The Effectiveness of Prophylactic Inferior Vena Cava Filters in Trauma Patients
A Systematic Review and Meta-analysis

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IMPORTANCE Trauma is known to be one of the strongest risk factors for pulmonary embolism (PE). Current guidelines recommend low-molecular-weight heparin therapy for prevention of PE, but trauma places some patients at risk of excess bleeding. Experts are divided on the role of prophylactic inferior vena cava (IVC) filters to prevent PE.

OBJECTIVE To perform a systematic review and meta-analysis examining the comparative effectiveness of prophylactic IVC filters in trauma patients, particularly in preventing PE, fatal PE, and mortality.

DATA SOURCES We searched the following databases for primary studies: MEDLINE, EMBASE, Scopus, CINAHL, International Pharmaceutical Abstracts, clinicaltrial.gov, and the Cochrane Library (all through July 31, 2012). We developed a search strategy using medical subject headings terms and text words of key articles that we identified a priori. We reviewed the references of all included articles, relevant review articles, and related systematic reviews to identify articles the database searches might have missed.

STUDY SELECTION We reviewed titles followed by abstracts to identify randomized clinical trials or observational studies with comparison groups reporting on the effectiveness and/or safety of IVC filters for prevention of venous thromboembolism in trauma patients.

DATA EXTRACTION AND SYNTHESIS Two investigators independently reviewed abstracts and abstracted data. For studies amenable to pooling with meta-analysis, we pooled using the random-effects model to analyze the relative risks. We graded the quantity, quality, and consistency of the evidence by adapting an evidence-grading scheme recommended by the Agency for Healthcare Research and Quality.

RESULTS Eight controlled studies compared the effectiveness of no IVC filter vs IVC filter on PE, fatal PE, deep vein thrombosis, and/or mortality in trauma patients. Evidence showed a consistent reduction of PE (relative risk, 0.20 [95% CI, 0.06-0.70]; I² = 0%) and fatal PE (0.09 [0.01-0.81]; I² = 0%) with IVC filter placement, without any statistical heterogeneity. We found no significant difference in the incidence of deep vein thrombosis (relative risk, 1.76 [95% CI, 0.50-6.19]; P = .38; I² = 56.8%) or mortality (0.70 [0.40-1.23]; I² = 6.7%). The number needed to treat to prevent 1 additional PE with IVC filters is estimated to range from 109 (95% CI, 93-190) to 962 (819-2565), depending on the baseline PE risk.

CONCLUSIONS AND RELEVANCE The strength of evidence is low but supports the association of IVC filter placement with a lower incidence of PE and fatal PE in trauma patients. Which patients experience benefit enough to outweigh the harms associated with IVC filter placement remains unclear. Additional well-designed observational or prospective cohort studies may be informative.
venous thromboembolism (VTE), including pulmonary embolism (PE) and deep vein thrombosis (DVT), affects as many as 600,000 Americans, killing more than 100,000 people each year and resulting in significant morbidity and mortality. Trauma is known to be one of the strongest risk factors for VTE. A prospective study reported rates of DVT as high as 58% among those who experience severe trauma without thromboprophylaxis, although other registry-based studies have reported lower rates. Guidelines recommend VTE prophylaxis with low-molecular-weight heparin in trauma.

However, a small proportion of patients who are at the highest risk of VTE owing to severe injury also have definite or relative contraindications to low-molecular-weight heparin therapy because of an ongoing risk of life-threatening bleeding. In these cases, debate about the role of prophylactic inferior vena cava (IVC) filters to prevent PE is ongoing. Some authors suggest that using IVC filters among trauma patients at very high risk of PE may prevent the most dramatic and life-threatening cases. Other authors suggest their use is not beneficial and should be curtailed. Inferior vena cava filters are associated with risk of thrombotic complications (ie, caval thrombosis) and mechanical complications (ie, strut fracture, filter migration/embolization).

The increased use of IVC filters in general and in trauma patients is well documented, with wide variation between trauma centers in the rates of IVC filter placement. This practice variation may result from conflicting guidelines. The Eastern Association for the Surgery of Trauma practice management guideline promotes IVC filters in certain patients. The American College of Chest Physicians has a more recent guideline stating that “for major trauma patients, we suggest that an IVC filter should not be used for primary VTE prevention.” For this systematic review and meta-analysis, we critically evaluated the data regarding the safety and efficacy of prophylactic IVC filters in trauma patients with the goal of providing evidence to guide practice and further research about their use.

