A Population-Based Study of the Effectiveness of Inferior Vena Cava Filter Use Among Patients With Venous Thromboembolism

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Background: There are few population-based data regarding the effectiveness of inferior vena cava filter use in the prevention of symptomatic pulmonary embolism.

Objective: To determine the 1-year cumulative incidence of rehospitalization for venous thrombosis or pulmonary embolism among patients with thromboembolism treated with a vena cava filter compared with the incidence in a control population with thromboembolism.

Patients and Methods: Population-based retrospective analysis of linked hospital discharge abstracts in California. From January 1, 1991, through December 30, 1995, 3632 patients were treated with a filter and 64,333 controls were admitted with a principal diagnosis of venous thromboembolism.

Results: Filter-treated patients had significantly greater comorbidity, with a higher frequency of previous pulmonary embolism, recent major bleeding, malignant neoplasm, and stroke. Patients who initially manifested pulmonary embolism were significantly more likely to be rehospitalized for pulmonary embolism than patients with an initial diagnosis of venous thrombosis alone, among filter-treated patients (relative risk, 6.72; 95% confidence interval, 3.61-12.49) and controls (relative risk, 5.30; 95% confidence interval, 4.61-6.10). Risk-adjusted proportional hazards modeling showed no significant difference between filter-treated patients and controls in the relative hazard of rehospitalization for pulmonary embolism. However, filter placement was associated with a significantly higher relative hazard of rehospitalization for venous thrombosis among patients who initially manifested pulmonary embolism (relative hazard, 2.62; 95% confidence interval, 2.09-3.29), but not among those who presented with venous thrombosis (relative hazard, 1.14; 95% confidence interval, 0.92-1.43).

Conclusions: Insertion of a vena cava filter was not associated with a significant reduction in the 1-year incidence of rehospitalization for pulmonary embolism. Use of a filter was associated with a higher incidence of rehospitalization for venous thrombosis, but only among patients who initially manifested pulmonary embolism. A prospective clinical study is needed to determine the efficacy of filter use among patients with pulmonary embolism who do not meet strict guidelines for insertion of a vena cava filter.

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The principal indications for insertion of an inferior vena cava filter are failure of anticoagulant therapy and a strict contraindication to anticoagulation therapy, such as active bleeding. However, an increasing number of vena cava filters are being used in patients with venous thromboembolism who meet less strictly defined indications, such as medically unstable patients, those with a large burden of clot, and patients deemed to be at increased risk for recurrent thromboembolism or anticoagulant-related bleeding. Further, based on small observational studies from single institutions, some authorities have suggested that use of a filter alone, without anticoagulant therapy, is associated with an equal or lower incidence of adverse outcomes compared with use of a filter plus treatment with heparin sodium followed by warfarin sodium.

Almost all reports of outcomes after insertion of a vena cava filter have been based on uncontrolled, unblinded retrospective reviews. In the only clinical trial that has evaluated the efficacy of vena cava filters, Decousus and coworkers randomized 400 patients with acute deep vein thrombosis to receive anticoagulation therapy alone or anticoagulation therapy plus a vena cava filter. After 2 years, there was a nonsignificant 2.9% reduction in the incidence of symptomatic pulmonary embolism among the filter-treated patients.
PATIENTS AND METHODS

DISCHARGE DATA SET
A detailed description of the California Patient Discharge Data Set has been published previously. Briefly, the State of California requires that all nonfederally licensed hospitals submit information about each inpatient after discharge, including demographic data, the principal diagnosis (ie, the condition chiefly responsible for occasioning the admission), up to 24 secondary diagnoses, a principal procedure, and up to 20 secondary procedures. One can readily identify patients admitted with a specific principal diagnosis, such as venous thrombosis or pulmonary embolism, and patients who have undergone a specific procedure, such as insertion of a vena cava filter. Since July 1990, an encrypted version of the social security number has been included, which permits tracking of serial hospitalizations within the state and also permits linkage with a state death registry. All procedures and diagnoses are coded using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). We used any 2 of the 3 components of the patient’s date of birth to confirm the validity of all linkages. This study was approved by the California Health and Welfare Agency Committee for the Protection of Human Subjects, and the University of California–Davis (UCD) Human Subjects Committee.

