Inferior Vena Cava Filters for Prevention of Pulmonary Embolism

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Thromboembolism from a venous source continues to be of clinical significance with an annual incidence of 300,000 to 600,000 cases. These episodes of pulmonary embolism result in at least 50,000 deaths per year despite the use of effective prophylaxis and availability of noninvasive techniques to establish early diagnosis and treatment of thrombotic events.[1] The main treatment modality continues to be effective anticoagulation, but this treatment may fail to control thromboembolism in 5% to 10% of patients, and anticoagulants have been associated with a mortality rate of up to 15%.[2]

HISTORY OF CAVAL INTERRUPTION

The history of surgical intervention for venous thromboembolism originated in 1784 when John Hunter performed the first femoral vein ligation to control complications of phlebitis. That was followed by inferior vena cava (IVC) ligation by Bottini in 1893 and Trendelenburg in 1910.

By the 1960s, femoral vein ligation was no longer the treatment of choice by most surgeons due to a reported 5% to 8% rate of fatal recurrent embolism.[3] IVC ligation became the treatment of choice despite an operative mortality rate of 14%, and a recurrent pulmonary embolism rate of 6% (2% were fatal). Vena cava ligation also produced hemodynamic instability, which was not toler-

ated well by critically ill patients and caval occlusion causing disabling edema and venous ulceration in 33% of the patients.[3] The high morbidity of vena cava ligation prompted the development of many new surgical procedures for partial occlusion of the IVC. The emphasis of these procedures was to provide protection from pulmonary embolism and ensure vena cava patency. However, these techniques still resulted in early IVC occlusion in some patients.

The partial occluding plastic clips, such as the Moretz, Miles, or Adams-DeWeese clips, then became the predominant treatment modalities of the 1960s and 1970s. Partial occlusion of the IVC was associated with a decrease in operative mortality and a significant decrease in chronic venous insufficiency as compared to total occlusion of the vena cava. The results of plication and clips showed an operative mortality rate of 12%, a recurrent pulmonary embolism rate of 4%, and a fatal pulmonary embolism rate of 1.7%. The IVC patency was 67% for patients with clips and 69% for patients treated by plication.[3] All these procedures required open surgical exploration and general or regional anesthesia.

In the late 1960s, the Eichelter catheter sieve, a temporary device, was developed.[4] The Pate clip was then developed and it was designed to flatten the vena cava.[5] This was followed by the Moser balloon,[6] which was designed for temporary obstruction, and the Hunter balloon[7] for permanent obstruction of the vena cava. The most widely used mechanical device then became the Mobin-Uddin umbrella.[8] The umbrella's initial enthusiasm waned when reports described problems with umbrella migration, massive thromboembolism, and vena cava occlusion occurring in more than 50% of patients.[3]

In 1973, the stainless steel Greenfield filter[9] was developed to address these problems, and it has revolutionized the treatment of those cases of venous thromboembolism that cannot be treated with anticoagulation or in cases where this treatment fails. Other intracaval devices were developed and are described later.

INDICATIONS FOR VENA CAVA FILTER

When selecting patients for a vena caval filter, it must be remembered that caval filter placement is not without risk to the patient. Reports in the literature have documented cases of caval thrombosis, insertion site thrombosis, filter migration, recurrent pulmonary embolism, and vena caval erosion, with all of these being secondary to the filter or its placement. Thus, over-zealous use of vena cava filtration should be avoided. The current absolute indications for filter placement include: (1) documented deep venous thrombosis (DVT), or pulmonary embolism with a recognized contraindication to anticoagulation; (2) recurrent pulmonary embolism despite adequate anticoagulation; (3) anticoagulant complications requiring their discontinuance; (4) patients who have undergone pulmonary embolectomy; and (5) patients with another form of caval interruption that has failed, which is demonstrated by recurrent thromboembolism.

Other relative indications include: (1) iliofemoral thrombosis with a 5-cm or longer free-floating tail;[1] (2) presence of recurrent septic pulmonary embolism; (3) chronic pulmonary embolism in a patient with cor pulmonale; and (4) patients with significant cardiopulmonary disease, patients with more than 50% of the pulmonary bed occluded who could not tolerate any recurrent thromboembolism, or both.[1] Other controversial prophylactic indications include cancer patients with DVT;[10] incidental caval interruption in high-risk surgical patients;[11] and DVT, pulmonary embolism in pregnant patients, or both.[11,12]

INTRACAVAL DEVICES

Multiple caval filters have been introduced. The following criteria should be met when transvenous endovascular filters are evaluated: (1) ease of insertion into the proper position under local anesthesia, (2) effective protection against further embolism, (3) maintenance of long-term caval patency, (4) stability of position over time, and (5) lack of any tendency toward caval wall penetration or erosion.[1] The following is a description of these devices.

