Review

Inferior Vena Cava Filters for Recurrent Thrombosis

Current Evidence

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Inferior vena cava filters are often used as alternatives to anticoagulant therapy for the prevention of pulmonary embolism. Many of the clinical data that support the use of these devices stem from relatively limited retrospective studies.

The dual purpose of this review is to examine the incidence of thrombotic complications associated with inferior vena cava filters and to discuss the role of anticoagulant therapy concurrent with filter placement. Device-associated morbidity and overall efficacy can be considered only in the context of rates of vena cava thrombosis, insertion-site thrombosis, recurrent deep venous thrombosis, and recurrent pulmonary embolism. ***(Tex Heart Inst J 2007;34:187-94)***

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Deep venous thrombosis (DVT) predisposes patients to pulmonary vascular occlusion and its secondary effects: an estimated 400,000 to 650,000 patients in the United States develop a pulmonary embolism (PE) each year, and there are 50,000 to 240,000 associated fatalities.[1-3] Medical anticoagulation with oral or injectable agents, usually in the outpatient-care setting, remains the treatment of choice for DVT and its sequelae; secondary prevention of PE is achieved in up to 95% of cases.[4-6] However, warfarin and heparin may be contraindicated for certain patients, particularly if interactions with concurrent medications or any active bleeding diathesis is suspected; in such cases, the placement of an inferior vena cava (IVC) filter may be appropriate.[7,8] Vena cava filter (VCF) placement may be performed via minimally invasive interventional radiologic techniques.[1,8] The steel Greenfield filter (Boston Scientific/Meditech; Watertown, Mass), initially used in 1973,[9] and its titanium revision (Boston Scientific Corporation; Natick, Mass) are the IVC filters perhaps most familiar to medical practitioners. Alternative filters in common use include the Gianturco-Roehm Bird's Nest® Vena Cava Filter (Cook Medical, Inc.; Bloomington, Ind), the Simon Nitinol Filter® (Bard Peripheral Vascular, Inc.; Tempe, Ariz), the Günther Tulip filter (Cook), and the Vena Tech™–LGR® (B. Braun Medical, Inc.; Bethlehem, Pa) (Figs. 1 and 2). An estimated 49,000 IVC filters are placed annually in the United States.[10]

Risks of Inferior Vena Cava Filters

Transjugular or transfemoral insertion of IVC filters may result in clinically significant complications, such as vena cava thrombosis, insertion-site thrombosis, intravascular migration, vena cava perforation, and recurrent DVT or PE.[8,11] In addition, while the weight of clinical evidence may support the view that IVC filters prevent recurrent PE with a resultant high IVC patency rate, some practitioners have expressed concern that the filters may increase the risk of thrombosis at the insertion site and within the venous system.[12,13] Clinical evidence supports the theory that clot accumulation within the device lumen itself is likely the cause of embolic complications.[14]

A single-center review[15] in 2000 found the overall incidence of PE among 1,731 patients with IVC filters to be 5.6%. Death from PE occurred in 3.7% of the patients (median time, 4 days after insertion). Vena cava thrombosis occurred in 2.7% of the patients. Most filters were placed due to a contraindication to, or prior failure of, anticoagulation (94%). Because the procedures were conducted over a 25-year period, some early filter failures may have been attributable to early practitioner inexperience in placement and management, and to new technology.