VENA CAVA FILTER–TREATED PATIENTS
We identified all hospital discharges from January 1, 1991, through December 30, 1995, with a procedure code for vena cava interruption (ICD-9-CM code 38.7). Discharge records with missing social security numbers or birth dates were excluded because they could not be linked. Because the predictive value of a principal diagnosis of venous thromboembolism is greater than 95%, we restricted our analysis to patients aged 18 years or older who were hospitalized with a principal diagnosis of venous thrombosis or pulmonary embolism. We excluded patients with a secondary diagnosis of pulmonary hypertension (ICD-9-CM codes 416.0, 416.8). Venous thrombosis was defined using ICD-9-CM codes 431.1x (thrombophlebitis of deep veins of lower extremity), 431.2 (thrombophlebitis of lower extremity veins, unspecified), 431.81 (thrombophlebitis of iliac vein), 431.9 (thrombophlebitis of unspecified veins), 433.1 (venous thrombosis, migratory), 433.2 (venous thrombosis of the vena cava), 433.8 (venous thrombosis of other specified veins), 433.9 (venous thrombosis of unspecified vein), 671.33 (venous thrombosis, antepartum), 671.44 (venous thrombosis, postpartum), or 997.2 plus a secondary diagnosis of venous thrombosis (venous thrombosis after surgery). Pulmonary embolism was defined using ICD-9-CM codes 415.1x, 673.2x (obstetrical blood clot embolism), or 997.2 plus a secondary diagnosis of code 415.1x. Procedure ICD-9-CM codes included pulmonary arteriography (88.43, 88.44), venography (88.66), vascular ultrasound (88.77), ventilation-perfusion lung scan (92.15), and impedance plethysmography (89.59). In the filter and no-filter cohorts, we categorized patients hospitalized with a principal diagnosis of venous thrombosis and a secondary diagnosis of pulmonary embolism as having pulmonary embolism. This definition functionally dichotomized patients into those with manifest pulmonary embolization and those with venous thrombosis alone.

To minimize bias in our comparisons, patients were divided into 3 subgroups that were based on the number of previous hospitalizations with a diagnosis of thromboembolism before the index hospitalization when the filter was placed. As shown in Figure 1, these groups had no previous hospitalization back to July 1, 1990, with a principal or secondary diagnosis of thromboembolism; 1 previous hospitalization with a diagnosis of thromboembolism; or more than 1 previous hospitalization for thromboembolism. We assumed that all of the patients with venous thromboembolism had percutaneous insertion of a vena cava filter because of the rarity of open filter insertion, pllication, or ligation as treatment for thromboembolism in the 1990s.

NO-FILTER CONTROL PATIENTS
After excluding the patients who received a vena cava filter, we identified patients aged at least 18 years who were admitted at least once during the study period for 3 or more days with a principal diagnosis of deep vein thrombosis or pulmonary embolism. In a previous validation study, we found that only 25.0% of patients hospitalized for no more than 2 days (only 5% of total) had objectively documented thromboembolism. This restriction on the length of hospital stay was not applied to the filter-treated patients, since use of a filter in conjunction with a diagnosis of venous thromboembolism strongly suggests the presence of acute thromboembolism.

For control patients who had more than 1 hospitalization for thromboembolism, we had to select a specific or index hospitalization for comparison. To minimize bias in our selection, we assembled 2 nonmutually exclusive groups, depicted in Figure 1. Inclusion in the group with no previous hospitalization for thromboembolism required that the first record with venous thromboembolism have a principal diagnosis of venous thromboembolism and a length of stay of at least 3 days. Inclusion in the group with 1 previous hospitalization required that the second record with thromboembolism have a principal diagnosis of venous thromboembolism and a length of stay of

but a significant 9.2% increase in the incidence of recurrent deep vein thrombosis. The findings of their study raised concerns that use of a filter may not be as beneficial as commonly believed, and that overuse may be detrimental.

We undertook an observational study of the effectiveness of inferior vena cava filters by means of the linked California Patient Discharge Data Set. Although information about treatment, such as the use of warfarin, is not collected, it is possible to determine the incidence of important outcomes, such as rehospitalization for venous thrombosis or pulmonary embolism and death. We hypothesized that patients hospitalized for acute venous thromboembolism and treated with a vena cava filter would have a significantly lower cumulative incidence of rehospitalization for pulmonary embolism at 1
at least 3 days. This second hospitalization served as the index hospitalization in all comparisons. Although some of the patients in the group with 1 previous thromboembolism were included in the group with no previous thromboembolism, the index hospitalization used for comparison was invariably different. There were too few patients in the filter group with 2 or more previous hospitalizations with thromboembolism to justify separate analysis of this group.

