Vena caval filters: a comprehensive review

Michael B. Streiff

Hematologists are often asked to treat patients with venous thromboembolic disease. Although anticoagulation remains the primary therapy for venous thromboembolism, vena caval filters are an important alternative when anticoagulants are contraindicated. To assess the evidence supporting the utility of these devices, a comprehensive review of the English language literature was performed. Except for one randomized trial, the vena caval filter literature consists of case series or consecutive case series. The mean duration of follow-up for each of the 5 filter types varies from 6 to 18 months. All are about equally effective in the prevention of pulmonary embolism (2.6%-3.8%). Deep venous thrombosis (6%-32%) and inferior vena cava thrombosis (3.6%-11.2%) after filter placement vary widely among different filter types primarily because of differences in outcome assessment. Thrombosis at the insertion site is a common complication of filter placement (23%-36%). In view of the absence of randomized comparisons, no filter can be designated as superior in safety or efficacy. Vena caval filters represent a potentially important but poorly evaluated therapeutic modality in the prevention of pulmonary embolism. Randomized trials are necessary to establish the appropriate place for vena caval filters in the treatment of venous thromboembolic disease. (Blood. 2000;95:3669-3677)

Introduction

Venous thromboembolic disease is a significant cause of morbidity and mortality in the United States. Pulmonary embolism (PE), the most deadly form of venous thromboembolic disease, is diagnosed in 355,000 patients and results in as many as 240,000 deaths per year.1 In most clinical situations, anticoagulation is the preferred form of therapy. Although generally associated with a small (less than 5% per year) risk of major hemorrhage in the average patient, anticoagulation is more risky in selected patient populations (patients with thrombocytopenia, central nervous system [CNS] metastases, active gastrointestinal bleeding, and so forth).2 In these instances, vena caval filters have been considered an effective alternative form of therapy for venous thromboembolic disease. As hematologists, we are often asked to make decisions on the placement of vena caval filters. Unfortunately, the literature supporting the utility of these devices is scattered among a diverse collection of journals not typically read by many practitioners. The purpose of this comprehensive review is to summarize and critique the published data on vena caval filters and thus facilitate informed clinical decision-making by hematologists.

Methods

A comprehensive search of the Medline database was performed using the keywords Greenfield filter, bird’s nest filter, titanium Greenfield filter, Simon nitinol filter, Vena-Tech filter, temporary vena caval filter, vena caval filter, thrombosis, deep venous thrombosis, pulmonary embolism, anticoagulation, and bleeding. Additional articles were identified by a careful review of reference lists. Study design was reviewed and data from each article were abstracted and entered into a database for analysis. Complication rates were calculated by dividing the number of patients suffering a particular complication by the population examined for that event. Patients listed as lost to follow-up or dead were not included in the denominator when calculating complication rates. None of the studies reviewed fulfilled the recently published guidelines for vena caval filter placement and patient follow-up.2

Results and discussion

Vena caval filter studies: stainless steel Greenfield filter

Five different vena caval filters are available in the United States: the over-the-wire stainless steel alternating-hook Greenfield filter, the titanium Greenfield filter, the bird’s nest filter, the Simon nitinol filter, and the Vena Tech filter (Figure 1). The over-the-wire stainless steel alternating hook Greenfield filter has recently replaced the original stainless steel Greenfield filter, because its design modifications allow easier percutaneous placement.4 Both consist of a cone-shaped array of 6 stainless steel wires, which end in hooks that secure the device in the inferior vena cava (IVC).

Because the newer Greenfield filter has been evaluated in few patients, this review will focus on the original stainless steel Greenfield filter, which has been investigated in 40 different case series involving 3184 patients (Table 1).5-36 All the studies are case series and most are retrospective. The most common reasons for filter placement are a contraindication to anticoagulation, a complication from anticoagulation, or a failure of anticoagulation. In some series, a substantial number received filters for prophylaxis. Study populations vary from 6 to 642 participants. Serious procedural complications (eg, pneumothorax, 2 cases; cerebrovascular accident, 1 case; and death, 3 cases) are rare. The duration and intensity of the follow-up after filter placement varies considerably among studies (Table 1). In most cases, follow-up information is based on chart reviews, telephone questionnaires, or clinic visits (combined, 86% of study population). A minority of patients had

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radiologic surveillance (ultrasonography, 22%; computed tomography [CT] scans, 1.5%; and inferior venacavograms, 8.4%), a weakness that must be considered when reviewing event rates.

