The Novate Sentry Trial with a Novel Bioconvertible IVC Filter: Follow-up at 2 Years

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Disclosures
- Research/Research Grants, Clinical Trial Support
  - W. L. Gore
  - Cook Medical
- Consulting Fees/Honoraria
  - W. L. Gore
  - Cook Medical
  - Novate Medical
- Officer, Director, Board Member or other Fiduciary Role
  - VHA Physicians Group
  - Speaker’s Bureau
  - None

IVC Filter Controversies
- IVC filter use increased between 2005 & 2010 following release of retrievable devices
  - High incidence of reported complications led to FDA Advisory and a decline in use
- Complications are related to device design
- Broad range of reported retrieval rates – estimated < 50% overall
- Complication rates increase with implant time
  - Tilting, migration, fracture, perforation and embolization
- Retrieval success reduces with implant time
  - Often requires use of aggressive retrieval techniques with increasing levels of associated complications

PE Is Not Controversial
- Incidence 400,000 - 630,000 p.a.
  - 50,000 – 200,000 fatalities p.a.
  - ~ 1 / 10 hospital deaths are PE-related
- PE is expensive - $52,000 per event
- Used correctly, IVC filters save lives and reduce injury and cost related to PE
- Survival benefit has been shown in appropriate populations
- Existing retrievable technology has not effectively met the needs of patients and the medical system

BTG Sentry Bioconvertible IVC Filter
- Designed to protect patients at transient risk from PE and reduce complications of existing technologies
  - Stable frame with filter arms held together by a bioabsorbable filament, designed to:
  - Provide PE protection during transient risk period
  - Reduce IVC filter complications
  - Tilting, migration, fracture, perforation and embolization
- Designed to:
  - Automatically bioconvert after the PE risk period has passed
  - Hydrolysis of the bioabsorbable element allows the filter arms to reattach to the IVC wall leaving a patent lumen
  - Reduce the risk of IVC occlusion
  - Remove the requirement for, and risk /cost of, IVC filter retrieval
**BTG Sentry Bioconvertible IVC Filter: Filtering Configuration**

In Filtering Configuration at deployment

Easy & accurate placement – 7F delivery system

**BTG Sentry Bioconvertible IVC Filter: Bioconverted Configuration**

In Bioconverted Configuration – Ovine pre-clinical study

Leaves patent, unobstructed IVC lumen

**BTG Sentry IVC Filter Trial: Overview**

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

- Prospective, multicenter, single arm trial
- 129 subjects, 23 sites, 63 operators

**SENTRY IVC Filter Trial. Enrolled Subjects: Baseline Characteristics**

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<th>Enrolled Subjects: Baseline Characteristics</th>
<th>67.5%</th>
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<td>- 67.5% of subjects had current PE and/or DVT at the time of enrolment</td>
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<td>- 100% contraindication to anticoagulation for some/all of protection period</td>
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SENTRY IVC Filter Trial: Composite Primary Endpoint: 6 months

- Technical success 129/130 (99.2%)
- Freedom from symptomatic PE during the 60 day protection period, and 129/129 (100%)
- Freedom from IVC filter-related complications (to 6 months) including:
  - Tilt, migration, embolization, fracture, perforation: 112/114 (98.2%)
  - Symptomatic caval thrombosis: 2/114 (1.8%)
  - Other symptomatic filter related complications requiring invasive intervention, or filter-related death: 0/114 (0%)

Met all three (Defined as Clinical Success) 111/114 (97.4%)

- High degree of technical success - 100% of subjects received device
- 100% freedom from new symptomatic PE to 60 days
- 2 (1.8%) symptomatic caval thrombosis (day 8 & 32), treated - did not reoccur
- No tilting, migration, embolization, fracture or perforation

SENTRY IVC Filter Trial: Secondary Endpoints: 6 & 12 months

- No new symptomatic PE to 12 months
- No device-related complications out to 12 months

SENTRY IVC Filter Trial: Secondary Endpoints: 6 & 12 and 24 months

- 2 new symptomatic PEs (day 181 and 183) in subjects with a fully bioconverted filter. CEC adjudicated as non-device related.
- No device-related complications out to 24 months.
- Bioconversion rate (96.5%) compares favorably to published retrieval rates
- No new IVC filters placed to extend the Sentry protection period
- 3 new IVC filters placed for new indications between 6 & 24 months

SENTRY IVC Filter Trial: Conclusions at 24 months

- The most imaging intensive IVC filter study completed to date
- Primary endpoint at 6 months was met:
  - Clinical success 97.4%
- 12 month results:
  - 0% new symptomatic PE
- 24 month results:
  - 2.4% new symptomatic PE (non-device-related)
  - Symptomatic caval thrombosis between 62 days and 24 months
  - No new symptomatic PE and thrombosis between 62 days and 24 months

**Represents an important paradigm shift in the prevention of PE**