When we compared the filter-treated and control patients with 1 previous hospitalization for thromboembolism, we found that the year of the index hospitalization, the time between the thromboembolism hospitalizations (<6 months, 6 months to 1 year, 1-2 years, or >2 years), and the code level (principal diagnosis or secondary diagnosis) were similar in both groups, making matching unnecessary.

OUTCOMES

The principal outcomes were readmission with a principal diagnosis of venous thrombosis or pulmonary embolism. If a patient was admitted for venous thrombosis and had a secondary diagnosis of pulmonary embolism, the outcome was categorized as venous thrombosis because this was the condition prompting hospitalization. A secondary end point was death (using the linked State of California Death Registry).

MULTIVARIATE MODELING

Comparisons of outcomes between the filter-treated patients and controls were based on a time-to-event analysis. The Cox proportional hazards model (PROC PHREG; SAS Institute, Cary, NC) was used for this purpose, with adjustment for confounding risk factors known to be associated with recurrent venous thromboembolism. We tested the proportionality assumption by means of log-rank-minus-logarithm survival plots. Patients were censored from analysis at the time of death, which was determined by means of the hospital disposition code and the linked state death registry, or at the time of rehospitalization for a recurrent thromboembolic event. All 2-way interaction terms involving presence or absence of a filter and risk factors were systematically evaluated.

Based on previous literature, potential risk factors for recurrent thromboembolism included initial diagnosis (venous thrombosis vs pulmonary embolism), age (5-year increments), sex, ethnicity (Asian or Pacific Islander vs all others), presence of malignant neoplasm (ICD-9-CM codes 141-208, except 173 [nonmelanoma skin cancers]), major bleeding during the index hospitalization or within 3 months (intracranial bleeding, gastrointestinal tract bleeding, intrathoracic bleeding, and retroperitoneal bleeding, indicated by the use of 36 specific ICD-9-CM codes), trauma or fracture within 3 months (ICD-9-CM codes 800-959.9, surgery within 3 months (defined by surgical diagnostic-related group), and presence of comorbid conditions. Specific comorbid conditions identified from the index hospitalization or any hospitalization in the previous 6 months included acute myocardial infarction (ICD-9-CM code 410), congestive heart failure (ICD-9-CM codes 398.91, 428.x, 402.x1, 404.x1, and 404.x3), stroke (ICD-9-CM codes 430-436), and chronic obstructive lung disease (ICD-9-CM codes 490-496, 500-505, and 506.4). In addition, we also modeled a Charlson comorbidity score of greater than 2 points. In the model that analyzed patients with 1 previous hospitalization for thromboembolism, we also included as a risk factor previous hospitalization for thromboembolism within 3 months of the index hospitalization.

STATISTICAL ANALYSIS

Differences in continuous variables between filter and control groups were compared by means of the t-test, and differences in categorical data were analyzed by means of the chi-square test. Confidence intervals for relative risks were determined with the use of Epi-Info 6 (available at www.cdc.gov/epo/epi/introepi.htm). All multivariate modeling was performed with the use of SAS (SAS Institute) on a mainframe computer. Differences in thromboembolism-free survival between groups were compared by means of the log-rank test. Incidence density rates of rehospitalization were analyzed by means of Poisson and exponential regression.

VALIDATION STUDIES

To determine the sensitivity of a principal diagnosis of venous thromboembolism after vena cava filter placement, we attempted to contact via telephone all 295 patients who had had a vena cava filter placed for any indication at the UCD Medical Center from January 1, 1992, through December 31, 1994. Patients or family were asked if they recalled having a filter placed and if they required a subsequent hospitalization for a recurrent venous thrombosis or a pulmonary embolism after receiving the filter. Patients who recalled a rehospitalization for thromboembolism were asked to sign a form to release their medical information, and, if consent was granted, the corresponding records were obtained. Documented recurrent thromboembolic events were compared with the linked Patient Discharge Data. In addition, by reviewing the medical charts of 92 patients at the UCD Medical Center who had had an inferior vena cava inserted, we assessed the sensitivity of a code for venous thromboembolism among patients treated with a vena cava filter.

