CLINICAL STUDY

One-Year Analysis of the Prospective Multicenter SENTRY Clinical Trial: Safety and Effectiveness of the Novate Sentry Bioconvertible Inferior Vena Cava Filter

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ABSTRACT

Purpose: To prospectively assess the Sentry bioconvertible inferior vena cava (IVC) filter in patients requiring temporary protection against pulmonary embolism (PE).

Materials and Methods: At 23 sites, 129 patients with documented deep vein thrombosis (DVT) or PE, or at temporary risk of developing DVT or PE, unable to use anticoagulation were enrolled. The primary end point was clinical success, including successful filter deployment, freedom from new symptomatic PE through 60 days before filter bioconversion, and 6-month freedom from filter-related complications. Patients were monitored by means of radiography, computerized tomography (CT), and CT venography to assess filtering configuration through 60 days, filter bioconversion, and incidence of PE and filter-related complications through 12 months.

Results: Clinical success was achieved in 111 of 114 evaluable patients (97.4%, 95% confidence interval [CI] 92.5%–99.1%). The rate of freedom from new symptomatic PE through 60 days was 100% (n = 129, 95% CI 97.1%–100.0%), and there were no cases of PE through 12 months for either therapeutic or prophylactic indications. Two patients (1.6%) developed symptomatic caval thrombosis during the first month; neither experienced recurrence after successful interventions. There was no filter tilting, migration, embolization, fracture, or caval perforation by the filter, and no filter-related death through 12 months. Filter bioconversion was successful for 95.7% (110/115) at 6 months and for 96.4% (106/110) at 12 months.

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Appendices A–E can be found by accessing the online version of this article on *www.jvir.org* and clicking on the Supplemental Material tab.

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Conclusions: The Sentry IVC filter provided safe and effective protection against PE, with a high rate of intended bioconversion and a low rate of device-related complications, through 12 months of imaging-intense follow-up.

ABBREVIATIONS

CEC = clinical events committee, CI = confidence interval, DVT = deep vein thrombosis, FDA = US Food and Drug Administration, IDE = investigational device exemption, IVC = inferior vena cava, PE = pulmonary embolism, SAE = serious adverse event, VTE = venous thromboembolism

Pulmonary embolism (PE) leads to the hospitalization or death of approximately 225,000 Americans, 30,000 Canadians, and 300,000 Europeans per year, the incidence having increased during the past decade (1,2). In the United States, estimates of the nonfatal occurrence of PE range from 400,000 to 630,000 cases per year (3), and PE is the leading cause of preventable in-hospital mortality (4), with estimated annual cumulative costs ranging from $8.5 billion to $19.8 billion (5). Risk factors for PE include a history of deep vein thrombosis (DVT), recent surgical procedures, hospitalization for cancer and chronic conditions, prolonged inactivity or immobility, traumatic injury, obesity, and advanced age (6). The vast majority of PEs occur within 30 days of the index event (hospitalization, trauma, surgery) (7–9).

Whereas pharmacologic management with the use of anticoagulant agents is the established primary treatment for venous thromboembolic (VTE) disease, for many patients anticoagulation is ineffective, is contraindicated, or has to be discontinued during periods of high PE risk. Inferior vena cava (IVC) filters are recommended for these situations in accordance with careful selection criteria (3,10–12). In response to complications, such as IVC thrombosis, that have been associated with permanent IVC filters, retrievable devices have been available since 2003 for protection from PE during recognized periods of transient risk (13). However, even with the increased education and patient-tracking initiatives following the April 2010 US Food and Drug Administration (FDA) safety communication (updated in May 2014) advising prompt filter retrieval "as soon as protection from pulmonary embolism is no longer needed" (11,14,15), as many as 65%–80% of filters remain unretrieved, with an associated time-dependent increase in retrievable-filter–specific complications, including device tilting, fracture, migration, embolization, thrombosis, IVC perforation, surgery, and death (4,16–21). Prolonged indwelling time also increases the risk of failure and complications if filter retrieval is attempted (4,22).

The Sentry bioconvertible IVC filter (Novate Medical, Galway, Ireland) is designed to provide temporary protection against PE during transient high-risk periods and then to bioconvert, avoiding the need for a second (retrieval) intervention and leaving a patent IVC lumen. Bioconversion is defined as the release of filter arms from the filtering cone in the central portion of the IVC lumen after hydrolytic degradation of the bioabsorbable filament. Through 180 days in a preclinical study on the Sentry filter in an ovine model, there were no filter-related complications, and the devices were all bioconverted and stably incorporated, leaving all IVCs patent (23). Interim results are reported here from a prospective trial undertaken to evaluate the safety and efficacy of the Sentry IVC filter in patients with documented DVT or PE, or at temporary risk of developing DVT or PE, and with a contraindication to anticoagulation.

MATERIALS AND METHODS

Study Design and Conduct

The prospective, multicenter, nonrandomized, single-arm SENTRY Clinical Trial was conducted at 23 sites in the United States (n = 20), Belgium (n = 2), and Chile (n = 1). The protocol was approved by the appropriate Institutional Review Boards or Ethics Committees, and all study procedures were performed in accordance with the guidelines of good clinical practice and applicable regulations. Novate Medical was the sole sponsor of the study, which was conducted under an investigational device exemption (IDE G110111), in compliance with applicable provisions of 21 CFR Parts 50, 54, and 812 and in accordance with the ethical principles of the Declaration of Helsinki. The study was registered before the start of patient enrollment (*ClinicalTrials.gov* ID NCT01975090).

Patients eligible for inclusion were at least 18 years of age and were determined by their physicians to be at a temporary (< 60 days) risk of PE. All patients had documented DVT or PE or a high risk of developing DVT or PE and had a contraindication to or failure of anticoagulation. The indications for enrollment were consistent with American College of Radiology (ACR) and Society of Interventional Radiology (SIR) practice and quality improvement guidelines (3,12). The SENTRY trial administrative structure is summarized and the determination of patient eligibility is elaborated in **Appendix A** (available online on the article's Supplemental Material page at *www.jvir.org*).

Patient Population

A total of 129 patients were enrolled from September 2014 to February 2016. Baseline patient characteristics and medical history are detailed in **Table 1**. The patient indications for filter placement and the reasons for inability to use anticoagulation therapy are summarized in **Table 2**. Of the 129 patients, 87 (67.4%) met the criteria for a therapeutic intervention—including current DVT and PE (14.0%), PE only (8.5%), and DVT only (45.0%)—whereas 42 (32.6%) met the criteria for a prophylactic filter placement. All 129 patients had