The primary purpose of implanting a vena caval filter is to prevent PE. Only 66 patients suffered a PE following Greenfield filter insertion; 22 were fatal. These numbers compare favorably with anticoagulation in the management of venous thromboembolic disease.37-43 Deep venous thrombosis (DVT) developed in 6%. Only a portion of the study population was assessed for this event. Therefore, the actual DVT frequency after Greenfield filter placement is probably somewhat higher.

Insertion site thrombosis (IST) is a venous thrombus that develops at the vascular access sites where filters are initially inserted. IST was identified in 87 patients. However, as with other complications of filter placement, the frequency varies with the surveillance intensity. Studies with routine ultrason screening identified IST in 23% of participants (Table 2). Because most of these thrombi were asymptomatic, their clinical significance is unknown. Long-term follow-up studies of patients with asymptomatic IST are warranted.

Although a less common event with current methods of venous interruption, inferior vena cava thrombosis (IVCT) remains a complication of Greenfield filter placement. Anecdotal cases of massive lower extremity swelling and phlegmasia cerulea dolens have been seen in conjunction with IVCT, occasionally with lethal consequences.44-46 More commonly, by impairing lower extremity venous drainage, IVCT predisposes patients to recurrent DVT and the postphlebitic syndrome.47,48 The venous collateral vessels that develop after IVCT also can become alternative routes for PE.49,50 In the Greenfield filter series, IVCT appears to be a rare event. Only 73 (3.6%) patients developed it during follow-up. Incomplete follow-up and the use of insensitive diagnostic techniques, however, suggest that this event may be underdiagnosed.47,51

Penetration of the IVC wall by filter prongs, migration, tilting, and fracture of filters are infrequent and predominantly asymptomatic events noted during the follow-up of patients after vena caval filter placement. Penetration of the IVC wall by the legs of a Greenfield filter has been associated with perforation of the small bowel, ureter, and aorta as well as retroperitoneal hematomas and small-bowel obstruction.52-57 Fortunately, symptomatic penetration is a rare event. Only 63 of 1448 patients (4.4%) with stainless steel Greenfield filters had evidence of IVC penetration and only 6 (0.4%) were symptomatic.

Another highly publicized complication is filter migration into the heart or pulmonary arteries.58,59 Migration usually is defined as caudal or cranial movement in excess of 1 cm. Only 5.3% of

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**Table 1. Compilation of vena caval filter study data**

<table>
<thead>
<tr>
<th>Filter type</th>
<th>Study no.</th>
<th>Patient no.</th>
<th>F/U duration (in mo)</th>
<th>PE</th>
<th>DVT</th>
<th>IVCT</th>
<th>Postphlebitic syndrome</th>
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<td>Stainless steel Greenfield</td>
<td>40</td>
<td>3184</td>
<td>18 (1-60)</td>
<td>66/2561 (2.6%)</td>
<td>96/1634 (5.9%)</td>
<td>73/2033 (3.6%)</td>
<td>254/1353 (19%)</td>
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<td>fatal 22 (0.9%)</td>
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<td>(range 0-18%)</td>
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<td>(range 0-18%)</td>
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<tr>
<td>Titanium Greenfield</td>
<td>10</td>
<td>511</td>
<td>5.8 (0-81)</td>
<td>13/422 (3.1%)</td>
<td>5/22 (22.7%)</td>
<td>15/230 (6.5%)</td>
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<td>fatal 7 (1.7%)</td>
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<td>Bird’s nest</td>
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<td>1426</td>
<td>14.2 (0-60)</td>
<td>32/1111 (2.9%)</td>
<td>27/448 (6%)</td>
<td>36/940 (3.9%)</td>
<td>37/267 (14%)</td>
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<tr>
<td>Simon nitinol</td>
<td>8</td>
<td>319</td>
<td>16.9 (0-82)</td>
<td>10/265 (3.8%)</td>
<td>11/123 (8.9%)</td>
<td>17/220 (7.7%)</td>
<td>16/124 (12.9%)</td>
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<td>(range 5-11%)</td>
<td>(range 5-11%)</td>
<td></td>
</tr>
<tr>
<td>Vena Tech</td>
<td>15</td>
<td>1050</td>
<td>12 (0-81)</td>
<td>33/963 (3.4%)</td>
<td>8/25 (32%)</td>
<td>83/741 (11.2%)</td>
<td>95/232 (41%)</td>
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Abbreviations: F/U indicates follow-up; PE, pulmonary embolism; DVT, deep venous thrombosis; IVCT, inferior vena caval thrombosis.