RESULTS

From January 1, 1991, through December 31, 1995, 10,292 hospital discharge abstracts included a code for interruption (filter, ligation, or plication) of the vena cava. Of the total, 9,665 (93.9%) had valid social security numbers and birth dates that permitted linkage of records. The number of vena cava procedures increased steadily over time from 1446 in 1991 to 2447 in 1995. Figure 1 summarizes the selection of the groups of patients included in our analyses. Over all, 86.6% of the patients who received a vena cava filter had a principal or secondary diagnosis of venous thromboembolism.
boembolism. More previous hospitalizations with a diagnosis of thromboembolism, and 412 had 2 or more previous hospitalizations with a diagnosis of venous thromboembolism. Of these, 2607 had no previous hospitalization and 1025 had 1 previous hospitalization for a diagnosis of venous thromboembolism (back to July 1, 1990), 1025 had 1 previous hospitalization for a diagnosis of venous thromboembolism, including 6354 patients who were admitted with a principal diagnosis of venous thromboembolism. Of these, 2607 had no previous hospitalization for thromboembolism, the RR for rehospitalization for thromboembolism was significantly higher among the filter-treated patients, irrespective of the presence or absence of previous thromboembolism (P<.001). At the end of 1 year, 15.9% of the controls had died, compared with 35% of the filter patients (P<.001). Figure 2 shows Kaplan-Meier plots of rehospitalization within 1 year for recurrent venous thrombosis or pulmonary embolism among filter-treated and control patients with no and 1 previous hospitalization for thromboembolism. The rate of rehospitalization for venous thrombosis in the filter-treated group with no previous thromboembolism fell from 3.30 admissions per 100 patients per month during the first 30 days to 0.22 per 100 patients per month between the third and 12th months of follow-up. The corresponding rates in the control group were 1.90 per 100 patients per month and 0.28 per 100 patients per month.

**UNADJUSTED OUTCOMES**

The unadjusted 1- and 2-year Kaplan-Meier cumulative incidence of rehospitalization for venous thrombosis or pulmonary embolism in the comparison groups are shown in Table 2. The incidence of venous thrombosis and pulmonary embolism was significantly higher among the filter-treated patients, irrespective of the presence or absence of previous thromboembolism (P<.001). At the end of 1 year, 15.9% of the controls had died, compared with 35% of the filter patients (P<.001). Figure 2 shows Kaplan-Meier plots of rehospitalization within 1 year for recurrent venous thrombosis or pulmonary embolism among filter-treated and control patients with no and 1 previous hospitalization for thromboembolism. The rate of rehospitalization for venous thrombosis in the filter-treated group with no previous thromboembolism fell from 3.30 admissions per 100 patients per month during the first 30 days to 0.22 per 100 patients per month between the third and 12th months of follow-up. The corresponding rates in the control group were 1.90 per 100 patients per month and 0.28 per 100 patients per month.

**UNADJUSTED OUTCOMES BASED ON INITIAL DIAGNOSIS**

In the filter-treated and control patients, the initial diagnosis strongly affected the relative risk (RR) of rehospitalization within 1 year for pulmonary embolism or venous thrombosis. Control patients in the group with no previous thromboembolism who initially manifested pulmonary embolism were significantly more likely to be rehospitalized for pulmonary embolism than control patients who initially had venous thrombosis (RR, 5.30; 95% confidence interval [CI], 4.61-6.10). These findings were noted also among filter-treated patients with no previous hospitalization for thromboembolism (RR, 6.72; 95% CI, 3.61-12.49).

Conversely, control patients with no previous thromboembolism and with an initial diagnosis of venous thrombosis were more likely to be rehospitalized for venous thrombosis than control patients who initially manifested pulmonary embolism (RR, 2.48; 95% CI, 2.25-2.73). However, among filter-treated patients with no previous thromboembolism, the RR for rehospitalization for venous thrombosis was not significantly higher among patients with an initial diagnosis of venous thrombosis compared with those with an initial diagnosis of pulmonary embolism (RR, 1.15; 95% CI, 0.87-1.53).

**FILTER-TREATED PATIENTS**

Among the patients with venous thromboembolism who received a filter, 4044 (48.3%) had a principal diagnosis of venous thromboembolism. Of these, 2607 had no previous diagnosis of venous thromboembolism (back to July 1, 1990), 1025 had 1 previous hospitalization for a diagnosis of venous thromboembolism, and 412 had 2 or more previous hospitalizations with a diagnosis of thromboembolism.

**CONTROL PATIENTS**

During the 5-year study period, 61,188 patients were admitted with a principal diagnosis of venous thromboembolism who were never treated with a filter and had no previous hospitalization for thromboembolism in their linked records. There were 9499 patients who met criteria for having 1 previous hospitalization for thromboembolism, including 6354 patients who were also in the group with no previous hospitalization (Figure 1).

