The SENTRY Trial - 2 Year Update: Bio-convertible Inferior Vena Cava Filter

Robert Mendes, MD
Chief of Vascular Surgery
North Carolina Heart and Vascular Hospital
UNC Rex, Raleigh, NC

Disclosures:
• Boston Scientific - Advisory Boards, Consultant
• Cook Medical - Advisory Boards, Consultant
• Philips - Advisory Boards, Consultant

Pulmonary Embolism

• PE commonly originates from lower limb deep vein thrombosis (DVT)
  – 79% of patients presenting with PE have evidence of DVT
  – PE occurs in up to 50% of patients with proximal DVT

• PE is the leading cause of preventable mortality in hospitals
  – 50,000-200,000 fatalities from PE each year
  – Approximately 1 in 10 hospital deaths are PE-related

PE Risk Period

• PE’s following a traumatic event, generally happen early (>90% within 10 days)
  – The risk of PE is transient

• Anticoagulation (AC) is the primary therapy to protect against PE
  – 53% of PE patients that have a contraindication to AC develop subsequent fatal PE within the first 30 days of follow-up

Complications of IVC Filters:
• Tilting, Fracture, IVC occlusion, IVC perforation

Complications of IVC Filters:
• Migration

If the patient’s transient risk for PE has passed, the risk-benefit profile begins to favor removal of the IVC filter between 29 and 54 days after implantation.

Safety concerns included:
• Filter Embolization/Migration
• IVC Penetration/Perforation
• Filter Fracture
• IVC Occlusion

Disclosures:
• Boston Scientific - Advisory Boards, Consultant
• Cook Medical - Advisory Boards, Consultant
• Philips - Advisory Boards, Consultant

Pulmonary Embolism

• PE commonly originates from lower limb deep vein thrombosis (DVT)
  – 79% of patients presenting with PE have evidence of DVT
  – PE occurs in up to 50% of patients with proximal DVT

• PE is the leading cause of preventable mortality in hospitals
  – 50,000-200,000 fatalities from PE each year
  – Approximately 1 in 10 hospital deaths are PE-related

PE Risk Period

• PE’s following a traumatic event, generally happen early (>90% within 10 days)
  – The risk of PE is transient

• Anticoagulation (AC) is the primary therapy to protect against PE
  – 53% of PE patients that have a contraindication to AC develop subsequent fatal PE within the first 30 days of follow-up

If the patient’s transient risk for PE has passed, the risk-benefit profile begins to favor removal of the IVC filter between 29 and 54 days after implantation.

Safety concerns included:
• Filter Embolization/Migration
• IVC Penetration/Perforation
• Filter Fracture
• IVC Occlusion

Complications of IVC Filters:
• Tilting, Fracture, IVC occlusion, IVC perforation
• Migration

If the patient’s transient risk for PE has passed, the risk-benefit profile begins to favor removal of the IVC filter between 29 and 54 days after implantation.

Safety concerns included:
• Filter Embolization/Migration
• IVC Penetration/Perforation
• Filter Fracture
• IVC Occlusion

Complications of IVC Filters:
• Tilting, Fracture, IVC occlusion, IVC perforation
• Migration
IVC Filter Retrieval

**RETRIEVAL RATES**
- Mean retrieval rate is 35% based on 103 studies with 20,319 patients in Jia et al 2018 review.
- Despite patient follow-up programs and registries, retrieval rates only increased from:
  - 15.5% to 31.5%
  - 8% to 52%
  - 38.9% to 54%

**RETRIEVAL COMPLICATIONS**
- Standard retrieval methods are successful 73.2% of the time.
- Advanced techniques require longer fluoroscopy and associated with a higher complication rate.