Stainless Steel Greenfield Filter

The stainless steel Greenfield filter is the "gold standard" to which all current and future filters should be compared. It is a stainless steel, cone-shaped filter 4.6 cm in length from the apex to the base. It consists of six legs that affix to the wall of the vena cava with small, recurved hooks.[13] The legs are 2 mm apart at the apex and 6 mm apart at the base when it is expanded in the vena cava. It has the capability of catching emboli 3 mm or greater in diameter. Because the filter is cone-shaped, this allows the central portion of the cone or vena cava to become occluded by the thrombus or emboli while maintaining patency of the vena cava and filter around the circumference of the base. This functional capacity of the filter prevents progression of venous thrombosis, caval obstruction, and venous hypertension. For example, "when thrombus fills the filter to 70% of its depth, only 49% of the cross-sectional area is blocked. Experience has shown that no distal pressure increase occurs until 80% of the filter is filled with clot, at which point more than 64% of the cross-sectional area is blocked" (Figure 1).[1] It has also been noted that the centrally located trapped thrombi undergo breakdown with time due to continued blood flow around the perimeter. The filter is made of an inert metal and has been well-tolerated despite infection. Studies have also shown that entrapped thrombi that become infected can be sterilized with intravenous antibiotics. Due to its high patency rate, this filter has been placed above the renal veins in patients with thrombosis to the level of the renal veins. It has also been placed in the superior vena cava in rare circumstances. The largest clinical experience was reported by Greenfield and Michna where 469 patients were followed for 12 years.[14] This study showed a long-term patency rate of 98%. The study also showed a failure to insert the filter in 0.6% of patients, misplacement of the filter in 2.5%, tilt of the filter in 1.7%, proximal migration in 0%, venous stasis in 5%, and a recurrent pulmonary embolism rate in 4%. Other studies confirm and support these findings.[15,16] Suprarenal filter placement has similar results where a 100% patency rate was reported in 22 patients.[1] The filter was originally designed for placement by operative technique by way of the internal jugular or femoral veins.

The first percutaneous insertion was reported in 1984 through the jugular vein and subsequently through the femoral vein. The stainless steel Greenfield filter requires a 24 Fr carrier system and a 26 Fr introducer sheath. This large sheath is required to accommodate the carrier, but results in a 30% to 40% incidence of insertion site venous thrombosis.[12] This high rate of insertion site venous thrombosis prompted the development of the titanium Greenfield filter that requires a 12 Fr carrier system, and can be inserted

through a 14 Fr sheath. Percutaneous insertion decreases the patient's discomfort, decreases the cost of the procedure, and saves time. All these advantages are maintained without sacrificing the effectiveness of the filter to protect against thromboemboli.

Titanium Greenfield Filter

The titanium Greenfield filter (Medi-tech, Inc., Watertown, MA) is made of titanium alloy. Its cone shape is similar to that of the stainless steel Greenfield filter, but it is 8 mm wider at the base and 0.5 cm taller. It weighs 0.25 g as opposed to 0.56 g for the stainless steel Greenfield filter, and it can be compressed to a diameter of 0.144 inch.[13]

Initial testing of the titanium filter showed distal slippage of the filter and less secure fixation to the wall of the vena cava. This was felt to be due to the filter's increased flexibility, which prompted a modification in the hook design. A recurved hook design with an 80° angle was selected. This hook design serves as a barrier to penetration beyond the axis of the limb and should limit both upward and downward vectors of force that might induce migration.[3] The mechanical properties of the titanium Greenfield filter have been tested extensively and it shows a remarkable resistance to flexion fatigue and induced corrosion. It exerts a force of fixation on the wall of the vena cava measurably greater than the stainless Greenfield filter at diameters over 22 mm, but less than the stainless Greenfield filter at diameters less than 22 mm. The titanium Greenfield filter requires a 12 Fr carrier system and an introducer sheath of 14 Fr. This reduction in size of the overall system has led to a reduction in insertion site venous thrombosis.

Placement of the titanium Greenfield filter requires a guidewire inserted percutaneously or by way of cutdown in the right internal jugular or femoral vein over which a dilator system and attached 14 Fr sheath are passed. When the dilator and sheath are in the IVC at the desired level, the dilator is removed. The titanium Greenfield filter carrier system is then placed through the sheath with fluoroscopic guidance. Both the sheath and carrier are retracted as a unit to release the filter. The carrier and sheath are removed and gentle pressure is applied to the insertion site to promote hemostasis. This design reduces premature misfire, which would place the filter in the sheath rather than in the patient. A new control handle that allows no manipulation other than retraction of the carrier for discharge of the filter decreases the risk of premature discharge. The filter is also pre-loaded into the carrier system that decreases the concern of crossed limbs.