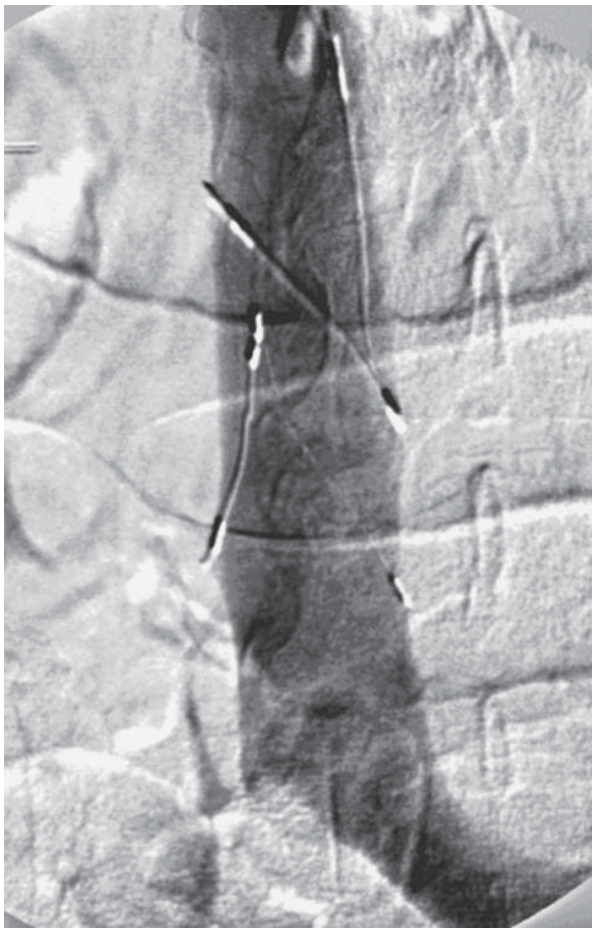
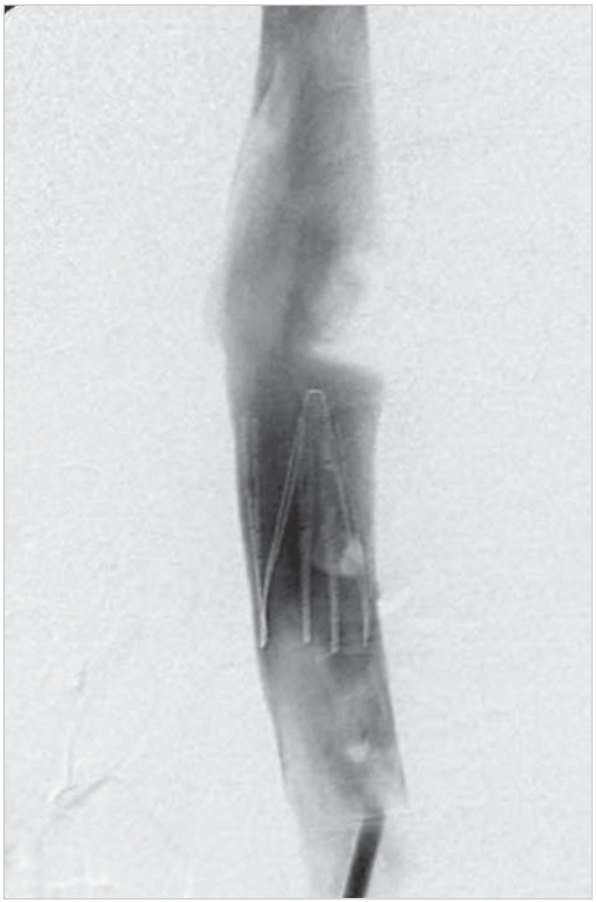


Fig. 1 *Manipulation of a Bird's Nest® vena cava filter within the inferior vena cava, under fluoroscopic guidance.*



