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# Guidelines for the Management of Patients Following Endoluminal Vein Dilation Procedures for the Treatment of Multiple Sclerosis

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**Report Submitted to the Minister of Health and Long-Term Care**

**By the Ontario MS Expert Advisory Group**

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## Guidelines for the Management of Patients Following Endoluminal Vein Dilation Procedures for the Treatment of Multiple Sclerosis

### 1) PURPOSE STATEMENT

These guidelines were developed by *The Ontario Multiple Sclerosis (MS) Expert Advisory Group* (see Appendix A for Membership List) to provide guidance to health care practitioners (i.e., family physicians/general practitioners, specialists, nurse practitioners) in the province of Ontario who are providing post-operative and ongoing follow-up care to patients with MS who have had an endoluminal vein dilation procedure for the treatment of MS in another country and have returned to Ontario.

While some research has suggested a relationship between narrowed veins in the neck and chest and the development of MS, this relationship has not been proven. It has also been suggested, but not proven, that endoluminal vein dilation procedures can improve the symptoms of MS. Some patients have chosen to undergo endoluminal vein dilation procedures outside of Canada. Typically, follow up of these patients after endoluminal vein dilation procedures is not done by the physician who carried out the procedure. The Expert Advisory Group developed these guidelines at the request of the Minister of Health and Long-Term Care of Ontario to address the care of patients with MS after endoluminal vein dilation procedures. These guidelines represent a consensus opinion based on the expertise of the members of the group, as well as the available evidence-based literature on this subject, which is acknowledged to be of limited scope and quality.

MS patients routinely seek care from primary care physicians or nurse practitioners, and these practitioners may need to refer patients to, or collaborate with, other health care practitioners, including physician specialists, to manage patients with MS after endoluminal vein dilation procedures. This document is meant to guide all health care practitioners in the province who may be involved in the care of these patients.

Practitioners should tell their patients that there are currently no evidence-based clinical guidelines for the treatment of complications of vein dilation procedures involving the azygous or jugular veins, that they will inform their patients if and when new information about treatment options becomes available, and that they will make referrals to other health care practitioners as appropriate.

It must be emphasized that individual practitioners' opinions regarding endoluminal vein dilation procedures for the treatment of MS should have no bearing on a practitioner's willingness to provide care for patients returning to Ontario after endoluminal vein dilation procedures, their willingness to refer such patients to other practitioners for care as indicated, their willingness to accept such a referral in a timely manner, or their willingness to accept such patients as new patients (see Appendix B for applicable legislation, regulations, policies, standards, and guidelines).

### 2) GUIDELINES FOR CARE

#### 2.1) Regular, Ongoing Care for the Management of MS

- a. Patients returning to Ontario after endoluminal vein dilation procedures should have ongoing, routine assessment by their health care practitioners as part of their regular care for the management of MS.
- b. Practitioners should encourage patients to attempt to find out as much information as possible about the out-of-country endoluminal vein dilation procedure performed, including whether stents were inserted into veins, as well as whether complications arose during or after the procedure.

## 2.2) Potential Complications of Endoluminal Vein Dilation Procedures

Patients may develop the following complications post-procedure:

- a. **Local complications:** may include deep vein thrombosis, bleeding from the vein that was cannulated to do the endoluminal procedure (femoral vein, brachial vein), infection at the site of cannulation, direct trauma to arteries or nerves adjacent to the vein that was cannulated (femoral artery or nerve, brachial artery or median nerve), skin necrosis, distal embolism and arterio-venous fistula formation.
- b. **Complications related to endoluminal vein dilation or dilation plus stenting of the internal jugular or azygous vein:** may include thrombosis of the azygous or internal jugular vein after vein dilation or following vein dilation plus stenting, extension of thrombus into adjacent intra-cranial or intra-thoracic veins, vein laceration or rupture, pulmonary embolism, stent migration, stent fracture or deformation, or compression of adjacent local structures, including cranial nerves and the common or internal carotid arteries.
- c. **Complications related to drugs or medications administered during the course of or after the endoluminal vein dilation procedure:** may include an allergic reaction to the radiographic contrast agent or anaesthetic agent, renal dysfunction that may result in renal failure secondary to contrast induced nephropathy, and problems related to anti-platelet agents or anti-coagulant medications, such as gastrointestinal bleeding or cerebral haemorrhage.
- d. **Infection with pathogens:** including those that may be endemic in the country where the patient underwent the endoluminal vein dilation procedure, but which are uncommon in Ontario.

