Five-Year Follow-up of Prophylactic Vena Cava Filters in High-Risk Trauma Patients

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Objective: To assess the short- and long-term outcomes of vena cava filter (VCF) placement for prophylaxis against pulmonary embolism in patients at high risk due to trauma.

Design and Setting: Case series at a level I trauma center.

Patients: Patients were considered for prophylactic VCF placement if they met 1 of the injury criteria—spinal cord injuries with neurologic deficit, severe fractures of the pelvis or long bone (or both), and severe head injury—and had a contraindication to anticoagulation.

Intervention: Vena cava filters were placed percutaneously by the interventional radiologists when the acute trauma condition was stabilized following admission.

Main Outcome Measures: Filter tilt of 14° or more, strut malposition, insertion-related deep vein thrombosis, pulmonary embolism, or inferior vena cava patency.

Results: There were 132 prophylactic VCFs placed. A 3.1% rate of insertion-related deep vein thrombosis occurred, all of which were asymptomatic. Filter tilt occurred in 5.5% of patients and strut malposition in 38%. Three cases of pulmonary embolism (1 fatal) occurred in a prophylactic VCF, and all patients had either filter tilt or strut malposition. The risk of pulmonary embolism developing was higher in those patients with filter tilt or strut malposition than in those who did not have these complications (6.3% vs 0%; P=.05; Fisher exact test). The 1-, 2-, and 3-year inferior vena cava patency rates (±SD) were 97%±3%.

Conclusions: Prophylactic VCF can be placed safely with an acceptable rate of insertion-related deep vein thrombosis and long-term inferior vena cava patency. Patients with prophylactic VCF remain at risk for pulmonary embolism if the filter is tilted 14° or more or has strut malposition. In such patients, consideration should be given to placing a second filter.

Arch Surg. 1998;133:406-411

TRAUMA patients are at high risk for pulmonary embolism (PE).¹,² A review at our institution (University of Vermont, College of Medicine, Burlington) revealed several injury categories (severe head injury, spinal cord injury, and severe fractures of the pelvis or multiple long bones [or both]) for which the relative risk of pulmonary embolism was 21 to 54 times that of the general trauma population.³ Beginning in July 1991, patients who met the high-risk injury categories for PE and who had a relative or absolute contraindication to anticoagulation had a prophylactic vena cava filter (VCF) placed. We sought to determine the short- and long-term results of such placement with respect to the occurrence of PE, insertion-related deep venous thrombosis (DVT), and caval patency.

RESULTS

During the study, which was conducted from July 1, 1991, to December 31, 1996, 5280 patients with trauma were admitted to the Medical Center Hospital of Vermont. Of these, 132 patients (2%) met the criteria and had a prophylactic VCF inserted. A small number of patients met criteria for filter insertion, but because of a poor prognosis or the attending surgeon’s discretion, a filter was not placed. Table 1 shows the demographics of the patients who received prophylactic VCFs. There were 93 (70.4%) titanium Greenfield filters, 21 (15.9%) stainless-steel Greenfield filters, 10 (7.6%) Vena Tech fil-
 PATIENTS, MATERIALS, AND METHODS

PATIENT POPULATION

Beginning in July 1991, patients admitted to the Medical Center Hospital of Vermont (Burlington) with trauma were evaluated for prophylactic VCF insertion if they had a relative or absolute contraindication to anticoagulant medications based on the following criteria: spinal cord injury with complete paraplegia or quadriplegia; severe (type III or IV4) pelvic fracture and long bone fractures; and severe head injury with a Glasgow Coma Scale score of 8 or less for 48 hours. Patients who fulfilled these criteria were referred for prophylactic VCF insertion as soon as they were hemodynamically and neurologically stable, usually within 72 hours of hospital admission. All VCFs were placed percutaneously through the femoral or jugular route by the interventional radiologists (C.S.M., K.E.N., and R.D.).

Before filter placement, an inferior venacavogram was done to determine the caval diameter, the location of the renal veins, the presence of venous anomalies, or the presence of thrombus within the cava. Patients whose inferior vena cava (IVC) diameter measured less than 28 mm on a venacavogram received 1 of 3 filter types. Early in the study, patients received a titanium Greenfield filter (Medi-Tech, Boston Scientific Corporation, Watertown, Mass). More recently, a modified hook over-the-wire stainless-steel Greenfield filter (Medi-Tech, Boston Scientific) has been used because of the reported superior strut position in the vena cava. Occasionally a Vena Tech VCF (B/Braun Burron OEM Division, Bethlehem, Pa) was used at the discretion of the interventional radiologist. Most filters were inserted from the right femoral vein because of the relatively straight course of the IVC with the right iliac vein. Patients whose IVC diameter measured greater than 28 mm on the venacavogram received a bird’s nest filter (Cook, Inc, Bloomington, Ind).