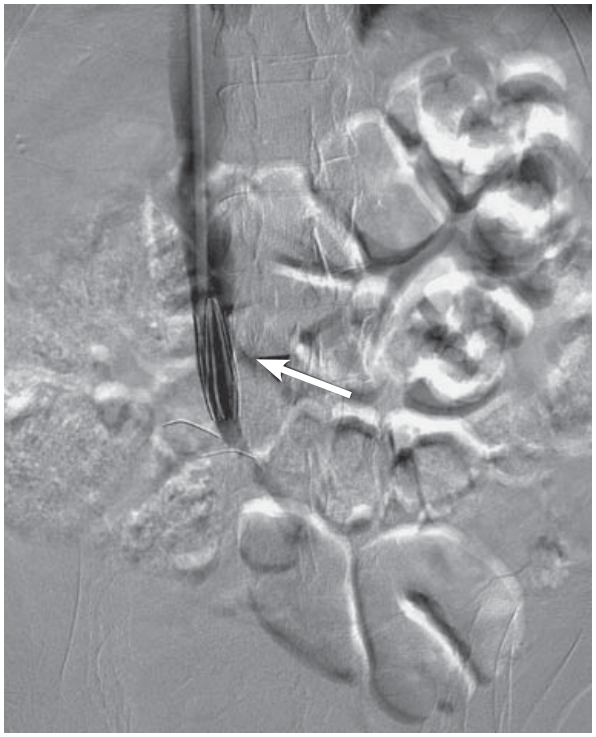


Fig. 2 *Vena Tech™–LGM® vena cava filter deployed in a suprarenal position (top); and, in a different patient, in an infrarenal position (bottom, arrow).*

Inferior Vena Cava Filter Efficacy: Primary Evidence

Before the advent of IVC filters in 1969 in the form of the Mobin-Uddin system,[16] interventional approaches to the prevention of PE were largely limited to open surgical femoral vein ligation or IVC clipping, introduced in the 1930s and 1940s, respectively, each with low reported efficacy and high possible operative morbidity. Subsequently, since their introduction, IVC filters have been subject to only a single randomized controlled trial[17] in which the efficacy of thrombosis rate reduction in patients was evaluated. A clear understanding of this landmark trial and its construction is important in evaluating the filters' benefits. Four hundred participants were randomly assigned, in a 2 × 2 factorial design, to receive anticoagulation with or without filter placement. Anticoagulation was achieved with either unfractionated heparin (205 patients) or enoxaparin (195 patients) for 8 to 12 days, along with warfarin initiated on day 4 and continued for at least 3 months. If warfarin was contraindicated, unfractionated heparin was substituted, again for at least 3 months. Half of the participants received a filter and half did not.

At the study's close,[17] a statistically significant reduction of PE at the 12-day mark was observed with filtration, compared with anticoagulation alone; however, this effect was lost upon follow-up at 2 years. Furthermore, the patients who had a filter ran a significantly higher risk of recurrent DVT at 2-year follow-up. Overall, no difference in 2-year mortality rate was observed between the filter and nonfilter groups, and no difference in bleeding was noted between the heparin-treated and enoxaparin-treated groups (Table I). The authors concluded that an IVC filter should be implanted with caution in high-risk patients, because any initial efficacy of the filters was negated in the long term and no favorable impact on mortality rate was noted.

Limitations of this trial[17] include its not having met original patient enrollment targets (800 subjects were originally envisioned) and the narrow range of the enrolled subjects' clinical diagnoses, which hindered both the study's statistical power and its general application.

Vena Cava Filter Efficacy: Subsequent Trials

Additional evidence has been collected in a systematic manner to determine whether the use of IVC filters is justified. An observational analysis[14] with 3,622 IVC-implanted patients and a control population of 64,333 patients with venous thromboembolism determined that an implanted filter was not associated with a significant reduction in later hospitalization for recurrent PE after 1 year. The patients who received filters and those who were medically managed were significantly more likely to be readmitted as inpatients if their initial presentation included PE (relative risk, 6.72; 95% confidence interval, 3.61–12.49) rather than venous thromboembolism (relative risk, 5.30; 95% confidence interval, 4.61–6.10). In addition, the filter was associated with a significantly higher risk of re-hospitalization for venous thromboembolism if the patient's initial presentation included PE (relative hazard, 2.62). The study was limited by a lack of documentation of anticoagulation and by a higher frequency of comorbidities and recurrent PE in the filter group.

