

Review Article

Long lives, short indications

The case for removable inferior cava filters

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Summary

Vena cava filters have been in use for decades to prevent pulmonary embolization from deep venous thrombosis. These filters have been shown to be effective, with fairly low rates of filter migration, fracture and thrombosis. However considering that filters remain *in situ* for the life of the patient and that studies do not show increased longevity in patients with filters, any complications from filters are significant concerns. In addition,

often patients require filters for only temporary indications, e.g. contraindication for anticoagulation because of impending procedures, or for only a transient risk period, as in trauma or pregnant patients. In these cases, removable filters may be more appealing. This review will examine the different types of removable filters and the indications in which removable filters may have an advantage over permanent filters.

Keywords

Temporary, removable, retrievable, vena cava filter

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Introduction

Vena cava filters have been in use for decades to prevent pulmonary embolism. Initially, filters had many difficulties; the first filter, the Mobin-Uddin umbrella developed in 1967, had an inferior vena cava (IVC) occlusion rate of up to 73% (1, 2). Although newer filters perform superiorly, recurrent thrombosis and embolization are still major concerns, as are equipment-related complications such as fracture, migration and perforation. An early follow-up study of permanent inferior vena cava filters demonstrated recurrent pulmonary emboli (PE) in 3% and fatal PE in 2.5%, IVC thrombosis in 19%, filter fracture in 2%, filter migration of >1cm in 6%, and IVC penetration of >3mm in 9% (3). Similar findings have been described in more recent analyses of permanent filters: deep venous thrombosis in 6–32% of cases (depending on the filter), IVC thrombosis in 2.6–11.6% and PE 2–4% (4, 5). Today, one of the commonly inserted filters is the titanium or percutaneous stainless steel over-the-wire permanent Greenfield filter. The earlier version of the stainless steel Greenfield filter was introduced in 1973, with a reported recurrent PE rate of 4% (6). Most of the filters developed after the Greenfield filter compare their efficacy and complication rates to the Greenfield filter. During the 1970s and 1980s, many types of permanent filters were introduced such as the Simon Nitinol

filter, the Bird's Nest Filter, the VenaTech Filter, each with its own distinctive features.

Currently, in the United States, the vast majority of the FDA approved filters are of the 'permanent' type, which require that they remain *in situ* for the life of the patient. There may be certain cases, however, in which a permanent filter is not desirable, especially if the indication for the filter is temporary and the patient has a long life expectancy. Some examples of such situations are trauma and pregnancy. In these groups, removable filters may be better options. Indeed, there are suggestions that the protective nature of the permanent filters is only short-lived. In the randomized trial performed by Decousus et al (7), patients with known proximal DVT were randomized between receiving filters and not receiving filters. In addition, all the patients were anticoagulated. The filter group had a significantly lower incidence of PE during the first 12 days than the non-filter group. However by the end of 2 years, there was a significantly higher rate of recurrent DVT in the filter group compared to the non-filter group, with no difference in the rate of PE between those two groups.

Whether these data hold true for prophylactic placement in patients without previously documented thromboses is not clear, but it does appear that long-term placement of permanent filters is not necessarily benign. A pertinent example of a transient pro-

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thrombotic state might be the trauma patient. Removable filters in these patients may be a more appealing option because they are at high risk for PE for only a short period of time. A survey of trauma surgeons in the US found that the potential removability of filters would increase the prophylactic placement from 29 to 53% (8).

The first removable filter was introduced in the mid-1980s. The two types of removable filters are temporary filters and retrievable filters (9, 10). Temporary filters remain attached to a wire or catheter that then exits the skin. Removal is thus mandatory because of the risk of infection from the wire. In addition to the infection risk, other complications include embolization of filter thrombosis during explantation, with or without clinically apparent thrombophlebitis and equipment related complications. Retrievable filters, on the other hand, are primarily designed as permanent filters but can be removed within a certain period of time. However, the removal itself is more difficult than that of the temporary filter and requires a separate retrieval kit.

