

Placement and Retrieval of Inferior Vena Cava Filters

A Case-Based Approach

Kush R. Desai
Osman Ahmed
Thuong Van Ha
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Editors

Kush R. Desai
Division of Interventional Radiology
Northwestern University Feinberg School
of Medicine
Chicago, IL
USA

Osman Ahmed
University of Chicago
Chicago, IL
USA

Thuong Van Ha
University of Chicago
Chicago, IL
USA

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Contributors

Osman Ahmed, MD University of Chicago, Chicago, IL, USA

Bulent Arslan, MD Section of Vascular and Interventional Radiology, Rush University Medical Center, Chicago, IL, USA

Zachary Berman, MD Division of Interventional Radiology, Department of Radiology, UC San Diego, San Diego, CA, USA

Shelly Bhanot, MD Rush University Medical Center, Chicago, IL, USA

Matthew A. Brown, MD Division of Interventional Radiology, University of Colorado Anschutz Medical Campus, Aurora, CO, USA

James X. Chen, MD Charlotte Radiology, Carolinas Medical Center, Charlotte, NC, USA

Kush R. Desai, MD, FSIR Division of Interventional Radiology, Northwestern University Feinberg School of Medicine, Chicago, IL, USA

Imogen Foster Department of Radiology, University of Chicago Medical Center, Chicago, IL, USA

Andrew C. Gordon, MD, PhD Department of Radiology, Northwestern University Feinberg School of Medicine, Chicago, IL, USA

Thuong Van Ha, MD, FSIR University of Chicago, Chicago, IL, USA

Q. T. Elizabeth Van Ha Department of Radiology, University of Chicago Medical Center, Chicago, IL, USA

Mark Hieromnimon, MD University of Illinois at Chicago College of Medicine, Chicago, IL, USA

Brian Holly, MD The Johns Hopkins Medical Institute, Baltimore, MD, USA

Michael Hong Jr, MD Division of Interventional Radiology, University of Colorado Anschutz Medical Campus, Aurora, CO, USA

Basem Jaber, MD Section of Vascular and Interventional Radiology, Rush University Medical Center, Chicago, IL, USA

Nathan Kafity, MD Division of Vascular and Interventional Radiology, University of Michigan Health System, Ann Arbor, MI, USA

John A. Kaufman, MD, MS Department of Interventional Radiology, Dotter Interventional Institute, Frederick S. Keller Professor of Interventional Radiology, Oregon Health & Science University, Portland, OR, USA

Minhaj S. Khaja, MD, MBA Division of Vascular and Interventional Radiology, University of Virginia Health System, Charlottesville, VA, USA

Wes Klejch, MD Department of Radiology, University of Chicago Medical Center, Chicago, IL, USA

Ethan T. Klepitsch, BA Division of Interventional Radiology, Northwestern University Feinberg School of Medicine, Chicago, IL, USA

Mark L. Lessne, MD Vascular & Interventional Specialists of Charlotte Radiology, Charlotte, NC, USA

The Johns Hopkins Medical Institute, Baltimore, MD, USA

Robert J. Lewandowski, MD Department of Radiology, Northwestern University Feinberg School of Medicine, Chicago, IL, USA

Department of Medicine-Hematology/Oncology, Northwestern University Feinberg School of Medicine, Chicago, IL, USA

Department of Surgery-Organ Transplantation, Northwestern University Feinberg School of Medicine, Chicago, IL, USA

Alex Lionberg, MD Department of Radiology, University of Chicago Medical Center, Chicago, IL, USA

Sreekumar Madassery, MD Section of Vascular and Interventional Radiology, Rush University Medical Center, Chicago, IL, USA

Kumar Madassery, MD Rush University Medical Center, Chicago, IL, USA

Jeet Minocha, MD Division of Interventional Radiology, Department of Radiology, UC San Diego, San Diego, CA, USA

Jennifer P. Montgomery, MD, PhD Section of Interventional Radiology, Imaging Institute, Cleveland Clinic, Cleveland, OH, USA

