Prophylactic Inferior Vena Cava Filters: Do They Make a Difference in Trauma Patients?

Robert A. Cherry, MD, FACS, Pamela A. Nichols, BSN, Theresa M. Snively, BSN, RN, Mauger T. David, PhD, and Frank C. Lynch, MD

Background: Inferior vena cava filters (IVCF) are used in trauma patients to reduce the incidence of pulmonary embolism (PE). This study investigates the efficacy of prophylactic IVCF (PIVCF) placement from implantation through outpatient follow-up.

Methods: Data were prospectively collected on PIVCF placed in trauma patients ≥18-years old from 2004 to 2006. Exclusion criteria include therapeutic IVCF, major burns, deviated from a modified EAST protocol, and deaths. Data were collected on age, gender, Injury Severity Score (ISS), filter type, total implant days, PE, deep venous thrombosis (DVT), and filter-related complications.

Results: Of 4,936 patients, 280 had an IVCF with 244 meeting inclusion criteria. Study group demographics: 63.5% men; 98.8% blunt; mean age 43.8 ± 20.3; ISS 26.7 ± 12.8. There were 176 of 244 (72.1%) patients who met traditional EAST guidelines for PIVCF. PIVCF increased significantly from 29 in 2004 to 127 in 2006 with no difference in the PE rate (0.7% to 0.4%). There were 4 PEs (1.6%) on postprocedure days 7, 14, 18, and 23. Five technical complications occurred: two filter fractures, two caudal migrations, and one filter tilt. A total of 140 retrievable filters had the opportunity for outpatient follow-up for 18 months with 58.6% removed, 15.7% declared permanent, 12.1% lost to follow-up, and 13.6% still considered potential removal candidates. Days to implant: 0 to 32; 3.89 ± 4.79. Implant days: 15 to 838; mean 231 ± 162.

Conclusions: PIVCF increased significantly without impacting the overall PE rate. There was a 1.6% PE rate among PIVCF, high retrieval rate (59%), low complication rate (0.1%), and satisfactory compliance with traditional EAST guidelines.

Key Words: Wounds and injuries, Vena cava filters, Venous thrombosis, Pulmonary embolism.

Table 1 Modified EAST Guidelines

<table>
<thead>
<tr>
<th>Injuries</th>
<th>N</th>
</tr>
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<tbody>
<tr>
<td>Long bone fracture</td>
<td>109</td>
</tr>
<tr>
<td>Pelvis fracture</td>
<td>99</td>
</tr>
<tr>
<td>TBI with GCS &lt;8</td>
<td>93</td>
</tr>
<tr>
<td>Spine fractures</td>
<td>80</td>
</tr>
<tr>
<td>Spleen injury</td>
<td>39</td>
</tr>
<tr>
<td>Liver injury</td>
<td>31</td>
</tr>
<tr>
<td>SCI with paraplegia or quadriplegia</td>
<td>27</td>
</tr>
</tbody>
</table>

PIVCF indicates prophylactic inferior vena cava filter; TBI, traumatic brain injury; SCI, spinal cord injury; GCS, Glasgow coma scale.

Table 2 Distribution of Injuries Among 176 Patients Meeting Traditional EAST Guidelines for PIVCF

<table>
<thead>
<tr>
<th>Injuries</th>
<th>N</th>
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</table>

The interventional radiology service assumed primary responsibility for retrievable filter follow-up. Patients not referred for filter removal by trauma surgery within 90 days were contacted directly by the interventional radiology service when removal was deemed appropriate after a review of the patient record. Patients were deemed removal candidates if they had returned to an ambulatory state and/or they were therapeutically anticoagulated. Occasionally, patients were able to be safely anticoagulated late in their inpatient course, or as an outpatient, after implantation of a retrievable IVC filter. Patients not anticoagulated at the time of removal underwent venous duplex examination to exclude occult DVT. IVC filter removal was deferred or delayed if acute DVT was detected. Anticoagulation was not held for the procedure as long as the INR was less than 3.0.