A unique issue of the temporary and retrievable filters is the maximum duration of implantation. Neointimal hyperplasia (or neointimal thickening) occurs naturally when there is a vessel injury or a foreign object within the vessel such as an inferior vena cava filter or a stent. With permanent filters, neointimal hyperplasia can be beneficial as it allows for the fixation of the device to the vessel wall and thus prevents migration. However, with the temporary or retrievable devices, concern is focused on the time point at which the neointimal hyperplasia prevents percutaneous removal of the filter without damaging the vessel wall. A variety of factors affect the rate of neointimal hyperplasia of the filter struts, including device design, material composition, and concomitant medication administration (11). Neointimal hyperplasia occurs in both arteries and veins and this response includes three major components: smooth muscle cells, endothelial cells, and extracellular matrix. The process of healing begins immediately after the vessel is injured and may last weeks or months (12).

Most studies on neointimal hyperplasia have been done to investigate the process in arteries, and it has been shown that neointima begins forming around the sites of filter contact within seven days in animals (13). However, there are differences between venous and arterial neointimal hyperplasia anatomically and physiologically which might lead to an increased tendency for venous thrombosis and stenosis (14). Veins have less internal elastic lamina, potentially allowing increased migration of the smooth muscle cells into the intima in response to injury. In contrast to arteries, veins produce lower levels of nitrous oxide and prostacyclins, are more sensitive to vasoconstrictors, and possess higher amounts of basic fibroblast growth factor receptors (15).

Lorch et al. reviewed a multicenter registry of temporary filters (16). The majority of patients who had temporary filters inserted had proven DVT before insertion (95.2%) and 34% had suspected PE. While under filter protection, 2.1% (4) of the patients died of fatal PE; all these were undergoing thrombolysis therapy. There were no filter-induced fatalities, although 1.6% had a new PE. The authors also noted that the major complications were: filter thrombosis (15%), equipment-related complications (2.7%), clinically apparent thrombophlebitis (2.1%),

and infection at puncture site (0.5%) (16). In support of the relatively low rate of major complications is another study, a single center evaluation (17). In this study, pulmonary embolism occurred in 1 of the 67 patients (1.5%) and was fatal. Other complications, related solely to the filter, were two instances (3%) of clinically insignificant subclavian vein thrombosis in surgery patients and 1 (1.5%) catheter-related infection. Technical problems were experienced by 4.5% of the patients but none of these complications worsened the patient's condition. These authors also did not find any relationship between the duration of filter implantation and complications.

The different types of removable filters currently approved, in preparation for approval, and their success rates are summarized below, followed by a review of the indications for these filters. It should be understood that the indications for filters will alter if the success rate increases or the complication rate decreases and that currently, there is very little data examining the value of concurrent anticoagulation with these filters. There are no randomized trials examining the use of anticoagulation in removable filters; in the only randomized trial comparing permanent vena cava filters placement to no filters, both sets of patients were receiving anticoagulation therapy (7). Anticoagulation can affect the milieu around filter and may affect the complication rates of PE, vena cava occlusion, or insertional site thrombosis. However, while most of the performance data that have been published cite the indications and patient characteristics (i.e. anticoagulation status) entering the trials, the outcome data are usually combined and it is difficult to tell if complication rates have been affected by anticoagulation status. Indeed, in many cases, the patients participating in these studies have contraindications or complications while on anticoagulation therapy which has necessitated alternative therapies such as filter placement.

Filter complications

Of the potential complications of inferior vena cava filters, occlusion of the filter itself is the most common. There are four postulated etiologies of vena cava occlusions (18): 1) inherent thrombogenicity of the device; 2) high efficiency of the filter leading to occlusion from capture of multiple small clots which by themselves may not have caused clinically significant disease; 3) natural progression of severe thrombosis leading to an upward propagation of iliac thrombi into the vena cava and resulting in eventual occlusion; and 4) capture of large, life-threatening emboli. It has been argued that the first reason may not be as applicable today, since current filters are made from alloys that are designed to be minimally thrombogenic. Newer filters also have higher patency rates after capture of small emboli. The third cause, natural progression of distal venous thrombosis, will occur regardless of filter presence and it may be that filter placement prevents further progression. Finally, the capture of large emboli will indeed cause varying degrees of vessel obstruction. However, it may be argued that these large emboli would result in more catastrophic outcome with the decreased protection against embolization, and that it is for precisely this reason that a filter is inserted. However, chronic vena cava occlusion from any cause can cause debilitating side effects including

increased swelling, chronic venous stasis syndromes, leg ulceration, or true phlegmasia cerulea dolens.

