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 2 Year Results

• Data on UH vs. LMWH

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
  • Wide variety of filters were placed
  • Lack of standardization is problematic
  • These filter have different rates of IVC thrombosis

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, illocaval thrombus
  • All filters retrieved at 3 months
  • Follow up at 3 and 6 months

PREPIC - Critical Appraisal

• Statistical analysis is subject to criticism
  • The analysis failed to correct for multiple comparisons (UH vs LMWH, Filter vs no filter)
  • Bonferroni correction would call for a p value of < 0.0125 to be statistically significant
  • PREPIC data show that PE can occur remotely from the incident event (VTE) and that filters are protective long-term
  • Retrieval of IVC filters does NOT provide protection from late events
PREPIC 2 - Results

| Table 5: Clinical outcomes in the Patients Who had a Bloodstream line Inserted in the PREPIC Trial |
|--------------------------------------------------|----------|----------|----------|
| **Risk Factors** | **Group** | **Risk Factor** | **Risk Factor** |
| **PrePIC** | **Group** | **Risk Factor** | **Risk Factor** |
| Baseline | 4.6 (2.5) | 2.6 (2.5) | 2.6 (2.5) | 10 (5) |
| Recurrence | 1.8 (1.8) | 2.6 (2.5) | 2.6 (2.5) | 10 (5) |
| Recurrence > 1 Bloodstream line | 1.8 (1.8) | 2.6 (2.5) | 2.6 (2.5) | 10 (5) |
| Total | 1.8 (1.8) | 2.6 (2.5) | 2.6 (2.5) | 10 (5) |

PREPIC- Fact or Fiction

• The PREPIC studies (1&2) are mostly FACT with a little FICTION mixed in!
• The data from PREPIC suggest that patients with IVC filters have:
  • Increased risk of DVT long-term
  • Decrease risk of PE long-term
• PREPIC 2 suggests that:
  • IVC filters may not decrease the risk of PE in high-risk patients
  • Did not show an associated between filters and recurrent DVT, but all filters were removed at 3 months