Methods

We developed the protocol for the review and posted it online following guidelines for systematic reviews. Additional methodological details are in our evidence report prepared for the Agency for Healthcare Research and Quality (AHRQ). The full protocol was posted online (http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/). We developed an analytic framework that depicts our population of interest, interventions tested for VTE prevention, outcomes of treatment, and harms of interventions.

Data Sources and Search

We searched the following databases for primary studies: MEDLINE, EMBASE, Scopus, CINAHL, International Pharma-ceutical Abstracts, clinicaltrial.gov, and the Cochrane Library (through July 31, 2012). We developed a search strategy based on medical subject headings terms and text words of key articles that we identified a priori. We also reviewed the reference lists of all included articles, relevant review articles, and related systematic reviews.

Study Selection, Data Abstraction, and Quality Assessment

Two independent reviewers assessed the titles and then abstracts to identify randomized clinical trials (RCTs) or observational studies with comparison groups reporting on the effectiveness and/or safety of IVC filters for VTE prevention in trauma. We used a software program (DistillerSR; Evidence Partners, 2010) to manage the screening and review process. Paired reviewers used standardized forms for data extraction from the articles.

We conducted a risk-of-bias assessment (for the quality of evidence) independently and in duplicate using the Downs and Black instrument. We found that 10 items were most relevant to this review and prioritized them in our assessment of risk of bias. We considered studies to have a low risk of bias if the article completely described the hypothesis, outcomes (in the Introduction or Methods section), characteristics of the included subjects, distribution of the potential confounders in each group, interventions and comparisons (if relevant), main findings, adverse events, and characteristics of participants unavailable for or lost to follow-up. We also required low-risk studies to have randomized participants to the intervention, concealed the assignment or allocation of treatment until recruitment was complete, and masked the study participants and those measuring the main outcomes (double blinding). We rated studies as having a moderate risk of bias if 1 of those items was not true. If 2 of the elements were not true, we considered the study to have a high risk of bias.

Data Synthesis and Analysis

We created a detailed set of evidence tables containing all abstracted information. Meta-analysis was performed to pool results for the effect of IVC filter placement on each clinically important outcome (PE, fatal PE, DVT, and mortality). We considered the clinical and statistical heterogeneity of the studies. We identified substantial statistical heterogeneity in the trials as an I² statistic greater than 50%.

We excluded studies from the meta-analysis if serious flaws, such as diagnostic imbalance, were found in key confounders that were not accounted for in an unadjusted analysis. For studies amenable to pooling with meta-analysis, we pooled using a DerSimonian and Laird random-effects model as the primary analysis.

Most of the outcomes occurred at frequencies of less than 1%, and several studies had 0 events. Because the usual statistical approach of adding 0.5 to estimate the relative risk (RR) in the presence of 0 events may produce biased estimates, we used the treatment arm continuity correction approach to estimate the RR by adding a reciprocal of the treatment arm. We conducted a sensitivity analysis using alternative continuity corrections (0.5 and 0.01) and no continuity correction (Peto odds ratio). Combined estimates for the RR are pre-
stated along with a 95% confidence interval. Given the fragility of the data set, 2 independent experts, including one of us (S.S.) replicated the results in 2 different statistical programs. All analyses were conducted using StatsDirect and replicated in STATA, version 11.0.21

We calculated the number needed to treat (NNT) to prevent PE with IVC filters among trauma patients using an online calculator (http://www.nntonline.net). We used a range of possible baseline PE rates (0.13%-1.15%) from the published literature22-23 and assumed that approximately 10% of PEs are fatal.

Grading the Evidence and Applicability
We graded the quantity, quality, and consistency of the best available evidence by adapting an evidence-grading scheme recommended by the AHRQ.2 4 In assigning evidence grades, we considered the following 4 recommended domains: risk of bias in the included studies, directness of the evidence to the question of interest, consistency across studies, and precision of the pooled estimate or the individual study estimates. We found that few of the studies reported precision, although we were able to calculate confidence intervals for some of the outcomes. We classified results by outcome into the following 4 grades: high (indicating high confidence that the evidence reflects the true effect and that further research is very unlikely to change our confidence in the estimate of the effect), moderate (indicating moderate confidence that the evidence reflects the true effect and that further research may change our confidence in the estimate of the effect and may change the estimate), low (indicating low confidence that the evidence reflects the true effect and that further research is likely to change our confidence in the estimate of the effect and is likely to change the estimate), and insufficient (evidence is unavailable or is so imprecise or of such low quality that the estimate of effect is unreliable).