Vena cava perforation by the filter is another complication (18). Often not precisely defined, perforation occurs when a filter leg accidentally and acutely penetrates the vessel and is, therefore, a true complication of filter placement. Usually there would be no bleeding associated with this event unless the filter leg is withdrawn, leaving an open hole: this is a rare event. However, what is considered a 'perforation' is in fact really transmural incorporation. Transmural incorporation, a physiological process that may not negatively affect the patient, occurs when the filter legs extend more than a few millimeters from the vena cava lumen and is usually noted on an imaging study.

Filter dislocation can be a serious complication and even lead to death. For example, one study examining the Tempofilter found three instances of filter migration to the atrium with two leading to fatal outcomes (19). In 2000, a multicenter registry found that temporary vena cava filters overall had a dislocation rate of 4.8% (16). That study found no deaths secondary to filter induced complications. The design of filters intended for temporary use must balance the need to affix the filter in one position while allow for its easy removal at a later time.

Description of filter types

Gunther Tulip retrievable vena cava filter

The Gunther Tulip retrievable filter (Cook Inc, Bloomington, IN) is inserted percutaneously through the jugular or femoral vein using an 8.5 French introducer (Fig. 1). This filter had been approved by the FDA for permanent use in the United States and has as of October 2003 now received approval for temporary insertion with retrieval limited to the jugular approach. The filter can provide permanent or temporary protection against PE with a low complication rate (20). The cone-shaped filter consists of four struts constructed of stainless steel with hooks at the end acting as anchors. A retrieval hook sits on the nose of the filter.

The Gunther Tulip has been used extensively in Europe since 1992 and in Canada since 1998. In a review of the Canadian Registry of the Gunther Tulip Retrievable Filter, Millward et al. reported a 98% success rate of attempted retrievals (26). There were no subsequent major complications, although 8% of the patients did require insertion of a permanent filter after the temporary filter had been removed. The rate of recurrent PE while the filter is in place was low, ranging from 0–3.6% (20, 21), while vena caval thrombosis occurred in 0–9.6% (20–22). However, not all patients had follow-up information available, and therefore these figures may be underestimated. There have been reports of filter failure, probably as a result of high pressures secondary to filter thrombosis and a tendency to subsequent embolize in response to a large clot (23). In the study presented to the FDA, 41 patients were enrolled; retrieval was attempted and successful in 26 cases with 6 of these occurring on Day 14 and 1 on day 20. Mean implantation time was 11.4 days (24). Although originally devised to be retrieved up to 10 days after implantation, initial reports using repositioning of the Gunther Tulip filter to prolong the implantation time by preventing the filter from incorporating into the caval wall (25) have helped in prolonging implantation time to over one month (26).

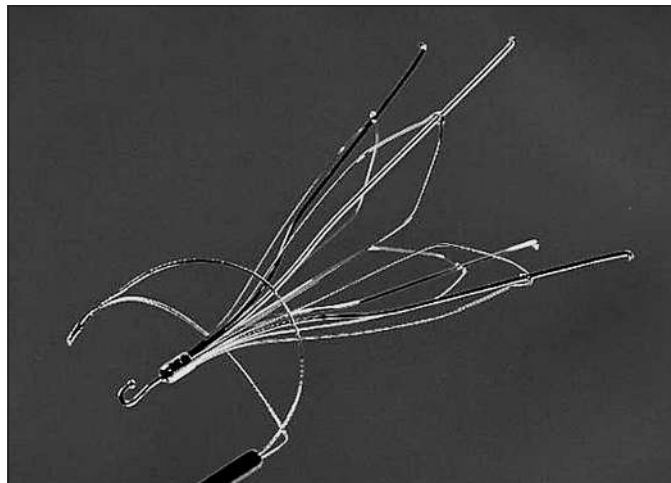


Figure 1: Gunther Tulip Filter. Photo courtesy of Cook Inc, Bloomington IN, USA.