Note: The denominators of the various complications only include patients who were evaluated (ie, patients lost to follow-up or dead are not included. Only a portion of the studies evaluated patients for all these events).
Follow-up information was available on 75% (450 of 599) of participants. More intense radiologic surveillance (abdominal radiograph, 258 of 599, 43%; ultrasonography, 144 of 599, 24%; CT scan, 76 of 1426, 5%) was used compared with the stainless steel Greenfield filter, but the mean follow-up duration was only 5.8 months (range, 0-81 months).

The modified-hook titanium Greenfield filter appears to be as effective as the stainless steel model in preventing PE. Data on the frequency of DVT after filter placement were not routinely collected, so comparisons are difficult for this complication. Theoretically, the lower profile of the titanium Greenfield filter should result in fewer insertion site thrombi; however, the frequency (13.1%, 35 of 267) was similar to that seen with the bulkier stainless steel filter. In studies with routine IST surveillance, 28% of patients developed thrombosis (Table 2). Thus, regardless of catheter size, IST remains a frequent complication of filter placement.

Inferior vena cava thrombosis occurred in 6.5% of patients with the modified-hook titanium Greenfield filter. Greater radiologic surveillance probably accounts for the higher frequency of IVCT compared with the stainless steel Greenfield filter. Postphlebitic syndrome developed in only 14% of the recipients of the titanium Greenfield filter recipients. This favorable outcome is likely a consequence of the shorter follow-up compared with the stainless-steel filter (5.8 versus 18 months).

Migration (33 of 258, 12.8%) and tilting (11 of 89, 12.4%) were more common among the titanium Greenfield filter series, whereas IVC penetration (10 of 258, 3.5%) occurred at a comparable rate to the stainless steel filter. Filter fracture, which was assessed in only 1 series, was not noted in any patients. All of these events were without apparent clinical consequences.

**Bird’s nest filter**

In 1984, Roehm et al reported the initial clinical investigation of the bird’s nest filter. Unlike the conical design of the Greenfield filters, the bird’s nest filter consists of 4 stainless steel wires, 0.18 mm in diameter and 25 cm in length, which are affixed to the vena cava wall by V-shaped struts bearing hook-like anchors (Figure 1). Its unique design allows it to be loaded into an 14F insertion catheter and gives it the flexibility to be placed into vena cavae up to 40 mm in diameter, the largest of any filter on the market (other filters are limited to cavae of 30 mm or less).

Unfortunately, the original design of the bird’s nest filter had a tendency to migrate, which resulted in several deaths. Thereafter, stiffer, wider struts were used, which greatly diminished this tendency. Sixteen case series of the bird’s nest filter exist in the English literature involving 1426 patients (Table 1). In common with all the filter literature, a mixture of prophylactic and therapeutic indications was cited as the reason for filter insertion. Study populations varied from 5 to 568 participants. Significant procedural complications were rare and compare favorably with the Greenfield filter models. A weakness of the bird’s nest filter studies performed to date is the intensity of patient follow-up. The majority of the patients had clinical/chart follow-up alone (1182 of 1426, 83%). Radiologic surveillance was rare (abdominal radiograph, 166 of 1426, 12%; ultrasonography, 144 of 1426, 10%; CT scan, 76 of 1426, 5%; inferior venacavogram, 27 of 1426, 1.9%). The mean duration of follow-up was 14.2 months (0-60 months).