**CLINICAL FEATURES**

The clinical characteristics of the patients who received a filter and the controls are shown in Table 1. There were clinically significant differences between the filter and control groups in their subgroups with no previous
RISK-ADJUSTED OUTCOMES

The results of the risk-adjusted multivariate analysis are shown in Table 3, stratified by initial diagnosis. Among patients with an initial diagnosis of venous thrombosis, there was no difference between filter-treated patients and controls in the 1-year relative hazard (RH) of rehospitalization for venous thrombosis or pulmonary embolism. In contrast, among patients with an initial diagnosis of pulmonary embolism, the RH of rehospitalization for recurrent venous thrombosis was significantly higher in the filter-treated patients. This relationship was found among patients with no previous hospitalization for thromboembolism (RH, 2.62; 95% CI, 2.09-3.29) and among those with 1 previous hospitalization for thromboembolism (RH, 2.47; 95% CI, 2.23-2.72). Similarly, the RH of rehospitalization for pulmonary embolism was slightly higher among the filter-treated patients with an initial diagnosis of pulmonary embolism, but this was statistically significant only among patients with no previous hospitalization for thromboembolism (RH, 1.33; 95% CI, 1.01-1.75).

RISK-ADJUSTED PREDICTORS OF VENOUS THROMBOSIS

Using patients with pulmonary embolism not treated with a filter as the referent group, significant independent predictors of rehospitalization for venous thromboembolism included initial pulmonary embolism treated with a filter (RH, 2.62; 95% CI, 2.09-3.29), initial venous thrombosis treated (RH, 2.82; 95% CI, 2.23-3.57) or not treated (RH, 2.47; 95% CI, 2.23-2.72) with a filter, age (RH, 0.94 for 5-year increment; 95% CI, 0.93-0.95), surgery within 3 months (RH, 0.82; 95% CI, 0.75-0.89), major bleeding during the index hospitalization or

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Table 1. Characteristics of Study Groups Treated and Not Treated With a Vena Cava Filter

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Filter (n = 2607)</th>
<th>No Filter (n = 61,188)</th>
<th>Filter (n = 1025)</th>
<th>No Filter (n = 9,499)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>66 ± 14.8†</td>
<td>63 ± 16.4</td>
<td>63.4 ± 15‡</td>
<td>63.6 ± 17</td>
</tr>
<tr>
<td>Median</td>
<td>69</td>
<td>67</td>
<td>67</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>52.6†</td>
<td>54.9</td>
<td>50.0†</td>
<td>56.0</td>
</tr>
<tr>
<td>Ethnicity‡</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>80.6</td>
<td>80.7</td>
<td>81.2</td>
<td>79.8</td>
</tr>
<tr>
<td>Black</td>
<td>7.8</td>
<td>7.7</td>
<td>9.0</td>
<td>9.0</td>
</tr>
<tr>
<td>Hispanic</td>
<td>7.1</td>
<td>8.4</td>
<td>6.0</td>
<td>8.4</td>
</tr>
<tr>
<td>Venous thrombosis alone</td>
<td>44.5†</td>
<td>70.7</td>
<td>44.2†</td>
<td>72.2</td>
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<tr>
<td>Diagnosis of pulmonary embolism</td>
<td>55.5†</td>
<td>29.3</td>
<td>55.7†</td>
<td>27.8</td>
</tr>
<tr>
<td>Surgery within 3 mo</td>
<td>24.2†</td>
<td>21.3</td>
<td>21.7§</td>
<td>22.7</td>
</tr>
<tr>
<td>Major bleeding within 3 mo</td>
<td>20.6†</td>
<td>3.0</td>
<td>16.8§</td>
<td>4.8</td>
</tr>
<tr>
<td>Trauma or fracture within 3 mo</td>
<td>8.3†</td>
<td>6.9</td>
<td>7.2‡</td>
<td>9.2</td>
</tr>
<tr>
<td>Malignant neoplasm within 6 mo</td>
<td>32.0†</td>
<td>16.0</td>
<td>27.4†</td>
<td>17.4</td>
</tr>
<tr>
<td>Stroke within 6 mo</td>
<td>9.7†</td>
<td>3.2</td>
<td>10.5†</td>
<td>6.4</td>
</tr>
<tr>
<td>Heart failure within 6 mo</td>
<td>14.2†</td>
<td>9.8</td>
<td>11.8§</td>
<td>12.7</td>
</tr>
<tr>
<td>Chronic lung disease within 6 mo</td>
<td>20.1†</td>
<td>15.7</td>
<td>23.9†</td>
<td>19.9</td>
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<tr>
<td>Myocardial infarction within 6 mo</td>
<td>3.0†</td>
<td>1.9</td>
<td>2.6§</td>
<td>2.3</td>
</tr>
<tr>
<td>Charlson score ≥2</td>
<td>21.5†</td>
<td>12.4</td>
<td>22.4†</td>
<td>20.0</td>
</tr>
<tr>
<td>Previous thromboembolism within 6 mo</td>
<td>0</td>
<td>0</td>
<td>67.0†</td>
<td>55.0</td>
</tr>
<tr>
<td>Length of hospitalization, d</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>10.4 ± 9.5†</td>
<td>7.1 ± 4.4</td>
<td>8.8 ± 7.2†</td>
<td>7.9 ± 6.9</td>
</tr>
<tr>
<td>Median</td>
<td>8</td>
<td>6</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Death in hospital</td>
<td>5.2†</td>
<td>1.3</td>
<td>4.5†</td>
<td>2.3</td>
</tr>
</tbody>
</table>