Rakesh Navuluri, MD Department of Radiology, University of Chicago Medical Center, Chicago, IL, USA

D. Alexander Paratore, DO Section of Interventional Radiology, Imaging Institute, Cleveland Clinic, Cleveland, OH, USA

Robert K. Ryu, MD, FSIR Division of Interventional Radiology, University of Colorado Anschutz Medical Campus, Aurora, CO, USA

S. William Stavropoulos, MD Department of Radiology, Division of Interventional Radiology, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA, USA

Scott O. Trerotola, MD Department of Radiology, Division of Interventional Radiology, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA, USA

Steven Zangan, MD Department of Radiology, University of Chicago Medical Center, Chicago, IL, USA



Current Data and Trends on Inferior Vena Cava Filter Placement and Retrieval

1

John A. Kaufman

Vena cava filters are important yet controversial devices utilized to prevent pulmonary embolism (PE). Originally designed to replace more invasive inferior vena cava (IVC) interruption techniques (such as plication or clip placement), the first filters still required surgical cutdown on the jugular or femoral vein for insertion [1]. Over time, percutaneous placement became the norm, with a simultaneous increase in the overall number of filter insertions and dissemination of the procedure to interventional radiology and interventional cardiology. In the late 1990s, nonpermanent vena cava filters became commercially available, and filter utilization increased even more rapidly [2]. With more widespread use came increased awareness of complications associated with these devices [3]. The current vena cava filter environment is one of doubt and uncertainty, which is reflected in the decreasing utilization [4, 5]. Nevertheless, vena cava filters remain clinically important tools for protecting patients at risk of PE who cannot be managed with conventional strategies (anticoagulation) [6].

History

The links between deep vein thrombosis (DVT) and PE, and PE and death, are well established. In 1761, the Italian anatomist Giovanni Morgagni described large blood clots in the pulmonary arteries of patients who had experienced sudden death. The association between deep venous thrombosis and pulmonary embolism was formally recognized by the German pathologist Rudolf Virchow in 1846 when he described “the detachment of larger or smaller fragments from the end of the

J. A. Kaufman (✉)

Department of Interventional Radiology, Dotter Interventional Institute, Frederick S. Keller
Professor of Interventional Radiology, Oregon Health & Science University,
Portland, OR, USA
e-mail: kaufmajo@ohsu.edu

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softening thrombus which are carried along the current of blood and driven into remote vessels. This gives rise to the very frequent process on which I have bestowed the name Embolia” [7]. In the classic article by Dalen and Alpert, it was estimated that 11% of patients died within the first hour of the PE event [8]. Of the surviving patients, 8.7% died despite treatment, while 30% died if the diagnosis was missed (and presumably therefore are untreated).

The accepted primary therapy for all venous thromboembolism (either deep vein thrombosis (DVT) or PE) is anticoagulation [9]. The overall rate of recurrent PE in adequately treated patients is 1.2–1.4%, and the incidence of fatal recurrent PE may be as low as 0.1% [10]. The strategy of interruption of the vena cava to prevent pulmonary embolism in patients with VTE who cannot be anticoagulated is attributed to Trendelenburg, who performed the first IVC ligation for this indication in 1906 [11]. Placement of an external clip on the IVC was described in 1959, and the first successful intraluminal filter (the Mobin-Uddin “umbrella”) in the early 1970s [12, 13]. The Kimray-Greenfield filter became commercially available shortly after the Mobin-Uddin filter and with the conical design and stainless steel construction became the industry standard [1]. The external diameter of the original Greenfield filter delivery capsule was 24 Fr, requiring surgical access through either the internal jugular or common femoral vein. Percutaneous insertion was first described in 1984, involving serial dilation to 24 Fr and achievement of hemostasis with compression [14]. Smaller diameter devices that could be delivered percutaneously through sheaths were subsequently developed, all of which were intended to remain in place permanently [15]. The materials used to construct the filters included stainless steel, nitinol, egioloy, and titanium. These devices completely supplanted the 24 Fr Greenfield filter.

