Inferior Vena Cava Filters for Primary Prophylaxis: When Are They Indicated?

Eric Wehrenberg-Klee, M.D.¹ S. William Stavropoulos, M.D.²

¹Department of Internal Medicine, Brigham and Women's Hospital, Boston, Massachusetts

²Radiology, Division of Interventional Radiology, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania

Address for correspondence and reprint requests S. William Stavropoulos, M.D., Division of Interventional Radiology, Department of Radiology, Hospital of the University of Pennsylvania, 3400 Spruce Street, Philadelphia, PA 19010 (e-mail: stav@uphs.upenn.edu).

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Abstract

Keywords

- ivc filter
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- pulmonary embolism prophylaxis

Over the past several years there has been a rapid increase in the number of inferior vena cava (IVC) filters placed for primary thromboprophylaxis. Increased use has occurred in settings where other methods of thromboprophylaxis are viewed to be inadequate, technically challenging, or that place patients at an unacceptably high bleeding risk. These clinical services include trauma, bariatric surgery, neurosurgery, cancer, intensive care unit populations, and patients with a relative contraindication to anticoagulation. We review the studies to date addressing filter placement for these indications. Although preliminary data are promising, the patient populations most likely to benefit from prophylactic IVC filter placement have not been well defined, and randomized studies demonstrating efficacy have not been conducted. Moving forward, it will be critical to accomplish these two tasks if IVC filters are to continue to have a role in primary thromboprophylaxis.

Objectives: Upon completion of this article, the reader should be able to identify the controversy surrounding the placement of IVC filters for primary prophylaxis against pulmonary embolism.

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Thromboembolic disease causes significant morbidity and mortality, with an estimated 300,000 people dying of pulmonary embolism (PE) annually.¹ Rates of thromboembolism are particularly high in trauma patients, intensive care unit (ICU) patients, certain surgical populations, and cancer patients.² Reducing the rate of thromboembolism with appropriate prophylaxis is thus a topic of considerable clinical interest. Proven methods of thromboprophylaxis include chemical

prophylaxis, mechanical prophylaxis with intermittent compression devices or stockings, as well as early ambulation. Optional inferior vena cava (IVC) filters are also now being increasingly used for thromboprophylaxis in certain high-risk patient populations. In a review of the Hospital Discharge Survey, Stein and colleagues found that between 1979 and 1999, reported IVC filter placement increased from 2,000 to 49,000. A total of 19% of those inserted in 1999 were placed in patients without documented deep vein thrombosis (DVT) or PE but presumed to be at high risk of a venous thromboembolic event.³ A recent review of the Medicare population found a doubling in IVC filter placement from 1999 to 2008.⁴ This increased rate of placement of IVC filters, particularly for prophylactic indications, comes in the absence of definitive data demonstrating efficacy of IVC filters in the prevention of PE, as to date only one randomized controlled trial has been conducted with IVC filters for the prevention of PE in patients with preexisting DVT.⁵

Even in the absence of level 1 evidence, however, observational data on the prophylactic use of filters are increasing. Studies have focused on patients considered to be at high risk

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of thromboembolism and for whom other methods of thromboprophylaxis are inadequate, technically challenging, or thought to place patients at an unacceptably high risk for bleeding. Some of these preliminary data are encouraging. The purpose of this article is to discuss the indications for prophylactic placement of IVC filters.

Trauma

Venous thromboembolism (VTE) is the third most common cause of death in trauma patients surviving >24 hours and is responsible for 10.7% of such deaths.^{6,7} Trauma patients are at high risk of thrombosis, and DVT can occur in as many as 58% of trauma patients, with proximal DVT found in 18%.⁷ Many trauma patients have injuries such as intracranial hemorrhage and spinal or ocular injuries that make chemical prophylaxis risky, as well as lower extremity injuries that may prohibit the use of pneumatic compression devices. In these patients, placement of an IVC filter may provide an alternative means of PE prophylaxis.

