Vena Cava Filters In PE Treatment: Do We Need To Do This, And If So, When

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Disclosures:

• Consultant: Boston Scientific, Cordis, Medicines Company
• Speakers Bureau: Penumbra, Covidien
• Research Support: BTG, Venite, Spectranetics, Boston Scientific, Philips Healthcare, Merit Medical
• DSMB/CEC: Shockwave

Where are we in 2015?

• What do the guidelines say?
• How do we make sense of the data?
• How do we treat PE currently and are there opportunities for improvement?

Vascular Medicine

Massive Pulmonary Embolism

Nils Kucher, MD, Elias Rosset, BS, Maria De Rosa, PhD, Samuel Z. Goldhaber, MD

Background—Acute massive pulmonary embolism (PE) remains an exceptionally high mortality event. We explored how
choke inhaled gases, particularly thrombolytics and additional venous caval (VC) filter placements, may be performed
and how these strategies affect the clinical outcomes of patients with massive PE.

Preventive Cardiology

Eight-Year Follow-Up of Patients With Permanent Vena Cava Filters in the Prevention of Pulmonary Embolism

The PREPIC (Prévention du Risque d’Embolie Pulmonaire par Interruption Cave) Randomized Study

The PREPIC Study Group

Background—In a randomized trial in patients with previous deep-vein thrombosis, permanent vena cava filters reduced
the incidence of pulmonary embolism but increased that of deep-vein thrombosis at 2 years. An 8-year follow-up was
performed to assess their long-term effect.

Methods and Results—Five hundred patients with previous deep-vein thrombosis with or without pulmonary embolism
were randomized either to receive or not receive a filter in addition to standard anticoagulant treatment for at least 3
months. Patients were followed up for a median of 4 years (1-8 years). All-cause mortality was similar (14% vs 12%
within 2 years of randomization and 20% vs 18% at 4 years). Pulmonary embolism occurred in 18 patients in the
filter group (2.8% per 100 patient-years) and 36 patients in the placebo group (6.0% per 100 patient-years)...

Conclusion—At 8 years, vena cava filters reduced the risk of pulmonary embolism but increased that of deep-vein
thrombosis and had no effect on survival. Although these results have been described in patients at high risk of pulmonary
embolism, we also report the long-term outcomes in the general population with venous thromboembolism who were not

Key Words: vena cava filters • prevention • thrombolysis • trails • pulmonary embolism
Recommendations on IVC Filters in the Setting of Acute PE

1. Adult patients with any confirmed acute PE (or proximal DVT) with contraindications to anticoagulation or with active bleeding complications should receive an IVC filter (Class I; Level of Evidence B).

2. Anticoagulation should be resumed in patients with an IVC filter once contraindications to anticoagulation or active bleeding complications have resolved (Class I; Level of Evidence B).

3. Patients who receive retrievable IVC filters should be evaluated periodically for filter retrieval within the specific filter’s retrieval window (Class I; Level of Evidence C).
4. For patients with recurrent acute PE despite therapeutic anticoagulation, it is reasonable to place an IVC Filter (Class IIa; Level of Evidence C).

5. For DVT or PE patients who will require permanent IVC filtration (eg, those with a long-term contraindication to anticoagulation), it is reasonable to select a permanent IVC filter device (Class IIa; Level of Evidence C).

6. For DVT or PE patients with a time-limited indication for an IVC filter (eg, those with a short-term contraindication to anticoagulation therapy), it is reasonable to select a retrievable IVC filter device (Class IIa; Level of Evidence C).

7. Placement of an IVC filter may be considered for patients with acute PE and very poor cardiopulmonary reserve, including those with massive PE (Class IIb; Level of Evidence C).

8. An IVC filter should NOT be used routinely as an adjuvant to anticoagulation and systemic fibrinolysis in the treatment of acute PE (Class III; Level of Evidence C).
Acute PE

- Vital Signs
- Functional Status
- CT Angiogram
- BNP, TTE, Troponin

Moderate Risk
(RV strain w/o hypotension)
Evaluate for Intervention

High Risk
(Hypotension)
Evaluate for Intervention

Low Risk
Anticoagulate or filter if contraindicated

Algorithm for Submassive PE

Submassive PE
(RV strain w/o hypotension)

Abnormal Vitals
BNP>500
Troponin ++
Tachycardia/Hypoxia/Tachypnea

Catheter Directed Therapy
Low dose lysis
Aspiration
Fragmentation
IVC filter
Surgical Embolectomy if contraindication to lysis
IVC filter

Stable Vitals
BNP<500
Troponin –
HD stable
Anticoagulate or IVC Filter if contraindication

Retrieval Filters:
Denali
Tulip
Celect
Optease
ALN
Crux

1987

Vena Cava/Veins
Retrieving the Amplatz Retrievable Vena Cava Filter

2006-2007

Loop-Snare Technique for Difficult Inferior Vena Cava Filter Retrievals
Lisa Rubenstein, MD; Albert K. Chen, MD; Muam Chow, RN, BSN, and Christian A. Borkert, MD, MBA

Retrieval of Trapped Günther Tulip Inferior Vena Cava Filters: Snare–over-Guide Wire Loop Technique
William T. Kuo, MD; Andrew S. Baniph, MD; Christopher T. Loh, MD; Joan K. Fretwell, MD, PhD; and Michael J. Pochaczewski, MD

Use of Rigid Bronchoscopic Forceps in the Difficult Retrieval of the Günther Tulip Inferior Vena Cava Filter
Charles T. Becker, MD; Robert G. Dixon, MD; and Joseph M. Stevens, MD

At present
- In my institution for acute PE……
- Low risk and intermediate risk patients who are unable to receive medical therapy due to a contraindication
- High risk patients including those that undergo surgical embolectomy that cannot receive medical therapy
How did we go from this?

