May 10, 2012

Society of Interventional Radiology Responds to FDA Safety Communication on Chronic Cerebrospinal Venous Insufficiency Treatment in Multiple Sclerosis Patients

On May 10, the Food and Drug Administration issued a medical alert noting that individuals with multiple sclerosis should be aware of the risks of serious injuries and death associated with treatments for chronic cerebrospinal venous insufficiency—and that benefits of those treatments and promotion as an MS treatment “may lead people with the disease to make treatment decisions without being aware of the serious risks involved.”

As always, the Society of Interventional Radiology strongly urges close communications between doctor and patient. Those persons with MS are encouraged to talk to their interventional radiologists and their other doctors about any concerns or questions. SIR members—interventional radiologists who specialize in minimally invasive targeted treatments and who pioneered venous angioplasty and stenting—endovascular techniques that may be central to novel treatments for MS—may note an increase in calls from concerned individuals who have—or are seeking—treatment for CCSVI.

About 500,000 people in the United States have MS, and SIR understands the public’s desire to advance treatment for MS, generally thought of as an autoimmune disease in which a person’s body attacks its own cells. Currently, medicines may slow the disease and help control symptoms. The role of CCSVI (a reported abnormality in blood drainage from the brain and spinal cord) in MS and its endovascular treatment (through a catheter placed in a vein to widen) by an interventional radiologist via balloon angioplasty and/or stents to open up veins could be transformative for patients and is being actively investigated.

The FDA communication is directed toward individuals with MS, health care providers (including interventional radiologists, neurosurgeons and vascular surgeons) and clinical investigators. Health care providers were advised to inform patients that (1) there is conflicting evidence about CCSVI as a clinical entity, (2) CCSVI’s relationship to MS is scientifically unproven and (3) consensus on the diagnostic criteria of CCSVI has not been reached. The FDA also indicated that it has not cleared or approved any angioplasty device or stents for CCSVI treatment and that the use of those devices in treating CCSVI is considered off label. “While the FDA does not regulate the practice of medicine and health care practitioners may choose to use a legally marketed device, based on their clinical assessment, for purposes other than the cleared or approved use, the FDA believes the safety issues observed to date warrant a communication on the subject,” stated the FDA announcement.

SIR supports and agrees with the FDA’s recommendations to encourage research on CCSVI and the current knowledge regarding the safety and effectiveness of treatment procedures. SIR also agrees that clinical research of CCSVI should be performed through well-designed clinical trials, which should require approval through the FDA investigational device exemption (IDE) program.

In 2010, the SIR published the position statement “Interventional Endovascular Management of Chronic Cerebrospinal Venous Insufficiency in Patients With Multiple Sclerosis: A Position Statement by the Society of Interventional Radiology, Endorsed by the Canadian Interventional Radiology Association,” which specifically notes:

- SIR recognizes the urgent need for more effective treatments for MS patients and the public’s interest in rapidly making such therapies available to this patient group.
- SIR recognizes that patients with MS constitute a particularly vulnerable population, whose safety must be protected as new therapeutic approaches are evaluated.
- At present, SIR considers the published literature to be inconclusive on whether CCSVI is a clinically important factor in the development and/or progression of MS and on whether balloon angioplasty and/or stent placement are clinically effective in patients with MS.
- SIR strongly supports the urgent performance of high-quality clinical research to determine the safety and efficacy of interventional MS therapies and is actively working to promote and expedite the completion of needed studies.
SIR recognizes the challenge and the potential opportunity presented by promising early studies of an interventional approach to the treatment of MS. SIR is pleased that public advocacy groups have pushed the medical community forward to meet this challenge and is committed to assuming a national leadership role in launching needed efforts.

Interventional radiology is a recognized medical specialty requiring dedicated training that encompasses clinical patient evaluation and management, non-invasive venous imaging and the delivery of targeted, image-guided minimally-invasive treatments to patients. Interventional radiologists perform balloon angioplasty and stent placements on a daily basis in thousands of patients with diverse venous conditions, including acute deep vein thrombosis, post-thrombotic syndrome, superior vena cava syndrome and portal hypertension; they also perform procedures to maintain hemodialysis access. Interventional radiologists perform many of the CCSVI procedures in the United States; they are highly qualified to perform such treatments when appropriately indicated.

**SIR will provide additional information for patients as it becomes available.**