Development of a Research Agenda for IVC Filters

A preliminary report from a multidisciplinary research consensus panel.

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PANEL PARTICIPANTS

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Caval interruption, first proposed in 1865 by Armand Trousseau, is an important part of the treatment of venous thromboembolism (VTE).[1] Caval interruption is now accomplished with the percutaneous image-guided insertion of a filtering device into the vena cava. Up to 15% of patients with a diagnosis of deep vein thrombosis (DVT) undergo this widely available procedure.[2] However, the same rigor that has been applied to the most common treatment of VTE, anticoagulation therapy, is lacking in studies of vena cava filters.[3,4] The great majority of scientific publications on filters have been retrospective, noncontrolled, and often from single institutions. There has been only one randomized, controlled prospective trial of filters and that was in patients who do not meet the typical indications for these devices (none of the patients had an indication for a filter; filters were used in addition to anticoagulation).[5,6] To address the lack of level 1 data for vena cava filters, the Society of Interventional Radiology (SIR) Foundation convened a multidisciplinary research consensus panel to develop an agenda for vena cava filter research in June 2008. This is a preliminary report of the proceedings from that meeting.

MEETING ORGANIZATION

This multidisciplinary meeting of physicians and researchers with expertise in inferior vena cava (IVC) filters was convened in June 2007 by the Cooperative Alliance for Interventional Radiology Research (CAIRR), the clinical trials network of the SIR Foundation. The purpose was to establish and prioritize a research agenda for IVC filters that examines preclinical and health technology research, pilot clinical studies, and pivotal multicenter clinical trials.

The 11-member research consensus panel (RCP) was originally developed by the RCP Chair and CAIRR Advisory Committee from a list of physicians with expertise in vena cava filters and VTE. The panel included members drawn from interventional radiology, surgery, and medicine. Representatives from industry and the federal government were present as observers, as were other interested physicians and researchers. The session moderator was the CAIRR network chair.

Before the meeting, the panelists were provided an agenda describing the structure and intent of the session. The meeting was structured into four parts according to standard SIR Foundation process: (1) introductory presentations, (2) moderated roundtable panel discussion followed by comments from industry and governmental representatives, (3) research topic prioritization, and (4) preliminary discussion regarding the development of a clinical research protocol.

Nine of the panel participants made presentations of selected background materials before the roundtable discussion. The intent was to provide a starting point for dialogue about current and developing IVC filter therapies and directions for future investigations. The panel was presented with a summary of the previously reported outcomes of IVC filters and additional information regarding other VTE therapies. These presentations included The Natural History of VTE (Michael Streiff, MD); Current Status of Therapy of VTE (Susan R. Kahn, MD); Prophylaxis of VTE (William Geerts, MD); How Vena Cava Filters Are Used Today (David Gillespie, MD (Table 1); The Outcomes of Vena Cava Filters (Frederick B. Rogers, MD); The Filter as a Risk Factor for VTE (John A. Kaufman, MD, FSIR); Variability in Devices (S. William Stavropoulos, MD, FSIR); The IVC as a Dynamic

Environment (John Rectenwald, MD); and Designing VTE Trials—A New Paradigm (Suresh Vedantham, MD).

PANEL DISCUSSION

After the presentations, the panel began a dialogue on research priorities for IVC filters. The panelists were allowed to briefly present their opinions regarding knowledge gaps and opportunities for IVC filters research. Then, to determine the research priorities, each panelist and audience member wrote down two clinical priorities and one basic science priority, with the option to write down one organizational priority. The panelists' priorities were collected and copied to a screen.

A total of 32 clinical research topics, eight basic science, and six organizational research topics were initially proposed. After the panel discussed each priority, another vote was taken. The highest total score was 67 points for a randomized control trial of prophylactic filters in trauma patients. The next three clinical topic selections by the expert panelists, in order, were a randomized controlled trial of prophylactic filters in a wide range of patient populations, with evaluation of retrieval (47 points); randomized controlled trial of filters in populations at high risk for PE (46 points); and to repeat a multicenter prospective PREPIC-like trial[5] of filters in anticoagulation candidates (41 points). The two top basic science topics were a long-term structural study of implanted devices and study of intrinsic thrombogenicity of filters with attention to metallurgy and filter/blood interactions.

