Multiple Sclerosis and Chronic Cerebrospinal Venous Insufficiency
Information Sheet

What is Chronic Cerebrospinal Venous Insufficiency?

Chronic Cerebrospinal Venous Insufficiency (CCSVI) is a term coined by Dr. Paolo Zamboni to describe a reduced flow of blood in veins draining the brain and spinal cord. According to Dr. Zamboni, CCSVI is the result of an abnormal variation of extracranial venous anatomy.

Is CCSVI linked to MS?

There is currently no clear evidence of a link between CCSVI and MS.

In April 2009, Dr. Zamboni's group reported that 100% of MS patients have internal jugular or azygos venous abnormalities, and 0% of normal healthy controls show CCSVI. This study suggested that CCSVI might be the underlying cause of MS.

Since then, several additional studies on this topic have been published and/or presented at international conferences. Conflicting results as to whether CCSVI exists and whether it is associated with MS have emerged from these studies. For instance, the results of an observational study from Dr. Robert Zivadinov and his team in Buffalo, using ultrasound to examine 260 MS patients and 161 healthy controls, reported a wide variation in the incidence of venous abnormalities among normal healthy subjects (ranging from 22.4% to 25.9%), and as well as among MS patients (56.4% to 62.5%). Patients with other neurological diseases were reported to have a 45% rate of abnormalities, all of which clouded the interpretation of this data. In a more recent study, Dr. Zivanov and his team also demonstrated, through magnetic resonance venography, that there were no significant differences in the extracranial venous systems between MS patients and healthy control subjects. The authors highlighted the necessity of developing standardized guidelines to define parameters for the presence of venous anomalies.

Several recent studies have also demonstrated a wide variation in the patterns of venous drainage of the brain in both MS patients and people with no evidence of MS (controls), underlining the difficulty involved in concluding that a vein that is 'narrowed or blocked' will cause MS.

In an editorial commentary recently published in the Journal of Neurointerventional Surgery, Dorne et al. concluded that more evidence is still needed to establish a link between CCSVI and MS.

What is currently being done to research Zamboni’s claim?

The MS Society of Canada and the National MS Society (USA) decided to support seven studies that are currently looking at the question of whether CCSVI is linked to MS. These studies propose rigorous protocols (e.g., blinded experiments as opposed to the un-blinded pilot study of Dr. Zamboni) and resort to a variety of imaging techniques to provide solid evidence to answer
this question. Together, these studies will also help identify optimal methods for screening for the CCSVI condition, which would represent a necessary step before conducting clinical trials.

To monitor the results from these studies, as well as from related studies from around the world on venous anatomy and MS, the Canadian Institutes of Health Research (CIHR) has set up a scientific expert working group. This group is made up of the principal investigators of the seven MS Society-sponsored studies, of the scientific leadership from CIHR and the US, Canadian and Italian MS Societies, and of a representative from the provinces and territories. The members of the Working Group are reviewing evidence as fast as possible and will meet next June to assess any preliminary results of the seven studies.

**What is the treatment for CCSVI and is it safe?**

Angioplasty and stenting have been used in clinics in India, Costa-Rica Bulgaria, Poland and elsewhere to treat CCSVI.

Arterial angioplasty and the insertion of stents into certain arteries are established medical procedures. However, venous angioplasty is rarely used because the incidence of re-stenosis is so high. The prevailing medical opinion is that while "balloon angioplasty" for veins may be relatively safe, it is difficult to justify the procedure as the veins eventually will re-stenose. In addition, there is a distinct possibility that the damage to the inner lining of a vein can increase the risk of thrombosis of that vein and can cause pulmonary embolus.

Venous stent placement usually requires the use of blood thinners, which can lead to complications, such as internal bleeding. Potentially fatal outcomes due to the migration of a venous stent into the heart have also been reported.

There are increasing reports of complications related to the CCSVI treatments offered abroad, and many national and international MS associations advise MS patients against these treatments.

**What are the recommendations of Canadian health associations with respect to the CCSVI treatments offered abroad?**

The Canadian Medical Association, the Association of Faculties of Medicine of Canada, and the Canadian Society for Vascular Surgery concur with CIHR's position on the need for an evidence-based approach to determine whether there is a link between CCSVI and MS. These associations are of the opinion that clinical trials on the safety and efficacy of angioplasty and/or stenting of the extracranial veins should be conducted, only if and when a link between CCSVI and MS can be clearly established.

Some professional associations such as the Collège des médecins du Québec are of the opinion that MS patients should not be involved in any interventional clinical trials involving venous angioplasty or venous stents until the efficacy and the safety of the CCSVI treatments has been proven.
What follow-up are recommended for patients who chose to go abroad for Zamboni’s procedure?

MS patients who have received a venous procedure abroad should be reassured that they will continue to be cared for by their physicians and/or regular MS specialists as any other patients.

They should be informed that contrary to what has been reported in the press, clinical trials are being carried out on CCSVI and MS, but in a scientifically sound, step-wise fashion.

