The PREPIC Trial—Fact or Fiction?

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No Disclosures

The Last 10 IVC Filters Developed and Approved by the FDA

PREPIC – Study Design

- First prospective, randomized trial comparing anticoagulation to IVC filters
- From 9/91-2/95 in 44 French centers
- 400 patients with DVT "at risk" for PE
- Randomized to
  - UH or LWMH
  - IVC filter or no IVC filter
    - Greenfield, Cardial, LOM, or Bird's nest filter
- All patients were anticoagulated with warfarin at discharge when possible

PREPIC – Study Design

- Primary outcome
  - Pulmonary Embolism
- Secondary outcomes
  - Deep venous thrombosis
  - Death
  - Major filter complications
  - Major bleeding
- Data published at 2 (NEJM 1998) and 8 years (Circulation 2005)
PREPIC- Results @ 2 yrs

- V/Q scans, PA angiograms
  - Baseline, 12 days, and study endpoint

### Table 1: PrePIC-1 Results at 2 Years

<table>
<thead>
<tr>
<th>Event</th>
<th>Filtered</th>
<th>No Filter</th>
<th>Filtered vs. No Filter</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic PE</td>
<td>2</td>
<td>4</td>
<td>2.00 (0.27)</td>
<td>0.002</td>
</tr>
<tr>
<td>Asymptomatic PE</td>
<td>4</td>
<td>10</td>
<td>4.00 (1.00)</td>
<td>0.002</td>
</tr>
<tr>
<td>Recurrent deep vein thrombosis, any duration</td>
<td>3</td>
<td>6</td>
<td>3.00 (0.33)</td>
<td>0.036</td>
</tr>
<tr>
<td>Mortality</td>
<td>2.25%</td>
<td>0.25%</td>
<td>8.00 (3.00)</td>
<td>0.002</td>
</tr>
<tr>
<td>Death</td>
<td>0.25%</td>
<td>0.25%</td>
<td>0.00 (0.00)</td>
<td>1.000</td>
</tr>
</tbody>
</table>

(Precipitation does not necessarily mean recurrence for 28 patients. Precipitation then used for the 28 patients who were included)

PREPIC - Critical Appraisal

- Now thought of as a study of filter randomization in patients with DVT but actually included randomized treatment to unfractionated and LMW heparins
  - Weak study design
  - Underpowered- for multiple comparisons
  - Wide variety of filters were placed
  - Lack of standardization is problematic
    - These filter have different rates of IVC thrombosis
    - Likely affected recurrent DVT rates in the study

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PREPIC 2 - Design

- Do patients with acute PE and high risk of recurrence benefit from an IVC filter in addition to anticoagulation alone?
  - Authors were interested in the significantly lower PE rate at 12 days in PREPIC 1
  - Multicenter, randomized, controlled trial, 2006-2012, Intention-to-treat analysis
  - 399 patients- 200 IVC filter, 199 no filter, all anticoagulated
  - Risk factors: age>75, CHF, COPD, cancer, RV dysfunction, MI, stroke, bilateral DVT, iliocaval thrombus
  - All filters retrieved at 3 months
  - Follow up at 3 and 6 months

PREPIC 2 - Results
PREPIC- Fact or Fiction?

- Title should be: “PREPIC- A Mixed Bag…”
- The data from PREPIC suggested that high-risk patients with IVC filters have:
  - IVC filters decrease PE – with in two weeks
  - Increased risk of DVT long-term
  - Decrease risk of PE long-term
- PREPIC 2 suggests, conversely, that:
  - IVC filters may not decrease the risk of PE in high risk patients at early time points
  - Did not show an associated between filters and recurrent DVT, but all filters were removed at 3 months

Conclusion