Retrievable vena cava filters were first approved for this indication in the United States in 2003, although devices were used earlier in both Europe and Canada [16]. The initial devices were believed to become permanently attached to the IVC wall within a few weeks of indwelling time, leading to initial conservative recommendations for the retrieval window [17]. Over time, clinical experience demonstrated that devices could be retrieved safely months and years after placement, and design features were incorporated to permit extend the retrieval window [18]. In 2016, the Food and Drug Administration (FDA) approved the first convertible filter, the B. Braun VenaTech (B. Braun, Bethlehem, PA). This device introduced the concept of a filter that converts to an open stent-like structure after percutaneous removal of an apical constraining cap. In 2017, the FDA approved a bioconvertible device (Sentry, Boston Scientific, Marlborough, MA), a filter that converts to an open configuration after 60 days without the need for an additional procedure [19]. Completely absorbable filters are currently in development and early clinical trial phase [19].

Why Filters Are Inserted

Any discussion of filter utilization must begin with revisiting the sole purpose of these devices – to prevent clinically significant PE. Perfect protection from PE is not achievable for a device that must preserve patency of the IVC while capturing

Table 1.1 FDA-approved indications for IVC filters [20]

Pulmonary thromboembolism when anticoagulants are contraindicated
Failure of anticoagulant therapy in thromboembolic diseases
Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced
Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated

emboli that might result in hemodynamic compromise. Therefore, small and usually (but not always) clinically insignificant emboli may escape the filter.

The FDA-approved indications for vena cava filters are listed in Table 1.1 [20]. These represent the most conservative indications, in which a diagnosis of PE is required in most instances. Of note, interruption of anticoagulation due to a complication of anticoagulation is not specifically approved. Furthermore, prevention of PE in patients who have a diagnosis of DVT only and cannot be anticoagulated is not included.

The clinical application of vena cava filters includes a much broader set of indications [21]. These can be roughly divided into patients with or without documented venous thromboembolism (VTE) [22]. There is little debate among clinicians that patients with documented VTE who cannot be anticoagulated should be considered for filters, although there remain great institutional, regional, and international variations in the application of this indication [23]. For example, a major trauma patient with high bleeding risk and a small incidental lower lobe PE on abdominal CT scan in the setting of normal lower extremity venous duplex studies might receive a filter in one institution and be observed in another.

The most controversial indication for a vena cava filter is in the patient who does not have but is considered at high risk of developing VTE, yet cannot receive medical prophylaxis or be adequately screened for DVT. This is the “prophylactic” indication, which includes patients with major trauma, undergoing bariatric surgery, or undergoing major orthopedic or spine surgery [24–26]. Trauma patients make up the largest segment in this group and present the additional problems of often being relatively young, with extend life expectancies provided they survive the trauma, and the most variable follow-up. Many believe that filter placement in this group was a major reason for the increase on filter placements between 1990 and 2010 [2].

Regardless of the indication, the type of filter (permanent, retrievable, convertible, and someday absorbable) should not factor into the decision to place the device. The availability of nonpermanent filters does not change the indications for placement, although in practice this has likely led to a relaxation of indications [27]. The decision to place a filter should be careful, deliberate, individualized, and clearly documented in the medical record. The type of filter placed should depend on the expected required duration of high risk of PE. If this is indefinite, a filter that can remain in place as a filter should be used. Conversely, for patients with short-term protective needs, an optional (meaning retrievable or convertible) filter should be utilized.

Trends in Filter Placement

Filter utilization is inexplicably variable. As mentioned earlier, the United States places more filters than any other country. Roughly 15% of all patients with VTE receive these devices in the United States, whereas in an international registry less than 1% of patients had filter placement [23, 28]. There are major differences in utilization between regions, states, and even hospitals within cities [29, 30, 31]. For example, teaching hospitals in cities tend to use more filters than rural hospitals or those owned by managed care networks [30]. Although patient mix likely has impact upon the prevalence of VTE within a region or institution, the degree of variability is not explained by these factors alone. The availability of practitioners capable of placing filters and the local medical malpractice environment seem to contribute to a lower threshold for filter placement [29].