And this……?...

To THIS?!?

And THIS??

Venogram from Right Femoral with legs stuck

Retrievable IVC filter data??

- Lack of recognized complications
- Lack of rigorous clinical trials prior to FDA approval
- Lack of clear reporting
- Professional culture of products as commodities

Complications/ Adverse events

- Caval Thrombosis
- Tilting or embedding leading to difficult retrieval
- Migration
- Fracture
- Penetration
## Complications/Adverse events

- Caval Thrombosis
- Tilting or embedding leading to difficult retrieval
- Migration
- Fracture
- Penetration

### Table 7

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Case (95% CI)</th>
<th>Door</th>
<th>Teluca</th>
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<td>Filter retrieval</td>
<td>5 (0-15)</td>
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<tr>
<td>Filter embolization</td>
<td>0 (0-4)</td>
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<tr>
<td>All caval occlusion/ thrombosis</td>
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<td>Symptomatic caval occlusion</td>
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<tr>
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<tr>
<td>SVC thrombosis</td>
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</tr>
<tr>
<td>Penetration</td>
<td>0 (0-1)</td>
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### Table 8

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<tr>
<td>Penetration</td>
<td>0 (0-1)</td>
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58 patients with attempted retrieval.
Perforation

Fracture/Migration

A Comparison of Retrievability: Celect versus Option Filter
Robert K. Ryu, MD, Kush Desai, MD, Jennifer Karp, RN, Ramona Gupta, MD, Alan Emerson Evans, MD, MBA, Shankar Rajeswaran, MD, Riad Salem, MD, MBA, and Robert J. Lewandowski, MD

Table 3. Results of Celect and Option Retrievals

<table>
<thead>
<tr>
<th></th>
<th>Celect</th>
<th>Option</th>
<th>P Value</th>
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<tr>
<td>Filter retrieval failure, n (%)</td>
<td>2 (3.4)</td>
<td>5 (7.7)</td>
<td>.45</td>
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<tr>
<td>Fluoroscopy time (min)</td>
<td>4.25</td>
<td>6</td>
<td>.006</td>
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<td>Significant device tilt, n (%)*</td>
<td>5 (8.9)</td>
<td>10 (16.7)</td>
<td>.27</td>
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<tr>
<td>Adjunctive retrieval technique, n (%)</td>
<td>3 (5.4)</td>
<td>11 (18.3)</td>
<td>.045</td>
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<tr>
<td>Strut perforation of IVC, (%)</td>
<td>24 (43)</td>
<td>0 (0)</td>
<td>&lt;.0001</td>
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Caval Penetration by Retrievable Inferior Vena Cava Filters: A Retrospective Comparison of Option and Günther Tulip Filters
Olufolade G. Olotureola, MD, Maureen P. Kohi, MD, Nicholas Fidelman, MD, Antonio C. Westphalen, MD, Pallav K. Kolli, MD, Andrew G. Taylor, MD, PhD, Roy L. Gordon, MD, Jeannie M. LaBerge, MD, and Robert K. Kerlan, MD

200 filters
17% penetration rate
No difference
Twenty-six limb fractures (all short limbs) were identified in 20 patients; the earliest occurred at 4.1 months. Eight fragment migrations occurred into pulmonary arteries, seven into iliac/femoral veins, one into the right ventricle, and one into the renal vein. Seven fragments were intracaval near the filter, one was extracaval, and one could not be located. Kaplan–Meier survival estimates predicted a fracture rate of 40% at 5.5 years. Of the 20 patients with filter fractures, three died of unrelated causes and 17 remain asymptomatic.

In Summary

• Retrievable IVC filters are not commodities
• Different device do have unique characteristics and different failure modes
• Every vascular specialist should be familiar with the characteristics of the devices implanted at their institution and even prefer certain devices over others.
• More Data is Needed........

Trial Leadership

Sponsor: IVC Filter Study Group Foundation
• Society of Interventional Radiology
• Society for Vascular Surgery
Steering Committee:
• David Gillespie, MD, Co-Chair
• Matthew Johnson, MD, Co-Chair
• Jeanne Laberge, MD
• James Spies, MD
• Rodney White, MD
Contract Research Organization:
• New England Research Institutes, Inc

PRESERVE Methods

• Prospective, multicenter, single-arm clinical trial of adults (≥ 18 years of age) in whom IVCF are clinically indicated
• Primary endpoints
  – Safety = freedom from major complications
  – Effectiveness = freedom from PE
• ~2100 subjects will be enrolled, with a minimum of ~300 subjects per filter type
PRESERVE Methods

Table 1: Time and Event Schedule for Trial

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<tr>
<th>Event</th>
<th>Day Off</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 7</th>
<th>Day 14</th>
<th>Day 21</th>
<th>Day 28</th>
<th>Day 42</th>
<th>Day 49</th>
<th>Day 56</th>
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<td>Eligibility</td>
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<td>Physical exam</td>
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<td>Labs: CBC + opt, Cr, C-reactive protein</td>
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<td>Imaging: Venogram</td>
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<td>Imaging: Abdominal CT scan</td>
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<td>Imaging: X-ray (AP &amp; LAT)</td>
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Enrollment Status

First subject enrolled on October 13, 2015 at Indiana University
5 (of up to 60) centers activated as of November 16, 2015 (Cornell activated yesterday)
4 subjects enrolled as of November 15, 2015

Public website for more information: [www.preservetrial.com](http://www.preservetrial.com)