Pulmonary emboli, DVT, and IST occurred at frequencies comparable to those with the Greenfield filter models (Tables 1 and 2). Substantial increases in the number of IST diagnosed were seen...
in studies using routine screening procedures. IVCT and postphlebitic syndrome developed in a minority of patients. Only 4 of 15 studies documented postphlebitic symptoms among their patients.54,87,89

Phlegmasia cerulea dolens was reported in only 2 patients after filter insertion. Filter migration (11 of 588, 1.9%) and fracture (3 of 107, 2.8%) were infrequent and asymptomatic except for migration causing the death of 1 patient. Penetration of the IVC wall was only noted in a few studies. It happened frequently (52 of 137, 37.9%) but was asymptomatic.

Simon nitinol filter

The Simon nitinol vena caval filter is constructed of a nickel-titanium alloy that has thermal memory properties. At 4°C to 10°C, the wires, which compose the filter, are folded into a straight and compact form fitting into a 9F catheter carrier. At body temperature, the wires are programmed to unfold into an umbrella filter composed of 7 “petals” and 6 hooked legs that anchor the device in the vena cava (Figure 1).

Since 1989 when the first clinical study of the Simon nitinol filter was published, it has been studied in 8 different trials comprising 319 patients (Table 1).51,72,74,76,93-96 Procedural complications are extremely rare. Difficulty releasing the filter into the IVC was noted in 1 patient (0.3%). Chart review follow-up of 99.4% (317 of 319) of the study population is available for a mean duration of 16.9 months (0-62 months). Ten percent (32 of 319) of patients had follow-up clinic visits; 31% (99 of 319) had at least 1 abdominal radiograph in follow-up. Ultrasonography was performed in 41% (132 of 319) of patients, whereas magnetic resonance imaging (MRI) and CT scans were done in 12.2% (39 of 319) and 18.2% (58 of 319), respectively. Ventilation-perfusion scans (1 of 319, 0.3%), inferior venacavograms (8 of 319, 2.5%), and intravascular ultrasound (5 of 319, 1.6%) were rarely performed.

Pulmonary emboli, both fatal (1.9%) and nonfatal (10 of 265, 3.8%), were uncommon. DVT and IVCT occurred in 8.9% (11 of 123) and 11.5% (22 of 191) of patients (Tables 1 and 2). Routine surveillance for IST documented thrombosis in 31% of patients.74,76 Thrombosis of the IVC occurred in 7.7% (17 of 220) of patients. More liberal use of effective screening studies (MRI and CT scans) may be responsible for the higher rate of IVCT. Postphlebitic symptoms occurred in 12.9% (16 of 124) of the study population. Only 2 patients (0.7%) developed phlegmasia cerulea dolens after filter placement.

Penetration of the IVC wall (45 of 122, 36.9%), migration (3 of 135, 2.2%), and fracture (10 of 71, 14.1%) were recorded in only a few studies; therefore, the frequency of these complications may not be accurate. Only 1 patient with IVC penetration (0.8%) was symptomatic.94 Crossed filter legs were noted in 4 of 44 participants (9.1%) in 1 study. Although theoretically this event might be predicted to impair the filter efficiency, no clinical sequelae were noted.90 Thirty-nine percent of patients received oral anticoagulants for several months after filter insertion.

Vena Tech filter

The Vena Tech vena caval filter is constructed of Phynox, a unique nonparamagnetic alloy (cobalt 42%, chromium 21.5%, iron 8.85%, nickel 18%, molybdenum 7.5%, magnesium 2%, and a maximum of 0.15% carbon and beryllium 0.001%). Six struts are fused into a cone-shaped filter reminiscent of the Greenfield filter. Side rails attached to the filter cone anchor it to the vena cava wall (Figure 1).

Fifteen studies of the Vena Tech filter have been published involving 1050 patients (Table 1).46,48,71,73,75,76,97-104 The only common procedural complication was incomplete filter opening, which occurred in 57 of 842 participants (5.2%). In 5 patients (0.6%), a second filter had to be placed. Serious procedural complications were rare (death, myocardial infarction, and cardiac tamponade, 1 patient each). Eighty-nine percent of patients (931 of 1050) had at least telephone or chart review follow-up. Abdominal radiography was obtained in 600 (57.6%) patients; ultrasound was performed on 51% (539 of 1050). Inferior venacavograms were done in 259 patients (25%). CT scans (51 of 1050, 4.9%), ventilation-perfusion scans (46 of 1050, 4.4%), autopsies (4 of 1050, 0.4%), and venograms (2 of 1050, 0.2%) were obtained less often.