The ease of placement of vena cava filters and the ready availability of the skill set among several specialties in the 1990s may have contributed to the increased utilization in patients with VTE as an adjunct to anticoagulation. Filters may be placed as an additional therapy when clinicians are concerned about issues such as the ability to maintain adequate and safe anticoagulation, the assessment that an additional PE while anticoagulated could be lethal due to lack of physiologic reserve, and a high risk of substantial PE from a large volume of lower extremity thrombus. This concept has been studied in two randomized prospective trials, the PREPIC and PREPIC II trials [32, 33]. The former utilized a variety of permanent vena cava filters, and the latter allowed only a single retrievable device. These two studies compared anticoagulation alone to anticoagulation plus a filter in patients with acute VTE [32, 33]. In the PREPIC trial, there was an early (12-day) survival benefit with the addition of a filter, but this was not sustained. At 8 years, patients with filters had more DVT, while patients without filters had more PE, but survival was equivalent in both groups [32]. The PREPIC II trial was underpowered for discrimination between the two groups based on recurrent PE, recurrent lethal PE, and overall mortality due to a lower than expected event rate in the anticoagulation group [33]. However, the study did demonstrate that stable patients who could be anticoagulated were subjected to more procedures without a discernable reduction in PE or death.

More recently, overall filter utilization in the United States has decreased, with fewer placements overall and a shift in indications toward patients with established VTE (and presumably away from prophylactic indications) [34, 35]. The explanation for this has not been established with certainty, but filter placement started to decline after 2012. This roughly coincided with FDA advisories to remove nonpermanent filters whenever possible, the rise of large class action lawsuits against filter manufacturers, increased reporting of filter complications, and skepticism about the clinical benefit of the devices [19].

Although it would seem intuitive that interruption of the IVC would decrease the likelihood of PE, especially in patients with DVT, this has not been adequately tested in a prospective randomized manner in patients who cannot be anticoagulated. Rather than attempt such an ethically challenging trial, population-based studies using large databases have been utilized to test this question. Turner et al.

utilized state-level inpatient data to evaluate the impact of IVC filter placement in patients with VTE who were not anticoagulated [36]. After correcting for immortal time bias (patients who lived long enough to receive a filter had a better chance of surviving than those who died before filter placement), they concluded that filters were associated with an increased hazard ratio of 30-day mortality (1.18; 95% CI, 1.13–1.22; $P < 0.001$). The study is limited by lack of patient-level data including extent of VTE, method of diagnosis of subsequent PE, subsequent anticoagulation, and absence of adjudication of the causes of mortality. Nevertheless, the data contributes to the increasing reluctance to place filters even in patients who meet current FDA indications.

Filter placements in trauma patients have decreased as well [37–39]. The benefit of these devices in preventing patient morbidity and mortality has been difficult to demonstrate, and there does appear to be an increased incidence of DVT in patients who do receive filters. Ho et al. conducted a randomized prospective trial of severely injured patients who could not initially be anticoagulated, with half undergoing early placement of a vena cava filter [40]. Although there was a trend toward decreased PE with filters, including lethal PE, in the subgroup that could not be anticoagulated for a sustained period, there was no overall difference in the study endpoint (PE and all-cause mortality). This study is consistent with the conclusions of several recent meta-analyses and population-based studies that suggest no benefit to placing filters in trauma patients who do not have VTE [41–44].

Filter use in US trauma patients follows the general geographic trends in filter utilization, with the South and Midwest placing the most devices in this patient population [45]. Understanding the variations in practice is as challenging in this population as others who undergo filter implantation. In Michigan, review of state-wide trauma registries demonstrated that lower level trauma centers placed proportionally more filters, suggesting that higher level trauma centers were more discriminating in patient selection [46].

