The PREPIC Trial- Fact or Fiction?
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The Last 10 IVC Filters Developed and Approved by the FDA

Prevention du Risque D’Embolie Pulmonaire Par Interruption Cave (PREPIC) study

PREPIC – Study Design
- Only 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, LGM, or Bird’s nest filter
- All patients placed on oral anticoagulation at discharge when possible
- Primary outcome
  - Pulmonary Embolism
- Secondary outcomes
  - Deep venous thrombosis
  - Death
  - Major filter complications
  - Major bleeding
- Data published at 2 (NEJM) and 8 years (Circulation)
PREPIC 2 - Design

- Do patients with acute PE and high risk of recurrence benefit from an IVC filter in addition to anticoagulation alone?
  - 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

<table>
<thead>
<tr>
<th>Study 2 Clinical Outcomes For Patients With at Least One Event in the PREPIC Trial</th>
<th>Study 2: No. of Patients (n)</th>
<th>Study 2: No. of Events</th>
<th>Relative Risk: 95% CI (P-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>11,919</td>
<td>1,050</td>
<td>1.08 (0.95, 1.23) (0.48)</td>
</tr>
<tr>
<td>Malignant</td>
<td>0.01</td>
<td>1.00</td>
<td>0.01 (0.00, 0.25) (1.00)</td>
</tr>
<tr>
<td>Acute (&lt;6 months)</td>
<td>1.01</td>
<td>1.00</td>
<td>1.00 (0.25, 3.50) (1.00)</td>
</tr>
<tr>
<td>Acute (&gt;6 months)</td>
<td>1.01</td>
<td>1.00</td>
<td>1.00 (0.25, 3.50) (1.00)</td>
</tr>
<tr>
<td>Mean time to thrombolysis</td>
<td>1.01</td>
<td>1.00</td>
<td>1.00 (0.25, 3.50) (1.00)</td>
</tr>
<tr>
<td>Mean time to surgery</td>
<td>1.01</td>
<td>1.00</td>
<td>1.00 (0.25, 3.50) (1.00)</td>
</tr>
<tr>
<td>Mean time to death</td>
<td>1.01</td>
<td>1.00</td>
<td>1.00 (0.25, 3.50) (1.00)</td>
</tr>
</tbody>
</table>

PREPIC - Fact or Fiction

- Interesting study with controversial findings
- The data from PREPIC suggest that patients with IVC filters have:
  - Increased risk of DVT long-term
  - Decrease risk of PE long-term
- No other data to suggest that removal of IVC filters lowers the risk of DVT long-term
- PREPIC 2 did little to answer these questions