

“As President and CEO of the MS Society, I am aware of the tremendous interest across Canada and around the world caused by the recent news coverage of the CCSVI study. Indeed, I share your excitement and hope in the preliminary findings of this study. I also celebrate and respect the integrity of our research funding programs, which will continue to ensure that the very best projects are selected and supported.”

Yves Savoie

President and Chief Executive Officer
Multiple Sclerosis Society of Canada

What exactly is CCSVI?

The term “chronic cerebrospinal venous insufficiency” (CCSVI) designates a condition in which the venous system is not able to efficiently remove blood from the central nervous system. It is stated that this is related to the narrowing of small venous structures in the neck, chest and spine.

Why is there a sudden interest in CCSVI and MS?

Recent research reports have revived the hypothesis that MS may be attributable to poor blood circulation in the brain or poor blood drainage from the brain.

More specifically, one such report concerned a study by Dr. Paolo Zamboni and his team that compared 65 people with MS (all forms) with 235 people who were healthy or had other neurological disorders. This preliminary

study revealed that the majority of participants who had MS also had venous insufficiency. The data available at present are interesting, and Dr. Zamboni’s initial observations are currently the subject of rigorous scientific studies with the aim of validating them.

Moreover, the preliminary results of a study carried out at the University of Buffalo on CCSVI and MS were published in February 2010. According to their data, 56.4% of participants who had MS showed evidence of CCSVI, compared to 22.4% of people who did not have MS. We are closely following this study and other research concerning CCSVI. The full results of this study will be presented in Toronto, at the American Academy of Neurology meeting, in April 2010.

These studies open up new research avenues in the field of MS and could lead to the development of new treatments.

What did the experimental treatment consist of?

Researchers interested in CCSVI have made use of two methods: dilatation with small “balloons,” which is meant to increase the diameter of veins that have narrowed, and the insertion of stents, which prevent the veins from narrowing further. These operations are only at their earliest stages and have only been done on a very small number of patients. Balloon dilatation consists of inserting a catheter through a vein to the area of narrowing in order to be able to expand it.

Dr. Zamboni and his team published the

results of their experiment in December 2009. Their study examined 65 patients: 35 with a relapsing-remitting form of MS and 30 with a progressive form (primary or secondary). To obtain conclusive results, studies would have to be done with samples of 500 to 1,000 patients.

The design of Dr. Zamboni’s study does not rule out the placebo effect, as he himself emphasizes in a publication. To eliminate any doubts regarding the possibility of the placebo effect, it is important to do what is called a “double-blind” study: this would involve doing real dilatation in one group of patients, while another group would have a catheter inserted without any dilatation. Neither the patients nor the doctors would know who had undergone the real dilatation, and thus their observations would be objective. The real effect, which abstracts away from the placebo effect, would be measured by comparing the two groups.

What were the conclusions of Dr. Zamboni’s study?

In the relapsing-remitting form of the disease, 73% of the patients had had an attack in the year preceding the treatment; in the 18 months following the treatment, 50% had an attack. However, the observation period was too short to conclude that there was any significant change in the annual rate of attacks. A slight improvement was seen in the MSFC (Multiple Sclerosis Functional Composite) score, which measures the ability to concentrate, the time needed to walk a distance of 25 feet, and hand coordination.

In the primary – and secondary-progressive forms of the disease, Dr. Zamboni’s study did not show any improvement in MSFC score, in either concentration, walking or hand coordination. However, the patients treated did observe a slight improvement in their quality of life at 6 months but not anymore after 18 months.

In light of these results, Dr. Zamboni concluded in his December 2009 article that other studies should be carried out with larger samples and done on a double-blind basis.

Do the treatments have risks?

These treatments (balloon with or without a stent) are not without risk: in particular, they present a risk of bleeding or the formation of abnormal blood clots. For safety reasons, it is recommended that patients receive treatments for CCSVI only within established scientific studies.

Can I be tested now to see if I have symptoms of CCSVI?

The research on CCSVI is still in its infancy and no related treatment has yet been scientifically proven to be effective for MS. So it would not be valuable at this point to undergo such tests outside an established research protocol, since the results could turn out to be unusable.

Does CCSVI cause MS?

Not necessarily. Based on the data published to date, all we can say for now is that the

appearance of MS could be associated with poor venous drainage of the central nervous system. It is possible that these drainage anomalies cause MS, but it could also turn out that they are entirely unrelated to MS. It is important to remember that some people who did not have MS also presented these drainage anomalies. In other words, more research needs to be done in this field before a definitive statement can be made.

Will the treatment of CCSVI be effective against the different forms of MS?

Whether this type of treatment will be effective against any form of MS is currently unknown, as research on this question is at a very early stage. Much more work needs to be done.

What are the next steps in studying CCSVI?

As in any research study, it is important to validate and replicate the results obtained and to answer questions to verify the validity of the theory proposed. Thus, we can divide the next steps into two:

FIRST STEP: DETERMINE THE PREVALENCE OF CCSVI IN PEOPLE WITH MS.

In the United States, researchers at the University of Buffalo are currently doing a study with 1,600 adults and 100 children to determine the frequency of CCSVI in people with MS and compare their results to those of people who do not have MS. It should be noted that this is not a

clinical trial intended to evaluate a treatment. The aim of this study is to measure the prevalence of venous obstruction in people with MS; it does not examine any treatment of the obstruction itself.

SECOND STEP: DETERMINE THE EFFECTS OF TREATMENT OF VENOUS INSUFFICIENCY.

If the first step is completed successfully and the results show that a sufficient number of people with MS have a venous obstruction, researchers will no doubt consider treating this obstruction and evaluating the risks related to this intervention.

Researchers around the world, including in Canada, are now working to design research protocols to understand the possible link between CCSVI and multiple sclerosis.

What is happening in Canada to further the understanding of CCSVI and MS?

In November 2009, the MS Society created a special fund to finance research on the relationship between CCSVI and MS. The call for specific research proposals is unique and unprecedented in the MS Society's 60-year history.

In June 2010, following a rigorous examination of the proposals received, an international committee of scientists will announce which research protocols will be funded. This special program provides for the awarding of an amount up to \$200,000 for each project retained (\$100,000 per year for two years).

In addition to this special fund, the annual research

grant program operated by the MS Society and its MS Scientific Research Foundation will also allow interested researchers to submit applications for larger grants for work concerning CCSVI.

What is the MS Society's role in CCSVI research?

The MS Society's primary role in research is to fund the avenues of greatest potential and scientific excellence. By financing research on this topic, the MS Society hopes to shed light on the possible link between CCSVI and multiple sclerosis.

If the scientific community proves that treatment of CCSVI is a valid therapeutic treatment option for people with MS, then the MS Society would have a role in lobbying to make it widely accessible.

The Multiple Sclerosis Society of Canada is an independent, volunteer-run, non-profit organization. It neither approves nor recommends any product or therapy, but gives its clients information so that they can make informed decisions.

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For more information on CCSVI and MS, visit www.mssociety.ca or call 1-800-268-7582.

Chronic Cerebrospinal Venous Insufficiency (CCSVI) and MS



April 2010