The mean follow-up duration was 12 months (range, 0-81 months). Nonfatal and fatal PE occurred at comparable rates to other filters. DVT was documented in only 1 study, which identified it in 32% of participants (8 of 25).72 IST was assessed in 5 studies in which the combined rate was 16.7% (36 of 215) (Table 2).73,75,76,97,103 Thirty-six percent of patients with routine imaging had an IST diagnosed.73,76

Thrombosis of the IVC occurred in 11.2% of patients receiving the Vena Tech filter. Postphlebitic syndrome developed in 95 patients (41%). The more intense follow-up procedures used in the Vena Tech studies are probably responsible for these higher complication rates. Filter migration (55 of 661, 8.3%), tilt (30 of 640, 4.7%), and fractures (2 of 117, 1.7%) occurred infrequently and were asymptomatic in all participants. Anticoagulant use was frequent after filter placement, being present in 68% of patients at follow-up.

**A randomized trial of vena caval filters**

Until 1998, the only clinical data available on vena caval filters were derived almost exclusively from retrospective unrandomized case series. In 1998, Decousus et al105 published the first and only randomized study of vena caval filters in the prevention of PE. They randomized 400 patients using a 2 × 2 factorial design to a vena caval filter or no filter and enoxaparin or unfractionated heparin. Four different types of vena caval filters (titanium Greenfield, bird’s nest, Vena Tech, and Cardial filters) were used. All were placed within 48 hours. Ventilation-perfusion scans were performed at baseline and after 8 to 12 days of anticoagulation. Vena caval filters were associated with a significant decrease in the incidence of PE compared with anticoagulation alone (1.1% versus 4.8%, .03) at 8 to 12 days of follow-up. After 2 years, however, this difference was no longer statistically significant although the trend still favored vena caval filters (3.4% versus 6.3%, .16). Symptomatic PE occurred at a similar frequency in both groups after 3 months (filter, 4; no filter, 6) (Figure 2). Fatal emboli were more common among patients treated solely with anticoagulation (0.5% versus 2.5%).105

In contrast, vena caval filters were associated with significantly more recurrent DVT than anticoagulation alone (20.8% versus 11.6%, .02) (Figure 3). No difference in bleeding or overall mortality was documented. Sixteen of the 37 patients (43.2%) with vena caval filters who had recurrent DVT also had IVCT (8% of filter population).105

In light of these data, one can conclude that vena caval filters in combination with standard anticoagulation do appear to offer...
By 24 months of follow-up, significantly more filter patients had developed a DVT than patients receiving anticoagulation alone. Vena caval filters have a significantly higher cumulative incidence of recurrent DVT than patients receiving anticoagulation alone. Filters significantly reduced the incidence of PE at 8 to 12 days ($P = .05$). This protection was no longer significant after 2 years of follow-up ($P = .18$). Data adapted from Decousus et al.\textsuperscript{105}

significantly more protection from PE than anticoagulation alone. This additional protection, however, appears to be short-lived and does not decrease overall mortality. In addition, vena caval filters are associated with a higher incidence of recurrent DVT over 2 years of follow-up. Further follow-up of participants in this study should be highly informative, providing important information about the long-term risks and efficacy of vena caval filters in comparison with standard anticoagulation. Because almost all participants (94%) in this trial received anticoagulants for at least 3 months, however, the outcome of these patients cannot be generalized to the typical patient with a filter who does not receive anticoagulation.

**Clinical controverses surrounding vena caval filters**

Is anticoagulation necessary after vena caval filter placement?

If feasible, many investigators recommend routine anticoagulation after vena caval filter placement.\textsuperscript{106,107} However, little data are available to support the utility of this practice. Several case series have attempted to address this issue.\textsuperscript{14,31-33} Although none of these investigators were able to demonstrate any benefit of anticoagulation, the retrospective, unrandomized nature of the studies as well as the limited duration and intensity of anticoagulation used in some of the studies suggest that randomized comparisons will be necessary to resolve this issue.