A review by Streiff[18] reported rates of thrombosis during follow-up of patients who had undergone filter placement; included within the analysis were case series with relatively short follow-up periods of 6 to 18 months. Patients lost to follow-up before the completion of the study were not included in the analysis. The reported rates of complications, such as DVT (5.9%–32%), IVC thrombosis (3.6%–11.2%), and insertion-site thrombosis (23%–36%), were highly variable. However, all filter types were equally effective in preventing PE, which occurred in 2.6% to 3.8% of patients.[18] The rates of PE in this study corroborate prior reports of a 4% recurrence with the stainless-steel Greenfield filter, 3.5% with the titanium Greenfield filter, 2.7% with the Bird's Nest filter, and 2.9% with the Simon Nitinol filter.[6,19-21]

Concurrent Anticoagulation

To prevent thrombosis during filter insertion, anticoagulation is recommended unless otherwise contraindicated.[4,22-24] A prospective study of intraprocedural bleeding in 100 patients with concurrent anticoagulation (including 87 patients with prolonged bleeding times) uncovered no cases of arterial puncture or venous bleeding during a venous interventional radiology procedure. The authors concluded that the continuation of anticoagulation therapy is indicated in patients with severe thromboembolic conditions.[23]

TABLE I. Summary of Endpoints during 12-Day and 2-Year Follow-up in 200 Patients[17]

Clinical Endpoint	VCF with Anticoagulation No. (%)	Anticoagulation Alone No. (%)	Odds Ratio (95% CI)	*P* Value
Pulmonary embolism				
12 d	2 (1.1)	9 (4.8)	0.22 (0.05–0.90)	0.03
2 yr (symptomatic only)	6 (3.4)	12 (6.3)	0.50 (0.19–1.33)	0.16
Recurrent DVT*				
12 d	N/A	N/A	N/A	–
2 yr	37 (20.8)	21 (11.6)	1.87 (1.10–3.20)	0.02
Major bleeding				
12 d	9 (4.5)	6 (3.0)	1.49 (0.53–4.20)	0.44
2 yr	17 (8.8)	22 (11.8)	0.77 (0.41–1.45)	0.41
Death				
12 d	5 (2.5)	5 (2.5)	0.99 (0.29–3.42)	0.99
2 yr	43 (21.6)	40 (20.1)	1.10 (0.72–1.70)	0.65

CI = confidence interval; DVT = deep venous thrombosis; n = incidences reported as number of occurrences; N/A = not applicable; VCF = vena cava filter

*Diagnosed by a new intraluminal filling defect on venography, by a lack of compressibility at a new site, or by an extension to a new venous segment of thrombus on duplex ultrasonography.

The proper protocol for administration of warfarin or heparin after filter replacement is far less clear. Aside from the randomized trial led by Decousus and colleagues,[17] a paucity of complementary studies exists. A long follow-up period distinguishes a study by David and associates,[25] which identified 10 patients with recurrent PE; 4 patients (who had thrombi <5 cm in length, measured from the apex of the filter) were treated with anticoagulation, and 6 patients (who had larger thrombi) received a 2nd VCF. Warfarin therapy proved beneficial in the short and long terms. Dissolution of the thrombi was observed in all warfarin-treated patients; at the 5-year mark, recurrent PE occurred in 1 patient after the discontinuation of anticoagulation.

A separate study,[26] with shorter follow-up, presented additional (non-thrombus-related) benefits of anticoagulation: 47 patients with previous DVT were treated with anticoagulation after IVC placement. Anticoagulants significantly improved symptoms associated with post-thrombotic syndrome over early (<6-week) and late (>6-week) follow-up periods.

Of note, a small number of well-designed trials have shown no significant association between medical therapy and the reduction of thromboembolism in recipients of VCFs. Ortega and colleagues[24] examined the records of 199 patients who received IVC filters, both with and without anticoagulation upon hospital discharge. Warfarin treatment extended from 1 to 8 weeks (mean period, 2 weeks). Data on 89 anticoagulated patients and 81 patients with a VCF alone were available for follow-up. Over a follow-up period of 3 to 60 months (mean, 39 mo), no differences in early recurrent DVT or PE were detected between groups.

