54 days after placement.

Subsequent studies following the FDA advisory identified a reversal in national trends toward a decline in IVC filter utilization, likely a result of improved physician compliance and the negative medicolegal implications associated with IVC filter complications.[2-4] Similar declines in this time period were also observed on a statewide level.[5] Conversely, retrieval rates for IVC filters increased in the Medicare population between 2012 and 2016. Until this time, one systematic review had found that up to nearly 66% of retrievable filters that had been placed were never retrieved, despite the observation that 85% were inserted for temporary indications.[6] Given this preexisting state, the highlighted trends describing decreased placements and increased removals ultimately demonstrate the positive impact of the safety communication and reinforce the increasing efforts among the endovascular community to decrease the incidence of filter-related complications, while also protecting patients from life-threatening PEs.

Despite these favorable shifts in overall utilization, motivating factors for placement remain uncertain. Several studies have reported variation in the utilization of filters across hospitals and regions. White et al showed that among California hospitals, the frequency of filter placement depended on the hospital providing care after adjusting for clinical and socioeconomic factors.[7] Meltzer et al described greater utilization of filters in the Eastern coast states and a higher rate of filter placement per patients with DVT despite a similar incidence of DVT.[8] Chen et al used the Nationwide Readmissions Database and showed that the highest quartile of hospitals placing filters in VTE patients were more often private, for profit, and nonteaching. This quartile also tended to include older patients as well.[9] Another recent study showed that the elderly age group, teaching hospitals, urban location, and larger bed–sized hospitals were associated with increased IVC filter placements among patients admitted with VTE using the National Inpatient Sample.[10] Overall, these population-based studies show that a variation in filter utilization is certainly present and warrants further investigation.

PROPHYLACTIC FILTER PLACEMENT

Moving forward, the timing for when a "steady state" between IVC filter placement and retrieval is achieved remains to be seen. Efforts toward realizing this equilibrium are dynamic and largely depend on multiple factors. Among them, clarification regarding the role of prophylactic filter placement as well as other "relative" indications for filtration will play a large role in shaping the future of IVC filter utilization. One large cohort in which this indication has been called into question is the trauma patient population.

Figure 1. IVC venogram demonstrates a tilted IVC filter with the apex and hook of the filter embedded within the wall of the vena cava.

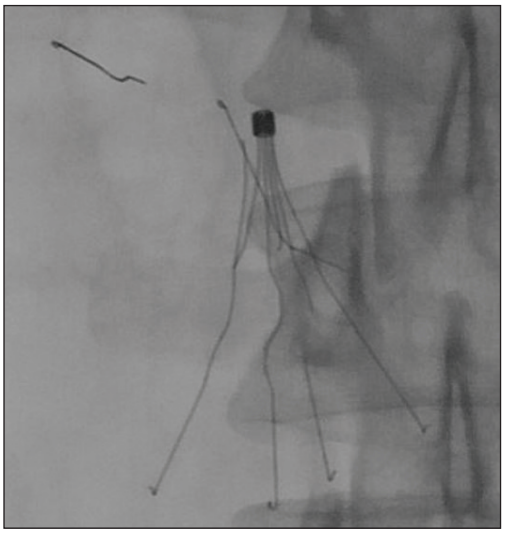

Figure 2. Spot radiograph of the abdomen demonstrates an IVC filter with multifocal fractures. One fractured leg can be seen in the extra-vascular space within the retroperitoneum.

In these patients, recent literature has found no mortality benefit of IVC filtration despite a high degree of variability in utilization across hospitals. Furthermore, poor retrieval rates have been observed in the trauma population, along with an increased risk of DVT associated with IVC filter usage.[11,12] Overall, these observations have driven the use of prophylactic IVC filters down and contributed to an overall decline in national usage.

LIMITED DATA

At present, there is a limited body of evidence-based literature to support the high utilization rates for IVC filters. To date, there are only two randomized prospective trials that have investigated the efficacy of filters to prevent PE: the PREPIC 1 and 2 studies.[1,13] Both trials studied patients with proven VTE who were placed on anticoagulation. The patients were randomized to a control group composed of those on anticoagulation alone versus a group on anticoagulation plus an IVC filter. PREPIC 1 trial included permanent filters, while PREPIC 2 trial included retrievable filters. PREPIC 1 results showed that filters provide protection from symptomatic recurrent PE but with an increased risk of DVT and no long-term survival benefit. Similar results were shown in the PREPIC 2 trial. However, all patients in both studies were treated with anticoagulation, the standard of care for VTE, which limited interpretation of the data given that the current clinical role for IVC filters is mainly for patients with contraindications to anticoagulation.

The lack of prospective evidence to support IVC filter usage represents a major challenge moving forward, as designing trials to test efficacy is difficult given ethical concerns of randomizing patients who are contraindicated for anticoagulation to a "no filter" arm. Growing skepticism surrounding the benefits of IVC filter use has further magnified this void in evidence. At present, most data surrounding IVC filters are limited to observational and retrospective analyses from single centers or national public databases, which have shown conflicting results. The conclusions from studies in which a positive benefit has been identified remain guarded and continue to suggest that prospective data are warranted to confirm these results.[14,15] Moving forward, single-arm prospective studies, such as the PRESERVE trial, may shed light on the risks and potential benefits offered by IVC filters. PRESERVE is an ongoing, large-scale, multispecialty, prospective clinical study with a target enrollment of 2,100 patients and is being sponsored by the Society of Interventional Radiology and Society for Vascular Surgery with the goal of evaluating the use of IVC filters and the related follow-up treatment in the United States.