The behavior of the titanium Greenfield filter seems comparable to the stainless steel Greenfield filter with increased corrosion resistance and tolerance to flexion stress. In addition, due to its decreased carrier size, both entry and positioning have been facilitated and bleeding during percutaneous filter insertion has been eliminated.

Preliminary experience in 164 patients indicates that this filter has approximately a 1.5% incidence of post-insertion venous thrombosis.[16] Early clinical experience has shown an insertion failure of 2%, a tilt rate of 2%, and a recurrent pulmonary embolism rate of 3%. The early reported rate of misplacement of the filter, caval occlusion, venous stasis, and proximal migration is 0%.[2]

Bird's Nest Filter

The use of the bird's nest filter was first reported in 1984,[17] and a large series of 568 patients was reported in 1988.[18] The device consists of four stainless steel wires 25 cm long and 0.18 mm in diameter. The wires are pre-shaped into a criss-crossing, non-matching array of bends intended to provide multiple barriers to thromboemboli. The end of each wire is attached to a strut that ends in a hook for fixation to the wall of the vena cava.[13] One strut is z-shaped so that a pusher wire can be attached for insertion. The initial filter was pre-loaded into an 8 Fr Teflon catheter, but this was associated with a high rate of proximal migration. The filter was redesigned in 1986 using a stiffer 0.46-mm wire to improve fixation. Modification of the filter resulted in an increase in the pre-load system to a 12 Fr size. During insertion of the filter, the pusher is used to set the first group of hooks into the caval wall. The wires are then extruded with the goal of closely packing the formed loops into a 7-cm segment of the infrarenal vena cava. The second group of hooks are then pushed into the wall of the cava, and the pusher is removed by unscrewing it from the filter. The theoretic advantages of this filter include: (1) the ability to trap small emboli by virtue of the tighter meshing of wires; (2) the ability to accommodate cavae as large as 40 mm in diameter; (3) the possibility that wires may be able to occlude nearby collaterals; (4) avoidance

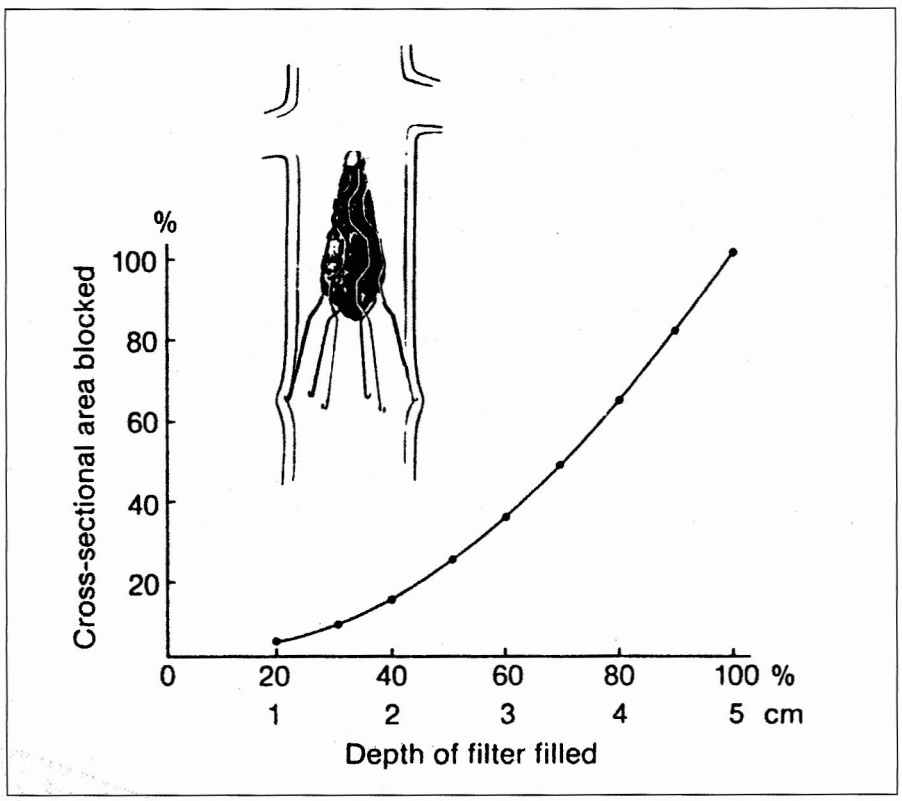

Figure 1: Relationship between the depth of filling of the Greenfield filter with thrombus and the obstruction to cross-sectional area. Even when 80% of the filter length is filled, less than 65% of the area is obstructed. (With permission from Greenfield LJ, Whitehill TA. New developments in caval interruption: Current indications and new techniques for filter placement. In: Veith FJ, ed. *Current Critical Problems in Vascular Surgery, Vol. 4.* St. Louis, MO: Quality Medical Publishing, 1992:113-21.)