In another retrospective study, Poletti and coworkers[27] evaluated 114 IVC filter patients who were treated with or without anticoagulation. After a mean period of 27 months, there were no statistically significant differences in recurrence of PE (4.3% vs 3.9%, respectively), IVC filter thrombosis (2.2% vs 5.9%), or insertion-site thrombosis (6.5% vs 2.0%).

In a prospective trial, Greenfield and Proctor[28] monitored 465 VCF patients for a mean period of 9 years. New DVT occurred in 12% of 241 patients given anticoagulation versus 15% without anticoagulation (P= 0.35); new PE in 2% versus 4%, respectively (P=0.16), and vena cava thrombosis in 0.4% in both groups. The results of this study were weakened by inconsistent documentation of both levels and duration of anticoagulation. Although no statistically supported difference was found, the general trend favored anticoagulant therapy for the prevention of recurrent DVT in VCF patients.

Evolving Filter Systems

Filters such as the Günther Tulip™ (Cook Medical) and the TrapEase® (Cordis Corp., a Johnson & Johnson company; Miami Lakes, Fla) have been proposed for deployment in thrombosis-prone patients during short, high-risk periods (Fig. 3). The underlying assumption behind such systems is that long-term complications such as recurrent DVT, vena cava thrombosis, and vena cava perforation can be avoided. Indications for nonpermanent filters include pregnancy, trauma, and surgery (Table II). The Günther Tulip and the OptEase® (Cordis) have received approval from the U.S. Food & Drug Administration for use as retrievable devices. Temporary filters usually remain in place for 10

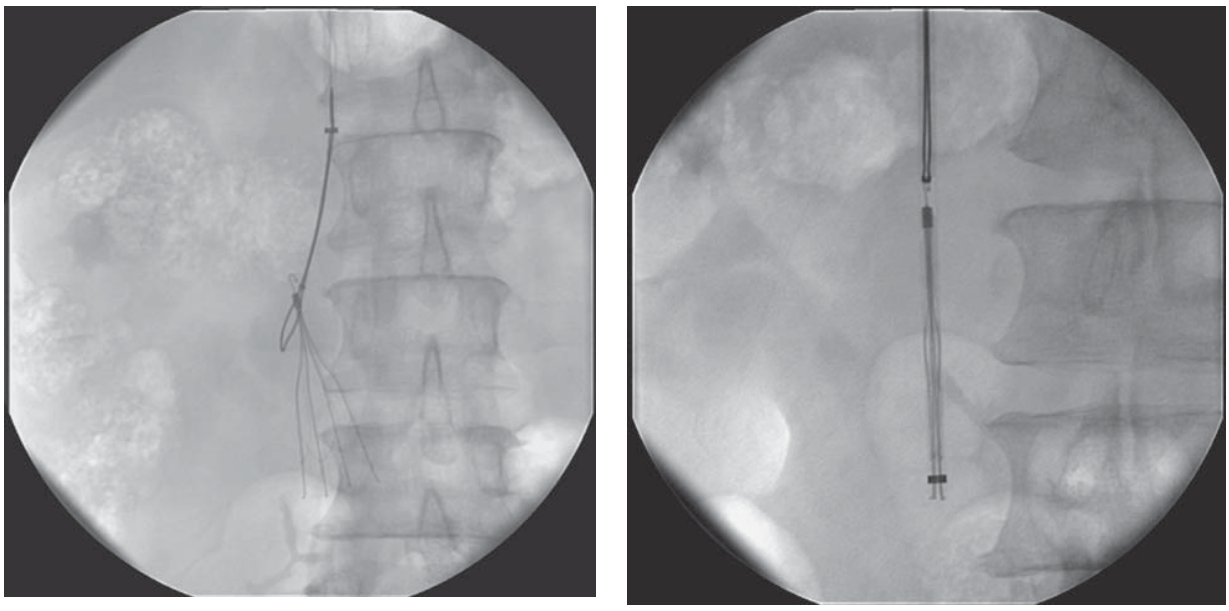


Fig. 3 *Snaring of a removable Günther Tulip™ vena cava filter (left) and its capture in a catheter sheath (right).*

