

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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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

BTG Sentry IVC Filter Trial 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*

Indications: The Sentry IVC Filter is indicated for the prevention of recurrent Pulmonary Embolism via percutaneous placement in the inferior vena cava in patients at transient risk of PE, in the following situations: Pulmonary thromboembolism when anticoagulants are contraindicated, failure of anticoagulant therapy in thromboembolic diseases, and emergency treatment following massive PE where anticipated benefits of conventional therapy are reduced.

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