of the need for intraluminal centering because of the configuration of the device; and (5) the lack of radically oriented struts, thereby limiting the tendency toward caval wall penetration.[1] Only 37 of 481 patients with the filter in place for more than six months were available for follow up. Seven (19%) patients had occlusion of the vena cava, three symptomatic patients had pulmonary angiography for recurrent thromboembolism that was confirmed in one (3%), and proximal migration was seen in five patients resulting in one death secondary to the filter being embedded in a massive pulmonary embolus.[1] These results occurred before strut modification. In a study of the new modified strut, there were three cases of filter migration in 32 placements.[19] Two of these were identified within 24 hours of placement and were corrected by angiographic manipulation. The third was not detected until six months after placement, and it was embedded in the right atrium and ventricle and could not be repositioned. Further clinical studies and possible design modifications are in progress.[19]

Simon Nitinol Filter

The nitinol filter, first described in 1977, is made of a nickel-titanium alloy and is a pliable straight wire when cool, but transforms rapidly into a previously imprinted, rigid shape when warmed. The filter is a 28-mm dome shape with eight overlapping loops below which the wires are shaped into a cone with six diverging legs with terminal hooks, used to affix it to the vena cava wall.[13] The filter wire is advanced rapidly with a feeder pump using iced, normal saline infused through a 9 Fr delivery catheter. When it is discharged from the storage tube, it expands instantly, assumes the appropriate shape, and is locked into place.

Of 103 patients undergoing placement at 17 centers, only 44 were available for follow up.[20] There were three cases of recurrent pulmonary embolism, seven cases of confirmed vena cava occlusion, and two suspected cases based on clinical examination. Five of 18 patients studied by ultrasound showed insertion site thrombosis. Of the 44 patients followed, ten were studied at three months, but only four completed a six-month follow up. Of these patients, six occlusions of the vena cava were documented and two additional occlusions were suspected, for an occlusion rate of 18%. Five patients developed edema with signs of filter thrombus, two developed recurrent embolism, and one filter migration was seen. In a more recent study of 224 patients, 65 (29%) patients completed a six-month follow up.[21] Four percent of patients developed recurrent pulmonary embolism, one being fatal; 19.6% had caval occlusion; and three deaths were associated with massive caval thrombosis. It is currently believed that the nitinol filter may be thrombogenic.[21]

Amplatz Filter

The Amplatz filter was first introduced in 1984. This filter is also cone-shaped and made from a stainless steel alloy, but is inserted in the IVC in an inverted position.[13] It has pronged loops that limit caval wall penetration to 2 mm, preventing injury to pericaval structures. Also, a loop is located at the apex to allow for retrieval or repositioning. The denser arrangement of wire results in greater clot-trapping efficiency, but may lead to a higher rate of filter caval occlusion. There may also be an increased tendency for clots to propagate through this filter.

The clinical experience has been limited to 52 patients.[22] A mean follow up of 11 months showed one (3%) insertion site venous thrombosis, one distal migration, and tilting of the filter in one. Thrombi in the apex of the filter were seen in nine of 34 (26%) patients, which was on the unprotected side of the filter. Larger thrombi trapped by the filter were seen in four of 34 (12%) patients, and two of these cases were propagation through the filter. The third patient had thrombus propagating through the filter, but with a benign course. The fourth patient had clots on both sides of the filter and had a pulmonary embolism at the time of autopsy. Nine of 42 (21%) patients had a thrombosed IVC upon follow-up examination. Two patients subsequently required a Greenfield filter placement above the Amplatz filter.

Venatech Filter

The venatech filter was first introduced in France in 1986. It is a cone-shaped filter with added stabilizing struts on each limb designed for percutaneous use. The filter is made of phynox and is a stamped, six-prong device with hooked stabilizers with sharp ends intended to center and affix the device.[13] The filter uses a 12 Fr catheter system usually inserted through the right internal jugular vein over a guidewire.