χ² tests were used for the statistical analysis. Mean and SD were reported as summary statistics for quantities with normal distributions. Statistical analyses were performed using SAS Version 9 (SAS Institute, Cary, NC). All p values <0.05 were used to denote significant differences between study groups. The study protocol was approved by the Institutional Review Board at the Penn State Milton S. Hershey Medical Center.

RESULTS

There were 280 IVC filters implanted during the study period. Of these, there were 16 therapeutic IVC filters, 11 deaths, 8 institutional protocol deviations, and 1 burn patient. All 36 of these patients were excluded from the study. The study group of 244 patients all underwent PIVCF. The group included 63.5% men, 37.5% women, and 98.8% blunt trauma patients with a mean age of 43.8 ± 20.3, an ISS of 26.7 ± 12.8, and a TRISS of 0.821 ± 0.269. There were 176 of 244 (72.1%) patients who met traditional EAST guidelines for PIVCF placement. The distribution of injuries meeting inclusion criteria among these 176 patients are shown on Table 2. The distribution of injuries for the 68 patients who met our modified EAST criteria is shown in Table 3.

There was a statistically significant increase in the number of PIVCF implanted between 2004 and 2006 (see Table 4). This was not associated with increased screening for PE. The incidence of DVT in the study group was 9.0%. The DVT rate among those implanted with a PIVCF decreased from 24.1% in 2004 to 8.0% in 2005 and 6.3% in 2006. Despite the placement of a PIVCF, there were four PE cases (1.6%) in the study group on postprocedure days 7, 14, 18, and 23. One of these patients had a documented DVT. The statistical significance increase in PIVCF placement was not associated with a difference in the PE rate (see Table 4).
Table 3 Compliance With Traditional and Modified EAST Guidelines

| Patients meeting modified EAST Guidelines for PIVCF* | 68 (27.9%) |
| Complex fractures without long-bone fractures | 53 |
| Spine fractures with prolonged immobility greater than 72 h | 7 |
| High grade liver/unable to anticoagulate within 72 h | 6 |
| High grade spleen/unable to anticoagulate within 72 h | 2 |
| Patients meeting traditional EAST Guidelines for PIVCF | 176 (72.1%) |
| Total | 244 |

PIVCF indicates prophylactic inferior vena cava filter. * p < 0.05 compared to 2004.

Table 4 Prophylactic IVCF Implanted and Number of PEs

<table>
<thead>
<tr>
<th>Year</th>
<th>Adult trauma patients</th>
<th>Prophylactic IVCF</th>
<th>PEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>1,388</td>
<td>29 (2.1)</td>
<td>10 (0.7)</td>
</tr>
<tr>
<td>2005</td>
<td>1,737</td>
<td>88 (5.1)*</td>
<td>13 (0.7)</td>
</tr>
<tr>
<td>2006</td>
<td>1,811</td>
<td>127 (7.0)*</td>
<td>8 (0.4)</td>
</tr>
<tr>
<td>Total</td>
<td>4,936</td>
<td>244 (4.9)</td>
<td>31 (0.6)</td>
</tr>
</tbody>
</table>

Values in parentheses indicate percentage. IVCF indicates inferior vena cava filter; PE, pulmonary embolism. * p < 0.05 compared to 2004.

There were five filter-related technical complications (0.1%): two filter fractures (Bard Recovery), two caudal migrations (Bard G2), and one filter tilt (Bard G2).

The total number of retrievable filters was 181 (74.8%). The days to implant ranged from 0 to 32 (3.89 ± 4.79) and the total number of implant days was 15 to 838 days (231 ± 162). The distribution in filter types were as follows: Bard G2 (n = 116), Bard Recovery (n = 64), and Cook Gunther Tulip (n = 1). A total of 140 retrievable filters had the opportunity for outpatient follow-up for at least 18 months. The remaining 41 patients had filters placed after June of 2005 and therefore did not have the full opportunity for an 18-month follow-up period as part of the study protocol. Of the 140 retrievable filters with an 18-month follow-up, we found that 58.6% were removed, 15.7% were declared permanent, 12.1% were lost to follow, and 13.6% were still considered potential removal candidates (see Table 5). The majority of IVC filters that were removed occurred in the first year after implantation (77 of 82 or 93.9%).