TABLE II. Potential Indications for Temporary Filter Placement[2,18,29-41]

Contraindication to anticoagulant-only therapy
Documented failure of anticoagulant therapy
Concurrent administration of fibrinolytic therapy
Pregnancy
Labor and delivery
Severe trauma to the head or spinal cord
Severe trauma to or multiple fractures of the long bones
Major pelvic or acetabular fractures
Iliofemoral venous injury
Prolonged immobilization with multiple injuries
Prophylaxis in the setting of specific surgical procedures, such as malignancy resection, facial injury repair, or gastric bypass
Acute withdrawal of oral anticoagulants before general surgery
Period of transition to oral anticoagulants due to heparin-induced thrombocytopenia
Pulmonary embolus in the setting of diminished cardiopulmonary reserve
Young patients at short-term high risk for pulmonary embolus
Free-floating vascular thrombus on venography

to 14 days; after this window, device endothelialization has been observed.[21,40,42] However, Millward and colleagues[43] and Pieri and co-authors[44] have shown high efficacy rates with such filters in place for as long as 25 days (90 patients) and 63 days (18 patients), respectively. In these nonrandomized, retrospective reports, vena cava thrombosis, insertion-site thrombosis, and recurrent PE occurred rarely, if ever.[18,43,44] The results of these studies have been tempered by a retrospective review of 17 patients by Millward,[45] in which no reduction in the rate of inferior vena cava and insertion-vein thrombosis was recorded.

Nonpermanent VCF systems are a focus of active basic research; several manufacturers are developing or refining devices. Two such models, the recoverable ALN filter (ALN Implants Chirurgicaux; Ghisonaccia, France),[46] and the Recovery nitinol filter (Bard), have been implanted in human beings, with promising initial published data.[42] The Recovery was subsequently removed from market availability by the manufacturer. Research into permanent devices is less common, but it continues. For instance, the Cordis Keeper (Cordis) has been tested in a porcine model at the University of Gröningen (The Netherlands) with mixed results: 5 animals showed IVC patency for either 2 or 6 months, but 1 filter caused nonfatal caval wall penetration at 6 months.[39]

Discussion

Table III presents a summary of complications that have been reported in the medical literature. The number of patients participating in the trials has varied, and the average follow-up period has been 1 to 1.5 years. In these trials, common forms of routine surveillance for complications consisted of abdominal radiography, ultrasonography, computed tomography, magnetic resonance imaging, and vena-cavography. Should patients require follow-up abdominal magnetic resonance imaging, there are several filters that do not obscure the IVC with a metallic artifact (Table IV).

Robust evidence indicates that IVC filters effectively reduce the incidence of PE. However, patients in several studies were restarted on anticoagulation after filter placement: as many as 76% of study patients received this concurrent therapy. In addition, the rates of vena cava thrombosis, insertion-site thrombosis, and recurrent DVT are highly variable, and the long-term safety and efficacy of many VCFs remains unknown. Furthermore, the overall complication rates associated with each filter type have yet to be clearly delineated in long-term studies.

In regard to the generally expanding use of IVC filters over the past decade, a prospective study[53] (2001–2002) was performed by Buller and colleagues and comprised more than 5,400 U.S. inpatients and outpatients who had ultrasonographically confirmed DVT. That study determined that 14% of those patients had received IVC filters and that 33% of filter recipients had received their filters for primary prevention of PE. The authors of this multicenter study expressed concern that the risks of VCFs ought to temper their use, and suggested that patients without histories of anticoagulant complications or hemorrhage should be strongly considered for medical therapy alone.