Results
Study Characteristics
We identified 30,902 unique citations, of which 21,687 were excluded by title screen (Figure 1). Fifty-eight studies addressed IVC filter use in trauma, although most (n = 48) were uncontrolled studies. We included 8 controlled studies that assessed the effectiveness of IVC filter compared with no filter placement on VTE events in trauma patients (Table 1). Of the 8 studies, 1 was a small pilot feasibility RCT;25, 2, prospective cohort studies with concurrent comparison groups;26, 28, 4, prospective cohort studies with historical controls;27, 29-31, and 1, a retrospective cohort study.32 All 8 studies were performed within single institutions in North America, most of which were level I trauma centers.

All studies analyzed patients in 2 groups. One group received standard therapy alone, and the other group received prophylactic IVC filter placement in addition to standard VTE prevention. The most common standard therapy was a combination of venous compression devices with subcutaneous low-molecular-weight heparin. Most studies used duplex ultrasonography for DVT diagnosis, although some older studies used outdated modalities, such as impedance plethysmography.26, 27 For the diagnosis of PE, most studies used computed tomographic angiography, but some used conventional angiography or, infrequently, ventilation/perfusion scans.

We excluded 2 studies26, 29 from the pooled analyses because we considered them to have substantial flaws. The first study had severe prognostic imbalance in Injury Severity Scores (ISSs) between study groups (mean ISS, 22.8 vs 9.8, filter vs control).26 The second study was excluded because of concerns about overlapping participants with another study by the same authors from the same institution and the same study period.29

Participant Characteristics
The patients in the controlled observational studies ranged in mean age from 31.4 to 58.4 years. Most of the patients in each study were men (58.0%-96.0%). Seven studies reported mean ISS. Mean ISS for patients receiving IVC filters ranged from 22.8 to 31.5, with 5 of 7 studies reporting a mean ISS greater than 25, a common cutoff for very severe injury. Mean ISS for patients not receiving filters were not uniformly reported, but the scores were lower than those for the patients receiving IVC filters in all 5 studies in which they were reported (Table 1).

Outcomes
Pulmonary Embolism
We included 6 controlled studies for the meta-analysis on PE outcomes.25-27, 28, 30-32 We found fewer PEs with IVC filter use compared with no IVC filter use without evidence of statistical heterogeneity (RR, 0.20 [95% CI, 0.06-0.70]; I² = 0%) (Figure 2). Our results were robust to alternative approaches for continuity correction and showed largely similar results.

In the small RCT,25 we found no statistically significant difference in the incidence of PE between the 2 groups, with no PEs in the IVC filter group and 1 PE among patients without filters. Five of the 6 observational studies included in the meta-analysis reported lower PE rates with IVC filter placement27-31 (Supplement [eTable 1]). The single study with a higher incidence of PE with IVC filter placement31 included only patients with spinal cord injuries and a single patient who had a PE diagnosed after placement of an IVC filter. Both studies by Rogers et al,26, 29 which were excluded from the meta-analysis, reported higher rates of PE. The study that reported ISS26 had dramatically higher ISS in the IVC filter group.

Assuming a baseline risk of PE of 1.15% among trauma patients,22 the NNT to prevent 1 additional PE with IVC filters is estimated to be 109 (95% CI, 93-110). If the lowest reported baseline risk is used (with all National Trauma Data Bank patients in the denominator),22 the NNT is 962 (95% CI, 819-2565) (Supplement [eTable 2]).

