Inferior Vena Cava Filters—Current Role and Controversies

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Abstract

Inferior vena cava filters (IVCFs) remain an indispensable part of an interventionalist's toolbox. Increased recognition of filter-related complications, largely from off-label use and casual approach to filter retrieval, has led to tremendous uncertainty surrounding their use. More stringent regulations on their use and development of newer and safer anticoagulants are gradually changing their role in the management of venous thromboembolism. Herein, the authors review the current role of IVCFs, indications for their use and retrieval, as well as filter-related complications.

Keywords
- inferior vena cava filter
- venous thromboembolism
- retrievable filter
- anticoagulation
- temporary filter
- optional filter
- superior vena cava filter

Introduction

Patients with concurrent risk for venous thromboembolism (VTE) and hemorrhage pose a daily medical dilemma, as anticoagulation may be contraindicated. Anticoagulation is the mainstay for VTE prophylaxis and treatment. Those with absolute contraindications to anticoagulation may benefit from inferior vena cava filter (IVCF) placement to prevent an impending or recurring embolism. However, quantification of risk for either VTE or hemorrhage is quite subjective, both in terms of the intensity and duration of elevated risk. This subjectivity is well reflected within the heterogeneity of the multiple societal guidelines on IVCF placement.[1]

Currently, approximately 15% of patients admitted with acute VTE will receive an IVCF.[2] Since the development of retrievable IVCFs (rIVCF), a sharp sinusoidal trend in use has been seen. A steep rise in IVCF use was noted in the early 2000s, which declined precipitously after increased recognition of their long-term risks, specifically after warnings by the Food and Drug Administration (FDA). Additionally, lowering of Medicare reimbursements in 2012[3] and multiple medicolegal lawsuits[4] that gained widespread media attention also contributed to this decline. However, a correctional trend is seen in the more recent literature.[5] Interventional radiology consultation approach to IVCF placement with planned follow-up has been shown to improve filter-related outcomes.[6]

In-depth knowledge of the underlying disease pathophysiology and tailoring the available body of evidence to the individual patient scenario are of paramount importance in making a judgment on the choice and technical feasibility of filter placement and/or retrieval. This review presents an update on the current role of IVCF that is supported by best available evidence to facilitate judicious clinical use of rIVCF and provide a glimpse of recent developments that would affect their use in the future.

Dynamic Risk Assessment in a Patient Referred for Inferior Vena Cava Filter

A multitude of prothrombotic and hemorrhagic factors are usually at play in a hospitalized patient. Establishing the baseline risk status in this dynamic spectrum is essential in decision making regarding further therapy (anticoagulation, its duration, and the need for IVCF). Two factors need to be assessed:

1. **Assessment of risk of hemorrhage:** Hemorrhagic risk (generalized or organ specific), especially when high, is given the upper hand in deciding whether the patient can receive therapeutic anticoagulation.[7]

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2. **Assessment of risk of deep vein thrombosis (DVT)-VTE recurrence:** When plausible risk factors for DVT are identifiable, it is said to be "provoked." Instead, when no identifiable factors are present, a DVT is referred to as "unprovoked."[8] A provoked DVT-VTE implies a more temporary risk and is considered to be less likely to recur, whereas the unprovoked DVT is often associated with a permanent risk factor and, as such, is considered more likely to recur.[9] The duration of anticoagulation, or alternatively the choice of retrievable versus permanent filter, depends on the estimated period of elevated prothrombotic risk.

Rationale for Inferior Vena Cava Filter Use

Inferior vena cava filters are mechanical devices placed typically in the infrarenal IVC to prevent migration of large thrombi up into the cardiopulmonary system, while maintaining relatively unimpeded venous outflow from the lower extremities. They neither treat the existing venous thrombosis nor prevent local thrombus progression. Ironically, with prolonged dwell time, IVCFs themselves, being an intravascular foreign body, can incite thrombosis and become occluded. All considered, the modern-day rIVCFs with their ease of placement and retrievability, are still a significant medical advancement as they allow for prevention of fatal VTE in the acute high-risk period while avoiding potential long-term IVCF-related complications. It is vital that rIVCF use be perceived as a temporizing measure, essentially allowing for postponement of final decision making on appropriateness of anticoagulation. This final decision should be based on periodic follow-ups with longitudinal assessment of the continual presence or lack of IVCF indications.