FOLLOW-UP

All patients receiving a VCF were given venous thromboembolism prophylaxis with venous compression boots to the lower extremity if not contraindicated. For the first 2 years of the study, patients who had VCFs were observed with impedance plethysmography, duplex ultrasonography, or both, after 48 hours and weekly until discharge. An inability to compress the vein or actual visualization of a thrombus on duplex ultrasonography was characteristic of DVT.

We defined an insertion-related DVT as one that occurred within 48 hours of filter insertion. Because of the high cost and the low thrombosis rate related to VCF insertion, patients in the later part of study did not have routine studies but underwent duplex ultrasonography only if the clinical condition dictated.

All patients were observed clinically for signs and symptoms of PE. Any patient in whom signs and symptoms of PE developed underwent a workup consisting of a ventilation-perfusion lung scan, pulmonary angiogram, or both. Patients receiving mechanical ventilation who had a drop in oxygen saturation of more than 10% without a substantial change in static compliance were also examined for PE.

Following discharge, patients were studied at 30-day, 6-month, and yearly intervals with a deep abdominal venous duplex ultrasonogram scan (Hewlett-Packard Sonos 3000, Hewlett-Packard Corp, Andover, Mass) with a 3.5-MHz probe to determine the filter position and caval patency. Patency was determined by direct visualization of the IVC and the presence of spontaneous, phasic Doppler signals and the augmentation of flow after a Valsalva maneuver. Thirty-day and yearly patency rates were determined by life-table analyses. Life-table analysis was considered reliable if the SE was less than 10%. All follow-up studies were done in accordance with a protocol approved by the University of Vermont Committee on Human Research.

ASSESSMENT OF FILTER AND STRUT MALPOSITION

All assessments of strut malposition (SM) and filter tilt (FT) were done by radiologists (C.S.M., K.E.N., and R.D.) who were unaware of the clinical outcome of the trauma patients who received prophylactic VCFs. To determine SM on the postinsertion radiograph, a cone or triangle was made with the nose of the filter as the apex and the most lateral projecting feet of the filter as the base. A line was drawn down the epicenter, thus bisecting the base of the triangle. Greenfield and Vena Tech filters each have 6 limbs. If 2 or fewer limbs or 4 or more limbs were identified on either side of the epicenter, we considered this an SM. To determine FT, we assessed the longitudinal axis of the IVC on the cavogram and defined that as the reference line. Then we used a goniometer to measure the angle between the epicenter of the filter and the longitudinal axis of the IVC.

We used an angle of 14° or more as substantial FT. We chose an angle of 14° or greater as substantial FT because of in vitro studies5 that suggest that the clot-trapping ability of the Greenfield filter is reduced at this degree of tilt.

STATISTICAL ANALYSIS

All values are expressed as the mean (±SD). The rates of PE in the patients with FT or SM vs those without FT or SM were compared using the Fisher exact test. Significance was attributed to a P value of less than .05.

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reduction and internal fixation of his severe acetabular fracture on hospital day 10. He was making an excellent recovery when, 10 days after the operation, he was sitting in a chair and became abruptly short of breath and unresponsive. Despite aggressive resuscitative efforts, the patient died. An autopsy showed a large saddle PE straddling the bifurcation of the pulmonary trunk (Figure 1). There was also a right femoral DVT.

Review of this patient’s completion radiograph at the time of the filter insertion revealed the filter well centered but with a marked asymmetric strut distribution in a 5:1 configuration (Figure 2).

The second case occurred in a 76-year-old woman with multiple injuries including bilateral tibial and fibular fractures, bilateral superior and inferior pubic ramus fractures with a widened sacroiliac joint, multiple rib fractures with a flail chest, and a severe closed-head injury. On day 5 following the injury, the patient underwent uneventful insertion of a stainless-steel Greenfield filter. Because of her multiple injuries and flail chest, she required a prolonged course of mechanical ventilation with tracheostomy. On day 24 after the injury, she was noted to have a sudden drop in oxygen saturation without a change in static compliance. Abdominal ultrasonography at the time revealed a free-floating clot emanating from the tip of the filter (Figure 3). A second suprafemoral VCF was placed that night, and anticoagulation was started for the patient’s bilateral lower extremity DVTs. Review of her completion radiograph at the time of the original filter insertion demonstrated an FT of 15° to the right.

