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SIR Foundation Sets Research Priorities for Minimally Invasive Treatments for MS Patients

Society of Interventional Radiology Foundation: Careful, Well-designed Studies Needed for Evaluating Patients With Multiple Sclerosis Who Have Narrowed Neck, Chest Veins; “Much Work Needs to Be Done”

FAIRFAX, Va.—Evaluating patients with multiple sclerosis who have narrowed jugular and azygos veins—and the value of widening those veins with angioplasty—warrants careful, well-designed research, noted members of a Society of Interventional Radiology Foundation’s Research Consensus Panel. And, the multidisciplinary panel indicated that while specific parameters for a large-scale, pivotal multicenter trial are not now available, that type of study is the “mandatory goal” in exploring a condition called chronic cerebrospinal venous insufficiency (or CCSVI).

“Much work needs to be done to better define, explore and prove the concept of vein obstruction playing a role in causing multiple sclerosis,” said Gary P. Siskin, M.D., FSIR, one of the 12 research consensus panel members. The concept that a blockage in the veins that drains blood from the brain and spinal cord and returns it to the heart (CCSVI) might contribute to MS and its symptoms—and that widening those veins with angioplasty to improve blood flow may help lessen the severity of MS-related symptoms—are poorly understood, said Siskin, an interventional radiologist and chair of the radiology department at Albany Medical Center and the co-chair of the SIRF panel. “This is an entirely new approach to the treatment of patients with neurologic conditions, such as MS, and could be transformative for patients,” noted Siskin. “Continued investigation is needed in this area. Researchers are clearly very early in their understanding of both the condition and the treatment,” he added.

About 500,000 people in the United States have MS, generally thought of as an incurable, disabling neurologic disease in which a person’s body attacks its own cells. Currently, MS is treated with disease-modifying drugs, which modulate or suppress the immune response believed to be central in the progression of the disease, and these drugs carry significant risk. “The idea that there may be a venous component that causes some symptoms in patients with MS is a radical departure from current medical thinking. There is a healthy level of skepticism in both the neurology and interventional radiology communities about the condition, the treatment and the outcomes,” said Gordon McLennan, M.D., FSIR, an interventional radiologist with the Cleveland Clinic in Cleveland, Ohio, and chair of the SIR Foundation, which supported the project.

The special communication in the *Journal of Vascular and Interventional Radiology* noted that individuals with MS are seeking treatment for CCSVI “despite the still-limited available scientific evidence.” Siskin explained that patients are learning about this therapy and the role of interventional radiology in venous angioplasty through the Internet. “Individuals are discussing it among themselves—through blogs and social networking sites—and then turning to interventional radiologists for this minimally invasive treatment,” said Siskin.

To address the needs and concerns of MS patients who feel they cannot wait until definitive studies are completed, many doctors are currently offering endovascular therapy (or angioplasty, the nonsurgical procedure of threading a thin tube into a vein or artery to open blocked or narrowed blood vessels) to patients with MS. These treatments are provided with the hope of helping MS patients who suffer from intractable symptoms, but it is hoped that this work will also provide insights that improve the design of peer-reviewed studies that clarify the role in MS of treating venous disease with angioplasty (and possible stent placement), noted “Development of a Research Agenda for Evaluation of Interventional Therapies for Chronic Cerebrospinal Venous Insufficiency: Proceedings From a Multidisciplinary Research Consensus Panel.”

The panel recommended that safety and efficacy trials should be conducted in well-defined and potentially smaller controlled populations under institutional review board approval and supported continued basic science studies to better understand the relationship between closed veins and the subsequent contribution of CCSVI to patients with MS. Siskin himself released details of a study in March that found that angioplasty is safe and hoped that those results would encourage additional studies for its use as a treatment option for individuals with MS. The SIRF report concluded that if such additional studies confirm initial reports in favor of CCSVI diagnosis and treatment, then large-scale, pivotal multicenter trials must be developed.

Research consensus panelists represented the fields of interventional radiology, imaging physics, surgery and neurology. Authors of “Development of a Research Agenda for Evaluation of Interventional Therapies for Chronic Cerebrospinal Venous Insufficiency” include Siskin, panel co-chair Ziv J Haskal, M.D., FSIR, and Walter Royal III, M.D., both University of Maryland, Baltimore; McLennan, Michael D. Dake, M.D., Stanford University, Stanford, Calif.; E. Mark Haacke, Ph.D., Wayne State University, Detroit, Mich.; Sandy McDonald, M.D., Barrie Vascular Imaging, Barrie, Ontario, Canada; Suresh Vedantham, M.D., FSIR, Washington University School of Medicine, St. Louis, Mo.; David Hubbard, M.D., and Heidi Sauder, Ph.D., both Applied fMRI Institute, San Diego, Calif.; Salvatore J.A. Sclafani, M.D., FSIR, Kings County Hospital Center, Brooklyn, N.Y.; and R. Torrance Andrews, M.D., FSIR, Swedish Medical Center, Seattle, Wash.

For more information about the Society of Interventional Radiology and minimally invasive treatments, visit online at www.SIRweb.org. More information about the Society of Interventional Radiology Foundation can be found online at www.SIRFoundation.org.

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About the Society of Interventional Radiology Foundation

SIR Foundation is a scientific foundation dedicated to fostering research and education in interventional radiology for the purposes of advancing scientific knowledge, increasing the number of skilled investigators in interventional radiology and developing innovative therapies that lead to improved patient care and quality of life. Visit www.SIRFoundation.org.

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