## 2.3) Recommendations Regarding Care

- a. Patients should be advised that the decision to stop MS disease-modifying therapies after endoluminal vein dilation procedures needs to be discussed with the treating practitioner, including the family physician/general practitioner, neurologist or nurse practitioner.
- b. The decision to treat asymptomatic patients with anti-platelet agents after an endoluminal vein dilation procedure should be made on a case-by-case basis, and physicians should carefully evaluate patients for the risks associated with anti-platelet therapy. Many patients who undergo an endoluminal vein dilation procedure for indications other than the potential treatment of MS are routinely placed on anti-platelet agents, and these anti-platelet agents are often continued after the endoluminal vein dilation procedure unless there is a specific contraindication to this therapy.
- c. It is unknown if anti-platelet agents promote vein patency after venoplasty or venoplasty with simultaneous stent placement in patients with MS. Based on the overall health benefit of taking low-dose aspirin, however, it is not unreasonable for asymptomatic patients with or without MS to take low-dose aspirin indefinitely, if tolerated, and if no contraindication to this therapy exists.

## 2.4) Indications for Diagnostic Imaging

- a. After an endoluminal vein dilation procedure, follow-up imaging studies such as Duplex Doppler ultrasound or magnetic resonance (MR) venography are not indicated, unless the patient has symptoms and signs consistent with a complication of the vein dilation procedure. This is because the findings of such

imaging studies are of uncertain significance in a patient without symptoms related to the vein dilation procedure, and because the results of such studies would not change the ongoing management of the patient.

- b. Stents are not designed to be placed in veins, and are not approved by Health Canada for placement in veins. However, stents are occasionally placed in veins to manage patients with recurrent central vein stenosis secondary to central venous or hemodialysis catheters. After the insertion of a stent in a vein, MS patients who have undergone stent placement should be considered for imaging studies if they exhibit symptoms that may be directly related to stent thrombosis, or if a complication of vein dilation and stent placement is suspected, to determine if stent thrombosis, stent deformation, fracture or migration has occurred. Imaging studies of the internal jugular or azygous veins are not indicated in asymptomatic patients after endoluminal vein dilation or stenting procedures.
- c. Worsening or recurrence of MS symptoms (including MS relapse) after a vein dilation procedure does not currently constitute an indication for venous imaging studies.
- d. Computed tomography (CT) or MR venography are required to assess stents placed in the azygous vein for possible thrombosis or other complications, if clinically indicated.

### **2.5) Symptoms and Treatment of Stent Thrombosis**

- a. The symptoms associated with stent thrombosis in the neck are not completely known at the present time, but may include (but not be restricted to) pain and/or swelling in the head and neck. Embolization of thrombus within a stent to the pulmonary circulation may cause chest pain, shortness of breath, hemoptysis and/or pleuritic chest pain. The symptoms related to stent migration are likely to depend on where the stent migrates. For example, stent migration to the right side of the heart may cause arrhythmia, incompetence of the tricuspid or pulmonary valves, or sudden cardiac decompensation.
- b. If stent thrombosis is identified, the patient should be referred to a thrombosis expert such as a haematologist and/or vascular surgeon for ongoing management. If a pulmonary embolus is identified, patients should be told that pulmonary embolism may be a life-threatening condition that will require emergency assessment and treatment.
- c. In the absence of evidence specific to the management of thrombosis of the internal jugular or azygous veins, the management of thrombosis of these veins should be based upon the evidence-based management of deep vein thrombosis (DVT) in more common locations, such as the deep veins of the lower extremities. For further information on management of venous thrombosis, and to start treatment while waiting for a specialist referral, please refer to guidelines for DVT management at: [http://chestjournal.chestpubs.org/content/133/6\\_suppl/454S.full.html](http://chestjournal.chestpubs.org/content/133/6_suppl/454S.full.html).
- d. Thrombolysis is not indicated and is not approved by Health Canada for patients with stent thrombosis, because of the significant and potentially life-threatening bleeding risks associated with this therapy. In addition, the benefit of lysing a clot in a thrombosed internal jugular or azygous vein in a patient with MS, in the presence or absence of a stent, has not been established. Therefore, at this time, the risk of internal jugular or azygous vein thrombolysis likely outweighs the potential benefits of this therapy in patients with MS.