Recovery Filter

The Recovery Filter (Bard Peripheral Vascular, Tempe, AZ) was the first filter to be given 510K clearance for removal (July 2003) although it had received European CE clearance in 1999. The Recovery Filter (Fig. 2) is designed to allow retrieval even after incorporation into the wall of the IVC. This filter is a two level filtration system composed of Nitinol (mixture of nickel and titanium) delivered via a 7 Fr introducer, a dilator and a pusher. The six legs end in elastic anchoring hooks. When pressure is applied to pull the filter out, the hooks straighten so that the legs slide out of the neointimal sleeves that have formed during implantation. The filter requires the use of the Recovery Cone inserted percutaneously which consists of nine struts bearing a urethane membrane that forms a cone around the filter and withdraws it into the sheath for retrieval (Fig. 2). Efficacy and safety of the Recovery Filter were evaluated in a preliminary study of 32 patients (27). Patients had to meet the following inclusion criteria: indication for filter placement (recent PE, recent DVT, or prophylaxis), anticipated return to anticoagulation therapy 10

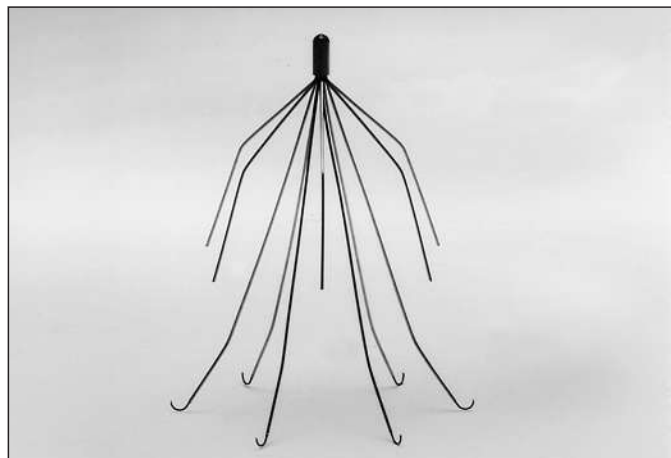


Figure 2: Recovery vena cava filter. Photo courtesy of Bard Peripheral Vascular, Tempe, AZ, USA.



Figure 3: OptEase Filter. Photo courtesy of Cordis Endovascular, a Johnson & Johnson company, Miami, FL, USA.

days to 12 weeks after the procedure, or did not require anticoagulation for 10 days to 12 weeks, and estimated life expectancy was greater than two years. Of the 32 filters placed, 30 were placed without incident. In two cases, minor difficulties were encountered which were overcome and resulted in successful filter placement; there were no complications related to filter insertion. In 7 patients, trapped thrombi were seen within the filter and significant migration occurred in one (28). Removal was successful in 24/24 patients in whom it was tried with a mean implantation time of 53 days and a maximum of 134 days. In other studies, a maximum time of 161 days has been achieved (24).

OptEase Filter

The OptEase permanent vena cava filter (Cordis Endovascular, A Johnson & Johnson Company, Warren, NJ, Fig. 3) received 510K approval in 2004, as a successor to the TrapEase (24). The OptEase is delivered with a 6 French introducer and has a caudal hook for percutaneous retrieval. Improvements have been made in the barb design to prevent migration resistance and allow easier retrieval. A retrospective analysis in their 510K approval request described 29 patients with a mean implantation time of 16.4 days and a maximum of 48 days.

