1. Reddy.

Sentry Bioconvertible IVC Filter:
Risk / Reward of Placing IVC Filters
In Filtering Configuration at deployment.

Semin Intervent Radiol 2016; 33:93-100

Current IVC Filter Controversies

PE Is Not Controversial
JAMA Internal Medicine 2017; Published online July 10

patients and healthcare providers

Existing retrievable technology has not effectively met the needs of

Used correctly, IVC filters save lives and reduce injury/ cost related to PE

Incidence 400,000 - 630,000 p.a.

Broad range of reported retrieval rates – estimated < 50% overall

Complication rates increase with implant time

Effect of FDA advisory on trends in IVC filter placement in US 2005 to 2014

Remove the requirement for, and risk/cost of retrieval

Reduce risk of IVC occlusion

Hydrolysis of the bioabsorbable element allows the filter arms to retract

Automatic bioconversion after the PE risk period has passed

Reduce IVC filter complications

Stable frame with filter arms held together by a bioabsorbable filament

Intact

Filtering Configuration

Sentry Bioconvertible IVC Filter: A new paradigm in PE protection

Designed to protect patients at risk from transient PE and reduce complications of existing technologies

Stable frame with filter arms held together by a bioabsorbable filament

Provide PE protection during transient risk period

Reduce IVC filter complications

Tilting, migration, fracture, perforation & IVC complications

Automatic bioconversion after the PE risk period has passed

Hydrolysis of the bioabsorbable element allows the filter arms to retract to the IVC wall leaving a patent lumen

Reduce risk of IVC occlusion

Remove the requirement for, and risk/cost of retrieval

Sentry Bioconvertible IVC Filter: A new paradigm in PE protection

Filtering Configuration

Bioconverted Configuration

In Filtering Configuration at deployment.
Easy & accurate placement.
Leaves patient,undisturbed, free-flowing IVC lumen.

In Bioconverted Configuration (ovine study).
Leaves patent,unobstructed, free-flowing IVC lumen.

Timing of PE

>90% of PEs

<10 days

< 20 days

>25 days

>99% of PEs

>95% of PEs

< 10 days

< 20 days

>25 days

>99% of PEs

<10 days

< 20 days

>25 days

>99% of PEs

<10 days

<20 days

>25 days

>99% of PEs

<10 days

<20 days

>25 days

>99% of PEs

<10 days

<20 days

>25 days

>99% of PEs

<10 days

<20 days

>25 days

>99% of PEs

<10 days

<20 days

>25 days

>99% of PEs
**SENTRY IVC Filter Trial**

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

**Robust Study Design**
- Prospective, multicenter, single arm trial
- 129 subjects, 23 sites, 63 operators

**Intensive Imaging Protocol**
- Index Procedure: US & Venogram
- 1 month: US & CT Venogram
- 2 months: X-ray
- 6 months: CT
- 12 months: X-ray
- 24 months: CT Venogram

**Rigorous and Independent**
- 100% of eligible subjects imaged at 12 months (n=111)
- Subjects follow-up to 2 years

**Long Term Follow Up**
- Independent CEC and DSMB
- Independent Core Lab
- External monitoring with 100% source data verification

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### Timing of PE

**Target PE Protection Period 60 days**

*FDA advisement / Risk/benefit profile favors IVC removal between 29-54 days post implant*

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### SENTRY IVC Filter Trial

**Composite Primary Endpoint – 6 months**

1. Technical success: 129/130 (99.2%)
2. Freedom from symptomatic PE during the 60-day protection period: 129/129 (100%)
3. Freedom from IVC filter-related complications (incl. tilting, migration, embolization, fracture, perforation): 112/114 (98.2%)
4. Asymptomatic caval thrombosis: 2/114 (1.8%)
5. Any new symptomatic PE (6 months): 0/114 (0%)
6. Stability complications (1 month): 0/114 (0%)
7. Stability complications (2 months): 0/114 (0%)
8. Stability complications (6 months): 0/114 (0%)
9. Stability complications (12 months): 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 symptomatic PE to 60 days
- 2 (1.8%) symptomatic caval thrombosis (day 8 & 31), treated - did not recur
- No tilting, migration, embolization, fracture or perforation
- No requirement to increase PE protection time in any subject
- Clot in the filter and bioconversion did not result in symptomatic PE
- 2 year follow-up in progress

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### Conclusions

- The most imaging intensive IVC filter study completed to date.
- Primary endpoint at 6 months was met
  - FDA 510(k) clearance February 2017
- 12 month results show:
  - 0% symptomatic PE
  - 0% tilting, migration, perforation, fracture or embolization
- 96% bioconversion rate - better than published retrieval rates
- No requirement to increase PE protection time in any subject
- Clot in the filter and bioconversion did not result in symptomatic PE
- 2 year follow-up in progress

Represents an important paradigm shift in the prevention of PE