Medical Literature and Vena Cava Filters*
So Far So Weak

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Study objective: With the development of percutaneous inferior vena cava (IVC) filters, IVC interruption has become a widely used procedure in patients with or at risk for venous thromboembolism. In an attempt at clarifying the indications for filter placement, a systematic literature review was undertaken.

Design: Bibliographic search and analysis.

Measurements and results: A systematic MEDLINE search about vena cava filters produced a total of 568 references with abstracts between 1975 and 2000 inclusively. Each reference was analyzed according to predetermined criteria. Nearly two thirds (65.0%) of these publications were retrospective studies or case reports (33.3 and 31.7%, respectively), 12.9% were animal or in vitro studies, 7.4% were prospective studies, 6.7% were reviews, and 8.1% reported on miscellaneous related topics. Among the prospective studies, only 16 studies included >100 patients, only 1 study was a randomized controlled trial (0.02% of 568 references), and heterogeneity among series precluded any relevant comparison. In a similar search about heparin and venous thromboembolism, 47.4% of 531 references were randomized controlled trials.

Conclusions: Until more relevant data become available, literature reviews about vena cava filters will remain narrative, and many if not most indications for filter placement will remain a matter of opinion.

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Key words: anticoagulants; pulmonary embolism; thrombophlebitis; vena cava filters

Abbreviations: DVT = deep venous thrombosis; IVC = inferior vena cava; PE = pulmonary embolism

Interruption of the inferior vena cava (IVC) to prevent pulmonary embolism (PE) arising from deep venous thrombosis (DVT) is the oldest proposed treatment for venous thromboembolic disease.1 This logical approach has gained wide acceptance and popularity after IV “umbrellas” or “filters” became available in the early 1970s.2,3 These devices could be released in the IVC under fluoroscopic control after simple femoral or jugular vein dissection. Further technical refinements included a reduction in the caliber of the introducers, which allowed percutaneous insertion and transformed this onetime surgical procedure into an easily accessible technique that has encountered great success among clinicians and radiologists.4

Vena cava interruption, however, is an incomplete treatment of venous thromboembolic disease. Unlike anticoagulant therapy,5,6 IVC interruption has no beneficial effect on the prevention of DVT, as well as on the prevention of DVT extension, recurrence, and subsequent postthrombotic syndrome (Table 1). Further, anticoagulant therapy effectively prevents PE in patients with DVT.5 Therefore, only absolute contraindications to and documented failures of anticoagulant therapy in patients with acute venous thromboembolism represent obvious and widely accepted indications for IVC interruption.5 Controlled trials would be unethical in such settings. Other indications, however, such as “prophylactic” IVC interruption for “high-risk” patients who have no DVT or PE, or “adjuvant” IVC interruption for patients with thromboembolism who can receive anticoagulant therapy, remain a matter of debate.5,6 Furthermore, evidence suggests that, at least in certain populations, most patients treated with a filter have neither of the two widely accepted indications.7 The huge range of IVC filters insertion

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rates among countries, eg, from 3 to 140 per million inhabitants per year in Sweden and in the United States, respectively, is a spectacular reflection of these uncertainties. In an attempt at clarifying the issue of the indications for IVC interruption, a systematic literature review was undertaken.

**Materials and Methods**

A MEDLINE search was undertaken through the PubMed database (http://www.ncbi.nlm.nih.gov/PubMed), accessed on October 15, 2001. The terms “cava filter OR caval filter OR cava filters OR caval filters OR cava interruption OR caval interruption OR vena filter OR vena filters OR Greenfield filter OR Greenfield filters” were entered in the search field. Using the “limits” tool, the search was restricted to the above-mentioned terms appearing as title words, references with abstracts, and years of publication ranging from 1975 to 2000 inclusively. All obtained references were then imported into an EndNote library (EndNote. Windows version 5.0; ISI ResearchSoft: Carlsbad, CA). The same PubMed search was repeated with the additional limitation of “randomized controlled trial” in the “publication types” menu.

All references imported in the EndNote library were then checked one by one and classified, according to the information provided in the title and/or key words and/or abstract, into one of the following categories: case reports (arbitrary limit < 10 patients), retrospective clinical series (with three subtypes: 10 to 49 patients, 50 to 99 patients, and ≥ 100 patients), prospective clinical series or trials (with the same subtypes according to the number of patients), animal and/or in vitro studies, reviews, and miscellaneous (imaging studies, technical comments, surveys, and otherwise unclassifiable references). Additional details were searched, on a case-by-case basis, in the library or in the original (full text) articles.