Indications for filter placement

In a multicenter review, the main indications for nonpermanent filter placement were thrombolytic therapy (51.2%), preoperative implantation excluding Caesarean section (41.5%), pregnancy with DVT (2.7%), and prophylactic implantation in the absence of DVT (4.8%) (26). Prophylaxis in trauma patients, short-term contraindication to anticoagulation, and prophylactic placement after PE have also been proposed as indications for removable filters. A contraindication for temporary filter, but not

retrievable filters, would be in patients in whom the need for the protection of the filter exceeds the maximum implantation period.

Thrombolytic therapy

The most common indication for insertion of temporary vena cava filters in Europe was for use during thrombolytic therapy, seen in 53% of the patients who received temporary filters in a multicenter registry and 69% of the patients in another report (16). In the multicenter registry, fatal pulmonary embolism occurred in four patients (2.1% of patients). An additional three patients suffered from non-fatal PE (two during filter protection and one during filter removal) (16). In a single center review of patients who received thrombolytic therapy with a temporary filter, 6.5% of the patients required transfusion for groin hematomas with arm hematomas requiring compression in an additional 6.5% (17). The authors also noted that all of the patients treated with thrombolytic therapy developed hematomas in the regions of all puncture sites and not just the sites of filter implantation.

Free-floating ilio caval thrombus has often been mentioned as a possible indication for placement of a temporary or removable vena cava filter especially when the patient is undergoing thrombolysis. There are few published trials regarding the use of removable filters in ilio caval thrombolysis (29–31). While there are no randomized studies, there is one retrospective study and case reports on the use of these filters in humans undergoing ilio caval thrombolysis. In the retrospective study, the authors studied the efficacy of temporary vena cava filters in 45 patients with iliac or ilio caval thrombus who underwent ultrahigh-dose streptokinase thrombolysis. Fatal PE occurred in 1 patient (2%). No other PE's were noted although silent PE could have been missed. Complications due to the filter alone and in conjunction with thrombolysis occurred in 11 (24%) and 9 (20%) patients, respectively. Complications caused by thrombolysis alone occurred in 12 patients (27%) (29).

Trauma

Major trauma carries a high risk of venous thromboembolism. Geerts et al. found that 58% of major trauma patients had DVTs documented by venography. In an autopsy study by Sevitt and Gallagher, the authors found a 65% incidence of DVT and 16.5% incidence of PE in major trauma patients. Additionally, Sevitt found that PE was the cause of death in 20% of fatally injured patients. The most critical period for a trauma patient in terms of PE is the first few days after the trauma, although there is no demonstrable correlation between mortality and the interval between injury and PE. The use of thromboprophylaxis in trauma patients is, therefore, very important but standard prophylaxis may not be possible in such patients due to the nature of their injuries. Patients with ongoing bleeding cannot undergo anticoagulation. Orthopedic injury or the need for immobilization often prevents the use of sequential compression devices. In one trauma center, 14% of patients could not receive any type of prophylaxis because of their injuries.

The use of prophylactic filters (filters placed in patients without any evidence of thromboembolic disease but who are at high risk) in trauma patients remains a controversial issue (37–39). In the 2002 Eastern Association for the Surgery of Trauma practice

management guidelines for prevention of VTE in trauma patients, the group made only a level III recommendation (supported by retrospective data, expert opinion, or case report) that prophylactic vena caval filters should be considered in very high-risk trauma patients who cannot receive anticoagulation and who have injuries that would immobilize them for a prolonged period of time (8). However one must also consider the possible long-term complications of placing prophylactic filters if they are to stay in the patient permanently. In a study examining acute complications and long term follow up, the authors found that 47% of their trauma patients with prophylactically placed permanent Greenfield filters had duplex evidence of chronic lower extremity DVT and 37% had symptoms suggestive of chronic venous insufficiency or postphlebotic syndrome (40).

Hughes et al. reported on the successful use of a temporary filter (Protect Infusion Catheter) in two trauma patients with interregal hemorrhages (41). The devices remained in for 6 and 10 days and were removed. No complications relating to the filters were noted. Both patients were started on standard anticoagulation after resolution of their hemorrhages. A study of prophylactically placed temporary inferior vena cava filters in critically ill surgical patients also found their use to be safe and effective (10). There were no complications with filter insertion or retrieval including insertional or retrieval site thrombosis, filter migration, vena cava perforation or occlusion. In addition, there were no PE or hospital deaths.