Are vena caval filters superior to anticoagulation for treatment of venous thromboembolism?

No randomized studies have been performed to address this question. The randomized study of Decousus et al\textsuperscript{105} suggests that filters may provide additional short-term protection against PE in anticoagulated patients but does not address the comparative efficacy of these therapies. An unrandomized retrospective case series found no significant differences in recurrence rate or lower extremity symptoms between the patients treated with anticoagulation and filters.\textsuperscript{36} Yet, the significant design flaws of this small study suggest that larger randomized trials will be required to answer this question conclusively.

Suprarenal vena caval filters

Concern about the possibility of IVCT precipitating acute renal failure has prompted many to recommend that vena caval filters be placed in the infrarenal portion of the inferior vena cava. Occasionally, however, placement below the renal veins is impossible. Six studies encompassing 187 patients have been published focusing on this subgroup (Table 3). All but 1 used Greenfield filters exclusively.\textsuperscript{5,11,108-111} Mean follow-up is 70 months. Follow-up data from chart reviews or clinic visits are available on 59%. Radiologic imaging was performed in 56%. PE occurred in 6% (7 of 112); venous insufficiency developed in 75% (55 of 73). Although IVCT was diagnosed in 3.6% (4 of 112), no evidence of significant renal morbidity was noted. Only 2 studies evaluated patients for DVT, which occurred in 3 participants (17.6%). Migration occurred in 18% (16 of 91) but all were asymptomatic.

In comparison with data on infrarenal filters, suprarenal filters appear to have a higher rate of PE and venous insufficiency. Careful inspection suggests that these events probably reflect differences in the study populations rather than filter location. The mean follow-up in the suprarenal filter studies is considerably longer than the infrarenal group (70 versus 18 months). Previous PE and malignancies were more common among the population with suprarenal filters, suggesting that this study population was at particularly high risk for further thrombotic events and venous stasis.\textsuperscript{108} Therefore, further information will be required to clarify the comparative safety of suprarenal vena caval filters.

Superior vena caval filters

A few investigators have published small experiences with placement of filters in the superior vena cava (SVC). These studies consist of scattered case reports and a single small case series.\textsuperscript{112-117} Thus far the results have been mixed, with some patients remaining asymptomatic and others developing SVC thrombosis. Larger patient numbers and longer, more complete follow-up will be necessary before a conclusion can be made about the safety and efficacy of SVC filters.

Free-floating iliofemoral thrombus: an indication for an IVC filter?

A rare but commonly proposed indication for vena caval filter placement is the presence of a free-floating iliofemoral thrombus.\textsuperscript{118} In their retrospective review of 78 patients with venographically proven iliofemoral DVT treated with anticoagulation, Norris et al\textsuperscript{119} documented an extremely high risk of PE among patients with free-floating thrombi (60%). Several other retrospective
studies have reached similar conclusions. In contrast, Pacouret et al recently reported no significant difference in the occurrence of PE between patients with (3.3%) or without (3.7%) free-floating iliofemoral thrombi treated with anticoagulation. Although differences in study patient populations may explain these conflicting conclusions, vena caval filters have yet to be demonstrated to be superior to anticoagulation in the treatment of these patients.

**Vena caval filters for venous thromboembolic disease in other patient populations**

A number of investigators have suggested that vena caval filters should be considered as first-line therapy for DVT and PE in patients with cancer as well as prophylaxis for PE in patients after trauma and with orthopedic problems. Although a considerable amount of literature has been devoted to examining the utility of filters in these settings, none of the studies are randomized and careful follow-up is often lacking. Vena caval filters have also been endorsed for treatment of DVT and PE in patients with limited cardiopulmonary reserve, chronic obstructive pulmonary disease, postpulmonary embolectomy, after renal or cardiac transplantation, and during pregnancy. Yet, only a small number of unrandomized reports exist to support these recommendations. Because viable alternative regimens are available for all of these situations, careful assessment of the efficacy and safety of vena caval filters in these settings is necessary before firm recommendations can be made.

