Large-scale study on vein filter use launches

November 12 2014

The first large-scale, multispecialty prospective clinical research trial to evaluate the use of inferior vena cava (IVC) filters and related follow-up treatment in the United States—initiated by a collaboration between the Society of Interventional Radiology (SIR) and the Society for Vascular Surgery (SVS)—is set to enroll the first patient in spring 2015 with participation from seven filter manufacturers.

Predicting the Safety and Effectiveness of Inferior Vena Cava Filters (PRESERVE) will directly address an August 2010 FDA medical alert detailing the possibility that retrievable IVC filters could move or break, potentially causing significant health risks for patients. SVS and SIR collaboratively formed the IVC Filter Study Group Foundation, a 501(c)(3) not-for-profit entity that sponsors and oversees PRESERVE. The study will have the goal of obtaining a real world view of the safety and effectiveness of most filters placed in the United States.

"Patient safety is imperative, which is why interventional radiologists and vascular surgeons are working together collaboratively to respond to FDA's concerns regarding filter safety and effectiveness," said John A. Kaufman, M.D., FSIR, foundation president. "The PRESERVE study will benefit patients by helping determine how well filters prevent pulmonary embolism and when retrievable filters should be removed," noted Peter Lawrence, M.D., foundation vice president.

Filter manufacturers are providing financial support to the IVC Filter Study Group Foundation to sponsor the PRESERVE study. The manufacturers and devices that will be included in the study are ALN

Implants Chirurgicaux (ALN Vena Cava Filters); Argon Medical Devices, Inc. (Option Elite Retrievable Vena Cava Filter designed and manufactured by Rex Medical); B. Braun Interventional Systems Inc. (VenaTech LP Vena Cava Filter); Bard Peripheral Vascular, Inc. (DENALI Vena Cava Filter System); Cook Incorporated (Cook Günther Tulip Vena Cava Filter); Cordis Corporation (Cordis OptEase Retrievable Vena Cava Filter/ Cordis TrapEase Vena Cava Filter); and Volcano Corporation (Crux Vena Cava Filter System).

The five-year study will evaluate the overall safety and efficacy of filters placed by doctors and intends to enroll 2,100 patients at approximately 60 centers in the United States. There will be at least 300 patients enrolled for each participating manufacturer filter, and patients will be evaluated every six months post procedure up to 24 months or filter retrieval. Principal investigators are Matthew S. Johnson, M.D., FSIR, Indiana University School of Medicine, Indianapolis, Ind., and David L. Gillespie M.D., FACS, Southcoast Health System, Fall River, Mass.

Protocol development has been completed, and an investigational device exemption (IDE) study with HIPAA (Health Insurance Portability and Accountability Act) compliance has been granted by FDA. Members of the IVC Filter Study Group Foundation have been working with the contract research organization New England Research Institutes Inc. (NERI), and it's expected that the first patients may enroll in spring 2015.

According to the U.S. Surgeon General, between 350,000 and 600,000 people each year in the United States are affected by blood clots and between 100,000 and 180,000 people die of pulmonary embolism (a blood clot that travels to the lungs) each year. IVC filters are placed inside patients by vascular specialists to prevent blood clots from traveling to the lungs and causing a pulmonary embolism. FDA recommendations are that physicians remove the filters, which are

designed to be retrievable, once the threat of pulmonary embolism has passed. The FDA warning said that all physicians were encouraged to consider the benefits and health risks of IVC filter removal for each patient.

Provided by Society of Interventional Radiology