**DISCUSSION**

Although our study demonstrated a statistically significant increase in PIVCF placement over a 3-year period, this was not associated with a decrease in our incidence in PEs. We initially adopted the EAST guidelines for PIVCF placement after our trauma center experienced an increase in the number of PEs in 2004. Several reports in the literature found a statistically significant decrease in the incidence of PE after the implementation of protocols for the use of prophylactic IVC filter placement.3–7 We introduced modifications to the EAST protocol based on our performance improvement program. There was a statistically significant increase in the number of IVC filters implanted on the Trauma Service between 2004 and 2006. We did notice a reduction in our PE rate from 0.7% to 0.4%. However, despite the more aggressive use of prophylactic IVC filters, the decreased incidence of PEs was not statistically significant.

It is possible that the current use of LMWH for VTE prophylaxis may have reduced the impact that prophylactic IVC filters have on the incidence of PEs. The investigations cited above that showed significant reductions of PEs after PIVCF use are older studies. The benefits of LMWH may not have been fully realized at that time. More recently, Antevil et al.8 also reported a threefold increase in prophylactic retrievable IVC filters. Their low PE rate of 0.2% remained unchanged. Interestingly, McMurty et al.9 actually found a significantly higher incidence of PE following a period of high PIVCF use. The cost-effectiveness of IVC filters in the prevention of PE among trauma patients has been questioned previously.10,11

In our study, the sample size is probably not large enough to analyze a statistically significant reduction in the PE rate. The PE rate would need to decrease to <0.1% to obtain a p value of 0.45 at 80% power. On the other hand, to have a PE rate <0.1%, there would need to be no more than one PE among the 1,811 patients in 2006. Because one of the PEs occurred on postprocedure day 14 after implantation of a PIVCF in 2006, this would mean that none of the 1,684 without an IVC filter would be allowed to have a PE. This outcome measurement is probably not possible to achieve clinically. The overall incidence of PEs in our state is 0.6% with a mortality rate of 8.5% in 2006.12

In order for prophylactic IVC filters to result in meaningful reductions in the incidence in PE, there is a need for better defined risk factors for VTE and improved indications for prophylaxis. Age, spine fractures, prolonged ventilator days, major venous injury, major operative procedure, lower
extremity fractures and closed head injury with AIS \( > 3 \) should also be considered.\(^2\,13\) The difficulty, however, is to develop strategies of risk stratification that minimize the number of unnecessary prophylactic IVC filters.\(^14\) In an era in which the Centers for Medicare and Medicaid Services is discontinuing coverage for selected hospital complications, additional studies are needed to reduce or eliminate the incidence of pulmonary embolism.

The four patients who suffered a PE despite an IVC filter were particularly concerning. Although the time to filter implant had a wide range in our study (0–32 days), there is no indication that this had a possible effect on these four patients. They were noted to be implanted on hospital days 2, 4, 8, and 13. Three of these patients were diagnosed after developing acute respiratory distress. Bilateral PEs were found in one patient following a surveillance CT scan for a grade IV liver laceration. This patient was asymptomatic at the time and had their IVC filter placed on hospital day 13.

There are several possible reasons for the occurrence of a PE despite IVC filter placement. First, clot may have embolized and extruded through the filter. Second, an upper extremity DVT may have embolized to the pulmonary veins. The incidence of pulmonary embolism among inpatients with a known upper extremity DVT has been reported to be 0% to 28%.\(^15\) The presence of a duplicated vena cava system or circumaortic renal vein may also allow for emboli to bypass the filter. However, these anomalies were excluded with a prefilter placement cavagram and review of the preprocedure CT scan. Of note, in all four of these patients with a post-IVC PE, LMWH was either held or not started at all because of the risk for bleeding. All of this suggests that prophylaxis with low dose heparin or LMWH is still important in patients of the risk for bleeding. All of this suggests that prophylaxis with low dose heparin or LMWH is still important in patients.