Clearly, additional well-designed clinical trials—prospective and sufficiently powered—are warranted in order to define the risk of filter-associated thrombosis. Until further information is available, the weight of evidence dictates VCF use only for patients in whom anticoagulation is contraindicated or ineffective. In support of this viewpoint, the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy has recommended against the use of IVC filters in most patients as a routine addition to an anticoagulant regimen.[53]

As a means of prophylaxis in high-risk patients who are being successfully treated with anticoagulants, permanent VCF insertion is not an established treatment, and it may increase the risk of thrombus-associated morbidity or death. In the high-embolic-risk patients, however, temporary filters appear to protect against PE and might be particularly useful as a bridge to oral anticoagulation, because the existing evidence most strongly supports VCF efficacy over short periods, such as 1 month.

Further testing is necessary to determine the cost-effectiveness of temporary VCFs. In addition, advances in basic VCF design, such as drug-eluting variants or stent-filter combinations, and in the development of recovery technology, may improve the overall cost-benefit ratio. As yet unclear are the merits of anticoagulation

TABLE III. Summary of Reported Inferior Vena Cava Complications[7,13,15,18,27,35,42,43,46-51]

(No. = Number of subjects through completion of study. All other values are percentages, with ranges in parentheses.)

Filter Type	No.	Follow-Up (mo)	Pulmonary Embolus	Deep Venous Thrombosis	Inferior Vena Cava Thrombosis	IST without Surveillance	IST with Surveillance	Anticoagulation Resumed Post-Placement
Greenfield: Stainless Steel								
Streiff MB[18]	3,814	18 (1–60)	2.6 (0–9)	5.9 (0–18)	3.6 (0–18)	9.6 (1–47)	23 (14–41)	37
[a]Mohan CR, et al.[47]	68	12 (0–87)	3.0	N/A	0.0	N/A	N/A	(See [a2])
Becker DM, et al.[7]	1,094	N/A	2.4	N/A	N/A	2.0	N/A	N/A
[b]Athanasoulis CA, et al.[15]	455	16 (0–203)	8.4	N/A	3.3	N/A	N/A	N/A
Greenfield: Titanium								
Streiff MB[18]	511	5.8 (0–8.1)	3.1 (0–3.8)	22.7 (0–36)	6.5 (1–31)	13.1 (2–50)	28 (25–50)	N/A
[a]Mohan CR, et al.[47]	28	12 (0–87)	1.0	N/A	3.6	N/A	N/A	(See [a2])
Greenfield LJ, et al.[13]	113	12 (12)	3.5	N/A	1.0	N/A	2.0	N/A
[b]Athanasoulis CA, et al.[15]	134	16 (0–203)	4.5	N/A	0.7	N/A	N/A	N/A
Greenfield: Percutaneous Steel								
Greenfield LJ, et al.[13]	231	12 (12)	2.6	7.8	N/A	N/A	4.3	76
Bird's Nest								
Streiff MB[18]	1,426	14.2 (0–60)	2.9 (0–4.2)	6 (0–20)	3.9 (0–15)	7.4 (0–33)	23 (21–33)	N/A
[a]Mohan CR, et al.[47]	48	12 (0–87)	4.2	N/A	14.6	N/A	N/A	(See [a2])
Nicholson AA, et al.[48]	78	N/A	1.3	N/A	4.7	N/A	N/A	N/A
[b]Athanasoulis CA, et al.[15]	255	16 (0–203)	7.0	N/A	0.4	N/A	N/A	N/A
Simon Nitinol								
Streiff MB[18]	319	16.9 (0–62)	3.8 (0–5.3)	8.9 (8–11)	7.7 (4–18)	11.5 (0–64)	31 (16–64)	N/A
[c]Poletti PA, et al.[27]	114	32.2 (5–62)	4.4	5.3	3.5	N/A	3.5	40
[b]Athanasoulis CA, et al.[15]	594	16 (0–203)	3.0	N/A	3.7	N/A	N/A	N/A
Vena Tech								
Streiff MB[18]	1,050	12 (0–81)	3.4 (08)	32 (32)	11.2 (0–28)	16.7 (8–44)	36 (34–44)	68
[a]Mohan CR, et al.[47]	51	12 (0–87)	2.0	N/A	4.0	N/A	N/A	(See [a2])
[d]Wittenberg G, et al.[49]	76	36 (1d–81 mo)	4.0	N/A	17.0	N/A	N/A	N/A
[b]Athanasoulis CA, et al.[15]	239	16 (0–203)	5.9	N/A	2.0	N/A	N/A	N/A
Günther Basket								
[e]Becker CD, et al.[50]	78	36	6.4	N/A	3.9	N/A	9	N/A
Günther Tulip								
Millward SF, et al.[43]	76	103d; 85d (5–420)	0	1.3	2.6	N/A	N/A	(See [f])
TrapEase								
Rousseau H, et al.[35]	34	6 (6)	0	45.7	2.8	N/A	N/A	N/A
[g]Schutzer R, et al.[51]	189	4.2 (0–24)	0.5	N/A	1.5	N/A	N/A	13
ALN								
Imberti D, et al.[46]	30	18.2	0	7	10	N/A	N/A	(See [h])
Recovery								
Asch MR[42]	32	53d (5d–134d)	0	N/A	0	0	0	47[i]