Fatal PE
We included 4 studies that reported on fatal PE25-27, 30, 31; one of these had no events in either arm26 (Figure 3). We found consistent evidence of a reduction in fatal PE with IVC filters...
compared with no IVC filters, without evidence of statistical heterogeneity (RR, 0.09 [95% CI, 0.01-0.81]; I² = 0%). Despite the precise and consistent evidence of a reduction in fatal PE with IVC filters, sensitivity analyses with alternative continuity corrections (used if 0 events occurred in 1 treatment arm) were not uniformly robust to the outcome of fatal PE. The Peto odds ratio approach showed a statistically significant reduction in fatal PE (Peto odds ratio, 0.22 [95% CI, 0.08-0.58]), which is consistent with the primary analysis. Alternative continuity corrections, such as the 0.5 correction (RR, 0.22 [95% CI, 0.04-1.16]) or 0.01 correction (0.01 [0-425.5]), were not statistically significant. The NNT to prevent 1 fatal PE with IVC filters is estimated to be 1099 (95% CI, 1011-5264), although this assumption is fragile with multiple assumptions (Supplement [eTable 2]).

No fatal PEs occurred in the IVC filter arms of any included study (Supplement [eTable 1]). Twenty fatal PEs occurred in the 407 patients not receiving IVC filters. No VTE-related deaths were recorded in the RCT.²⁵ The prospective cohort study with historical controls identified a statistically significantly higher incidence of fatal PE in patients who did not receive IVC filters (4% vs 0%; P = .03).³⁰

We used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist to refine the search for eligible studies, resulting in 8 controlled studies for analysis. HIT indicates heparin-induced thrombocytopenia; IVC, inferior vena cava; VTE, venous thromboembolism.

*Total exceeds the number excluded because reviewers were allowed to mark more than 1 reason for exclusion.
Deep Vein Thrombosis

The RR for the outcome of DVT was 1.76 (95% CI, 0.50-6.19; \( P = .38 \)) \(^{25,30,32} \) (Supplement [eFigure 1]). Substantial statistical heterogeneity was found among the included studies \( (I^2 = 56.7\%) \). The sensitivity analyses had similar results. In the RCT, only a single DVT was reported (in the IVC filter group), and no significant difference in DVT incidence between groups was found\(^{30} \) (Supplement [eTable 1]).

Mortality

We included 3 studies reporting mortality in the meta-analysis\(^{25,30,31} \). The pooled RR for the outcome of mortality was 0.19 (95% CI, 0.07-0.51; \( P = .001 \)).

Table 1. Characteristics of Controlled Studies of Prophylactic IVC Filters Among Trauma Patients

<table>
<thead>
<tr>
<th>Source</th>
<th>Design</th>
<th>No. of Patients</th>
<th>Mean Age, y</th>
<th>Male Sex, %</th>
<th>Mean ISS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IVC Filter Group</td>
<td>No IVC Filter Group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rajasekhar et al(^{25} ) 2011 (^{a} )</td>
<td>RCT</td>
<td>18</td>
<td>41.2</td>
<td>53.7</td>
<td>26.6</td>
</tr>
<tr>
<td>Rogers et al(^{26} ) 1997</td>
<td>PC</td>
<td>35</td>
<td>58.4</td>
<td>38.9</td>
<td>22.8</td>
</tr>
<tr>
<td>Gosin et al(^{28} ) 1997</td>
<td>PC</td>
<td>99</td>
<td>42.6</td>
<td>NR</td>
<td>23.4</td>
</tr>
<tr>
<td>Rogers et al(^{29} ) 1995 Historical comparison</td>
<td>Historical comparison</td>
<td>63</td>
<td>38.9</td>
<td>NR</td>
<td>31.5</td>
</tr>
<tr>
<td>Wilson et al(^{27} ) 1994 Historical comparison</td>
<td>Historical comparison</td>
<td>15</td>
<td>31.4</td>
<td>30.0</td>
<td>30.0</td>
</tr>
<tr>
<td>Gorman et al(^{22} ) 2009</td>
<td>RC</td>
<td>54</td>
<td>37.1</td>
<td>48.1</td>
<td>96.0</td>
</tr>
<tr>
<td>Rodriguez et al(^{31} ) 1996 Historical comparison</td>
<td>Historical comparison</td>
<td>40</td>
<td>44.0</td>
<td>41.0</td>
<td>58.0</td>
</tr>
<tr>
<td>Khansarinia et al(^{30} ) 1995 Historical comparison</td>
<td>Historical comparison</td>
<td>108</td>
<td>35.9</td>
<td>38.3</td>
<td>76.0</td>
</tr>
</tbody>
</table>

Abbreviations: ISS, Injury Severity Score; IVC, inferior vena cava; NR, not reported; PC, prospective cohort; RC, retrospective cohort; RCT, randomized clinical trial.