*Unless otherwise indicated, data are given as percentage of patients.
†P < .001.
‡P < .05.
§Differences were not significant.

Table 2. 1- and 2-Year Kaplan-Meier Cumulative Incidence of Rehospitalization for Recurrent Thromboembolism

<table>
<thead>
<tr>
<th>Group</th>
<th>Recurrent Venous Thrombosis</th>
<th>Recurrent Pulmonary Embolism</th>
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</thead>
<tbody>
<tr>
<td>No previous thromboembolism</td>
<td>8.7†  6.0</td>
<td>3.3†  1.6</td>
</tr>
<tr>
<td>1 Year</td>
<td>10.3†  8.1</td>
<td>4.1†  2.2</td>
</tr>
<tr>
<td>2 Year</td>
<td>11.4†  9.1</td>
<td>4.2†  2.0</td>
</tr>
<tr>
<td>1 Previous thromboembolism</td>
<td>13.8†  12.3</td>
<td>4.9†  2.7</td>
</tr>
</tbody>
</table>

*No or 1 previous hospitalization in linked record for venous thrombosis or pulmonary embolism.
†P < .001, all comparisons of filter and no-filter groups.
within 3 months (RH, 1.19; 95% CI, 1.00-1.40), diagnosis of a malignant neoplasm within 6 months (RH, 1.80; 95% CI, 1.66-1.96), and Charlson score of at least 2 (RH, 1.06; 95% CI, 1.01-1.13). Similar results were found among patients with 1 previous hospitalization for thromboembolism, except that recent hospitalization for chronic lung disease was also a significant predictor (RH, 1.47; 95% CI, 1.21-1.78).

**RISK-ADJUSTED PREDICTORS OF PULMONARY EMBOLISM**

Using patients with venous thrombosis not treated with a filter as the referent group, significant independent predictors of rehospitalization for pulmonary embolism among patients with no previous thromboembolism included initial pulmonary embolism treated (RH, 7.21; 95% CI, 5.40-9.60) or not treated (RH, 5.40; 95% CI, 4.70-6.25) with a filter, initial venous thrombosis treated with a filter (RH, 1.66; 95% CI, 0.91-3.06), Asian ethnicity (RH, 0.48; 95% CI, 0.25-0.92), surgery within 3 months (RH, 0.62; 95% CI, 0.52-0.74), presence of a malignant neoplasm (RH, 1.29; 95% CI, 1.07-1.55), myocardial infarction within 6 months (RH, 1.63; 95% CI, 1.12-2.38), and a diagnosis of chronic lung disease within 6 months (RH, 1.25; 95% CI, 1.03-1.52). Among patients with 1 previous hospitalization for thromboembolism, the only significant predictors were an initial diagnosis of pulmonary embolism (RH, 3.70; 95% CI, 2.80-5.10), presence of a malignant neoplasm (RH, 1.77; 95% CI, 1.26-2.51), and surgery within 3 months (RH, 0.49; 95% CI, 0.32-0.73).

**DEATH**

Using death in the first year as the outcome in a risk-adjusted model, the RH of dying was significantly greater among filter-treated patients than among control patients, whether the patient had no (RH, 1.71; 95% CI, 1.55-1.88) or 1 previous hospitalization for thromboembolism (RH, 1.42; 95% CI, 1.10-1.84).