### **2.6) Risks Associated with Repeat Endoluminal Vein Dilation Procedures**

Repeat endoluminal vein dilation procedures carry the risk of vein damage, including re-stenosis, thrombosis or vein rupture, and are associated with increasing exposure to ionizing radiation.

## Appendix A - Ontario MS Expert Advisory Group Membership List

Name	Title and Organization
Dr. Barry Rubin (Co-Chair)	Program Medical Director, Peter Munk Cardiac Centre, University Network Hospital (UHN)
Dr. Paul O'Connor (Co-Chair)	Director, MS Clinic and MS Research and the Evoked Potentials Laboratory, St. Michael's Hospital
Dr. Marcelo Kremenchutzky	Director, Multiple Sclerosis Clinic, London Health Sciences Centre
Dr. Julian Spears	Co-Director, Neurovascular Program, St. Michael's Hospital
Dr. Liesly Lee	Consultant Neurologist, Sunnybrook Health Sciences Centre and Director, Sunnybrook MS Clinic
Dr. David Henry	President and CEO, Institute for Clinical Evaluative Sciences (ICES)
Dr. Andreas Laupacis	Executive Director, Li Ka Shing Knowledge Institute of St. Michael's Hospital
Dr. Phil Wells	Professor, Chief and Chair, Department of Medicine, The Ottawa Hospital and University of Ottawa
Two patients living with MS	

## Appendix B - Applicable Legislation, Regulations, Policies, Standards, and Guidelines

Physicians must act in accordance with applicable legislation, including the *Regulated Health Professions Act, 1991* and the *Medicine Act, 1991*, and regulations made under such Acts, as well as policies of the College of Physicians and Surgeons of Ontario (CPSO), including policies regarding accepting new patients and ending the physician-patient relationship.

Relevant CPSO policies can be accessed and viewed through the following links:

Accepting New Patients - [http://www.cpso.on.ca/uploadedFiles/policies/policies/policyitems/Accepting\\_patients.pdf](http://www.cpso.on.ca/uploadedFiles/policies/policies/policyitems/Accepting_patients.pdf)

Ending the Physician Patient Relationship - [http://www.cpso.on.ca/uploadedFiles/policies/policies/policyitems/ending\\_rel.pdf](http://www.cpso.on.ca/uploadedFiles/policies/policies/policyitems/ending_rel.pdf)

Physicians and the Ontario Human Rights Code - [http://www.cpso.on.ca/uploadedFiles/downloads/cpsodocuments/policies/policies/human\\_rights.pdf](http://www.cpso.on.ca/uploadedFiles/downloads/cpsodocuments/policies/policies/human_rights.pdf)

Non-allopathic (Non-conventional) Therapies in Medical Practice (*Note: a revised draft of this policy is currently out for public consultation*) - <http://www.cpso.on.ca/policies/consultations/default.aspx?id=4310>

The Practice Guide: Medical Professionalism and College Policies - <http://www.cpso.on.ca/policies/guide/default.aspx?id=1696>

Nurse practitioners must act in accordance with applicable legislation, including the *Regulated Health Professions Act, 1991* and the *Nursing Act, 1991*, and regulations made under such Acts, as well as standards and guidelines of the College of Nurses of Ontario (CNO).

Relevant CNO standards and guidelines can be accessed and viewed through the following links:

Professional Standards (*currently undergoing revision*) - [http://www.cno.org/Global/docs/prac/41006\\_ProfStds.pdf](http://www.cno.org/Global/docs/prac/41006_ProfStds.pdf)

Nurse Practitioners Practice Standard - [http://www.cno.org/Global/docs/prac/41038\\_StrdRnec.pdf](http://www.cno.org/Global/docs/prac/41038_StrdRnec.pdf)

Refusing Assignments and Discontinuing Nursing Services - [http://www.cno.org/Global/docs/prac/41070\\_refusing.pdf](http://www.cno.org/Global/docs/prac/41070_refusing.pdf)

Ethics Practice Standard - [http://www.cno.org/Global/docs/prac/41034\\_Ethics.pdf](http://www.cno.org/Global/docs/prac/41034_Ethics.pdf)

The recommendations and other opinions expressed in the following documents are those of the MS Expert Advisory Group and its members, and do not necessarily reflect those of the Ministry of Health and Long-Term Care (MOHLTC). The MOHLTC is making these materials available for informational purposes only, and they are not a substitute for sound clinical judgment or medical advice. The MOHLTC cannot and will not accept any liability associated with an individual's decision to rely on the contents of these documents.