The question of appropriate use of prophylactic IVC filters in the trauma patient population has yet to be definitively answered. The current data suffer from a lack of randomized trials, as well as an inconsistent definition of patients at high risk of developing PE. In the absence of randomized clinical trials comparing IVC filters with other modes of thromboprophylaxis, multiple retrospective studies have examined the impact of prophylactic IVC filter placement in trauma patients.^{8–14} These cohorts vary significantly in terms of indications for IVC filter placement, patient population, surveillance methods, length of follow-up, and filter type. Almost all of these studies show a significantly decreased rate of PE compared with historical controls in patients with prophylactic IVC filters. At least three studies have not shown a decreased PE rate among their patient population. McMurty et al did not show a decreased PE rate when compared with historical controls within their hospital, in a study of 248 trauma patients with a mean injury severity score of 23.1 ± 13.5 .¹⁵ A retrospective study by Antevil et al of trauma patients with filters placed during time periods of low filter utilization or high filter utilization showed no significant difference in PE rate (0.2% versus 0.2%; $p = 0.636$). However, it should be noted that during the high-utilization time period, only 42% of patients who received prophylactic filters met Eastern Association for Surgery of Trauma (EAST) criteria¹⁶ for filter placement, whereas 73% of patients did meet the same criteria during the low-utilization time period ($p < 0.01$).¹⁷ Lastly, Cherry et al found that among 244 patients meeting EAST inclusion criteria in whom a prophylactic IVC filter was placed, there was no difference in PE rates between low-utilization and high-utilization time periods (0.7 to 0.4%).¹⁸ Singh et al found in their retrospective study of patients receiving prophylactic filters either within EAST guidelines or outside of guidelines that only the patients within guidelines derived benefit from the procedure.¹⁹ This emphasizes the importance of defining a high-risk population that will derive benefit from prophylactic IVC filter placement.

Three different guidelines have been published on the use of prophylactic IVC filters in trauma patients, also with differing recommendations. The most recently released guidelines were published in 2008 by the Inflammation and Host Response to Injury Collaborative Research Project. Their recommendations are for prophylactic IVC filter placement in patients with contraindications to low molecular weight heparin (LMWH), namely spinal cord injury with tetraplegia or paraplegia, complex pelvic fractures in association with long bone fractures, multiple long bone fractures, and contraindications to LMWH expected to persist beyond 72 hours.²⁰

The EAST published similar guidelines in 2002. Noting the lack of conclusive evidence, they make only a level 3 recommendation for the use of prophylactic IVC filters in very high-risk trauma patients who cannot receive anticoagulation because of increased bleeding risk (intracranial hemorrhage, ocular injury with associated hemorrhage, solid intra-abdominal organ injury and/or pelvic or retroperitoneal hematoma requiring transfusion, and/or medical conditions that predispose to coagulopathy or bleeding) or have specific injury patterns including severe closed head injury (Glasgow Coma Scale [GCS] < 8), incomplete spinal cord injury with paraplegia or quadriplegia, complex pelvic fractures with associated long bone fractures, or multiple long bone fractures. The EAST guidelines also note the increased risk of thromboembolism with age and suggest there may be an increased need to place a prophylactic IVC filter in an older patient with the injuries just described.¹⁶

These recommendations are in contrast to the 2008 American College of Chest Physicians (ACCP) guidelines that state, "We do not recommend the use of an IVC filter as thromboprophylaxis, even in patients who are at high risk for VTE. IVC filter insertion is indicated for patients with proven proximal DVT, and either an absolute contraindication to full-dose anticoagulation or planned major surgery in the near future. In either case, even with an IVC filter, therapeutic anticoagulation should be commenced as soon as the contraindication resolves."²¹