**RETRIEVAL COSTS**
- Median Payment: $1,767.49
- Median Cost: $3,129.57
- Difference: $1,362.08

Advanced Techniques of Filter Retrieval

Sentry Filter Configurations

- Filtering Configuration
- Bio-converted Configuration

Sentry Filter Components

Sentry Filter Deployment

Sentry Clinical Trial

Objective: To evaluate the safety and efficacy of the BTG Sentry Bioconvertible IVC filter

- Preoperative, multicenter, single arm trial
- Study P1: - Dr. Mike Davis
- 125 subjects, 24 hem. 63 operators
- Index Procedures - US & Venogram
- 1 month - US & CT Venogram
- 6 month - CT
- 12 month - X-ray
- 24 month - CT Venogram
- Independent CEC and DSMB
- C. Ray MD (Chair)
- Independent Core Lab
- External monitoring with 100% source data verification

Follow Up
- 100% of eligible subjects imaged at 12 months (n=179)
- 100% of eligible subjects imaged at 24 months (n=85)
Endpoints

Composite Primary Endpoint
• Technical success
• Freedom from new symptomatic PE during the 60-day protection period
• Freedom from IVC filter related complications (to 6 months):
  - tilting, migration, embolization, fracture, perforation
  - symptomatic caval thrombosis
  - other symptomatic filter related complication requiring invasive intervention
  - filter-related death

Secondary Efficacy Endpoints

1. Technical success rate at day 0
2. Filter status at months 1 and 2
3. Bioconversion status at months 6, 12, and 24

Baseline Characteristics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>N=129</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Median)</td>
<td>61.6 years</td>
</tr>
<tr>
<td>Gender (Male)</td>
<td>63.8% (81)</td>
</tr>
<tr>
<td>BMI (Median)</td>
<td>29.8 lbs</td>
</tr>
</tbody>
</table>

Thromboembolic Disease Status

<table>
<thead>
<tr>
<th>N=129</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current DVT but no PE</td>
</tr>
<tr>
<td>Current DVT and PE</td>
</tr>
<tr>
<td>Current PE but no DVT</td>
</tr>
<tr>
<td>No current PE or DVT but high risk of PE</td>
</tr>
</tbody>
</table>

Primary factor for Filter Placement

<table>
<thead>
<tr>
<th>N=129</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
</tr>
<tr>
<td>Medical Condition</td>
</tr>
<tr>
<td>Trauma</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

Primary Endpoint Results

<table>
<thead>
<tr>
<th>Composite Primary Endpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical success</td>
</tr>
<tr>
<td>Freedom from new symptomatic PE during the 60-day protection period</td>
</tr>
<tr>
<td>Freedom from IVC filter related complications (to 6 months):</td>
</tr>
</tbody>
</table>
  • tilting, migration, embolization, fracture, perforation | 0% (0/114) |
  • symptomatic caval thrombosis | 1.8% (2/114) |
  • other symptomatic filter related complications requiring invasive intervention | 0% (0/114) |
  • filter-related death | 0% (0/114) |

Clinical Success (defined as meeting all three above) | 97.4% (111/114) |

Secondary Endpoint Results

Secondary Endpoint Results

<table>
<thead>
<tr>
<th>Results</th>
<th>6 months (n=129)</th>
<th>12 months (n=129)</th>
<th>24 months (n=129)</th>
<th>36 months (n=129)</th>
<th>60 months (n=129)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PE</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Migration</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Fracture</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Embolization</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>IVC Perforation</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

No new symptomatic device-related PE to 24 months
No device-related complications out to 24 months

Study Conclusions

• Primary endpoint at 6 months was met:
  - 97.4% Clinical Success
• 12 month results:
  - 0% new symptomatic PE
• 24 month results:
  - 0% new device-related symptomatic PE
  - 0% tilting, migration, perforation, fracture or embolization
  - 96.5% bioconversion rate - better than published retrieval rates
Potential Concerns?

• Accurate, easy to deploy
• Does NOT:
  – Migrate
  – Perforate
  – Tilt
  – Fracture
• Safe to place future filters
• Bioconversion rate greatly exceeds retrieval rates of currently available filters

THANK YOU!