



W5 - Liberation Treatment Q and A

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A group of doctors in Italy is investigating a fascinating new treatment for multiple sclerosis based on a theory that, if proven true, could radically alter the lives of patients. An investigation by CTV's W5 reveals this treatment appears to stop the disease from progressing. Here are further details on the treatment.

What is CCSVI?

CCSVI is a condition called "Chronic Cerebrospinal Venous Insufficiency" and was discovered by Dr. Paolo Zamboni, a vascular surgeon at the University of Ferrara in Italy. It refers to a narrowing or blockage of the primary veins draining blood from the brain to the heart. These include the jugular veins, veins along the spinal column and the azygos vein in the upper chest.

This narrowing restricts the normal outflow of blood from the brain. As a result, the blood often "refluxes" that is: it flows backwards into the brain. Some think the resulting flow and building pressure pushes blood into the tissue around vessels in the brain, resulting in toxic iron deposits that some believe may trigger inflammation, injury to brain tissue and cell death.

Here is a full list of [Zamboni's published studies and presentations](#).

What is CCSVI's relationship to MS?

Dr. Zamboni has used Doppler ultrasound to scan the heads and necks of over 500 MS patients and found the blocked, narrowed and sometimes missing veins of CCSVI in almost 100 per cent of them. These problems were found only in MS patients, not in healthy people, nor in those with other neurological conditions.

Dr. Zamboni's first study involving Doppler ultrasound was published in 2007 in the journal *Current Neurovascular Research*. Most of the MS patients have CCSVI either in the jugular veins or in the main vein in the central chest called the azygos. The more vein malformations that impede flow, the greater the severity of symptoms, the researchers contend.

Dr. Zamboni says his findings are considered "proof of concept" that CCSVI is strongly associated with MS. In December, 2008, Dr. Zamboni and his team published their findings in the *Journal of Neurology, Neurosurgery and Psychiatry*.

There are also studies beginning in Bulgarian, Greece and Jordan.

What role does iron play in MS?

Scientists have long recognized MS patients have increased amounts of iron in the brain compared to healthy people. Iron is dangerous to the brain because it produces free radicals which kill brain cells. Zamboni noticed iron deposits occurred around veins and he surmised the iron accumulation was caused by a problem with drainage in the veins that flow from the brain.

He believes the narrowing or blockages in the veins of MS patients cause blood to flow backward into the vein and deposit the toxic iron. According to Zamboni's theory, this causes inflammation, and triggers an immune response -the picture of MS. New MRI technology is allowing scientists to more clearly see iron in the brain, speeding study.

Here are [pictures of iron deposits](#) in MS and normal brain tissue.

Has this theory been raised before?

It has, most recently in 2003. Researcher Rohit Bakshi and colleagues at the University of Buffalo suggested iron deposits deep in the brain might cause MS. In the 1980s, [Dr. Franz Schelling](#) in Austria also made a link. But it wasn't until Zamboni began doing his ultrasounds on patient necks followed by his experimental treatment that the idea has developed any traction.

What causes CCSVI?

Doctors are not sure but they believe that veins that are susceptible to blocking and twisting develop in the womb as a congenital birth defect or early in childhood. There could be environmental factors as well.

There is also a theory that low levels of vitamin D might play a role. It's been well-documented that higher rates of MS are seen in countries with lower exposure to vitamin D through sunlight and diet. Since vitamin D is critical to the normal development of the immune system and also in the development of blood vessels and endothelial tissue -- the thin layer of cells that line the interior surface of blood vessels. The theory is that low levels of vitamin D in utero or early in childhood may impair the body's ability to form healthy vessels and lead to the narrowing and blockages seen in CCSVI. But this is not yet proven; more research is needed.

An international group of doctors who specialize in disorders of the veins has issued a consensus document on the diagnosis and treatment of these problems, including CCSVI. The International Union of Phlebology officially classified CCSVI as a congenital vascular malformation, outlining official guidelines for diagnosis and treatment.

Dr. James Laredo, a vascular surgeon at Georgetown University Hospital, and one of the authors of the statement, said the members of the group voted unanimously in favour of including CCSVI as a venous malformation. The statement also says the origins of this novel condition appear to take root during development in the uterus.