Pregnancy

The overall incidence of thromboembolism ranges from 0.3 to 1.2% of all pregnancies, going up to 2.3% in the puerperium (42). Acute lower extremity DVT occurs six times more frequently in pregnant women compared to non-pregnant women (43). Since pregnancy is a temporary state, the use of removable filters in pregnant patients who have either contraindications or complications from anticoagulation is a consideration. In addition, given the age of these women, they usually have a long life span ahead of them, making the use of permanent devices less appealing. There have been reports of the use of both retrievable and temporary filters in pregnant patients. In one multicenter study, the authors found that 2.7% of all temporary filters inserted were placed in pregnant women who were undergoing Caesarean section and thrombectomy (16). In the first case report of using a retrievable filter (Gunther Tulip) in a pregnant woman to prevent recurrent PE, the filter was in place during the elective caesarean section and removed 8 days after insertion without any complications. Oral anticoagulation was able to be resumed after the pregnancy (44). In another case report the authors placed an emergent retrievable filter (Prolyser) in a pregnant woman with PE and venous thrombosis of the lower extremity who was to undergo surgical iliofemoral venous thrombectomy. The filter was placed to prevent PE from the dislodged clots during the procedure. The operation was successful and upon removal of the filter two days later, medium sized clots were found caught in the filter (45). In Japan, two temporary filters were placed in a pregnant woman in her third trimester (46). The first filter was placed prior to Caesarean section for an

iliofemoral thrombosis to prevent PE after the procedure. Fifteen days after the first filter was placed, the authors decided to insert a second filter to prevent PE from the captured thrombus within the first filter during its removal. Both filters were then removed without complications.

Conclusion

With the increasing ease of insertion since percutaneous placement of IVC filters was introduced, filters have become more widely used and for wider indications. The first filters used were permanent and thus long-term complications were an issue, particularly in patients with long life expectancy and short-lived indications. These problems have increased interest in the development of removable filters. Indeed it appears that the retrievable filter would be ideal since it can be left in place as a permanent filter if the need for PE protection became more long-term or if the filter were unable to be retrieved. There is still much work to be done in terms of developing these removable filters and in characterizing the safety and efficacy of these devices, especially in the United States. The ease of use and the potential for removal may lead to overuse of the devices; this may in and of itself be problematic since, although the removable devices are designed to minimize long-term complications associated with IVC filters, they are not without their own complications. Arnold et al. warned of the potential overuse of the permanent IVC filters in patients. They reviewed the records of 69 patients who received IVC filters (47). 65% of the patients had a clear indication for a filter; i.e. they had PE or DVT with a contraindication to anticoagulation. Twenty percent of the patients had PE or DVT but were given filters without consideration to anticoagulation. The remaining 14% of the patients had suspected DVT without objective evidence but were still given filters. In the latter two groups, there was a combined morbidity and in-hospital mortality rate of 29% and 33%, respectively. Although not necessarily related to filter placement, the high mortality rate may call into question the appropriate use of filters in such critically ill patients, especially when anticoagulation is known to be safe and efficacious in preventing PE in most cases (48, 49).

With temporary filters, one must also bear in mind that the patient may actually require a permanent filter if the length of time of the patient's filter indication extends beyond the recommended maximum implantation time of the filter for ease of removal or if the indication recurs after the filter is removed. In the studies reviewed, 2–25% of the patients receiving temporary and retrievable filters required subsequent placement of permanent filters (9, 26, 50). In these cases, placing permanent filters initially or a retrievable filter which may be left in the patient as a permanent filter may prevent subsequent procedures to place additional filters.

Filters are becoming safer and easier to use. New investigations will hopefully be aimed at further delineating the risks and benefits of inserting these foreign objects as therapeutic interventions, while delineating the role of anticoagulation and other vasoactive therapies in defined situations.

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