Filter placement prior to major surgery in patients without acute VTE but considered at high risk of postoperative venous thrombosis has been most prevalent in the bariatric patient population. Certain risk factors such as extreme BMI, prior VTE, and the type of surgery have been proposed in observational studies as indications for a prophylactic vena cava filter based on low observed rate of PE after filter placement [47, 48]. This practice has never been studied in a randomized prospective manner, and meta-analyses have questioned the benefit of prophylactic filters in this population [49]. More recently, two population-based studies have suggested no measurable survival benefit with routine prophylactic filter use in bariatric patients and possibly increased adverse events (DVT) and treatment costs [50, 51].

Trends in Filter Complications

The increased reporting of adverse filter outcomes has occurred during the same time period in which newer retrievable filters have replaced older permanent devices in clinical practice, leading some to conclude causality, that newer devices designed with a nonpermanent option were technically inferior to the older permanent devices

[3, 52]. An alternative explanation is that as more filters are placed, complications become more obvious. None of the complications attributed to newer filters are unique to these devices; all have been reported in the past. For example, in 1992 penetration of the IVC by filter legs was noted in 41% of patients with the original Greenfield filter [53].

The management of IVC filter complications in the era of retrievable filters is different compared to when all filters were permanent. In the past, complications were managed expectantly unless the patient experienced significant harm – such as aortic pseudoaneurysm related to penetration by a filter strut [54]. More recently, complications that were underappreciated – such as pain associated with IVC filter penetration or asymptomatic penetration of adjacent structures – are now considered indications for IVC filter retrieval. Of interest is the phenomenon of back pain associated with IVC filter penetration, which in the past was considered a diagnosis of exclusion after elimination of all other potential causes of back pain. Patients reliably report relief of this symptom after removal of these devices, although this observation is confounded by the majority of patients with obvious penetration who remain asymptomatic [55].

Regardless of the actual incidence of IVC filter complications, and whether newer devices have higher rates, awareness of adverse outcomes is heightened. The increase in reports in the FDA Manufacturer and User Facility Device Experience (MAUDE) database influenced the agency's stance when it recommended retrieval of these devices whenever possible and reasonable [35, 56]. The legal profession has taken notice of this as well, with a number of ongoing large lawsuits against manufacturers in the United States [57].

Filter Retrieval

There is consensus that patients who undergo filter placement should be tracked prospectively, ideally by the physician or unit that placed the filter [58]. Many institutions and practices now have dedicated follow-up protocols and clinics [59, 60]. These improve retrieval rate of filters and can provide assistance in decision making about the devices [61–63]. In some institutions, focused follow-up by the hematology service achieves similar results [64].

The ideal rate for filter retrieval or conversion (for devices which require a second intervention to achieve the desired result) is unknown. Although most clinicians recognize that perfection is impossible in medicine, all agree that current retrieval and conversion rates in actual practice are too low [65, 66]. Retrieval rates have notably increased since 2014, likely in response to the FDA communications and heightened clinician and patient awareness of potential complications of these devices [66]. Bioconvertible and absorbable devices will introduce a new variable into decision making, in that patients will need to be followed for indications for continued IVC interruption as the devices open or dissolve.

Filter retrieval procedures are generally safe, but major complications have been reported [67, 68]. Complications of these procedures can have significant long-term

morbidity but are likely underreported [69]. Open retrieval of IVC filters is rare but has been reported in unique situations such as patients with associated aortic pseudoaneurysms due to perforation or penetrated apical hooks that have resisted percutaneous attempts by experienced operators [70].

The technical success rates of filter retrieval procedures have improved over time, particularly with the widespread adoption of more advanced techniques [71–76]. Duration of implantation, filter tilt, filter design, and operator experience all impact retrieval success [73, 77]. The ability to remove most retrievable filters even after extended implantations has encouraged percutaneous removal of devices that only have a permanent indication, but this experience remains largely anecdotal [78].

Conclusion

The environment of vena cava filters continues to be very unsettled. Overall utilization is decreasing, and removals are increasing. The very utility of caval interruption in VTE, particularly with these devices, is questioned by some. Better data, such as that anticipated from prospective post-market trials, will inform the management of VTE and clarify the role of vena cava filters [79]. Until that time, the careful and thoughtful application of these devices in patients at high risk for PE who cannot be otherwise protected, with careful follow-up with the aim to discontinue the filtration as soon as possible, will result in the best outcomes for our patients.