Inferior Vena Cava Filter Indications

Many professional groups have guidelines regarding filter insertion; these guidelines vary widely and often conflict. On the one hand, the American College of Chest Physicians (ACCP) guidelines recommend restricting their use to the so-called classic indications where their use is clearly the only available option.[10] On the other hand, the American College of Radiology and Society of Interventional Radiology guidelines allow for much more liberal use of rIVCFs in prophylactic situations for patients at high risk of developing VTE, divided into "expanded" and "prophylactic" subset of indications.[11] This has led to a large variation in IVCF utilization in the past two decades, both internationally and even between different types of practices within the United States.[12] An international effort at web-based rIVCF registry in the post–FDA-warning period shows a decreased proportion of prophylactic insertions compared with those for classic indications, 24 and 40%, respectively.[13]

Modern Inferior Vena Cava Filter Design and Functionality

Ideal IVCF should be safe and easy to deploy, be least thrombogenic, be able to securely attach to the IVC wall, and function with high efficiency. Based on intended purpose and duration of use, IVCFs can be divided into five types: permanent, retrievable, temporary, convertible, and biodegradable. The permanent filters are designed to remain and get incorporated into IVC wall whereas retrievable filters are recommended for temporary use and should be ideally retrieved within 30 to 59 days. ►**Fig. 1** demonstrates the design of a prototypical retrievable filter. The latter three categories are newer subtypes with limited data so far to support their clinical use. Largely, these categories are strictly for use where the VTE risk is definitively temporary like in a perioperative setting. A temporary filter is tethered to an external catheter or wire for removal within 30 days. Convertible filters are permanent implants that get converted into a stent through a subsequent conversion procedure or spontaneously after a certain period of time. Recently, 1-year follow-up data from the first 100 patients were published for the autoconvertible Sentry filter (Novate Medical) with encouraging results.[14] Biodegradable filters are filters made completely with special biodegradable materials that allow for delayed disintegration of the filter at approximately 10 weeks post-insertion.[15]

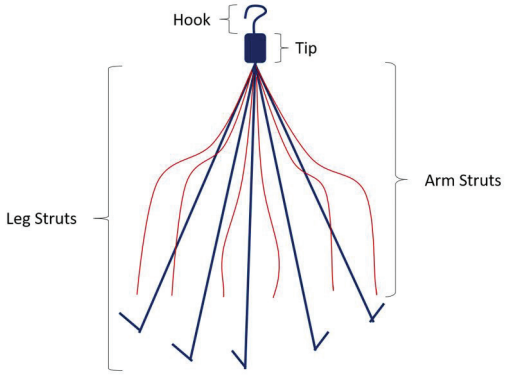

Fig. 1 Prototypical conical retrievable IVCF and its component parts—tip with hook, arm struts, and leg struts.

Current Evidence on Filter Efficacy

No randomized controlled trials (RCTs) exist that directly compare the use of IVCF alone versus anticoagulation alone because ethical approval for filter use in patients who are not anticoagulated is impracticable. All current data pertain to the comparison between IVCF with and without anticoagulation.