IVC FILTER COMPLICATIONS

The growing recognition of complications associated with long-term IVC filtration has no doubt played a large role in the risk/benefit discussion surrounding placement. This has led to extremely high uncertainty about the appropriate usage of IVC filters among medical practitioners. Complications such as filter tilt, penetration, migration, fracture, strut embolization, and/or IVC thrombosis serve as major sources of morbidity and potentially mortality for patients (Figures 1 and 2). Increased awareness of these complications has been highlighted by both the FDA safety communication as well as the medical literature. Between 2000 and 2017, 57% of articles listed on Pubmed about IVC filters pertained to filter-related complications as compared with 43% of articles from the time period before (1985–2000).[16] Growing public awareness of such complications has also shed negative light on the practice of filtration and has resulted in increased litigation directed primarily at IVC filter manufacturers. The results of ongoing "bellwether" trials against these companies will attempt to define the medicolegal landscape and its associated financial implications and potentially impact the practice of

filter implantation in the United States.[2] Previous literature pertaining to filter usage and the legal climate has already shown a correlation between overutilization (ie, increased prophylactic filter placements) and regions of the United States with a more litigious medicolegal environment.[8]

FUTURE CONCEPTS

For these reasons, methods or designs to mitigate filter-associated complications can significantly affect the utilization of IVC filters amid growing public and medicolegal concerns and help justify continued usage despite a paucity of evidence supporting their efficacy. Recently, "temporary" IVC filters that are physically attached or tethered to a wire or central venous catheter have been introduced as devices that can be implanted for up to 30 days. Such devices may be particularly useful in critically ill or trauma patients, as the presence of an externalized component serves as a visual aid to lessen concerns of poor retrieval rates in this population. At present, the Angel catheter (Bio2 Medical, Inc.) is the only temporary IVC filter approved for use in the United States and Europe. Although early experience with the Angel catheter has been promising, recent reports have highlighted cases of filter fracture with subsequent complex retrieval associated with the device, suggesting that temporary filters are not immune to the complications of its retrievable or permanent counterparts.[17]

Another alternative filter design includes "convertible" IVC filters, which are devices that have the ability to change configuration over time to a nonfilter design. Examples include the Sentry bioconvertible IVC filter (Novate Medical Ltd.), which is held together by a biofilament that hydrolyses over time and undergoes transition into the form of an IVC stent at a minimum of 60 days, and the VenaTech convertible vena cava filter (B. Braun), which requires interventionalists to remove the hook percutaneously via an endovascular procedure. Permanent filters such as these have the ability to mitigate concerns over low retrieval rates and address those about complications that can occur due to long-term implantation.

IMPROVED RETRIEVAL RATES AND EXPERTISE

In the current era, optimizing the retrieval rate for IVC filters once protection from PE is no longer needed is of utmost importance to prevent the aforementioned negative long-term consequences of filter placement. Also as previously mentioned, the retrieval rates for filters at present are increasing in the Medicare population.[18] Although retrieval rates will never realistically reach 100% due to patient compliance/preference, mortality, and/or unexpected need for long-term filtration, available evidence suggests that national retrieval rates remain low.[19] One driving factor for improvement has been the establishment of dedicated IVC filter clinics, which have been shown to significantly increase retrieval rates at an institutional level.[20] IVC filter registries have also been established by some institutions for the same reason. Wang et al studied filter placement and retrieval rates using the Kaiser Permanente National IVC Filter Registry and demonstrated an increase in retrieval rates after a targeted physician education program.[21] The Cardiovascular and Interventional Radiological Society of Europe established a registry of retrievable filter use in 2010 and showed a 92% retrieval rate across various filter types.[22]

Improving expertise at removing filters with extended dwell times or pre-existing complications has also sparked considerable interest in the arena of "complex" filter removal. Advancement in filter retrieval techniques with devices such as excimer laser and endobronchial forceps have resulted in improved rates of technical success in filter retrieval approaching up to 98%.[23,24] Furthermore, such techniques have demonstrated a high degree of safety when used by an experienced operator. Moving forward, documenting the benefit of using such advanced techniques for complex filter retrieval needs to be investigated to further support its practice.

CONCLUSION

IVC filter utilization and retrieval has been evolving in the post-2010 FDA advisory era, but quality evidence supporting their use remains poor. Attempts at identifying optimal usage are underway through prospective studies, such as the PRESERVE trial, but remain limited in their ability to assess the true efficacy of filters. In the future, establishing consensus and a higher quality of evidence for filter placement will remain challenging, particularly for prophylactic filter indications. New filter concepts, such as temporary and convertible filters, along with improved expertise with filter retrieval provide avenues of hope toward mitigating the negative consequences associated with prolonged filter implantation. ■

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