Bariatric Surgery

Patients undergoing bariatric surgeries are increasingly considered for perioperative placement of a prophylactic IVC filter. Extreme obesity (body mass index [BMI] >50) is known to be a strong independent risk factor for PE,²² as well as other features common to this population such as immobilization, venous insufficiency, prior VTE, pulmonary hypertension, and obstructive sleep apnea.^{23,24} VTE has been shown to be the leading cause of postoperative death in bariatric surgery patients.^{25,26} The incidence of PE is 0.3 to 2%, but as many as 30% of these patients die.^{27,28} Furthermore, adequate chemoprophylaxis in this patient population is undefined and DVTs are challenging to detect clinically. In response, some have begun to advocate for consideration of perioperative placement of IVC filters as an alternative thromboprophylaxis strategy.²⁹

However, data on the risks and benefits of perioperative IVC filter placement in bariatric surgery patients are lacking, and to date there have been no randomized trials. The cohort studies that do exist vary in their definition of high-risk patients, their inclusion criteria, additional thromboprophylaxis methods, and length of follow-up. Gargiulo et al offered perioperative IVC filter patients to patients with a BMI $>55 \text{ kg/m}^2$; 17 of 35 subjects opted for IVC filter placement. In this study, the PE rate in patients receiving an IVC filter was 0% versus 28% in the nonfilter group, and PE mortality rate was 11% in the nonfilter group.³⁰ All patients received the same pharmacological and mechanical thromboprophylaxis.

Overby et al compared the incidence of VTE in 160 high-risk patients offered preoperative IVC filters to 170 low-risk patients who were not offered filters.³¹ High-risk patients had clinical or laboratory evidence of a thrombophilia, poor ambulation, severe sleep apnea with obesity hypoventilation syndrome, BMI >60 , or a history of DVT or PE. All patients received stocking compression devices and subcutaneous heparin (5000 to 7500 U every 8 hours) until hospital discharge. One patient (0.6%) with a prophylactic filter had a PE occur immediately after filter removal. Five of the 170 patients (2.94%) who did not receive a filter developed a symptomatic PE. This difference in the two groups represented a trend toward decreased PE incidence but was not statistically significant ($p = 0.216$).

A retrospective study of preoperative IVC filter placement in 6376 patients undergoing gastric bypass in a consortium of Michigan hospitals used a propensity scoring system to correct for selection bias between patients who either did or did not receive filters.³² A total of 542 of these patients (8.5%) received preoperative filters. After propensity score correction, the authors found there to be no significant difference in rates of PE between patients who did and did not receive preoperative filters (odds ratio [OR]: 1.28; 95% confidence interval [CI], 0.51 to 3.2) nor death or permanent disability (OR: 2.49, 95% CI, 0.99 to 6.26), although a trend toward increased risk with filter placement was found. The authors did not identify any patient subgroups that benefited from IVC filter placement. Importantly, additional modes of thromboprophylaxis were not standardized across hospitals that participated in this study, and differences in thromboprophylaxis modality received were not accounted for in the propensity score.

A recent retrospective study was published describing 73,921 patients receiving any type of bariatric surgery that had been entered into the Bariatric Outcome Longitudinal Database (BOLD) and followed for 90 days after surgery³³ including 536 patients who received a prophylactic IVC filter. The authors classified both DVT and PE events as VTEs, and they did not use a propensity scoring system to differentiate between patients who did or did not receive filters. The vast majority (87.1%) of patients who received an IVC filter also received another mode of thromboprophylaxis. The authors found the overall risk of VTE to be 0.42% but determined that those patients who received an IVC filter had a greater risk of VTE (hazard ratio: 7.66; 95% CI, 4.55 to 12.91). The authors note that the higher VTE rate in patients receiving IVC filters

could reflect the "general high-risk nature of the patients receiving a filter and/or it might be attributed to the finding that patients with an IVC filter were less likely to receive anticoagulation or mechanical VPX [VTE prophylaxis]."³³ Additionally, separation of VTE into DVT and PE events would be valuable for interpretation of this data.