**Temporary or retrievable vena caval filters**

Because the long-term safety of permanent vena caval filters remains unknown and many patients have only temporary contraindications to anticoagulation, there has been considerable interest in developing effective temporary filtration devices. Several under investigation include the Tempo filter and the Gunther Tulip filter. The cone-shaped Tempo filter is attached to a catheter, which is anchored in the subcutaneous tissue at the insertion site. It can be left in place for up to 6 weeks before removal. Preliminary studies in Europe have demonstrated it to be safe and effective. The Gunther Tulip filter is a permanent vena cava filter, which can be retrieved if desired in the first 10 days after implantation. A small European study demonstrated an 80% success rate when retrieval was performed within 12 days. If proven safe and effective, these devices could be valuable tools in the treatment and prevention of venous thromboembolic disease.

**The risks and benefits of anticoagulation for venous thromboembolic disease**

Although significant safety concerns persist concerning the use of vena caval filters, an informed decision about their use must include a consideration of the risks and benefits of anticoagulation. The utility of anticoagulation in venous thromboembolic disease has been studied in numerous randomized trials involving thousands of patients worldwide. Long-term warfarin anticoagulation is associated with a rate of symptomatic recurrent thrombosis as low as 3% over 2 to 4 years of surveillance. Major hemorrhage (usually defined as an intracranial or retroperitoneal hemorrhage, one requiring a blood transfusion, or reducing baseline hemoglobin by 2 g/dL) occurs in approximately 3% of patients during heparin therapy (range, 0-7%) and 2% to 5% during subsequent warfarin anticoagulation. In patients on indefinite warfarin, Schulman et al noted major bleeding in 8.3% after 4 years of follow-up. A number of risk factors for bleeding have been identified, including duration of therapy, recent surgery or trauma, age above 65 years, concomitant aspirin therapy, renal or hepatic insufficiency, high intensity therapy, previous gastrointestinal bleeding, alcohol abuse, and in some studies, malignant disease and female gender. Although these conditions increase the risk of anticoagulation, they are not viewed typically as absolute contraindications. On the other hand, most physicians would be hesitant to use anticoagulants in the setting of recent CNS trauma or hemorrhage, active bleeding, significant thrombocytopenia (less than 50 000/µL), cerebral metastases, or a recent large embolic stroke. Although scant research is available to justify these concerns, anecdotal case reports and series suggest that anticoagulation is probably sufficiently hazardous that vena caval filters should be considered for patients with venous thromboembolic disease in these situations.

**Indications for vena caval filter placement**

In light of the published data on vena caval filters and anticoagulation, what are appropriate indications for their use? Clearly, it is appropriate to consider placing a vena caval filter when an absolute contraindication to anticoagulation exists or when a life-threatening complication from anticoagulation arises. Table 4 lists some common situations that would satisfy these criteria. Failure of

Table 3. Suprarenal vena caval filter studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Patient no</th>
<th>Chart/clinical F/U</th>
<th>Radiology F/U</th>
<th>Mean F/U duration</th>
<th>PE</th>
<th>IST/DVT</th>
<th>IVCT</th>
<th>Venous stasis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stewart, 1982 Ref. 110</td>
<td>12</td>
<td>91%</td>
<td>58%</td>
<td>17 mo</td>
<td>1/11 (9%)</td>
<td>NA/21/11 (18%)</td>
<td>NA</td>
<td>1/11 (9%)</td>
</tr>
<tr>
<td>Orsini, 1984 Ref. 11</td>
<td>11</td>
<td>100%</td>
<td>82%</td>
<td>12.3 mo</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Brenner, 1992 Ref. 5</td>
<td>6</td>
<td>100%</td>
<td>100%</td>
<td>12.5 mo</td>
<td>0</td>
<td>NA/16 (16.7%)</td>
<td>1/6 (16.7%)</td>
<td>NA</td>
</tr>
<tr>
<td>Greenfield, 1992 Ref. 109</td>
<td>71</td>
<td>85%</td>
<td>34%</td>
<td>53 mo</td>
<td>3/30 (5%)</td>
<td>NA</td>
<td>1/73 (1.4%)</td>
<td>55/73 (75%)</td>
</tr>
<tr>
<td>Greenfield, 1998 Ref. 108</td>
<td>148</td>
<td>49%</td>
<td>49%</td>
<td>81.6 mo</td>
<td>6/73 (8%)</td>
<td>NA</td>
<td>55/73 (75%)</td>
<td>2/73 (2.7%)</td>
</tr>
<tr>
<td>Matchett, 1998 Ref. 111</td>
<td>22</td>
<td>100%</td>
<td>82%</td>
<td>36 mo</td>
<td>1/22 (4.5%)</td>
<td>NA</td>
<td>1/22 (4.5%)</td>
<td>NA</td>
</tr>
</tbody>
</table>