An identical PubMed search (words in title, items with abstracts, 1975 to 2000) was performed using the terms “heparin vein thrombosis OR heparin venous thrombosis OR heparin pulmonary embolism OR heparin venous thromboembolism” in the search field, and the search was repeated with the limitation of “randomized controlled trial” as publication type. Only the number of publications for each search was recorded. No further analysis was performed on these references.

**Results**

A total of 590 references about vena cava interruption or filters were imported from the PubMed database into the EndNote library. A preliminary search result for duplicates was negative. Twenty-two references reporting on congenital interruption of the IVC or other anatomic abnormalities were excluded. The remaining 568 references constitute the subject of this analysis.

The annual number of publications ranged from 1 in 1976 to 42 in 1994 and 1998 (Fig 1). The authors’ addresses were available in 443 references (78.0%). Articles originated mainly from the United States (n = 241), followed by France (n = 57), Germany (n = 47), Japan (n = 17), the United Kingdom

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**Table 1—Role of IVC Interruption and Anticoagulant Therapy in the Treatment of Venous Thromboembolism**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Anticoagulants</th>
<th>IVC Interruption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention of PE</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Prevention of DVT (occurrence or recurrence)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Prevention of DVT extension</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Prevention of postthrombotic syndrome</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**Figure 1.** Annual number of publications about vena cava interruption and filters between 1975 and 2000 (see “Materials and Methods” section for selection of references).
(n = 13), Canada (n = 13), Poland (n = 10), Italy (n = 10), Austria (n = 7), Switzerland (n = 5), and others (n = 23).

Retrospective clinical series (n = 189) represented exactly one third (33.3%) of all publications (Fig 2), with only 59 series reporting on ≥100 patients, and 90 series reporting on <50 patients. Case reports (n = 180) represented nearly one third of the literature (31.7%). Animal (n = 38) and in vitro studies (n = 35) represented 12.9% of the literature, whereas prospective series accounted for only 7.4% of the literature (Fig 2).

Among prospective series, only 16 series (2.8% of the entire library) included ≥100 patients,9–24 and there was only one randomized controlled trial,24 representing 0.02% of the library. Among these 16 series, 9 series10–12,14–17,20,21 were partial and/or updated reports from the same authors and/or on the same patients. Table 2 summarizes the main characteristics of the nine independent studies; for multiple articles from the same authors and/or on the same patients, only the most recent report11,16 was kept in Table 2.

There were 26 clinical series reporting mainly or exclusively on prophylactic IVC interruption in trauma or major orthopedic surgery patients, all originating from the United States. Only one of these reports18 was a prospective series of ≥100 patients (Table 2).

Sixty of the 568 references (10.6%) reported on temporary filters, with only one prospective series25 of ≥100 patients (Table 2). The annual number of publications ranged from 1 article in 1985 (none before that date) to 10 articles in 1995 (9 articles in 2000).

The search about heparin and venous thromboembolic disease provided a total of 531 references. Two hundred fifty-two articles (47.4%) reported randomized controlled trials.

**Discussion**

To the clinician looking for reliable information about the indications for IVC interruption, the overall quality of the abundant literature on this subject looks disappointing. In the era of evidence-based medicine, the present search could find only one randomized controlled trial,24 and nearly two thirds of the literature consisted of retrospective clinical series and case reports (Fig 2). Further, even among the few large prospective series, the extreme heterogeneity of populations, indications for filter placement, evaluation criteria and follow-up (Table 2) precludes any relevant comparison and analysis. This is in sharp contrast with publications about heparin and venous thromboembolic disease, with nearly half the literature (47.4%) consisting of randomized controlled trials.

Obviously, reliable information is available despite the lack of randomized trials. Large careful retrospective and prospective series, and even well-documented case reports provide clinically helpful information about the technique and the safety profile of IVC interruption. Remarkable reviews25,26 have discussed these points in depth. Regarding indications, however, even such careful reviews cannot provide evidence-based recommendations. One of these reviews even acknowledged that “scientific evidence for filter effectiveness was lacking” and concluded that “the benefits . . . of filter placement should be determined by clinical trials.”26

An obvious limitation for performing randomized trials about IVC interruption derives from the fact that, unlike anticoagulant therapy, this procedure concerns relatively few patients with venous thromboembolism. Accordingly, the recruitment of 400 patients in the only randomized controlled trial25 of IVC interruption took 3.5 years in 44 centers. Some

![Figure 2. Distribution of references (n = 568) among six categories.](http://journal.publications.chestnet.org/pdfaccess.ashx?url=/data/journals/chest/21982/)
centers, however, perform up to 185 IVC interruptions a year, with a significant increase in recent years.27 Although the two “widely accepted” indications for filter placement typically represent 40 to 80% of patients in most series, a significant proportion of patients could be eligible for controlled trials. Cancer per se, for example, is presented as a contraindication to anticoagulant therapy and represents /H11022 30% of indications for filter placement in the largest retrospective series. 27 Similarly, in patients with severe trauma, some investigators28 compare prophylactic IVC interruption to historical control subjects, while others29 just compare different heparin regimens. A meta-analysis30,31 stressed the need for “well-designed studies” because the literature on venous thromboembolism prophylaxis in trauma patients provided “inconsistent data.” Undoubtedly, various thresholds for contraindications to preventive or curative anticoagulant therapy among clinicians explain the greatest part of the disparities in filter insertion rates among countries and centers.

