

SIR: Vascular MS Treatments Safe, but Efficacy Unclear

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CHICAGO -- Angioplasty for obstructed veins leading away from the brain and spine appears safe for multiple sclerosis patients, although whether it holds any more than a placebo effect for the degenerative disease remains to be proven.

That was the conclusion of several single-center series reported here at the Society of Interventional Radiology meeting on the controversial treatments for what has been termed chronic cerebrospinal venous insufficiency (CCSVI).



No Shortage of Questions

"Currently there are many unknowns and lots of uncertainty," said Michael D. Dake, MD, of Stanford University in Palo Alto, Calif., who called the field "a zone of chaos" in a session dedicated to the debate.

Venous angioplasty for CCSVI has generated enormous demand among MS patients, but there has been [deep skepticism](#) from the neurology community.

The theory is that blocked venous flow leaves iron deposits in the central nervous system that create the hallmark inflammation of MS -- not the autoimmune process conventionally thought responsible for the disease. The idea was raised by an Italian group that reported [CCSVI](#) in nearly every MS patient they studied; they then found MS symptoms improved in many patients who were treated with angioplasty.

Action Points

- Note that these studies were published as abstracts and presented at a conference. These data and conclusions should be considered to be preliminary until published in a peer-reviewed journal.
- Note that endovascular treatment of the internal jugular and azygos veins for chronic cerebrospinal venous insufficiency in patients with MS was a safe procedure when performed on an

Diagnosis has proven challenging, with many studies [failing to replicate](#) this high incidence of CCSVI.

Another problem is that poor central venous flow, malformed venous valves, and other problems in the jugular and azygos veins found in MS patients don't always translate to elevated pressure or other clear clinical relevance, noted Dake, who spoke at the session.

"Just because we see anatomic problems, does that really have any physiologic relevance?" he asked attendees, noting that diagnosing serious and significant lesions in veins is totally different from doing so for arteries.

No Room for Cowboys

outpatient basis in this study.

- Point out that sustained cardiac arrhythmias were observed in three patients during the procedure, suggesting that cardiac monitoring should be considered as an essential component.

An Ann Arbor, Mich., interventionist in the audience said he had treated one MS patient to spectacular effect despite no clear venous stenosis but "felt like the emperor putting on his new clothes, treating something I wasn't really sure what I was doing."

"We acknowledge that maybe the genie is out of the bottle with a lot of centers doing this," responded session moderator Ziv J. Haskal, MD, of the University of Maryland Medical Center in Baltimore.

He and others leading the charge in vascular MS treatments urged others at the meeting who are considering doing the procedure to practice safely in a controlled environment with methodical collection of data "and not have this become a Wild West situation."

That's what Kenneth Mandato, MD, of Albany Medical Center, Albany, N.Y., and colleagues decided to do.

The group reported outcomes of 231 CCSVI patients with MS treated with angioplasty under mild sedation at their hospital or medical offices nearby.

In their experience, 99.2% of patients were discharged within three hours of treatment. One patient had to be hospitalized for sustained arrhythmia (0.4%).

Major complications occurred in three patients (1.2%), all of whom had post-procedural venous thrombosis within 30 days and one of whom also had stress-induced cardiomyopathy (0.4%). Minor complications included the following:

- Thrombosis or dissection after angioplasty requiring stent placement in 10.5%
- Transient headache for 9.1%
- Transient neck discomfort for 16.9%
- Hives from x-ray contrast in 2.8%
- Transient arrhythmia in 0.9%

Since then, more MS patients have been treated with fewer complications, driving down the center's complication rates, Mandato noted.

"This is not a new technology," Mandato emphasized at a press conference where the results were discussed.

A second study of 24 MS patients treated by angioplasty with stenting in some cases for CCSVI yielded one case of inguinal bleeding, two cases of inguinal hematoma, and one retroperitoneal hematoma.

The initial clinical effect was "significant" improvement in MS symptoms in 16 of the 24 and "slight" improvement in five, with the other three seeing no benefit, reported João Martins Pisco, MD, of Hospital Pulido Valente and St. Louis Hospital in Lisbon, Portugal.

By six to eight months later, eight patients had a recurrence of venous obstruction, and one patient each downgraded their improvement to slight or none.

Haskal reported on another series of 18 consecutive MS patients treated for CCSVI with "uniformly positive" patient-reported improvements in outcomes and quality of life. The group also documented objective motor and balance improvements.

Complications included one case of contained left internal jugular vein valve rupture, resolved with balloon tamponade and stenting.

Mandato also anecdotally reported positive changes in symptoms for treated MS patients across the board for those with less severe disease to wheelchair-bound patients.

No Blanket Solution

While confirmation of efficacy will take much larger trials, these early safety reports are a reassuring backbone to support them, according to Mandato co-author Gary P. Siskin, MD, also of Albany Medical Center.

Three deaths have been reported in the worldwide experience with vascular treatments for MS, he noted, but all have been related to blood thinner or anticoagulant use.

"We acknowledge there are risks with this procedure, and we do believe, based on the data presented here, that overall this is a safe procedure with a very low risk of major complications," he told *MedPage Today*.

The Society of Interventional Radiology position is that physicians, in the face of inconclusive evidence, have to make the decision with patients and their families on an individual basis, taking into consideration disease status and response to prior therapies.

"The problem is these are really desperate patients," Lindsay Machan, MD, of the University of British Columbia Hospital in Vancouver, told *MedPage Today*.

With MS patient groups promoting the procedure over the Internet and through social networking, patients are jumping ahead of the scientific process to call asking for treatment, he said.

"This is an insight into our future as physicians," he predicted.

Mandato, Pisco, and Siskin reported having no conflicts of interest to disclose.

Dake reported consulting for Abbott Vascular, WL Gore, NovoStent, CVRx, Amaranth, and Vatrix; being on a board for VIVA Physicians; being an independent contractor or contracting research with Cook Medical; and being an advisory committee or review panel member for TriVascular.

Haskal reported speaking and teaching for Bard Peripheral Vascular and WL Gore.

Machan has reported being a consultant for and shareholder in Angiotech Pharmaceuticals; being on the clinical advisory board for Millimed, Calgary Scientific, and Novelis; being a steering committee member for Cook; and having received grant support from Boston Scientific and Angiotech Pharmaceuticals.

Primary source: Society of Interventional Radiology

Source reference:

Mandato K, et al "Safety of outpatient endovascular treatment of the internal jugular and azygos veins for chronic cerebrospinal venous insufficiency (CCSVI) in multiple sclerosis: a retrospective analysis" *SIR* 2011; Abstract 3.

Additional source: Society of Interventional Radiology

Source reference:

Haskal Z, et al "Feasibility evaluation of catheter directed interventions in multiple sclerosis CCSVI patients" *SIR* 2011; Abstract 382.

Additional source: Society of Interventional Radiology

Source reference:

Pisco JM, et al "Percutaneous transluminal angioplasty and stenting in patients with multiple sclerosis and venous insufficiency -- preliminary results" *SIR* 2011; Abstract 33.