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ISET: No Consensus on MS Theory

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Review

MIAMI BEACH -- Neurologists and endovascular interventionalists may be edging closer to agreement on how to evaluate the controversial vascular theory of multiple sclerosis, but important gaps still appear to divide the two groups.

That was the upshot of a panel discussion held here Monday at the International Symposium on Endovascular Therapy (ISET), featuring the Multiple Sclerosis Association of America's (MSAA) chief medical officer -- a neurologist -- along with several representatives of the interventional community and a patient advocate for more aggressive study of the theory.

Like North and South Korea glaring at each other across the demilitarized zone, relations between neurologists and endovascular interventionalists have become tense over the theory that obstructions in the jugular vein disrupt blood outflow in the brain, leading to the nervous-system inflammation characteristic of MS.

Although the theory isn't new, the current furor began in late 2008 when Italian researchers claimed they found "chronic cerebrospinal venous insufficiency," or CCSVI, in nearly every MS patient they studied, and that venous angioplasty (with stenting in some patients) reduced or eliminated signs of the disease in many of them.

Although many neurologists were deeply skeptical, MS patients who heard about the results rushed to their physicians by the thousands to demand the treatment. Many found vascular specialists who would accommodate them -- if not in the U.S., then in Poland, Mexico, Costa Rica, and India.

Many patients -- including panel member Sharon Richardson, who now leads an advocacy organization for the procedure -- have reported that the treatments helped them. But there have also been widely publicized failures, including a Canadian MS patient who died in Costa Rica in November following jugular vein angioplasty, which apparently ruptured the vessel and caused him to bleed out.

Neurologists cited the episode as a reason for patients and physicians to be more cautious, while advocates of the theory saw the neurologists themselves as the villains, because they had made it difficult for patients to receive the procedure closer to home.

Burks, the MSAA medical chief who participated in the ISET panel discussion, acknowledged that the divide was essentially "a turf war" between specialties.

Speaking with tongue partially in cheek, he said neurologists viewed the interventionalists as "cowboys" who "overstate the positive value" of vascular treatments in an effort to extract money from desperate patients. To neurologists, he added, "commercial interests are overriding scientific inquiry."

The attitude in the other direction, Burks said, was that neurologists are merely concerned about losing their own lucrative income, and that they are pawns of pharmaceutical companies whose product sales would plummet if the surgical therapy takes hold.

He suggested that the only way to make genuine progress would be to craft a "united message" that neurologists, endovascular specialists, and MS patients could all endorse. A task force of representatives of the three groups should draft such a statement this year, Burks said.

From his own perspective as a neurologist, Burks proposed that research to establish benefit and safety of CCSVI-based treatments should not be focused only on determining whether procedures genuinely help patients get better, but should be wider in scope.

Other goals listed by Burks include:

- The best test to determine if CCSVI is present
- Appropriate outcomes to measure
- Optimal procedures, such as use of balloons and stents
- Qualifications for CCSVI specialists and centers
- Establishment of a patient registry to track long-term outcomes
- Whatever it takes to end medical tourism for CCSVI procedures

Even before dealing with these points, Burks said, radiologists and interventionalists will need guidance in confirming that patients who come to them for CCSVI testing and correction genuinely have MS.

"Let me tell you something you're going to be experiencing if you haven't experienced it already," he told attendees. "If this thing is accepted as the major treatment for multiple sclerosis, [patients will say] if this helps in multiple sclerosis, it will surely help in Parkinson's and Alzheimer's and every other disease known to man."

Burks continued, "The patients will know how to get the procedure -- tell people they have multiple sclerosis, because that is the key to getting tested [for CCSVI]. So we have to have criteria for the diagnosis of MS, so that unsuspecting interventionalists aren't confronted with people who say they have MS but may not."

He also argued that all treatment should be conducted as part of formal research protocols, vetted by institutional review boards (IRBs).

James Benenati, MD, president of the Society of Interventional Radiology (an ISET co-sponsor), who also participated in the panel discussion, endorsed most of Burks's suggestions.

But he appeared to balk at IRB review as a requirement. "We strongly advocate that every patient be followed closely. But if you're not participating in a research trial, you have to at least design your own protocol and monitor your patients very carefully."

A third panelist took an even dimmer view of IRB review, saying he quit his university job rather than accept what the school's IRB was going to require.

Salvatore Sclafani, MD, was chairman of radiology at SUNY Downstate Medical Center in Brooklyn, and wanted to perform CCSVI testing in patients there, with treatment for those testing positive.

He told ISET attendees that the IRB rejected his application, telling him instead to conduct a double-blind, sham-controlled trial.

Sclafani said such a trial would be premature at this stage, with too many unknowns about techniques, patient selection, and follow-up treatment.

Rather than give up the research entirely, he left his post at SUNY Downstate and moved to an ambulatory center where, he said, he could evaluate "a thousand patients a year."

"This awful disease needed me to leave my practice," he said.

Benenati also pointed out interventionalists have been derided as "cowboys" before for procedures that eventually became standards of care.

"We were cowboys when we did iliac angioplasties, we were cowboys when we did TIPS [transjugular intrahepatic portosystemic shunt], we were cowboys when we started stroke therapy," he reminded attendees.

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