**VALIDATION SAMPLES**

We contacted 295 patients who had had a vena cava filter inserted at the UCD Medical Center from January 1, 1991, through December 31, 1994. Among the 136 patients or families who were located and agreed to an interview, 7 reported being rehospitalized for thromboembolism after receiving a filter. A review of the
corresponding hospital records confirmed thromboembolism in 5 of these patients. One additional patient had a pulmonary embolus after receiving a filter, but it occurred during the hospitalization when the filter was inserted. In the remaining patient, hospital records did not confirm recurrent thromboembolism. Thus, 100% of the filter-treated patients who were rehospitalized for recurrent thromboembolism received a code as having thromboembolism: 4 (80%) of 5 had a principal diagnosis of thromboembolism, and the remaining patient had a secondary diagnosis of thromboembolism. In our audit of 92 patients treated with a vena cava filter, 64 (98%) of 65 patients with objectively documented thromboembolism received a code as having thromboembolism.

Although vena cava filters commonly are inserted with the belief that they prevent symptomatic or fatal pulmonary embolism, there is little rigorous evidence to support their widespread use. In the only clinical trial of vena cava interruption among patients with deep vein thrombosis, Decousus et al.8 found no evidence that anticoagulant therapy combined with vena cava interruption reduced the long-term incidence of pulmonary embolism compared with standard anticoagulant therapy alone. However, their study can be criticized because the patients enrolled were not typical candidates for vena cava filter insertion. It is possible that use of a vena cava filter benefits sicker patients who are at high risk for dying if they sustain a pulmonary embolus.

We undertook this observational analysis of patients treated with vena cava filter interruption in an attempt to determine whether use of a vena cava filter improves thromboembolic outcomes. We addressed 2 specific questions. First, do patients treated with a filter have a lower risk of rehospitalization for pulmonary embolism during the first year after placement than patients not treated with a filter? Second, is use associated with a higher RR of rehospitalization for venous thrombosis, as reported by Decousus et al.?8 We could not address the fundamental question of whether use of a filter prevents death due to pulmonary embolization. Lacking hospital records or autopsy information, and recognizing the limitations of death certificates, we were unable to determine how many patients in each group died as a direct result of pulmonary embolism. Prospective studies are needed to determine whether use of a filter prevents fatal pulmonary embolism.

Our results indicate that patients with acute venous thromboembolism were just as likely to be rehospitalized for pulmonary embolism if they had had a vena cava filter placed as if they had not, even after adjusting for risk factors associated with recurrent thromboembolism. However, we found that use of a filter was associated with an increased risk of hospitalization for venous thrombosis, but intriguingly, only among patients who initially presented with pulmonary embolism. Another important new finding was that the time course of recurrent thromboembolism was similar among patients treated and not treated with a filter, with most recurrent events occurring in the first 3 months after hospital discharge. After the first 3 months, there was little difference in the incidence of pulmonary embolism or venous thrombosis between patients treated and not treated with a filter.

In interpreting our findings, it is important to keep certain limitations in mind, perhaps the most important being the absence of any information regarding the use of anticoagulant therapy, particularly among the filter-treated patients. If a substantial proportion of patients treated with a filter never received any anticoagulant therapy, the absence of this treatment might have significantly increased the incidence of rehospitalization for pulmonary embolism among filter-treated patients. The data do not support the view of some physicians that use of a vena cava filter by itself prevents pulmonary embolism.26,27

In addition to the absence of information regarding the use of anticoagulant therapy,28-30 we could not adjust for certain factors associated with recurrent thromboembolism, namely, the presence of acquired or genetic factors associated with thrombophilia21,31 and the location (calf vs proximal) of lower extremity thrombosis.22,23-24 However, findings were similar when we analyzed previous (ie, recurrent) thromboembolism, a patient group presumably enriched with patients with proximal clots and inherited thrombophilia. The fact that the 1-year risk-adjusted mortality was higher among filter-treated patients suggests the presence of other unmeasured confounders associated with illness severity that might also increase the likelihood of thrombo-

**Table 3. Adjusted 1-Year Relative Hazard of Rehospitalization for Venous Thrombosis or Pulmonary Embolism Among Filter-Treated Patients Compared With Controls*"**

<table>
<thead>
<tr>
<th>Group†</th>
<th>Initial Diagnosis of Venous Thrombosis</th>
<th>Initial Diagnosis of Pulmonary Embolism</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Outcome of Venous Thrombosis</td>
<td>Outcome of Pulmonary Embolism</td>
</tr>
<tr>
<td>No previous hospitalization with thromboembolism</td>
<td>1.14 (0.92-1.43)</td>
<td>1.66 (0.91-3.06)</td>
</tr>
<tr>
<td>1 Previous hospitalization with thromboembolism</td>
<td>1.35 (0.88-2.07)</td>
<td>1.40 (0.53-3.70)</td>
</tr>
</tbody>
</table>

