# Upcoming IVC Filter Data From the American Venous Registry

The importance of data collection and how you can participate in much-needed research.

**BY JULIE A. JACOB, MA, MFA**

In early 2013, when the American Venous Forum (AVF) releases an annual report for the inferior vena cava (IVC) filter module of the American Venous Registry, vascular physicians and allied health professionals will be able to tap into a much-needed nationwide database on IVC filters. The annual report will be the largest collection of data ever compiled on IVC filter patients and outcomes.

The AVF established the American Venous Registry in 2006 after members attending the AVF's Pacific Vascular Forum discussed the glaring lack of a national database on venous diseases. To fill the need for such a database, the AVF formed a steering committee to develop a registry of venous diseases. Brajesh K. Lal, MD, an Associate Professor and Chief of vascular surgery, physiology, and bioengineering at the University of Maryland, Baltimore, chairs the committee.

"Venous disease affects at least 25% of the US and worldwide population. It is, in fact, much more prevalent than arterial occlusive disease" said Dr. Lal. "However, there is very little standardization in the way physicians diagnose, classify, manage, and follow patients with venous disease. These patients are being cared for by a multiplicity of professionals with varied training backgrounds. This is compounded by large variations in access to clinical protocols and in the analysis of treatment outcomes."

He continued, "The American Venous Forum has made significant progress toward developing standardized ways to diagnose, classify, and evaluate treatment outcomes in venous disease. However, adoption of these standards is variable, and there is a great need for identifying venous disease practice patterns across specialties and geographic boundaries in a standardized fashion. This information will facilitate comparisons of indications, diagnostic accuracy, and treatment efficacy. This will, in turn, drive the implementation of improvements in multiple aspects of the management of venous disease."

"The AVR has been designed keeping the busy clinical environment of a venous practice in mind. It provides a real-time clinical practice tool to participating physicians that assists them in delivering care on a daily basis. At the same time, it allows individual physicians to benchmark their results with respect to the national aggregate, track data mandated by the Centers for Medicare and Medicaid Services or the Joint Commission for quality assurance purposes, and assemble reports for their boards to facilitate recertification. The first module of the AVR related to varicose veins has been a huge success, with data on more than 4,000 patients published in its Annual Report in February 2012. There are now close to 6,000 patients entered into that module of the registry," said Dr. Lal.

The IVC filter module, which opened in June 2011, is one of five modules in the registry. The other four modules address thrombectomy/thrombosis, upper extremity venous treatment, varicose veins, and venous stenting. The AVF published an annual report of the varicose vein data last February. The venous stenting module is also open; the thrombectomy/thrombolysis and upper extremity venous treatment modules are under development and will soon be ready for data entry.

The US Food and Drug Administration (FDA) projects that this year, approximately 259,000 people in the United States will have IVC filters placed to catch dangerous blood clots before they reach patients' hearts or lungs. That number is 92,000 more people than the 167,000 patients who had filters inserted in 2007. Despite the growing use of IVC filters, however, very little data are available about their real-world use such as indications for which they are being placed and retrieval rates, noted John Rectenwald, MD, Chair of the registry's IVC module subcommittee and an Associate Professor of surgery at the University of Michigan.

"Filters are one of the most poorly studied common procedures that we perform," said Dr. Rectenwald. "The common perception is that they are benign, but there has been only one large prospective clinical trial comparing IVC filters to anticoagulation alone. Current IVC filter use is mostly based on small observational studies."

The data from the registry will be especially helpful in improving physicians' understanding of the outcomes and true complication rates associated with filter use, especially in the group of patients who have filters placed for prophylaxis. In the past, filters were primarily used for patients who had pulmonary embolisms or deep vein thrombosis and who could not tolerate anticoagulant drugs, said Dr. Rectenwald. However, with the recent development of retrievable filters, IVC filters are increasingly being placed in patients who do not have either condition and can tolerate anticoagulants.

"No one really argues about filter use for classic indications … but more and more, patients are getting filters for prophylaxis," said Dr. Rectenwald.

The FDA is also interested in filter data, said Dr. Rectenwald, noting that in August 2010, the FDA published a letter recommending that physicians remove retrievable filters as soon as they are no longer needed in order to minimize the risk of filter parts breaking off or migrating to other parts of the body.

The IVC module data will provide clinicians with demographic information about the patients who receive filters, as well as detailed data on indications for placement, outcomes, and intraoperative and postoperative complications. The registry opened in June 2011, and so far, information from about 1,500 patients at 18 clinical sites has been submitted to the registry. Some of the clinical sites are teaching hospitals, including those affiliated with the University of Florida, Gainesville, and the University of Rochester, and others are private practice or community-based sites.

In addition to the data being entered now, the IVC filter module includes nearly 30 years worth of data that Lazar Greenfield, MD, creator of the Greenfield IVC filter, donated to the project. Physicians and hospitals entering data into the module can compare their data with Dr. Greenfield's aggregate statistics, which remain the benchmark to which all filters are currently compared.

No data have yet been analyzed, said Dr. Rectenwald, because "we are still actively accruing cases and recruiting sites, but we are anticipating an annual report with statistical analysis, charts, and an executive summary in the next 6 months."

Medical groups or individual physicians who are AVF members and who wish to participate in the IVC filter registry can sign up at www.veinregistry.org or contact the registry's administrator, Uchenna Onyeachom, at uonyeachom@veinforum.org. ■

*Julie A. Jacob, MA, MFA, is Director of Communications, Executive Director, Inc. She has disclosed that she has no financial interests related to this article. She may be reached at jjacob@execinc.com.*

### TAKE-HOME POINTS

- The forthcoming 2013 AVF annual report will be the largest collection of data ever compiled on IVC filter patients and outcomes.
- Brajesh K. Lal, MD, chairs the AVF steering committee tasked with forming a registry of venous diseases.
- An IVF filter module is one of five modules in the registry; the others being thrombectomy/thrombosis, upper extremity venous treatment, varicose veins, and venous stenting.
- The data from this registry will inform clinicians on indications for IVC filter placement, procedural outcomes, complication rates, and patient demographic data.
- AVF members are encouraged to participate in the registry by signing up at www.veinregistry.org.