Prospective Studies

Only two relatively small prospective randomized studies have been carries out by the same group. The landmark PREPIC (Prevention du Risque d'Embolie Pulmonaire par Interruption Cave) trial in 1998 randomized 400 patients with proximal DVT to receive adjunctive filter versus only anticoagulation. Permanent filters and conventional anticoagulants were used. At 2 years, while symptomatic VTE occurred with increased frequency in the nonfilter group, it remained short of statistical significance. On follow-up at 8 years in 2005, difference in VTE rate achieved statistical

significance; interestingly, however, one-half of the patients discontinued anticoagulation after 6 months of treatment, and most of the recurrences occurred after anticoagulation was stopped. Also, of note, there were significantly more symptomatic DVTs in the filter group with no difference in overall mortality.[16]

The PREPIC group published results from another RCT in 2015—PREPIC II with similar study parameters (400 patients with documented VTE randomized to adjunctive filter versus only anticoagulation) but with the use of rIVCFs. This study had unexpectedly low and comparable rates of VTE in the control group, thus implying futility of IVCF placements and removals in the test arm. Also, of note, an increase in DVT with IVCF use was not seen this time around, reinforcing the benefits of filter removal within 3 months, which was part of the study protocol.[17]

However, the results of both these trials are inapplicable to patients with classic indications who are most in need for IVCFs and cannot receive anticoagulation.

Retrospective Studies

Three large population-based studies have had major impact on IVCF literature:

1. Stein and Matta in 2014 evaluated outcomes of 19,480 IVCF placements in unstable patients with shock or ventilator dependence from a total of > 2 million unstable patients in the U.S. Nationwide Inpatient Sample (NIS) database (1999–2008). They showed that IVCF use, both standalone and adjunctive, reduced the in-hospital all-cause mortality in these unstable patients with VTE, with the greatest benefit achieved in patients aged > 81 years.[18]
2. White et al in 2016 compared outcomes of adjunctive versus standalone IVCF use in 80,697 and 3,017 patients, respectively, by using the California statewide patient discharge database. They showed significant reduction in short-term risk of death only with standalone IVCF use for classic indications.[19]
3. Wadhwa et al in 2018 evaluated 67,237 prophylactic IVCF placements in patients with congestive heart failure (CHF) from a total of > 400,000 CHF patients using the U.S. NIS database (2005–2014). They found significant all-cause mortality benefit in these VTE patients with CHF who received a IVCF while hospitalized.[20]

Inferior Vena Cava Filter–Related Complications

Definitions and Consensus on Safe IVCF Placement

In 2011, SIR established a long-due consensus document to guide standards of practice. They precisely defined the complications and set up acceptability thresholds for technical success. An overall technical complication rate of < 3% was considered acceptable. Specifically, ≤ 1% for rate of filter embolization or death and a ≤ 3% for rate of access-site thrombosis.[21] In a recent study by Oh and Hingorani, in which they looked at > 300 lawsuits related to IVCFs, the most common complication reported was a primary failure to prevent pulmonary embolism (PE).[14] Clinically significant VTE can occur even in the presence of an IVCF, either secondary to ineffective IVC filtration by migrated or maloriented filter or due to embolic thrombus propagation via a parallel collateral channel.

Understanding Popular Data on Filter-Related Complications

It is important to make the patients and referring physicians understand that the data from the much popularized FDA MAUDE database is not an accurate estimate of true prevalence of complications, given that it only includes voluntary patient-reported events and does not take into account the denominator of total filter placements.[11-17] On the other hand, the overall body of data looking specifically at IVCF-related complications may be underestimating the true incidence, given the fact that most filter-related complications are asymptomatic[22] and routine imaging follow-up post-placement is not done is most practices.

Core Facts on Filter-Related Complications

Even though we do not have a true estimate of IVCF-related complications, we do know two core facts about them.