\(^{a} \) Study did not report characteristics by treatment group.

Figure 2. Forest Plot of Relative Risk (RR) of Pulmonary Embolism (PE) With Use of Inferior Vena Cava (IVC) Filters vs No IVC Filters in Trauma Patients

Weights are calculated from random-effects analysis. Dashed line indicates the overall weighted point estimate (0.20); diamond, same overall weighted point estimate (95% CI). Shadow size varies relative to weight assigned to each study. Overall \( I^2 = 0\% \) \( (P = .48) \). Test of RR = 1 \( (z = 2.52, P = .01) \).

Figure 3. Forest Plot of Relative Risk (RR) of Fatal Pulmonary Embolism (PE) With Use of Inferior Vena Cava (IVC) Filters vs No IVC Filters in Trauma Patients

Weights are calculated from random-effects analysis. Dashed line indicates the overall weighted point estimate (0.20); diamond, same overall weighted point estimate (95% CI). Shadow size varies relative to weight assigned to each study. Overall \( I^2 = 0\% \) \( (P = .74) \). Test of RR = 1 \( (z = 2.14, P = .03) \).
0.70 (95% CI, 0.40-1.23; \(I^2 = 6.7\%\)) (Supplement [eFigure 2]). Our results were robust to alternative approaches for continuity correction and showed largely similar results.

No differences were observed in the RCT with regard to VTE and non-VTE mortality between groups.25 Both non-RCT studies included in the meta-analysis showed nonsignificantly lower all-cause mortality in the IVC filter group compared with the no IVC filter group.

**Filter Complications**

Filter-related complications were only sparsely reported in the controlled studies. The complete data on complications in these controlled studies and in many uncontrolled studies are contained in the full AHRQ report.23

**Risk of Bias**

We rated the only small RCT as having a high risk of bias; this was based primarily on issues regarding blinding of the outcome assessors.29 Among the controlled observational studies, we rated only 1 study as having a moderate risk of bias32 and the remainder as having a high risk of bias.

**Strength of Evidence**

We rated the strength of evidence as low to support a reduction in PE and fatal PE in trauma patients with the use of IVC filters relative to no use of filters (Table 2). Our estimates for PE were robust to alternative statistical approaches, whereas the estimates for fatal PE were more fragile, and this significant reduction in fatal PE should be viewed with caution. We rated the strength of evidence as insufficient to support a reduction in mortality in trauma with IVC filters. We rated the strength of evidence as insufficient to support any increased or decreased probability of DVT in trauma patients with IVC filters.

**Discussion**

Overall, we found low strength of evidence that prophylactic IVC filter placement is associated with a lower incidence of PE and fatal PE in hospitalized trauma patients when compared with no filter use. We found insufficient evidence to comment on mortality or DVT incidence associated with prophylactic IVC filter placement.

We identified only a single RCT, and it had significant methodological limitations. This pilot feasibility trial randomized patients to usual care plus IVC filter or usual care alone and was underpowered for all outcomes. There was significant heterogeneity among the other included controlled studies in design and eligibility and inconsistency in the efficacy outcome assessment methods. Although many of the studies reported on the VTE outcomes, most did not provide details about anatomic locations of the DVTs or the PEs. Some studies did not completely report all outcomes for DVT and PE, which is important because IVC filters may have opposing effects on DVTs and PEs.30 In addition, we found differences in reporting and duration of follow-up. The included studies lacked adequate details about enrolled patient characteristics, such as race and sex and details of the extent and severity of the trauma, limiting our ability to generalize findings from these studies to other ethnic groups or age categories. A wide variation in the use of IVC filters in trauma centers was found that cannot be explained by patient characteristics.31

Our present findings should be interpreted in the context of other systematic reviews. A recent review34 conducted a

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**Table 2. Strength of Evidence for Prophylactic IVC Filter vs No IVC Filter in Trauma Patients**