Zamboni, is part of the International Union of Phlebology.

What is "The Liberation Treatment"?

It's a still-experimental procedure developed by Zamboni and his colleagues, Dr. Fabrizio Salvi and Dr. Roberto Galleotti. Just as doctors do in angioplasty to unblock veins to the heart, with this treatment, doctors thread wires through the veins that drain blood from the brain. When they find a narrowing, they insert a balloon and inflate it. The pressure of the balloon usually opens the narrowed vein, though sometimes doctors need to use a balloon with small blades on it to cut through tissue that may be causing the blockage.

Doctors say the procedure is safe and have noted no side effects in the Italian patients they've treated. Some patients had to be treated twice before the narrowed vein stayed open. The doctors call the operation the "Liberation Treatment" because it "liberates" the blood, allowing it to flow freely.

According to Hilaroscere Foundation, which funds the research: "At 2-year follow-up, no major complications were observed... this treatment decreases pressure in the cerebral veins in a highly significant way, thus showing its enormous anti-inflammatory potential."

In a study published in the December issue of the *Journal of Vascular Surgery*, researchers report on 65 MS patients 18 months after surgery. W5 has reviewed the study, which found that patients, particularly those with relapsing-remitting MS, treated with endovascular therapy showed a decrease in the number of disease relapses, a marked reduction in the number of active brain and spinal lesions and also a clear-cut improvement in the patients' quality of life.

What do the early studies of the Liberation Treatment show?

Dr. Zamboni has treated about 120 MS patients using his new treatment, 65 of whom his team is following over several years to see the effects.

In preliminary data about the treatment, released at a Sept. 8 meeting of researchers interested in CCSVI, Zamboni and his team were able to show that in patients with the clinical form of relapsing-remitting MS - the most common - there was a drop in the number of active brain lesions in the patients that persisted up to 18 months after surgery. As well, in the two years before surgery, acute MS attacks were noted by 50 per cent of the recruited patients, but in the two years following surgery, 73 per cent of the patients had no more attacks. In all these patients, cognitive and motor activities assessed by an outcome measure called MSFC were significantly and persistently improved. The same finding was not made with patients with the progressive forms of the disease; in the latter, however, disease progression was stopped and the patients' quality of life improved.

A news release about the preliminary data from that study [can be viewed here](#).

Does the procedure remove iron from the brain?

Scientists don't know this for sure but they suspect that if blood is flowing freely out of the brain again, perhaps iron stores in brain tissue will diminish. This is an area of future study. The next question would be: if iron levels drop, do symptoms of MS diminish too?

What has been the MS Society's reaction?

The MS Society of Canada is reviewing proposals for research. The Italian Multiple Sclerosis Foundation says it will allocate up to \$4.5 million to fund ongoing research into CCSVI, a condition linked to multiple sclerosis.

The foundation says it is accepting research proposals until March 8 from scientists interested in studying "chronic cerebro-spinal venous insufficiency," a newly-discovered condition uncovered by a team at the University of Ferrara in Italy and lead scientist Dr. Paolo Zamboni.

"We await proposals from groups of Italian researchers, in particular by the research groups that are already active with Prof. Zamboni," the foundation said in an Italian news release.

Zamboni's team believes that CCSVI causes veins in the neck and upper chest to twist, narrow or become blocked; in some cases, these veins never form at all. The result is poor blood drainage from the brain. Zamboni has found that more than 90 per cent of patients with MS have these malformed veins, and improper blood flow from the brain.

Roberta Amaedo, president of the Italian Association for Multiple Sclerosis, said in the release: "We need certainty about the relationship between MS and CCSVI and on the clinical course that this can cause, and on that, clinical trials will make an important contribution."

The association also cautioned patients against seeking endovascular or surgical procedures to open these blocked veins outside of controlled research studies.

Where can I get tested for CCSVI?

CCSVI is such a newly identified condition, many doctors and MS centres are only learning about it now. Very few ultrasound technologists know how to perform the neck and head scan developed at the University of Ferrara.

Who is performing the Liberation Treatment?

The Liberation Treatment is still an experimental treatment and is not widely offered except as part of some studies underway in Europe. There are official studies underway in Canada or the U.S though a number of

centres, including UBC are planning research programs.

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