Rogers et al.\(^18\) investigated 132 prophylactic Greenfield filters implanted. This study reported a 3.1% insertion-related DVT rate, a 5.5% incidence of filter tilt, and a 38% prevalence of strut malposition. They reported three cases of PE occurring after IVC filter placement. All of these PEs were associated with either strut malposition or filter tilt. Rogers concluded that strut malposition and filter tilt greater than or equal to 14° for the Greenfield filter was a risk factor for PE. Of note, all of these cases involved the Greenfield filter. In our study, three of the four of the patients who developed postprocedure PEs had retrievable filters placed. All three had their IVC filters removed. There was no reported filter tilt or strut malposition in any of these patients during the retrieval. Patton et al.\(^19\) reported an early IVC complication rate of 7% among 110 patients with prophylactic IVCF. Malpositioning was reported in three patients and significant migration in one patient. There were no reported postfilter PEs.

The most common complication in trauma patients with following prophylactic IVC filters is a DVT. Girard et al.\(^20\) performed a systematic review of the literature and found the DVT rate to be 9.3% among 1,112 patients. The DVT rate of 9.0% found in this study is consistent with their study. The DVT rate among those patients with a PIVCF decreased from 24.1% in 2004 to 8.0% in 2005 and 6.3% in 2006. There has been no significant change in our duplex screening practice. The use of DVT prophylaxis with LMWH (dalteparin), after contraindications no longer existed, remained the agent of choice throughout this period. We are therefore unable to explain the decrease in the DVT rate over the 3-year period among patients who underwent IVC filter placement.

To our knowledge, the IVC filter removal rate of 59% is the highest reported in the literature to date. The removal rate has ranged from 21% to 52%.\(^8\,16\,21\,22\) In a recent multicenter study by Karmy-Jones et al.\(^21\) involving 21 trauma centers, the IVC removal rate was reported to be 21%. The authors found a sixfold increase in IVC filters when the service that placed the retrievable filter was also responsible for outpatient care with respect to the filter. The high removal rate of 59% in our study was achieved through the joint collaboration between trauma and interventional radiology.

There has been some discussion in the literature about the optimal timing for IVC filter retrieval. Stefanidis et al.\(^23\) suggested that trauma patients should have recovered from their injuries and be at least 30 days postdischarge, or be on a stable regimen of therapeutic anticoagulation for the treatment of a DVT or PE for at least 2 weeks. During outpatient follow-up visits at our institution, the original indications for IVC filters were again reviewed with the patient, as well as the process for retrieval of the filter. Removal was recommended if the patient was on a stable regimen of anticoagulation therapy or ambulating greater than 150 feet per day without the use of assist devices, such as a canes or walker. At the same time, Interventional Radiology maintained a database of all retrievable IVC filters implanted and contacted patients periodically about potential removal during their outpatient course.

Of note, there were 4,656 patients who did not receive an IVC filter over the 3-year period. We think that future studies should include all trauma patients who may be eligible for an IVC filter, evaluate their clinical outcomes, including the incidence of VTE, and compare eligible patients who did receive an IVC filter with those who did not have one implanted.

In conclusion, there was a statistically significant increase in PIVCF increase over 3 years without an impact on the overall PE rate among trauma patients. There was a 1.6% incidence of PE despite IVCF prophylaxis and a 9.0% DVT rate. The PIVCF group, however, had a relatively high retrieval rate (59%), a low rate of filter-related technical complications (0.1%), and satisfactory compliance with traditional EAST guidelines. PIVCF were removed safely greater than 800 days postprocedure. The instructions for use (IFU) for the Gunther Tulip Filter (Cook Group, Bloomington, IN) and the Recovery/G2 filters (Bard Peripheral Va-
cular, Tempe, AZ) state no specific recommendations or limitations regarding the timing of filter retrieval.

The results of this study contribute to the body of literature placing the effectiveness of IVC filters in doubt. The current criteria used for determining which patients will benefit are not sufficient enough to have an effect at reducing the overall rate of PE. Further investigation is required to define an optimal trauma population that lends itself prophylactic IVC filter placement.

REFERENCES