DVT = deep venous thrombosis; IST = insertion-site thrombosis; IVCT = inferior vena cava thrombosis; PE = pulmonary embolus

Notes on Table III

[a] Extrapolated from comparison data for several filters. The Mohan group placed 159 of 196 filters after anticoagulation contraindication or failure. Four patients with Simon nitinol filters were excluded from further study because the population size was too small to yield statistically rigorous efficacy.

[a2] The Mohan group restarted anticoagulation in 26 of 196 patients.

[b] The Athanasoulis group placed 85% of filters after anticoagulation contraindication or failure; 15% were placed for other indications.

[c] Radiologic follow-up conducted in all patients who survived (56%).

[d] Most filters were placed after anticoagulation contraindication or failure.

[e] Device removed from market by manufacturer; spontaneous disruption rate, 77%.

[f] Mean 103-day follow-up in group that underwent filter retrieval; mean 85-day follow-up in group within which the filters were not retrieved.

[g] The Schutzer group placed 70% of filters after anticoagulation contraindication or failure; 30% were placed for other indications.

[h] Removable device; median implantation period, 123 days.

[i] Device no longer available from manufacturer.

TABLE IV. Magnetic Resonance Imaging of Vena Cava Filters[52]

Filter	Composition
Nonferromagnetic Alloy	
Metallic artifact: None or minimal	
Greenfield Titanium	Beta-III titanium molybdenum alloy
Günther Tulip	Conichrome
OptEase	Nickel-titanium-cobalt
Vena Tech–LGM	Phynox
Metallic artifact: Minor	
Bard Recovery	Nickel-titanium-cobalt
Simon Nitinol	Nickel-titanium-cobalt
TrapEase	Nickel-titanium-cobalt
Ferromagnetic Alloy	
Metallic artifact: Moderate or substantial	
Bird's Nest	Stainless steel
Greenfield*	Stainless steel

*Routine magnetic resonance imaging not recommended.

with alternative agents, such as danaparoid, ximelagatran, or lepirudin, in conjunction with VCFs; this subject invites future exploration.

Conclusion

Observational studies and case series have shown that long-term anticoagulation provides no benefit above that of a VCF alone. However, many of these studies were nonrandomized, retrospective, and conducted in selected patient populations; therefore, the validity and applicability of their findings are controversial.

Current best-practice guidelines suggest anticoagulation during and after VCF insertion for patients who have no contraindications. This therapy, adjusted for individual risk factors, should continue for at least 3 months after VCF placement.[54]

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