In this climate of uncertain data it is not surprising that clear guidelines on prophylactic IVC filter use are lacking. The most recent ACCP guidelines recommend the use of pharmacological thromboprophylaxis for bariatric surgery patients.²¹ The American Society for Metabolic and Bariatric Surgery recommends early postoperative ambulation and perioperative lower extremity compression devices, as well as adjunct anticoagulant regimens.³⁴

Neurosurgery

The rate of thromboembolic disease in neurosurgery patients not receiving VTE prophylaxis is relatively high. In a prior review, the rates of VTE among neurosurgery patients was found to range widely, from 18% to 50% for DVT and 0% to 25% for PE.³⁵ Studies of spinal surgery patients have found the rate of PE to range from 0.5% to 6% depending on the surgery type.³⁶ Despite the high rate of DVT, the use of medical prophylaxis remains controversial in this patient population because of the risk of intracranial hemorrhage, which may increase from 1% to 3.9% to as high as 10.9% in the setting of heparin use.^{37,38}

In this clinical context IVC filters may have utility because they are effective for PE prophylaxis but do not concomitantly increase the bleeding risk. To date, however, only limited studies have addressed the role of IVC filters for thromboprophylaxis specifically in neurosurgical populations. Rosner et al conducted a two-institution prospective study of preoperative IVC filter placement in 37 high-risk patients undergoing complex spine surgery.³⁹ Patients received no other forms of thromboprophylaxis and were compared with a retrospective matched cohort of 122 patients. No patients who received an IVC filter developed a PE over the 16- to 18-month follow-up period, whereas in the matched cohort 16 patients (13.1%) developed a symptomatic PE, including two who died from a massive PE (1.6%). The authors noted that they could not determine what thromboprophylaxis method was received by patients in the matched cohort.

Another study described placement of a prophylactic permanent Greenfield IVC filter in 77 patients undergoing spinal surgery deemed at high risk for having a PE (due either to patient characteristics or nature of their procedure). Patients received filters prior to the first stage of spinal surgery, and they received no other prophylactic anticoagulation during the immediate perioperative period, although additional modes could later be added at the discretion of the surgeon. There were no deaths attributed to PE over 11 months of follow-up, and only one PE seen on imaging (1.3%). The authors found DVTs in 27 limbs in 23 patients. They noted that a third of these were insertion site thrombi and may have been attributable to the large size of the delivery system of the deployed filter.⁴⁰

A recent retrospective study compared 129 patients with prophylactic filters undergoing complex spinal surgery to a matched control cohort of 193 patients who received only mechanical prophylaxis. Among patients with a filter, symptomatic PE was detected in two patients (1.5%), occurring only in patients who had received a combined anterior-posterior approach surgery. There were no deaths. In the matched control cohort, eight symptomatic PEs (4.2%) were detected (only three of them in patients with a combined anterior-posterior approach), and one (0.5%) of these patients died from a massive PE.⁴¹

In light of the limited data on prophylactic IVC filter placement in neurosurgical patients, the use of IVC filters for thromboprophylaxis in such patients varies. In a survey of surgeon practice patterns for spinal surgery,⁴² 34 of 93 surveyed surgeons (37%) indicated that they used IVC filters “occasionally without anticoagulation,” 24 of 93 (27%) used filters “occasionally in combination with anticoagulant therapy,” and only 3 of 93 (3%) said they used IVC filters as their primary therapy. The remaining 34% of respondents replied “other,” demonstrating the high degree of variability in practice patterns.

Oncology

Patients with cancer are known to be at increased risk of thromboembolic events. This risk, however, differs significantly by primary cancer type, stage, histological subtype, treatment modality, the need for hospitalization, and variation in select biomarkers.⁴³ For example, one large case-control study found the OR of a thromboembolic event compared with the general population to be highest in hematologic malignancies (OR: 28.0), followed by lung cancer (OR: 22.2) and gastrointestinal malignancies (OR: 20.3).⁴⁴ The increasingly utilized antiangiogenic class of anticancer therapeutics are also associated with a significantly increased risk of thromboembolism, with an increase in relative risk of 30%.⁴⁵

