Medical societies to launch large-scale study on vein filter use

February 1 2013

The Society of Interventional Radiology and Society for Vascular Surgery jointly will launch PRESERVE—the first large-scale, multispecialty prospective study to evaluate the use of inferior vena cava (IVC) filters and related follow-up treatment.

The study—along with the formation of the IVC Filter Study Group Foundation—are direct actions taken to address the August 2010 FDA medical alert detailing the possibility that retrievable IVC filters could move or break, potentially causing significant health risks for patients. SIR and SVS are in the process of determining a framework for the PRESERVE (PREdicting the Safety and Effectiveness of InferioR VEna Cava Filters) study, with the goal of obtaining a functional view of all filters placed in the United States.

"PRESERVE data will allow a systematic, functional view, representative of all filters placed in the United States, thus, all stakeholders—individuals, health care professionals, insurers and government regulators—will be armed with the knowledge they need on patient risk and, subsequently, quality improvement in filter placement, management and retrieval," said SIR President Marshall E. Hicks, M.D., FSIR.

"This is a paradigm-shifting initiative: interventional radiologists and vascular surgeons collaborating to launch a large-scale prospective study evaluating inferior vena cava filters reveals a lot about each specialty's focus—and that focus is on patients, first and foremost," noted SVS

President Peter Gloviczki, M.D.

The five-year study will evaluate the overall safety and efficacy of filters placed by doctors and intends to enroll 1,800 patients at approximately 50 centers in the United States. Members of the IVC Filter Study Group Foundation collectively discussed ways to respond to the FDA's stated concerns. SIR and SVS are in the process of making a final decision for a contract research organization, completing protocol development and submitting the study for investigational device exemption (IDE) study with HIPAA (Health Insurance Portability and Accountability Act) compliance. Study directors are Matthew S. Johnson, M.D., FSIR, Indiana University School of Medicine, Indianapolis, Ind., and David L. Gillespie M.D., FACS, University of Rochester School of Medicine and Dentistry, Rochester, N.Y. Most filter manufacturers have agreed to participate in the study.

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 breaking free and traveling to the lungs or heart 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.

Members of the IVC Filter Study Group Foundation board of directors are SVS President Peter Gloviczki, M.D., Mayo Clinic College of Medicine, Rochester, Minn. (president); SIR President Marshall E. Hicks, M.D., FSIR, University of Texas MD Anderson Cancer Center, Houston (vice president); SVS Executive Director Rebecca M. Maron,

CAE (secretary); SIR Executive Director Susan E. Sedory Holzer, MA, CAE (treasurer); John A. Kaufman, M.D., MS, FSIR, Dotter Interventional Institute, Portland, Ore. (SIR representative); and Peter Lawrence, M.D., UCLA Medical Center, Santa Monica (SVS representative).