1. **Although complications may occur at any point post-implantation, the majority occur following a prolonged dwell time.** There is no absolute consensus on the length of time a filter can be left in place before removal can be safely attempted. Most manufacturers do not mention a recommended retrieval period that understandably corresponds to the fact that FDA approves only devices that can be left in place safely permanently. Various major studies and meta-analyses show a trend of increasing complications when the filters are left in place for longer periods.[23] Morales et al using a decision analysis model inferred that retrieval between 29 and 54 days after placement balances the risk of VTE versus the filter-related complications, which has been incorporated by the most recent FDA update.[24]
2. **Retrievable IVCF have consistently shown much higher complication rates in multiple studies, even though not proven by any RCT.**[23,25] Among rIVCFs, newer filter designs have been shown to perform better with lower complication rates than older devices. Recently, Deso et al from Stanford University compared the maximum reported filter-related complications between different filter geometries. They noted a generalized trend of higher perforation and fracture among conical filters and higher rates of IVC occlusion with those having a cylindrical or umbrella element.[26]

Retrieval of Inferior Vena Cava Filter

Concept of retrievability: Although retrieval is highly recommended when using rIVCFs, they are made such that they are FDA approved as permanent devices keeping in consideration that patient's prothrombotic risk and risk factors against anticoagulation are dynamic. In 2013, Eifler et al showed that four clinical parameters were positively correlated with rIVCFs being declared permanent: advanced age, male sex, history of underlying malignancy, and history

of anticoagulation failure.[27] The primary actionable reasons underlying lower retrieval rates include poor clinical follow-up and inadequate explanation of long-term risks to the patients, besides the many other extrinsic social and practical factors.[28,29]

Guidelines for Retrieval

1. **SIR guidelines** propose the following criteria for appropriate discontinuation of rIVCF[21]:
    1. An indication for a permanent filter is not currently present.
    2. The risk of clinically significant PE is estimated to be acceptably low due to sustained primary treatment (therapy or prophylaxis), or change has occurred in clinical status.
    3. The patient is not anticipated to return to a high-risk state for PE because of interruption of primary treatment, change in clinical management, or change in clinical condition.
    4. The life expectancy of the patient is long enough that the presumed benefits of discontinuation of filtration can be realized.

    Recently in 2017, ACR-SIR jointly included a 3 month post-procedural assessment for retrieval as a quality metric as part of their national quality strategy for effective clinical care.[23]
2. **The ACCP guidelines** recommend initiation of anticoagulant therapy in all patients with an indwelling IVCF once their risk of bleeding resolves, with the intent of early filter retrieval. It is however, a grade 2B recommendation secondary to conflicting data from studies comparing morbidity and mortality among all those with an IVCF who receive anticoagulation while still having an indwelling filter compared with those who do not.[30]

Newer techniques and better outcomes: With increasing concerns related to retained filters, progressively more retrievals are being done today. This has led to newer techniques being developed and improvement in retrieval outcomes even with longer dwell time as interventional radiologists and vascular surgeons get experienced and comfortable with these procedures.[31] Even true permanent filters have been successfully retrieved.[32]

Special Clinical Scenarios

Special clinical scenarios are as follows (►**Table 1**):

1. **IVCF use for isolated distal (infrapopliteal) DVT:** Recent ACCP guidelines recommend expert judgment on risk factors for thrombus extension in this situation and managing either with serial ultrasound to image progression or prophylactic anticoagulation. IVCFs are not recommended for distal DVT.[33]
2. **IVCF use for recurrence risk associated with isolated subsegmental emboli:** ACCP guidelines recommend clinical surveillance over anticoagulation as the thromboembolic risk falls much short of the opposing risk of either prophylactic anticoagulation or temporary filter placement. In fact, subsegmental PE can be seen in up to 5% of thoracic CT scans performed for non-PE indications, especially in the subgroup of oncology patients.[33]
3. **IVCF for expected prolonged interruption in anticoagulation:** In select patients who require interruption of therapeutic anticoagulation for more than a brief period (48–72 hours), a prophylactic rIVCF may be considered after appropriate consultation and with the goal of IVCF retrieval once therapeutic anticoagulation can be resumed. rIVCF should not be used for a brief interruption and for patients on prophylactic anticoagulation.
4. **IVCF for anticoagulation refractory or breakthrough VTE:** Recurrent VTE despite anticoagulation is rare, and data on this topic are limited. It can be due to either a recalcitrant prothrombotic state like cancer or patient noncompliance, the latter being partly amenable to modification. Two approaches can be considered in such a scenario: change or escalation in the anticoagulation regimen to full therapeutic doses versus IVCF placement. The ACCP 2016 guidelines recommend the former approach with mention of IVCF placement as a last resort in these patients. This also applies to recurrence with newer agents.[10] There is, however, wide international variation in management of these patients.[34]