<table>
<thead>
<tr>
<th>Outcome, Source</th>
<th>Risk of Bias</th>
<th>SOE and Magnitude of Effect, %a</th>
</tr>
</thead>
<tbody>
<tr>
<td>PE</td>
<td>High</td>
<td>Insufficient that IVC filter placement is associated with a lower incidence of PE in hospitalized trauma patients compared with no IVC filter placement; RR = 0.20 (95% CI = 0.06-0.70; (I^2 = 0%))</td>
</tr>
<tr>
<td>Rajsekhar et al,25 2011b</td>
<td>High</td>
<td>0 vs 6.2</td>
</tr>
<tr>
<td>Wilson et al,27 1994</td>
<td>High</td>
<td>0 vs 7.2</td>
</tr>
<tr>
<td>Gosin et al,26 1997</td>
<td>High</td>
<td>0 vs 4.8</td>
</tr>
<tr>
<td>Gorman et al,32 2009</td>
<td>Moderate</td>
<td>1.8 vs 0</td>
</tr>
<tr>
<td>Khansarinia et al,20 1995</td>
<td>High</td>
<td>0 vs 6.0</td>
</tr>
<tr>
<td>Rodriguez et al,21 1996</td>
<td>High</td>
<td>2.5 vs 17.5</td>
</tr>
<tr>
<td>Fatal PE</td>
<td>High</td>
<td>Insufficient that IVC filter placement is associated with a lower incidence of fatal PE in hospitalized trauma patients compared with no IVC filter placement; RR = 0.09 (95% CI, 0.01-0.81; (I^2 = 0%))</td>
</tr>
<tr>
<td>Rajsekhar et al,25 2011b</td>
<td>High</td>
<td>0 vs 0</td>
</tr>
<tr>
<td>Wilson et al,27 1994</td>
<td>High</td>
<td>0 vs 2.7</td>
</tr>
<tr>
<td>Khansarinia et al,20 1995</td>
<td>High</td>
<td>0 vs 5.5</td>
</tr>
<tr>
<td>Rodriguez et al,21 1996</td>
<td>High</td>
<td>0 vs 10.0</td>
</tr>
<tr>
<td>Mortality</td>
<td>High</td>
<td>Insufficient that IVC filter placement is associated with less mortality in hospitalized trauma patients compared with no IVC filter placement; RR = 0.70 (95% CI, 0.40-1.23; (I^2 = 6.7%))</td>
</tr>
<tr>
<td>Rajsekhar et al,25 2011b</td>
<td>High</td>
<td>5.5 vs 0</td>
</tr>
<tr>
<td>Khansarinia et al,20 1995</td>
<td>High</td>
<td>16.6 vs 21.7</td>
</tr>
<tr>
<td>Rodriguez et al,21 1996</td>
<td>High</td>
<td>5.0 vs 16.2</td>
</tr>
<tr>
<td>DVT</td>
<td>High</td>
<td>Insufficient that IVC filter placement is associated with a higher incidence of DVT compared with no IVC filter placement; RR = 1.76 (95% CI, 0.49-6.18; (I^2 = 56.8%); (P = .38))</td>
</tr>
<tr>
<td>Rajsekhar et al,25 2011b</td>
<td>High</td>
<td>5.5 vs 0</td>
</tr>
<tr>
<td>Rodriguez et al,21 1996</td>
<td>High</td>
<td>15.0 vs 18.7</td>
</tr>
<tr>
<td>Gorman et al,32 2009</td>
<td>Moderate</td>
<td>20.4 vs 5.2</td>
</tr>
</tbody>
</table>

Abbreviations: DVT, deep vein thrombosis; IVC, inferior vena cava; PE, pulmonary embolism; RR, relative risk; SOE, strength of evidence.

a Graded on filter-related thrombosis. Data were too sparse on other complications, such as filter tilt and migration, to provide meaningful SOE grades on these specific complications.

b Indicates only randomized clinical trial (RCT) to address this key question.

c No deaths related to venous thromboembolism occurred in the RCT.
Our report highlights the need for additional research on the comparative effectiveness and safety of IVC filters in hospitalized trauma patients. The American Venous Forum and the Society of Interventional Radiology Multidisciplinary Consensus Conference have placed a high priority on studies of IVC filters in trauma. The all-too-common answer that RCTs must be performed is at first glance appealing, and Rajasekhar et al have shown us that RCTs can be performed on this topic. However, an appropriately powered, multicenter RCT may be prohibitively expensive. We therefore suggest other possible options for well-designed observational research that may be less expensive yet still informative.