* Adjusted for age, sex, malignant neoplasm, Asian or Pacific Islander ethnicity, recent major bleeding, trauma or surgery within 3 months, and diagnosis within 6 months of myocardial infarction, congestive heart failure, stroke, chronic pulmonary disease, and a Charlson comorbidity score of greater than 2.0. Data are given as relative hazard (confidence interval).
†No or 1 previous hospitalization in linked record with venous thrombosis or pulmonary embolism.
embolism. It is possible that if we had been able to adjust for these other risk factors, vena cava filter use might have appeared more effective.

Because our small validation sample was drawn only from our university hospital, it is possible the results cannot be generalized to other hospitals in California. We found that 4 of 5 patients who were treated with a filter and who were rehospitalized for recurrent thromboembolism had a principal diagnosis code for venous thromboembolism (sensitivity, 80%). There is no reason to suspect, however, that previous placement of a filter affects the assignment or sequencing of ICD-9-CM codes when patients are readmitted for recurrent thromboembolism. Therefore, coding bias is unlikely to explain our results.

Two observations may explain the remarkable finding of a higher incidence of recurrent venous thrombosis only among the filter-treated patients with an initial diagnosis of pulmonary embolism. First, patients who manifest pulmonary embolism are more likely to manifest recurrent pulmonary embolism than patients who manifest venous thrombosis alone.30-37 We found that, among patients not treated with a filter, rehospitalization for pulmonary embolism was much more common among patients who initially manifested pulmonary embolism than among patients with venous thrombosis alone (RR, 5.30; 95% CI, 4.61-6.10). Although this observation may be explained by bias to diagnose pulmonary embolism among patients with a history of pulmonary embolism, the consistency of this finding in multiple studies30-37 suggests an underlying pathophysiological difference between individuals with venous thrombosis who manifest pulmonary emboli and those who do not. Second, vena cava filters frequently become partially or completely occluded by thrombus.8,38 Taken together, these observations suggest that patients with symptomatic pulmonary emboli who are treated with a filter are at increased risk for development of partial or complete vena cava occlusion because of accumulation of thrombus at the level of the filter. This accumulation of thrombus likely leads to venous stasis and a higher incidence of symptomatic deep vein thrombosis in the legs.

As seen in Figure 2, the incidence of venous thrombosis was increased only during the first 3 months after filter insertion, a time that corresponds with the highest rate of recurrent thromboembolic events among patients not treated with a filter. This suggests that vena cava filters are not inherently thrombogenic, but instead, merely collect clot formed more distally during the time that recurrent thromboembolism is most common.

The patients who received a vena cava filter were strikingly different from those who did not, as reported by Piccioli et al.39 Not surprisingly, filter-treated patients had a higher prevalence of previous pulmonary embolism, recent major bleeding, and greater comorbidity, especially malignant neoplasm and recent stroke. The longer average length of hospital stay, the 4-fold higher death rate during the index hospitalization, and the more than 2-fold higher incidence of death within 1 year in the filter group suggest that these patients were considerably sicker than the control group.

Our data suggest that most patients treated with a filter in California had neither of the two most widely accepted indications for filter use, ie, bleeding that precludes anticoagulant therapy or failure of anticoagulant therapy.1 Only 20% of patients in the filter-treated group who had no previous hospitalization for thromboembolism had a diagnosis of major bleeding during the index hospitalization or in the preceding 3 months. We assume that very few patients were taking warfarin at the time of hospital admission, making failure of outpatient anticoagulant therapy unlikely. The data suggest that physicians frequently use a vena cava filter in sick patients who do not meet strict criteria for filter insertion, but who are judged to be at high risk for anticoagulant-related bleeding or recurrent pulmonary embolism.30-42

Our findings are important because it is unlikely that there will ever be a large clinical trial organized to evaluate the efficacy of inferior vena cava filters in appropriate candidates, such as patients with a documented failure of treatment or a strict contraindication to anticoagulation therapy. Our data suggest that a clinical trial needs to be undertaken that will randomize those patients with pulmonary embolism who are candidates for anticoagulant therapy, but who are scheduled by their physician to undergo filter placement. Based on our findings as well as those of Decousus et al.,4 these patients appear to be at increased risk for development of subsequent venous thrombosis without any clear benefit.

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