The third patient was a 76-year-old man with multiple injuries, including a closed-head injury, a grade II liver laceration, and multiple rib fractures with an associated hemothorax. During the first 24 hours, the patient received several transfusions of packed red blood cells for the 1250-mL blood loss from his right hemothorax. He was able to be removed from the ventilator on the third day after his injury and was noted to have a painful swollen right leg that by ultrasonography showed a
right femoral DVT. A titanium Greenfield prophylactic VCF was placed without difficulty. On the 17th day after the injury, the patient was awaiting discharge when he suddenly became short of breath, with substantial hypoxia and hypotension requiring intubation and inotropic support. A pulmonary angiogram revealed a right upper lobe pulmonary embolus (Figure 4). A venogram done at the time of the pulmonary angiogram revealed 15° of tilt and residual clot noted within the interstices of the filter. A catheter was placed from a right femoral vein approach through the filter, and urokinase was infused directly into the branch of the pulmonary artery containing the embolus. In addition, a second suprarenal VCF was placed. During the next 24 hours, the patient had a dramatic improvement in oxygenation, with a second angiogram showing almost complete lysis of the clot. The patient continued to receive anticoagulant medication for 6 months following his discharge.

Follow-up abdominal ultrasonograms were performed on 47 (36%) of the patients. The mean (±SD) follow-up time was 590 (±510) days (minimum, 9 days; maximum, 1946 days). One asymptomatic vena cava thrombosis was detected. Patency of the vena cava was 97.1 (±2.9) at 3 years by life-table analysis.

Radiologists reviewed the films of 108 patients for SM or FT. Patients with SM or FT were compared with those without SM or FT. Six (5.5%) patients had FT, and 41 (38%) had SM. There was a higher incidence of PE in patients who had either SM or FT than in those who did not (6.3% vs 0%; P=.05; Fisher exact test).

Since their introduction in 1973,7 VCFs have become the standard mechanical means of protecting patients from PE. A 20-year review by Greenfield and Proctor8 involving 642 patients revealed that the most common indications for filter placement were a contraindication to anticoagulation (45%), a complication of anticoagulation (20%), and prophylaxis (13%). The use of prophylactic VCFs in patients with trauma has been advocated in several clinical reports.9-12 Jarrell et al9 inserted 21 Kimray-Greenfield filters (Medi-Tech, Boston Scientific Corporation, Watertown, Mass) in patients with spinal cord injury with DVT who had nonobstructing and free-floating clots of the large veins of the lower extremity (at high risk for embolism). In their series of prophylactic VCFs, no PEs occurred, and 2 patients had asymptomatic thrombosis of the vena cava. Webb et al10 noted a high incidence of PE in patients undergoing osteosynthesis of acetabular fractures. Beginning in 1984, they began placing prophylactic VCFs in patients with 2 or more risk factors in addition to their acetabular fracture. During a 3-year period, 21 patients met criteria for filter insertion, and 27 patients with acetabular fractures did not meet criteria. Pulmonary embolism did not develop in any patient in the group receiving a filter, whereas it did develop in 2 (7%) patients in the group not receiving a filter. Winchell et al13 analyzed the pattern of use of VCFs in trauma patients during a 7-year period and, using multivariate analyses, found that those patients with head injury, axial spine injury, posterior element pelvic fracture, and multiple long bone fractures were at a greater risk for PE than the general trauma population. The authors concluded that for prophylactic VCF to be of value, it must be used uniformly in these high-risk groups. Rosenthal et al12 placed prophylactic VCFs in 29 patients with an Injury Severity Score of greater than 16 and a contraindication to anticoagulation. In all patients, PE was prevented. In a retrospective review, Matous et al13 noted 53 trauma patients with prophylactic VCFs. No complications were referable to the IVC filter or its placement, and there were no PEs diagnosed after filter placement. Rodriguez et al14 prospectively placed 40 prophylactic VCFs in patients with 3 or more risk factors (age, >55 years; Injury Severity Score, >15; Automotive Injury Scale, >2 in the head, chest, or abdomen; multiple lower extremity fractures; pelvic fractures; spinal trauma; and/or subclavian vein cannulation). When the patients were compared with 80 matched historical controls, there was a significant reduction in the incidence of PE (1 vs 14 [2% vs 18%]; P<.02) and a clinical reduction in PE-related mortality. Khansarinia et al15 prospectively placed 108 prophylactic VCFs. The patients in their series were compared with 216 patients historically matched for age, sex, mechanism of injury, Injury Severity Score, and length of stay in an intensive care unit. None of the patients in the group receiving prophylactic VCFs had a PE, but in the control group, 13 patients had a PE, 9 of which were fatal. These differences were statistically significant for both PE (P<.001) and PE-related deaths (P<.03). A summary of studies related to the use of prophylactic VCFs in trauma patients is shown in Table 2.