Prospective observational studies, such as the National Study on Costs and Outcomes of Trauma, have answered other questions in trauma. Perhaps a study such as ours examining VTE prevention in trauma, focused on IVC filters specifically, could be performed. This prospective cohort study could compare an exposed group of trauma patients receiving filters with a carefully matched comparison group of patients with comparable injuries who do not receive IVC filters. A large-scale project like this would likely require a multicenter research collaboration and need national funding and/or sponsorship by a professional trauma organization.

In addition, observational research could be facilitated with use of registry data, such as from the National Trauma Data Bank. Although the National Trauma Data Bank currently contains insufficient detail about IVC filters, this problem could be rectified. Ideally, the registry could include data elements, such as indication, timing of placement, filter type, concomitant pharmacologic prophylaxis, complications, filter removal, and long-term follow-up. A newly published framework regarding ethics of clinical research suggests that not only do clinicians have a moral obligation to perform clinical research but patients are obligated “to contribute to the common purpose of improving the quality and value of clinical care and health care systems.” Retrospective cohort studies are valuable, but they need much better control for confounding by indication (sicker patients received IVC filters more often than less sick patients) than was performed in the included studies. The major flaw of the included retrospective studies was that the authors compared the outcomes for patients receiving filters with those of patients not receiving filters and paid little attention to important underlying clinical differences between these patient groups. Patients receiving IVC filters commonly had more severe injuries and a greater risk for VTE and mortality than did patients not receiving filters. With careful risk adjustment through regression or other methods (eg, propensity score matching, instrumental variable analyses), valid inferences can be drawn from retrospective studies.

The advent of removable IVC filters has been suggested as a major advantage. These removable filters may change the calculation of the benefit to harm ratio for patients by mitigating the long-term complications of having an indwelling IVC filter for life. Filter-related complications may be obviated by filter removal after the high-risk period for PE has passed. These concerns are particularly important considering the relatively young trauma population. However, the premise is based on the assumption that filters are removed in a timely, effi-
AHRQ report asked the question, “What is the optimal timing of initiation and duration of pharmacologic prophylaxis in patients considered to be at increased risk of bleeding (eg, traumatic brain injury) remains controversial. The AHRQ report asked the question, “What is the optimal timing of initiation and duration of pharmacologic prophylaxis to prevent VTE in hospitalized patients with traumatic brain injury?” The published data did not allow us to answer this question definitively. However, a retrospective series, a prospective observational case series, and clinical guidelines suggest that prophylactic IVC filter placement is associated with lower risk of PE and fatal PE.

The baseline risk of all VTE outcomes depends greatly on the use of appropriate, timely VTE prophylaxis in patients at risk. Although once thought to occur late after trauma, PE is frequently found earlier in the hospital course. However, the use of early pharmacologic thromboprophylaxis in patients considered to be at increased risk of bleeding (eg, traumatic brain injury) remains controversial. The AHRQ report asked the question, “What is the optimal timing of initiation and duration of pharmacologic prophylaxis to prevent VTE in hospitalized patients with traumatic brain injury?” The published data did not allow us to answer this question definitively. However, a retrospective series, a prospective observational case series, and clinical guidelines suggest that prophylactic IVC filter placement is likely safer than originally thought. If pharmacologic prophylaxis is initiated earlier, more patients would receive appropriate VTE prophylaxis, driving down the baseline VTE rate and changing the risk/benefit profile of IVC filters and the NNT to prevent PE and fatal PE.

Clinicians need guidance regarding the use of prophylactic IVC filters in high-risk trauma patients. Overall, we found that prophylactic IVC filter placement is associated with lower incidence of PE and fatal PE in trauma patients. However, risks to patients with IVC filter placement remain, and we were unable to fully examine these risks in this review. In most of the less severely injured trauma patients, particularly those receiving VTE prophylaxis, these risks likely outweigh the benefit of prophylactic IVC filter placement. However, the ratio of benefit to harm likely differs for patients with a higher underlying probability of developing PE, such as those who are more severely injured or who cannot receive pharmacologic prophylaxis. As with many patient care decisions, these difficult clinical judgments must balance the ratio of benefit to harm for individual trauma patients.
Prophylactic Inferior Vena Cava Filters


21. Stata Statistical Software [computer program]. Release 11.0. College Station, TX: StataCorp LP; 2009.