A large international registry by Shulman et al in 2015 showed less VTE recurrence with low-molecular-weight heparin (LMWH) compared with vitamin K analogues (VKAs). They also demonstrated acceptable safety of dose escalation, with an 8% major bleeding complication rate.[34] Another retrospective study also showed similar success with escalated or modified anticoagulation regimens.[35]

5. **IVC filter occlusion/thrombosis and its management:** A true thrombosis (native formation of thrombus) within an IVCF cannot be differentiated from captured emboli from the lower extremities. A large retrospective review by Ahmed et al in 2010 found IVCF thrombosis in up to 19% of patients with a denominator of 598 filter placements. Up to 84% of thrombosis occurred within the first 6 months after IVCF placement with a median of 35 days.[36] Understandably, lack of routine post-procedural follow-up explains the lack reliability for data on late (> 6 months) filter-related thrombosis.

Asymptomatic thrombosis: In general, for asymptomatic thrombosis, manufacturer guidelines for conical filters recommend retrieval despite the presence of thrombus that occupies up to 25% of the filter cone, whereas those for nonconical designs discourage filter retrieval in the presence of any thrombus.

A widely followed management algorithm for the most commonly used conical filters was laid out by Habito and Kalva in 2011.[37] They suggested that cases with > 25% thrombosis but otherwise none to minimal symptoms and acceptable IVCF orientation—anticoagulants for a minimum of 2 to 3 weeks can be tried before reassessment. However, available data on treatment success with this strategy are poor. In the aforementioned study by Ahmad et al, no significant difference in thrombus regression rates was seen on comparison on groups who did and did not receive short-term anticoagulation.[36]

Table 1 Evidence for IVCF use in special high-risk subgroups

High-risk subgroups	Reasoning	Benefit	No benefit	Overall
Polytrauma patients	Prothrombotic risk with prolonged immobilization and trauma-related endothelial injury. Severe hemorrhagic risk in head trauma and significant solid organ trauma. In mild-moderate hemorrhagic risk, ACCP endorses the use of early anticoagulation since 2008 guidelines.[10]	Rogers et al in 1998[49] Meta-analysis by Haut et al in 2014.[50]	Large systematic reviews by Kidane et al in 2012.[51] Hemmila et al in 2015[51] and Cook et al in 2017.[53]	Conflicting evidence/insufficient to support use. Overall decrease in prophylactic use in this population.
Bariatric surgery patients	Morbid obesity is an independent risk factor for VTE and weight-based VTE prophylaxis using anticoagulants alone is very challenging in these patients.	Gargiulo et al in 2006 for open bariatric surgeries[54] and Vaziri et al in 2009 for laparoscopic procedures.[55]	Systemic review by Rowland et al in 2015.[56]	Conflicting evidence/insufficient to support use. Large variation in use among North American bariatric surgeons with only 28% using them routinely.
Pregnant patients (peripartum period)	Hypercoagulable state associated with pregnancy takes effect, beginning in the first trimester and persists for up to 2 months postpartum with compression of IVC by gravid uterus in the last trimester further increasing risk. Anticoagulation in peripartum period carries risk of severe peripartum hemorrhage.	A rIVCF can be used if patient has a PE and/or DVT diagnosed in the peripartum period, up to 1 month prior to expected date of delivery. Systemic review by Harris et al in 2016[57] found total 124 high-risk pregnancies with IVCF placements and showed safety and efficacy data to be comparable to general population.	IVCF is not required in the early trimesters as prophylactic low-molecular-weight heparin can be used (does not cross the placenta). Oral warfarin is contraindicated, and none of the newer anticoagulants are approved.	Insufficient evidence to support prophylactic use, however, benefit in high-risk pregnancies.
Cancer patients	Cancer is a prothrombotic state and cancer-associated VTE is the second leading cause of death in these patients. Many of these patients have high risk of refractory VTE despite anticoagulation and on the other hand and increased risk of bleeding due to tumor and metastasis hypervascularity.	Meta-analysis by Noble et al. in 2008.[58]	Small RCT by Barginear et al. in 2012.[59]	Insufficient data to support prophylactic use, however, as many as 19% of cancer patients receive of IVCFs for either on-label or off-label use.