Most of the reports on prophylactic VCF use in trauma patients are small series with short follow-ups. Our series is the largest to date and with the longest follow-up. We demonstrated a low rate of insertion-related thrombosis (3%), a low rate of PE (2%), and a high rate...
of caval patency (97%). Our results suggest that prophylactic VCFs can be placed safely in trauma patients and have an acceptable long-term patency rate.

We also demonstrated that there have been 3 serious (1 fatal) PEs in our patients receiving prophylactic VCFs. These failures were due to either severe strut malposition or significant tilt. Filters manifesting severe malposition may not trap emboli. Clumping or maldistribution of filter struts and tilting appear to be frequent (38% and 5.5%, respectively) in our series. The marked clumping or tenting of the limbs can create large spaces between the filter struts and also disrupt the cone shape of the filter, possibly contributing to the 1 fatal case of PE seen. To allow for the percutaneous placement of VCFs, several modifications of the Greenfield filter have been made. The composition of the filter was changed from stainless steel to titanium, and the hook design was modified for more secure fixation. These changes in design for percutaneous placement came at the price of eliminating the guidewire for centering the VCF at the time of placement. Not having the ability to center the filter may allow the carrier to contact the wall of the vena cava at the time of insertion, leading to a higher incidence of SM or FT. Recent multi-institutional trials of percutaneously placed filters\(^6\) show that 5.3% to 10% had filter asymmetry, but the definition of what constituted limb asymmetry was not given in these studies.\(^7\) It is not clear what constitutes a clinically significant amount of FT or what is a clinically significant amount of SM. We chose an FT of 14° or more as significant because of the study by Katsamouris et al\(^5\) in which this degree of tilt was examined in an in vitro model. The authors found that this degree of tilt significantly affected clot-trapping ability. No other studies in this area are as explicit in the definition of what constitutes significant SM or FT. Certainly, the relative risk of developing PE may be better represented as a spectrum of degrees of SM or FT and not as a dichotomous variable that has been arbitrarily chosen. Further work needs to be done in this area to define significant SM or FT.

Several in vitro models have been used to evaluate the effect of filter tilt on the ability to capture clots. Greenfield and Proctor\(^8\) compared the several filter types (stainless-steel Greenfield filter with the modified hook, titanium filter, and percutaneous modified hook filter) in a cadaver vena cava using plastic emboli of 4 sizes. They found that the percutaneous modified hook model performed best in small vena cavae (<22 mm). Although it was determined that large caval size was the overriding factor affecting capture rates, tilted filters did show decreased capture rates. Filter limb configuration did not significantly affect capture rates in this study. Using a transparent polyethylene tube of 22 mm in diameter, Robinson et al\(^9\) looked at the clot-trapping ability of several filters in both the centered and tipped positions. The Greenfield filter had a reduced trapping efficiency in the tilted position compared with the centered position for 6×3-mm clots. The authors also stated that the Greenfield filter tended to catch 1 or 2 clots in its central cone, with subsequent emboli colliding with the trapped clot and then passing laterally between the widespread struts. In studies using plastic tubing and Greenfield filters, Katsamouris et al\(^5\) found that at 14° or more of tilting, the filter became ineffective at trapping all-sized clots.

Clinical reports of the filter tilt being related to recurrent PE have been relegated mostly to isolated case reports. In a series of 136 patients, Greenfield et al\(^10\) noted 3 (2%) cases of recurrent PE. In 1 of these, the filter was tilted and there was evidence of thrombus extending from the proximal tip of the filter. Early on, Greenfield\(^11\) noted a recurrent thrombus in an angiulated filter with its apex against the wall of the IVC. McAuley et al\(^12\) reported on 3 patients with recurrent PE that resulted from the proximal propagation of thrombus entrapped by the Greenfield filter. In only 1 patient was the filter obliquely situated. In a comparison of Mobin-Uddin and Kimray Greenfield filters (Medi-Tech, Boston Scientific Corporation, Watertown, Mass), Wingerd et al\(^13\) noted that of 2 tilted Greenfield filters, a venacavogram of 1 showed a thrombus extend-

