Prospective Multicenter SENTRY Clinical Trial: Safety and Effectiveness of the BTG Sentry Bioconvertible Inferior Vena Cava Filter

Michael D. Dake, M.D. et al, J Vasc Interv Radiol. 2018 Aug 31. pii: S1051-0443(18)31207-7.

Objectives

Evaluate the safety and efficacy of the BTG Sentry IVC filter.

- **Primary Endpoint:** Composite endpoint encompassing -
  - Technical success in deployment without acute events;
  - Freedom from new symptomatic Pulmonary Embolism at 60 days
  - Freedom from IVC filter related complications at 6 months
- **Secondary Endpoints Include:** Freedom from IVC filter complications and new symptomatic PEs at 12 months

Patients

- ≥ 18 years of age
- Requirement of transient PE protection of < 60 days
- Documented or high risk of PE or DVT
- Inability to use anti-coagulation due to contraindication, failure, complication or risk of injury from pharmacotherapy
- n= 129; 23 centers

Methods

- BTG Sentry IVC filter placed following IFU protocol
- Imaging at baseline, 1, 2, 6, and 12 months leveraging various imaging modalities
- Independent CEC, DSMB, and core lab
- External monitoring with 100% source data verification
- 100% of eligible subjects imaged at 12 months (n=111)
- Subjects followed for 2 years

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CLINICAL STUDY SUMMARY

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Key Results

- **97.4% met the primary composite endpoint:**
  - Technical success (129/130)
  - Freedom from new symptomatic PE at 60 days (0/129)
  - Freedom from IVC filter-related complications through 6 months (112/114) including:
    - No tilting, migration, embolization, fracture, or perforation
    - Two symptomatic caval thrombosis (one at day 8 & day 32)
    - No other symptomatic filter related complication requiring invasive intervention, or filter-related death
- **100% success in secondary endpoint – no new symptomatic PEs or IVC filter-related stability complications through 12 months**
- **96.4% of BTG Sentry filters bioconverted at 12 months (106/110)**
  - No need to place a second filter at any time during the original PE protection period

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Secondary Endpoints - to 6 & 12 months

	0-1 month (n-129)	1-2 months (n-127)	2-6 months (n-126)	6-12 months (n-117)	SIR reported rates[1]
New symptomatic PE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0.5-6%**
Stability complications	**1 month (n-129)**	**2 months (n-119)**	**6 months (n-114)**	**12 months (n-111)**	**Published rates[2]**
Tilt	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0-55%**
Migration	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0-25%**
Fracture	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0-50%**
IVC perforation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**1-100%**
Any complication found on imaging	0 (0%)	0 (0%)	0 (0%)	0 (0%)	

Conclusion

The BTG Sentry Bioconvertible IVC filter provided safe and effective protection against PE through transient risk period, with a high rate of bioconversion and a low rate of device-related complications, through 12 months of imaging-intense follow-up. The SENTRY Study represents an important paradigm shift in the prevention of PE with a next generation device.[3]

1 - Caplin. J. Vasc. Interv. Radiol. 2011; 22, 1499-1506; reporting periods vary for cited rates.
2 - Deso. Semin Intervent Radio 2016; 33:93-100; reporting periods vary for cited rates.
3 - Dake M., SENTRY Trial 1-year Update, VIVA Symposium, Sept 2017

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