Not only is the risk of thromboembolic events high in the cancer patient population, but cancer patients may also continue to have thromboembolic events despite adequate medical prophylaxis. In a randomized study comparing dalteparin with warfarin for cancer patients who had previously had a VTE, 9% of patients on dalteparin had a recurrent VTE compared with 17% while on warfarin.⁴⁶ The risk of bleeding events while on medical prophylaxis also remains high, with the risk of a major bleeding event found to be 4 to 6% in this study. Other studies have found rates of significant bleeds of up to 12.4% in patients with cancer.⁴⁷

In this context, an argument could be made for the use of prophylactic IVC filters in select high-risk cancer patient populations. To date, however, the question of IVC filter use in cancer patients has only been addressed in retrospective cohort studies that have examined the use of IVC filters in patients with a previous VTE.^{48–53} Although several of these studies show a reduction in the PE rate, it remains unclear whether or not filter placement provides a survival benefit in this patient population. In a study of 308 cancer patients with

VTE who had IVC filters placed, 30-, 90-, and 365-day survival rates were 81%, 60%, and 35%, respectively.⁵⁰ Similar survival statistics were found in a 26-year retrospective study of 926 patients with underlying malignancy who had IVC filters placed, with 85.7% survival at 30 days.⁵¹ However, other studies have shown poor survival after IVC filter placement. In a study of 116 cancer patients who had IVC filter placed for VTE, 30-, 90-, and 365-day survival rates were only 68.8%, 49.9%, and 26.8%, respectively.⁵² In a retrospective study of 175 patients with either brain malignancy or brain hemorrhage with VTE treated with filter or anticoagulation alone, IVC filter placement did not significantly improve overall survival compared with anticoagulation alone (20 weeks versus 11 weeks, respectively; $p = 0.177$), although the authors note that the study did not meet their accrual goals.⁵³

Guidelines regarding prevention of thromboembolism in cancer patients do not recommend the use of IVC filters.^{54,55} By these guidelines, the only recommendation for IVC filter use in cancer patients is in the context of a documented VTE with either contraindication to anticoagulation or recurrent PE despite standard anticoagulation.

Because cancer patients are at such elevated risk of thromboembolism, and IVC filters may offer additional protection over medical prophylaxis alone without the increased risk of bleeding, the question of prophylactic IVC filter placement in select high-risk cancer patient populations merits further study. A thromboembolic risk model developed by Khorana and Connolly is already being used in an active clinical trial for the use of dalteparin as primary prophylaxis in select cancer patients,⁴³ and it may be useful in the design of the necessary clinical trials to demonstrate efficacy of IVC filters in a subset of this population as well.

Intensive Care Unit Patients

Patients in medical and surgical ICUs are another population at high risk for VTE events. Patients have a high disease or injury burden, typically have multiple medical comorbidities that put them at greater risk of thromboembolic events, may be completely immobilized, and are more likely to have indwelling central venous catheters that can increase the incidence of venous clot.⁵⁶ ICU patients have reported rates of VTE ranging from 10% to 100% in select high-risk populations, in spite of thromboprophylaxis.^{57–59}

Despite the need for good thromboprophylaxis in the ICU population, several factors contribute to make appropriate pharmacological prophylaxis challenging, such as alterations in plasma binding proteins, volume of distribution, and drug metabolism.^{60,61} Additionally, unreliable systemic levels of heparins are typically achieved after subcutaneous administration in this population.⁶²

Due to the high burden of thromboembolic disease and the challenges of adequate medical thromboprophylaxis in ICU patients, placement of optional IVC filters in select patients may be appropriate as an additional prophylactic strategy. However, data on the benefits and drawbacks of IVC filter placement in this population are limited. Furthermore, most studies in surgical ICU patients include significant majorities

of multitrauma patients, making discussion of nontrauma ICU patients as a distinct patient group difficult. One study with a larger cohort of nontrauma surgical ICU patients is a 9-year experience with bedside ultrasound-guided placement of IVC filters in a total of 403 patients, 105 of them surgical and the remainder trauma patients. In these 403 patients, PE occurred in two patients (<1%), DVT occurred in 38 (8%), with 14 of these DVTs occurring at the site of filter insertion.⁶³