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**Table 2. Studies of Prophylactic Vena Cava Filter (VCF) Insertion in Trauma Patients**

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of Patients Receiving VCF/Total No. of Patients (%)</th>
<th>No. of PEs in Patients With VCF</th>
<th>Complications</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jarrell et al(^9)</td>
<td>21/209 (10)</td>
<td>1</td>
<td>2 Vena caval thromboses</td>
<td>Not reported</td>
</tr>
<tr>
<td>Winchell et al(^11)</td>
<td>29/9721 (0.3)</td>
<td>0</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td>Webb et al(^15)</td>
<td>21/51 (41)</td>
<td>0</td>
<td>4 Patients (17%) had leg edema</td>
<td>18 mo</td>
</tr>
<tr>
<td>Rosenthal et al(^12)</td>
<td>29/161 (18)</td>
<td>0</td>
<td>Not reported</td>
<td>4-58 mo</td>
</tr>
<tr>
<td>Matous et al(^13)</td>
<td>53/5280 (1)</td>
<td>0</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td>Rodriguez et al(^14)</td>
<td>40r… (…)</td>
<td>2</td>
<td>4 Vena caval thromboses</td>
<td>Significant reduction in PE and PE-related mortality</td>
</tr>
<tr>
<td>Khasanrinia et al(^15)</td>
<td>108/6556 (2)</td>
<td>0</td>
<td>Not reported</td>
<td>Significant reduction in PE and PE-related mortality</td>
</tr>
<tr>
<td>Current study</td>
<td>132/5280 (2)</td>
<td>3</td>
<td>3.1% Had insertion-related DVT;</td>
<td>599±510 df</td>
</tr>
<tr>
<td>Total</td>
<td>433/27 258‡ (…)</td>
<td>6 (1.1)§</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* PE indicates pulmonary embolism; ellipses, information not available; and DVT, deep venous thrombosis.
† Mean ± SD.
‡ Not a true total because of the missing information from one of the studies.
§ The percentage given in parentheses refers to the number of PEs that developed vs the total number of VCFs placed.
ing proximally from 1 of the tips of these filters. In a review of complications encountered with the Greenfield filter, Carabasi et al.²⁴ described a patient with recurrent embolism 6 weeks after filter placement. A venogram accompanying the article shows a large embolus trapped in the filter with a tail extending above the top limits of the device. This picture shows clearly that the filter is in a tilted position. Greenfield et al.²⁵ in a presentation to the American Venous Forum in 1997, looked at limb asymmetry (ie, strut malposition) in titanium Greenfield filters. In 783 filters placed, there was a higher incidence of recurrent PE in those filters placed with strut asymmetry, but this did not reach statistical significance (P=.1). They concluded that the asymmetric VCF is not a risk factor for a recurrent PE and does not justify placing a second filter.

We recommend that after the placement of a prophylactic VCF, the positioning should be carefully assessed with anteroposterior and oblique films. Patients with significant SM or FT could undergo transcatheter manipulation, as Moore et al.²⁶ have suggested. Several potential risks exist with transcatheter manipulation, including proximal migration of the filter into the heart, intimal injury inciting caval thrombosis, and caval perforation. An alternative would be to place a second VCF.

There are several flaws in this review. Postfilter completion radiographs were taken in only 1 plane (anteroposterior) in some patients, and the lack of an oblique film may have missed a substantial amount of tilt in the anteroposterior direction. This study also did not address filter migration, which may also be a source of recurrent PE. Although we presume that the PEs that occurred in these patients came from the lower extremity DVTs that were present, we cannot exclude the possibility that the PEs originated from upper extremity thromboses, as has been reported to occur in a substantial percentage of patients.²⁷ Finally, we have protracted the follow-up on only 47 patients. It is possible that PEs and IVC thrombosis may have occurred at a higher rate in the other 85 patients.

It is important to evaluate whether a suggested therapy is less dangerous than the condition being treated. Prophylactic VCFs have a role in the management of a trauma patient who is at high risk for venous thromboembolism and who has a contraindication for anticoagulation. A VCF can substantially decrease the incidence of PE in these patients, as others.¹⁴,¹⁵,¹⁸ have shown. Recent modifications of the VCF to allow percutaneous placement have led to a propensity for malposition. Filters placed percutaneously should be carefully evaluated for malposition. If significant malposition occurs, manipulation of the filter should be considered, as should the placement of a second filter.


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REFERENCES