

special report on CCSVI



National Multiple Sclerosis Society
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nationalMSsociety.org

What you need to know about CCSVI

Recent preliminary studies suggest that a phenomenon called chronic cerebrospinal venous insufficiency, or CCSVI, an abnormality in blood drainage from the brain and spinal cord, may contribute to nervous system damage in MS.

CCSVI means that blood returning to the heart from the brain and spinal cord is slowed down and may sometimes reflow back into brain and spinal cord tissues. It is caused by a narrowing of the veins.

It is not yet known how many people with MS have CCSVI, but preliminary

evidence from a prevalence study going on at the University at Buffalo suggests that a proportion of people without MS also show signs of CCSVI.

HOW CCSVI WAS FOUND

The first investigations — made possible by recent advances in ultrasound imaging — began at the University of Ferrara in Italy. Dr. Paolo Zamboni and colleagues published preliminary findings of their first study in June 2009 and named the abnormality CCSVI. Further studies are now taking place at other centers, including the University at Buffalo, where researchers are collaborating with Dr. Zamboni's team.

CAN CCSVI BE TREATED?

To date, endovascular surgical procedures to correct CCSVI in people with MS have been “open label” rather

than done in the context of controlled trials. Several private, mostly for-profit groups are advertising procedures to improve blood flow by inserting a tiny balloon or stents into blocked veins. It is prudent that such surgical procedures be undertaken in conjunction with formal clinical trials in order to assure that rigorous safety protocols and long-term monitoring standards are followed.

CCSVI POTENTIAL IN MS

Dr. Zamboni emphasizes the need for more research on his hypothesis, noting that it is still not proven whether CCSVI is a cause of MS or is related to MS in some other manner. He recommends that people with MS remain on their immunomodulatory therapies — as has his wife who has MS and has undergone the surgical procedure.

The Society's commitment

WHAT'S BEING DONE NOW

The National MS Society shares the public's sense of urgency to quickly advance any lead that may have the potential of stopping, repairing or preventing MS. The Society is committed to funding expanded research.

In December 2009, the Society called on investigators worldwide to apply for CCSVI research grants. International experts in MS and vascular diseases are currently reviewing proposals and new research projects are expected to begin July 1, 2010.

CCSVI WEBCAST

To open the discussion to a wide audience of scientists and lay people, the National MS Society and the

American Academy of Neurology co-hosted a Web forum on April 14. Panelists included: Dr. Zamboni; Dr. Aaron Miller, AAN Board member and chief medical officer of the Society; Dr. Robert Zivadinov, a neuroimaging specialist studying CCSVI; and Dr. Andrew Common, head radiologist at University of Toronto's St. Michael's Hospital. See next page for a report on the webcast. The complete April 14 program is now available online at nationalMSsociety.org/CCSVI.

CCSVI: What the experts say

A work in progress

BY ALISON DALE

The National MS Society arranged to have an independent freelance journalist who lives with MS attend and report on the April 14 Web forum.

As someone who remembers when there were no treatments for MS, I've gotten used to the fact that now there are many and more seem to be coming out all the time. My response to each new development is usually a mixture of hopefulness balanced with a healthy dose of skepticism. Personally, I think the successful management of MS requires an arsenal of medications, therapies and assistive devices. However, after attending the forum sponsored by the Society and the American Academy of Neurology in conjunction with the AAN's annual meeting in Toronto, I am here to report that the arsenal may have just expanded significantly.

A panel of four doctors participated in a 90-minute webcast that focused on the recent preliminary findings of Dr. Paolo Zamboni, a vascular specialist from the University of Ferrara in Italy.

Dr. Zamboni has identified the presence of a vascular abnormality in MS patients called chronic cerebrospinal venous insufficiency, or CCSVI. This is a condition where narrowed veins in the neck lead to abnormal blood drainage from the brain.

Furthermore, Dr. Zamboni reported that treating this condition with balloon angioplasty (a routine vascular procedure applied in a new way) corrects CCSVI and produces improvement in MS symptoms. Patients reported a loss of fatigue, fog and having a lot more energy. One subject stopped having headaches and another reported being able to dream for the first time in years.

Researchers have said that between 60 and 90% of MS patients showed signs of blocked veins, with the higher rates among those with more severe disease.

While these findings are extremely compelling, the consensus of all four doctors on the panel was that more research under carefully controlled

conditions is needed before the treatment can be made available. It should be viewed as a work in progress.

"Clearly, there is prevalence of CCSVI with ongoing disease, which must be investigated further," said Dr. Robert Zivadinov, who is studying the connection between MS and CCSVI at the University at Buffalo. His research shows that people with other neurologic disorders as well as some healthy people also exhibit what may be CCSVI. He offered the idea that CCSVI could turn out to be a risk factor for MS rather than a result of the disease.

"What can the MS community do to accelerate this process?"

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The forum in action. From the left, Dr. Zivadinov, Dr. Common, Dr. Miller and, at the podium, Dr. Zamboni.



Dr. Aaron Miller, Director of the MS Center at Mount Sinai, New York and Chief Medical Officer of the MS Society, called Dr. Zamboni’s findings “surprising and intriguing,” and joined the other panelists in cautioning that more research is needed to firmly establish the connection between CCSVI and MS.

