Guidance on Neurologic After-Care for CCSVI Procedures

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Authors and Disclosures

March 21, 2011 — At least 2 Canadian provinces are moving to ensure proper neurologic follow-up care for patients with multiple sclerosis (MS) who elect to undergo endovascular correction of chronic cerebrospinal venous insufficiency (CCSVI).

While underlining that they have no official standard of practice on the care of patients with MS who have obtained this procedure abroad, the College of Physicians and Surgeons of Alberta (CPSA) has issued what they are calling "advice" or general information developed by a multidisciplinary panel, including MS neurologists, on follow-up testing and treatment for these patients.

"This information does NOT represent an official College policy and should not be used by physicians as a substitute for individual clinical judgement," a statement on the ACPS Web site notes.

After-Care Committee

In Ontario, a panel has been established by Minister of Health Deb Matthews to provide similar guidance for physicians providing follow-up care in that province. Co-chairing the panel are Barry Rubin, MD, head of the Division of Vascular Surgery at the University Health Network and medical director of the Peter Munk Cardiac Center, Toronto, Ontario, and MS expert Paul O'Connor, MD, from St. Michael's Hospital and the University of Toronto.

The theory that MS might be caused by lesions in the extracranial veins draining the brain was first proposed in 2009 by Paolo Zamboni, MD, director of the Vascular Diseases Center at the University of Ferrara, Italy. Dr. Zamboni and others are now investigating whether opening these closed vessels using angioplasty with or without stenting improves symptoms. However, in the meantime, increasing numbers of patients with MS have elected to get the procedure done outside of Canada, Dr. O'Connor said.

"Originally people were travelling to Europe, India, and Costa Rica," he told *Medscape Medical News*. "More recently, because this service is now offered in the United States, I've noticed patients are tending to go to the US more."

The issue of after-care for these patients was thrown into sharp relief by the October 2010 death of an Ontario man, who reportedly had the procedure done in Costa Rica but developed a thrombosis around the stent when he returned. Mahir Mostic, a 35-year-old man with MS, had to return to Costa Rica to have the complication treated because, as his girlfriend told CBC News, Ontario specialists "didn't want to touch him because he was done outside of Canada." He died in the hospital there, and his death is thought to have resulted from a bleed after thrombolysis was attempted to dissolve the clot.

Besides shelling out a large sum of their own money, many others of these patients are returning and seeking follow-up care — no one knows how many. Some have had stents implanted, others have not, and some don't know what procedure they've had because there may or may not be any records provided. Many are receiving antiplatelet or anticoagulant regimens.

"Follow-up care is certainly not being provided by these non-Canadian proceduralists, so patients wind up going to their family doctor or their neurologist, mentioning what they've had done, and quite understandably are seeking guidance on what to do about the drugs that they've been told to take," Dr. O'Connor said.

The upshot is a lot of questions both from patients and their doctors about "what, exactly, you should do as far as the patients' follow-up care is concerned," he said.

The main job of the new Ontario panel, called the After-Care Committee, is to develop practical guidelines on follow-up care, he said. "I would say it's a difficult situation because there isn't a lot of literature on this subject, so coming up with recommendations is going to be a real challenge."

For example, it's not clear whether a stent placed in a vein requires treatment with antiplatelet agents and, if so, for how long. Should doctors reimage the stent when their patient returns, and, if it does show a clot or has deformed or migrated, what should they do?

The panel is not yet finalized but will include neurologists, epidemiologists, and vascular experts and others.

"This is meant to produce recommendations that we'll come out with in a few months, and we want to get input from as many quarters as possible, including patients," he said. "The whole idea is to get as much expertise as we can and of course also to be right on top of the literature, such as it is, on this subject."

An Ethical Obligation

In their own new advisory document, the Alberta College of Physicians and Surgeons begins by saying that Alberta physicians have an "ethical obligation to provide follow-up care to patients who have had procedures done out of country." However, the details of the follow-up care provided will be determined by the attending Alberta physician using his or her expertise and judgment and acting in the best interests of the patient, the College adds. Further, "the follow-up may not be the same care the patient would have received out of country."

They add that "Alberta physicians are NOT required to order diagnostic tests or medications requested or advised by an out of country physician. Decisions to order any tests must be made by the attending physician using appropriate clinical evidence and judgment."

Although it provides some guidance, the document again and again underlines the lack of evidence available for many aspects of care of these patients.

For example, in terms of prevention of thrombosis, the document states that "it is up to each individual physician to determine if they choose to accept the responsibility of continuing prescribed medications to prevent thrombosis. Without evidence to support their use, however, we cannot recommend off-label prescribing."

Monitoring for asymptomatic jugular vein thrombosis or restenosis is not recommended, even if MS relapse or worsening of symptoms occurs.

Management of jugular vein thrombosis, once it is detected, depends on the clinical situation, the recommendations note. Asymptomatic jugular vein thrombosis is fairly common after jugular vein catheterization but is not routinely treated with anticoagulation. There is a "small" risk for pulmonary embolism or clot propagation, but the literature is limited. Some hematologists think the risk is higher, they note. The frequency of clot extension is unknown.

Therefore, in the absence of specific evidence to guide decision-making, 'anticoagulation for a minimum of 3 months' and 'no treatment' may both be reasonable options.

"Therefore, in the absence of specific evidence to guide decision-making, 'anticoagulation for a minimum of 3 months' and 'no treatment' may both be reasonable options." The imaging modality of choice is also unknown because of the lack of comparative studies, they add.

Symptomatic jugular vein thrombosis after a CCSVI procedure "should not be managed differently than in any other patient but the presence of a stent may influence treatment options and possibly treatment duration," they write. "Patients who have had jugular vein procedures and are suspected to have intracranial, axillary, or superior vena cava thrombosis or pulmonary embolism should be sent to an emergency department for care whether jugular vein thrombosis is known to be present or not."

Thrombolytics are not approved by Health Canada for venous thrombosis, and their safety in this setting is not known, they add. "Patients should not be led to believe that thrombolysis or revision of previous CCSVI treatment will be offered."

MS follow-up after a CCSVI procedure should not differ from that of patients who have not had the procedure, the document adds. "Some patients believe that their symptomatic improvement ends if their veins become thrombosed or re-stenosed and, also, that loss of symptomatic improvement is due to thrombosis or re-stenosis of their veins. However, there is no evidence to support this."

Finally, the recommendation is for all patients who have had a procedure to be referred to an MS clinic.

"A 3-year observational study focusing on the complications and patient reported effects of venous procedures for CCSVI is being developed but cross sectional data is not expected to be available until 2012," the document concludes.