Abbreviations: P/E, follow-up; PE, recurrent pulmonary embolism; DVT, deep venous thrombosis; IST, insertion site thrombosis; IVCT, inferior vena cava thrombosis; NA, not assessed.


Table 4. Indications for a vena caval filter

1. Absolute contraindication to anticoagulation
   —CNS hemorrhage
   —Overt gastrointestinal bleeding
   —Retroperitoneal hemorrhage
   —Massive hemoptysis
   —Cerebral metastases
   —Massive cerebrovascular accident
   —CNS trauma
   —Significant thrombocytopenia (<50,000/µL)

2. Life-threatening hemorrhage on anticoagulation

3. Failure of adequate anticoagulation
Table 5. Proposed indications for vena caval filter placement

1. Prophylaxis for PE in trauma patients
2. Treatment of venous thromboembolism in cancer patients
3. Prophylaxis for PE in high-risk orthopedic patients
4. Pre- or postpulmonary embolectomy
5. Prevention of PE in patients with extensive free-floating iliofemoral thrombi
6. Prevention of PE in patients with chronic obstructive pulmonary disease and DVT
7. Prevention of PE in patients with minimal cardiopulmonary reserve and DVT
8. Treatment of venous thromboembolism in pregnancy
9. Treatment of venous thromboembolism in organ transplant patients

Anticoagulation is considered by many to be a reason for vena cava filter placement. Given their adverse effects, filters should be used judiciously for this indication. Objective documentation of thrombosis in the setting of adequate anticoagulation is essential. In the setting of warfarin resistance,Trousséau syndrome must be excluded. This hypercoagulable state associated with malignancies is characterized by disseminated intravascular coagulation and recurrent arterial or venous thrombotic events. Because thrombi develop throughout the vasculature, regional therapies such as vena cava filters are ineffective and may provide a nidus for clot formation. Heparin is the only useful therapy for Trousséau syndrome. Numerous other indications for vena cava filter placement have been endorsed; however, definitive evidence of their superiority to conventional care for these situations is lacking (Table 5).

Conclusion

Since the advent of modern venous interruption with the stainless steel Greenfield filter in 1973, numerous clinical studies have been performed to assess the utility of vena cava filters in the treatment of venous thromboembolic disease. Unfortunately, virtually all of these studies have been uncontrolled case series with follow-up of short duration and limited intensity. Consequently, although these devices appear to be effective in the prevention of PE, this conclusion must be considered preliminary. Furthermore, troubling concerns about the safety of these devices remain. Studies have linked filters with an increased risk of DVT, IVCT, and perhaps, postphlebitic syndrome. In the absence of randomized studies, no filter can claim superiority in effectiveness or safety over other filters or standard anticoagulation.

Because long-term safety and efficacy of filters remain uncertain, use of filters should be restricted to situations in which anticoagulation is clearly contraindicated. More liberal application of vena cava filters should be restricted to prospective randomized clinical trials. Undoubtedly, vena cava filters represent an important weapon in every clinician’s armamentarium for the treatment of venous thromboembolic disease, but the optimal application of this technology remains to be defined. Temporary filtration devices in clinical testing may provide many of the advantages of permanent filters without the potential long-term side effects. Carefully designed, prospective, randomized trials are needed to establish the safety and utility of both classes of vena caval filtration devices. New guidelines for vena cava filter placement and patient follow-up suggest that there is considerable interest within the clinical research community to initiate such studies.3 Until these studies are performed, the true potential and problems of vena cava filters will remain unknown.

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