This group perceived filter use in trauma patients as the most pressing area for clinical research in IVC filters. The utilization of vena cava filters in trauma patients, most of whom receive the devices for prophylactic indications, is a widespread but controversial practice.[7-12] The use of filters in trauma patients is suspected to comprise the majority of prophylactic filters placed in the US, which, as an indication, approached 20% of all filters placed in 1999.[13] The percentage of filters that are currently placed for prophylactic indications was suspected by the panelists to currently be 50% in some institutions. This population is generally young, with a long life expectancy. There have not been any randomized controlled studies to show the benefits or risks of filters in this group.[7]

The focus on trauma as a research topic was independent of the nature of the filter, permanent or optional. Although there was much discussion about optional filters and recognition of the pressing need for research on these devices, the panel decided that the priority of research should be evaluation of the most common prophylactic indication for vena cava filters—trauma.[14] The study that will be developed will likely include optional filters, because these devices are commonly utilized in this patient population, but not to the exclusion of permanent filters. The concern of the group for the study of filter indications is reflected in the second-most highly ranked topic, which was a study of prophylactic filters in general.

The top basic science research priority was the long-term behavior of filters. This priority also reflects the group's focus on the prophylactic trauma indication because these patients have among the longest life expectancies of patients receiving filters.[15] The sporadic reports of late filter fractures, perforations, and migrations are of more concern in patients who will have their devices for many decades. The average age of patients undergoing filter placement is steadily decreasing, in parallel with the increase in prophylactic indications.[16]

Lastly, the panelists recognized the imperative for a multidisciplinary effort in the development of research initiatives. Filters are placed in many types of patients by many different types of physicians. Most of the physicians placing filters do not have primary responsibility for the long-term management of VTE. The panelists voted for engagement of the major stakeholders in VTE treatment as one of the top organizational priorities for research. To this end, the American Venous Forum will likely collaborate with the SIR Foundation in the development and implementation of the clinical

TABLE 1. INDICATIONS FOR VENA CAVA FILTERS

Absolute Indications (Proven VTE)
- Recurrent VTE—acute or chronic—despite adequate AC
- Contraindication to AC
- Complication of AC
- Inability to achieve/maintain therapeutic AC

Relative Indications (Proven VTE)
- Iliocaval DVT
- Large, free-floating proximal DVT
- Difficulty establishing therapeutic AC
- Massive PE treated with thrombolysis/thrombectomy
- Chronic PE treated with thromboendarterectomy
- Thrombolysis for iliocaval DVT
- VTE with limited cardiopulmonary reserve
- Recurrent PE with filter in place
- Poor compliance with AC medications
- High risk of AC complications (such as ataxia and frequent falls)

Prophylactic Indications (No VTE, primary prophylaxis not feasible*)
- Trauma patient with high risk of VTE
- Surgical procedure in patient at high risk of VTE
- Medical condition with high risk of VTE

VTE, venous thromboembolism (eg, deep vein thrombosis and/or pulmonary embolism; PE, pulmonary embolism; AC, anticoagulation.

*Primary prophylaxis not feasible due to high bleeding risk, inability to monitor the patient for VTE, etc.

research. Ideally, formal collaboration with other disciplines, such as trauma, hematology, and vascular surgery, will also be possible.

SUMMARY

The body of knowledge about vena cava filters remains embarrassingly deficient in terms of data strength. Most of what we do with filters is based on expert opinion rather than fact.[17] The panel's goal was to use these opinions to begin the process of generating more level 1 data on filters. The prophylactic use of filters in trauma patients was considered the leading clinical research topic by a wide margin. A detailed description of the panel's presentations, discussions, and agenda for the research will be published in the peer-reviewed literature for anyone interested in filters to use. ■

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