Dr. Andrew Common, Radiologist in Chief at St. Michael’s Hospital in Toronto, warned patients against seeking treatment at one of the many clinics that are popping up and offering treatment for CCSVI for thousands of dollars. He suggested that patients needed to be in a clinical trial in order to receive the full benefits of the procedure. These would include having an experienced interventional radiologist for diagnosis, collaboration between the surgeon and a neurologist, as well as safety protocols and thorough follow-up.

WHAT DOES THIS FINDING MEAN ABOUT MS ITSELF?

For years we have been told that MS is an autoimmune disease in which the immune system attacks the myelin sheath that covers nerve endings in a process called demyelination. Common wisdom dictates that the disease is related to nerve damage, not blood flow. Could it be that the cause of MS lies elsewhere?

A whole new way of looking at MS is on the horizon. New studies are imminent. The experts have many questions to answer such as: Is CCSVI a result of MS or the cause of the disease?

Should all MS patients be tested for CCSVI? What are the long-range effects of treating CCSVI? What MS symptoms are impacted by treating CCSVI?

WHAT SHOULD WE DO NOW?

MS patients had questions of their own, which they called in during a Q&A session following the panel: Should I get tested for CCSVI? Is the treatment safe? Do the improvements last? Does gender make a difference? At what point will this be mainstream? In most cases, the doctors didn’t have answers because they don’t know what the outcomes of future studies will be.

One of the most important questions was: What can the MS community do to accelerate this process?

The answer was simple: Push for more funding dollars. (National Institutes of Health funding for research is now at an all-time low.)

WHEN WILL WE KNOW MORE?

Only rigorous research and further studies will provide the information needed to move forward. The doctors acknowledged urgency in the MS community to find out more about CCSVI and its treatment. They also stressed the importance of balancing this need with properly controlled trials to answer these essential questions. In the meantime, the doctors emphatically stated that MS patients should not stop their current treatments. If some-

“Is CCSVI a result of MS or the cause of the disease?”

one wants to be tested for CCSVI and receive the treatment, they should do so by enrolling in a trial.

In his charming Italian accent, Dr. Zamboni agreed only up to a point. He said that if an MS patient isn’t responding to traditional treatments and the disease is rapidly progressing, “I invite neurologists to consider to offer this treatment under compassionate grounds.”

Both Dr. Zamboni and Dr. Zivadinov speak with heavy accents that made this already complex subject matter even more difficult for me to understand. For instance, it took me about fifteen minutes to realize the word I kept hearing was “angioplasty.” But at the end of the day, what was absolutely clear was that this is an exciting time in the MS community.

APRIL 17, 2010

Alison Dale was diagnosed when she was 15. She lives in Los Angeles, is a member of the Writers Guild of America West and serves on their Writers with Disabilities Committee. Her most recent article for *Momentum* magazine, “Winning an Insurance Appeal,” appeared in the Spring 2010 issue.

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Staying informed about CCSVI

STEPS YOU CAN TAKE

Visit nationalMSSociety.org/CCSVI to find:

- Background and up-to-the-minute developments, including any clinical trials seeking volunteers.
- Recording of the 90-minute webcast on April 14, 2010, and information on the latest published studies, including those reported at the April 2010 American Academy of Neurology meeting.

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Webcast panelists

DR. PAOLO ZAMBONI, director of the Center for Interdepartmental Research and Services in Vascular Medicine and of the Department of Surgery, Anesthesiology and Radiology, and assistant professor at the University of Ferrara, Italy, and author of "Chronic cerebrospinal venous insufficiency in patients with multiple sclerosis," *J Neurol Neurosurg Psychiatry*, 2009.

DR. ROBERT ZIVADINOV, director of the Buffalo Neuroimaging Analysis Center and associate professor of Neurology at the University at Buffalo, State University of New York.

- A comprehensive list of answers to the most frequently asked questions.
- Abstracts and references on CCSVI to facilitate discussion with your neurologist or health-care and other professional advisors about your personal options.

Support CCSVI research by making a request in writing along with your contribution to the National MS Society.

Call the Society at 1-800-344-4867 for more assistance.

Sign up to receive National MS Society eNEWS in your inbox every month. The eNEWS has reported on CCSVI every month since October 2009. Go to nationalMSSociety.org/signup.

DR. ANDREW COMMON, radiologist in chief and division head of Interventional Radiology, and assistant professor, St. Michael's Hospital, University of Toronto, Department of Medical Imaging, Ontario, Canada.

DR. AARON MILLER, professor of Neurology and medical director of the Corinne Goldsmith Dickinson Center for MS at Mount Sinai Medical Center, New York, member of the American Academy of Neurology Board of Directors, and chief medical officer for the National MS Society.

MODERATOR, JAY MAC BRIDE, writer and editor for the American Academy of Neurology.

WEBCAST REPORTER, ALISON DALE, freelance writer for *Momentum*.

CCSVI Research Funding Timeline

DECEMBER 16, 2009

National MS Society issues a formal Request for Proposals, distributed worldwide.

FEBRUARY 2010

CCSVI research proposals received from numerous investigators in seven different countries.

MAY 2010

An international panel of MS and vascular disease experts conducts expedited reviews of all applications received.

JUNE 2010

Funding decisions announced.

JULY 1, 2010

Anticipated start date for funding any successful research applications.



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