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IVC Filter Placement: Accepted and Relative Indications

2

D. Alexander Paratore and Jennifer P. Montgomery

Introduction

The accepted first-line treatment for venous thromboembolism (VTE) is systemic anticoagulation. VTE, which includes deep venous thrombosis (DVT) and pulmonary embolism (PE), is one of the leading causes of preventable hospital death in the USA [1]. However, there are patients who cannot receive anticoagulation due to contraindications to therapy. In addition to the patients with these contraindications are those who fail therapy either from the development of complications or from an inability to maintain therapeutic anticoagulation levels. In patients who cannot or can no longer receive anticoagulation, inferior vena cava filters (IVCFs) are frequently utilized under accepted indications. Since the introduction of optionally retrievable IVCFs, there has been a significant expansion in relative indications for their use. This has occurred in spite of the lack of strong data to support it, and the expansion has mostly included criteria outside of the inability to administer anticoagulation. The rate of IVCF placement had been rapidly increasing following the advent of optionally retrievable filters, particularly for relative and prophylactic indications [2]. Since the FDA safety communication in 2010, however, the total IVCF placement rate as well as the percentage of prophylactic placements is now decreasing [3].

Accepted Indication for IVCF Insertion

The accepted (classic) indication that is recognized by major societies, including the Society of Interventional Radiology (SIR), American College of Radiology (ACR), Cardiovascular and Interventional Radiological Society of Europe (CIRSE),

D. A. Paratore (✉) · J. P. Montgomery
Section of Interventional Radiology, Imaging Institute, Cleveland Clinic,
Cleveland, OH, USA

American College of Chest Physicians (ACCP), American Heart Association (AHA), and British Society for Haematology (BCHS), is IVCF utilization in patients with VTE and a contraindication to anticoagulation [4–12]. Although small variations exist in the wording from these societies, for the most part, the societal guidelines are in general consensus over this classic indication (Table 2.1).

The accepted indication is largely derived from a small volume of available quality data. This includes very few randomized controlled trials along with a large number of observational studies. The randomized trials available include the original Prévention du Risque d'Embolie Pulmonaire par Interruption Cave (PREPIC) and the follow-up PREPIC-2. It is important to note the fact that PREPIC was itself a two-part study that generated two major papers; the first paper represented 2 years of follow-up and the second 8 years of follow-up.

PREPIC, which was the first randomized controlled trial of IVCFs, investigated the usage of anticoagulation alone against anticoagulation supplemented by a

Table 2.1 Accepted indication for IVCF placement by society

ACR/SIR	ACCP	AHA	CIRSE	BCHS
Patients with evidence of pulmonary embolus or DVT involving the IVC, iliac, or femoral-popliteal veins and 1 or more of the following: <ol style="list-style-type: none"> 1. A high risk of a complication from anticoagulation 2. An absolute or relative contraindication to anticoagulation 3. Failure of anticoagulation <ol style="list-style-type: none"> (a) Recurrent symptomatic PE despite adequate anticoagulant therapy (b) Inability to achieve or maintain adequate anticoagulation (c) Propagation or progression of DVT on therapeutic anticoagulation 	In patients with acute proximal DVT of the leg or acute PE and a contraindication to anti-coagulation (grade 1B)	Adult patients with any acute proximal DVT (or acute PE) with contraindications to anticoagulation or active bleeding complication (class I; level of evidence B)	Patient with evidence of pulmonary embolism or IVC, iliac, or femoral-pop DVT and one or more of the following <ol style="list-style-type: none"> 1. Contraindication to AC 2. Complication of AC 3. Failure of AC <ol style="list-style-type: none"> (a) Recurrent PE despite adequate therapy (b) Inability to achieve adequate AC 	Vena cava filters are indicated to prevent PE in patients with VTE who have a contraindication to anticoagulation (grade B, level III)