The early experience from France shows 100 attempts at insertion, resulting in 98 filter discharges. Eighty-two filters were in the correct position, eight showed a tilt of 15° or greater, and eight had opened incompletely, with three of these associated with a tilt.[23] A more recent report showed a 2% recurrent embolism rate, a 23% rate of insertion site venous thrombosis, a 63% rate of filter patency without thrombosis, a 14% migration rate, and a 6% rate of incomplete opening.[24] Breakage of the stabilizer struts has also been reported.[3] This filter was designed to prevent tilt, but continues to show a high incidence of tilting.

Gunther Filter

The Gunther filter was first described in 1987,[25] and is a percutaneous removable filter consisting of a helix of wires with an inverted cone above.[13] It is being tested in Europe and is not available in the United States. Preliminary results show a 7% caval thrombosis rate and a 70% caudal migration rate.[26] Caval penetration by the struts has been seen in 20% of patients and perforation by the retrieving hook in 78%.[26] Further investigation of this filter is pending.

Table 1 summarizes the results of these intracaval filters.[1]

OUR CLINICAL EXPERIENCE

We retrospectively reviewed 161 patients who underwent caval interruption between 1985 and 1990 (92 stainless steel Greenfield filters and 69 Adams-DeWeese clips) for both therapeutic and prophylactic reasons.[12] The operative mortality and morbidity rates were 0% and 3.3% for filter patients and 8.7% and 2.9% for clip patients, respectively; no procedure-related mortalities occurred. The late caval patency rate as documented by duplex ultrasonography/venography was 100% for filter patients and 88% for clip patients ($p=0.011$). Seven percent of the filter patients and 20% of the clip patients experienced late limb swelling postoperatively ($p=0.05$). The incidence of recurrent late pulmonary embolism was 2.5% in the filter group and 1.9% in the clip group. In the filter group, 10% of patients experienced postoperative thrombosis at the femoral vein insertion site and 0% at the jugular vein insertion site. We found that both devices were effective in preventing pulmonary embolism, the filter provided better caval patency than the clip, and the jugular vein had a better patency rate than the femoral vein after filter insertion. We are currently using the

COMPARISON OF INFERIOR VENA CAVAL FILTERS

	Greenfield Stainless Steel	Greenfield Titanium	Venotech	Bird's Nest	Simon Nitinol
Evaluation	Registry (1988)	Clinical trial (1991)	Clinical trial (1990)	Clinical trial (1988)	Clinical trial (1990)
Duration	12 yr	30 days	1 yr	6 mo	6 mo
Number	469	186 (123 at follow-up)	97 (77 at follow-up)	568 (440 at 6 mo)	224 (102 at follow-up)
Recurrent PE	4%	3%	2%	2.7% (33%-67% in subset with follow-up)	4% (based on those who had objective follow-up)
Caval patency	96%	100%	92%	97%	81%
Filter patency	98%	Not reported	63% without thrombus	81%	Not reported
Insertion site DVT	41% (percutaneous)	8.7%	23%	"Few," none objective	11%
Migration	35% greater than 3 mm	11% greater than 9 mm	14% greater than 10 mm	9% with original model	1.2% of those with follow-up
Penetration	Not reported	1%	Not reported	Not reported	0.6% of those with follow-up
Misplacement	4%	0%	Not reported	Not reported	Not reported
Incomplete opening	Not reported	2%	6%	Not reported	Not reported
Means of follow-up	PE, IVC scan, x-ray, noninvasive vascular examination	PE, x-ray, CT (noninvasive vascular examination, 2 sites)	Objective data are variable by site (cavagram, duplex, CT, x-ray)	Phone interviews, objective data random and available for 40 of 440 patients	Clinical, x-ray, laboratory

PE = pulmonary embolism DVT = deep venous thrombosis IVC = inferior vena cava CT = computed tomography

Table 1. (With permission from: Greenfield LJ, Whitehill TA. New developments in caval interruption: Current indications and new techniques for filter placement. In: Veith FJ, ed. *Current Critical Problems in Vascular Surgery, Vol. 4.* St. Louis, MO: Quality Medical Publishing, 1992:113-21.)

titanium Greenfield filter and have inserted over 30 filters to date with similar results as reported by others.

CONCLUSIONS

Many different and ingenious caval filters are currently available on the market for clinical use. The perfect filter has yet to be developed that eliminates morbidity and mortality at a reduced cost. The standard for comparison should remain the Greenfield filter, with a recurrent pulmonary embolism rate of 4% and long-term patency rate of 98% at 12-year follow up. The current titanium Greenfield filter, placed percutaneously at 58% of the total cost of surgical placement of a filter, is at the forefront. It is currently the most widely used filter at our institution. STI

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