Abbreviations: ACCP, American College of Chest Physicians; DVT, deep vein thrombosis; IVCF, inferior vena cava filter; rIVCF, retrievable IVCF; PE, pulmonary embolism; RCT, randomized controlled trial; VTE, venous thromboembolism.

Symptomatic thrombosis: In cases of symptomatic acute to subacute thrombosis, usually due to a large clot burden, the patient may benefit from catheter-directed thrombolysis.[38,39] Chronically thrombosed and difficult to retrieve filters are increasingly being managed with advanced techniques such as intravascular laser-assisted removal and stenting to lay open the IVC and permanently collapse the filter against the vena cava wall. These techniques have shown encouraging reported outcomes, but only from highly specialized IVCF removal centers.[40]

6. **SVC filters:** Upper-extremity DVT accounts for 5 to 10% of DVT.[41,42] The two greatest risk factors for upper-extremity DVT are central venous catheters and malignancy, and often these factors co-occur leading to a significantly high risk.[43] VTE rate has been reported to be approximately 12% in patients with upper-extremity DVT.[44] Placement of a superior vena cava (SVC) filter requires use of a modified technique and falls under the umbrella of off-label use. To maintain the correct orientation of the filter, a filter designed for jugular access is placed via a femoral approach, whereas the filter designed for femoral access is placed via a jugular approach. It is technically more demanding compared with an IVC filter placement, as the SVC has a shorter landing zone and is in close proximity to the brachiocephalic veins and right atrium. However, current data from experienced centers are promising, with good technical and clinical success even in high-risk patients.[45–47] In a systematic review on 21 publications and 209 SVC filter placements by Owens et al, the overall complication rate was only 3.8% with major complications that included cardiac tamponade, aortic perforation, and recurrent pneumothorax.[46]
7. **IVCFs and newer direct oral anticoagulants (DOACs):** Newer direct oral anticoagulants (e.g., dabigatran, rivaroxaban, apixaban, and edoxaban) have been shown to be noninferior to VKA for long-term risk reduction in recurrent VTE while being superior to VKAs in terms of risk profile for bleeding and convenience of use both

by the patient (orally administered as opposed to injectable) and physicians (wide therapeutic range allows for less patient oversight in a compliant patient). With FDA approval of direct anticoagulants since 2010 and interval generation of sufficient body of evidence, the recent ACCP 2016 guidelines favor long-term prophylaxis with DOACs over LMWH or VKAs in noncancer patients.[7-10] Currently, targeted reversal agents are being pursued and being fast-tracked and granted breakthrough therapy designation by the FDA to encourage use and allay reservations in the emergent setting.[48] Although still in their early implementation phase, these advantages of DOACs could potentially end up tipping the balance more in favor of pharmacologic anticoagulation and decrease the overall need for IVC filtration.

Conclusion

Inferior vena cava filter placement is not devoid of risk and should be considered on an individual patient basis in consultation with institution-specific experts. Prospective patient selection and responsible follow-up of nonpermanent filter placements with the goal of prompt retrieval when the patient has recovered becomes ambulatory and has reinitiated that anticoagulation should be emphasized. Prospective data from efforts at registry generation by the FDA, individual institutional endeavors at prudent use and newer advances in filter design, and use of newer anticoagulation agents hold significant promise for a more evidence-based approach to IVC filtration in the future.

Conflict of Interest
None.

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