In a review of an IVC filter patient registry with 2,600 patients, Greenfield and Proctor identified 175 patients with sepsis. These patients had a combined recurrent PE and caval occlusion rate of 1.7% after filter placement. A survival benefit was found in patients who also received anticoagulation.⁶⁴

There are no specific guidelines addressing the use of IVC filters in ICU patients. However, limited available data suggest there may be benefit in at least a subset of these acutely ill patients, and further studies should focus on identifying the appropriate high-risk patient population in which randomized studies are likely to demonstrate a benefit after IVC filter placement.

Contraindication to Anticoagulation

A contraindication to anticoagulation is often cited as an indication for prophylactic IVC filter placement in surgical populations. The exact definition of this varies across the literature, however. In the 2008 guidelines published by the Large Scale Research Collaborative "Inflammation and the Host Response to Injury,"²⁰ contraindication to anticoagulation in the trauma patient population was defined as (1) severe head injury with intracranial hemorrhage or craniotomy, (2) epidural catheter or hematoma, (3) ongoing hemorrhage or significant coagulopathy, (4) nonoperative management of an intra-abdominal solid organ injury, or (5) spinal column fracture. Consensus guidelines published by the Society of Interventional Radiology in 2006 do not define "contraindication to anti-coagulation" but state that, "the use of vena cava filters is indicated when primary therapy cannot be started, must be stopped, or is insufficient to protect patients from clinically significant PE who are at high risk."⁶⁵ Other prior guidelines also support the use of prophylactic filters in similar situations.⁶⁶ However, not all guidelines agree on the prophylactic use of IVC filters in situations where patients have a contraindication to anticoagulation. The 2008 ACCP guidelines recommend against the prophylactic IVC filters in any situation, citing, "the lack of any direct evidence of efficacy, the inability to predict which patients might benefit, and the high costs" of filter placement.²¹

There is additional uncertainty regarding the determination of a true contraindication to anticoagulation. There has been historical bias against the use of pharmacological thromboprophylaxis for many surgical patient populations due to the concern for serious bleeding risk. Some data, however, suggest that these risks may be overestimated in at least certain surgical populations. At least three studies, one of which was prospective, have shown no increase in

intracranial bleeds in brain injury patients placed on pharmacological prophylaxis.⁶⁷⁻⁶⁹ This accumulating data suggest that at least some of the patients who currently are viewed as having a contraindication to anticoagulation could in fact be safely initiated on pharmacological thromboprophylaxis.

Comment on Retrievable Filters

It is important to understand that most of the articles published, and most of those cited in this article, report results for the placement of permanent IVC filters. Although there have been several articles written focusing on retrievable filters, data are still lacking on the role of such filters placed in patients with prophylactic indications as outlined in this article. Although the long-term clinical outcomes with retrievable filters most likely parallels those of permanent filter designs (particularly for conical filter designs), the role of retrievable filters most likely lies in the placement of such devices in patients with temporary indications for filter placement (e.g., preoperatively in the neurosurgical or bariatric population). More data are required to determine the best use of retrievable filters placed prophylactically in the patient populations described in this article.

Conclusion

Prophylactic use of IVC filters has become widespread in a variety of patient populations, despite the absence of definitive data demonstrating efficacy. Some of the preliminary retrospective data are promising, and negative results appear more likely in studies where filters are placed in low-risk patients. It appears likely that prophylactic placement of optional IVC filters will have benefit in a well-chosen subset of very high-risk patients, but defining these patients remains a challenge. Well-controlled randomized trials are critical to quantify the benefit of IVC filters in comparison with other thromboprophylactic methods, for which large amounts of data exist.

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