Any systematic literature review targeted at indications for a given treatment requires the analysis of randomized trials and a certain homogeneity among publications. None of these criteria are met in the literature about vena cava interruption. A “vena cava filter consensus conference”32 could only recommend “reporting standards” for filter placement and patient follow-up (Table 3). This is a way to go. But until the results of such recommendations and those of hypothetical future randomized trials become available, literature reviews about IVC interruption will remain narrative, and many if not most indications for filter placement will remain a matter of opinion.

### Table 2—Main Characteristics of Nine Independent Prospective Series of ≥100 Patients

<table>
<thead>
<tr>
<th>Source</th>
<th>Patients With a Filter, No.</th>
<th>Filter Types</th>
<th>Main Indication for Filter (%)</th>
<th>Main Assessment in Study</th>
<th>Follow-up or Date of Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roehm et al22 (1988)</td>
<td>440</td>
<td>Bird’s nest</td>
<td>Contraindication to anticoagulant (74)</td>
<td>Clinical events</td>
<td>≥ 6 mo</td>
</tr>
<tr>
<td>Schliech et al23 (1993)</td>
<td>100</td>
<td>Two different types</td>
<td>Contraindication to anticoagulant (38)</td>
<td>Imaging of IVC</td>
<td>3 mo</td>
</tr>
<tr>
<td>Khansarinia et al18 (1995)</td>
<td>108</td>
<td>Greenfield</td>
<td>Prophylaxis (100)</td>
<td>Safety and efficacy</td>
<td>21 d (mean)</td>
</tr>
<tr>
<td>Aswad et al9 (1996)</td>
<td>174</td>
<td>Four different types</td>
<td>Major DVT (63)</td>
<td>Insertion site thrombosis</td>
<td>7–10 d</td>
</tr>
<tr>
<td>Decousus et al24 (1998)</td>
<td>200</td>
<td>Three different types</td>
<td>Adjuvant* (100)</td>
<td>Efficacy</td>
<td>2 yr</td>
</tr>
<tr>
<td>Crochet et al11 (1999)</td>
<td>142</td>
<td>LGM</td>
<td>Failure of anticoagulant (27)</td>
<td>Filter patency</td>
<td>9 yr</td>
</tr>
<tr>
<td>Dewald et al12 (2000)</td>
<td>119</td>
<td>Two different types</td>
<td>Contraindication to anticoagulant (48)</td>
<td>Imaging of IVC</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Lorch et al19 (2000)</td>
<td>188</td>
<td>Three different temporary filters</td>
<td>Thrombolysis (53)</td>
<td>Complications</td>
<td>5.4 d (mean)</td>
</tr>
</tbody>
</table>

*This study evaluated 400 patients with proximal DVT treated by anticoagulants, including 200 patients who were randomly assigned to receive a filter.

### Table 3—Categorical Indications for Filter Placement*

<table>
<thead>
<tr>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contraindication to anticoagulation (absolute or relative)</td>
</tr>
<tr>
<td>Complication of anticoagulation</td>
</tr>
<tr>
<td>Failure: objectively documented extension of existing DVT or new DVT or PE while therapeutically anticoagulated</td>
</tr>
<tr>
<td>Hemorrhage: major or minor</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
</tr>
<tr>
<td>Skin necrosis</td>
</tr>
<tr>
<td>Drug reaction</td>
</tr>
<tr>
<td>Evidence/probability of poor compliance</td>
</tr>
<tr>
<td>Prophylaxis: no thromboembolic disease</td>
</tr>
<tr>
<td>Prophylaxis with thromboembolism in addition to anticoagulation</td>
</tr>
<tr>
<td>Failure of previous device to prevent PE; central extension of thrombus through an existing filter or recurrent PE</td>
</tr>
<tr>
<td>In association with another procedure: thrombectomy, embolectomy, or lytic therapy</td>
</tr>
</tbody>
</table>

*Reporting standards as recommended by the Vena Cava Filter Consensus Conference.33*
REFERENCES


