

'This is what it must feel like to witness medical history in the making'

Notes from the first annual meeting of the International Society of Neurovascular Diseases

by [Anne Kingston](#) on Tuesday, March 22, 2011 1:38pm - [51 Comments](#)

Sitting through two days of research presentations at the first annual meeting of the [International Society of Neurovascular Disease](#) (ISNVD), three things became manifest: One, that this is what it must feel like to witness medical history in the making. Two, that science is just beginning to twig onto the complexity of the venous system—and the vascular system's role in neurodegenerative diseases. And three, that Canadian multiple sclerosis patients bear a double burden—living with a devastating, degenerative condition and residing in a country that's increasingly exhibiting a singular lack of political or medical will to treat them for something as basic as insufficient blood flow.

The three-day conference held last week in Bologna, Italy, focused on venous abnormalities and the association of these abnormalities in people with MS—a condition identified as chronic cerebrospinal venous insufficiency, or CCSVI, by Italian doctor Paolo Zamboni. Impaired blood flow in the jugular and or azygos veins, Zamboni posited, caused blood to reflux to the brain, where it creates iron deposits that could trigger MS symptoms. Administering an angioplasty—sending a tiny balloon up the vein to restore blood flow—caused MS symptoms to abate, sometimes dramatically, and even halt the disease's progression, he found.

Since Zamboni's research made headlines in November 2009, CCSVI has been hotly debated, embraced, rejected as scientifically unproven, and even ridiculed. The notion that MS might have a vascular component, a theory that's lurked in the background for more than a century, represents a huge paradigm shift for the medical establishment which has long defined the disease as a neurological-autoimmune condition, even though the autoimmune theory too remains unproven. MS is a medical mystery—it's cause unknown, no cure in sight. Symptoms and prognoses vary radically. Drug therapies, a \$10 billion industry primed to grow to \$15 billion by 2015, modify and reduce symptoms for some patients but come with exorbitant price tags and a host of side effects that can include death.

Dissatisfaction with the MS status quo can be measured by the number of patients estimated to have received CCSVI treatment internationally—more than 12,000. Among them are hundreds, maybe thousands, of the 75,000 Canadians with MS. Venous angioplasty is not available to MS patients here, so they're flocking to clinics in the U.S., India, Mexico, Poland, Costa Rica and Bulgaria, willing to pay upwards of \$10,000. Traveling offshore can be risky. Screening and treatment protocols are inconsistent. Some patients who've received treatment say they've been dropped by their doctor and denied aftercare. Use of stents to keep veins open, contrary to Zamboni's protocol, adds another level of uncertainty. Ontario resident Mahir Mostic died in Costa Rica last year after being forced to return to that country with post-surgery complications.

Still, CCSVI has gained international traction. The International Union of Pheology, of which Canada is a member, recognized it as an official stand-alone medical condition last year. Last July, Zamboni founded the ISNVD with a multidisciplinary group of vascular surgeons, interventional radiologists, physicists, even a few neurologists, including San Diego neurosurgeon David Hubbard, who broke ranks with colleagues after his 27-year-old son Devin was diagnosed with MS. Initially a CCSVI skeptic, Hubbard changed his mind after reviewing the science and observing improvements in his son after his treatment. He's now conducting research through the [Hubbard Foundation](#), which investigates the vascular component of neurological disorders. Some of his findings presented at the ISNVD conference, which have yet to receive peer review, confirm sluggish blood flow in MS patients and quantifiable post-treatment improvements.

The forum brought dozens of medical specialists from around the globe—the U.S., Poland, Jordan, the UK, New Zealand, Italy, India, Greece, Kuwait, Russia—to share research, and establish standardized protocols for diagnosis and imaging. There were sessions on the role of iron in the brain, oxygenation and tissue drainage, blood flow rates in MS patients, advanced diagnostic imaging, and the development of mice models of CCSVI. At a workshop, Zamboni demonstrated new technology designed to improve the ease and accuracy of CCSVI diagnosis.

Thanks to new scanning technology, the complexity of the brain's vascular network is revealing itself. Toronto-born physicist Mark Haacke, a world leader in diagnostic imaging affiliated with Detroit's Wayne State University and Hamilton's McMaster University, made two presentations in Bologna. His research has identified over 60 categories of vascular abnormalities in the chest, head, neck, and spine

Zamboni called the meeting "an overview of the possibilities." In an interview with Maclean's, he expressed delight with the quality—and quantity—of the research presented, which included positive results from the first double-blinded study on CCSVI treatment from the U.S. Zamboni was particularly buoyed by epistemological data from Greece, Jordan and northern Europe. "All of it shows a strong association between CCSVI and MS in more than 90 per cent across latitudes and genetic groups."

Still, these are early days. Many questions remain unanswered. Why are not all MS patients candidates for CCSVI treatment? Why do a small percentage of non-MS patients have CCSVI? Why do people respond differently to treatment? And what is CCSVI's role in unlocking the mysteries of blood-brain-barrier neurological conditions such as Alzheimer's and Parkinson's?

Ongoing research and the growing number of CCSVI procedures conducted internationally should shed light. Numerous clinical treatment trials are underway in the U.S. In the UK, British GP Tom Gilhooly, who has set up a clinic in Scotland, plans to open one in London.

Then there's Canada, which increasingly is odd-man-out in denying treatment—even in clinical trials. Yet venous angioplasty is a standard procedure in Canadian hospitals: if someone without MS exhibited compromised venous blood flow they'd be treated—and it would be covered by provincial health plans.

There's also odd symmetry in the fact the people making the decisions about CCSVI know the least about it—or have proved the most resistant to Zamboni's hypothesis. The "expert" panel convened by the Canadian Institute of Health Research and MS Society of Canada last August that recommended the federal government not fund clinical trials, for example, actively excluded anyone with experience diagnosing or treating CCSVI—i.e., actual "experts"—though it did include several doctors who'd expressed criticism of Zamboni's hypothesis.

The MS Society of Canada has adopted a "wait and see" attitude. Last year it donated \$700,000 to co-fund seven studies with its U.S. counterpart, none involving treatment, to investigate whether CCSVI warrants further investigation. Still, there's indication the society sees promise in CCSVI: it secured the domain name ccsvi.ca in November 2009 after Zamboni's research became public.

Liberal MP Kirsty Duncan, a Ph.D. scientist who led a House of Commons Sub-Committee on Neurological Disease that investigated CCSVI, has been a tireless advocate for clinical trials. "People are dying every day of this disease," she says. "We have to examine the science." The tragic example of Bill Peart of Pictou County, N.S., drives that point home. Peart appealed to the Nova Scotia government earlier this month to receive CCSVI treatment on compassionate grounds because his declining health prevented him from traveling to New York state for a scheduled appointment. His request was denied. He died on Saturday.

There are signs of snail-like movement—much stemming from patient pressure or elected officials who have relatives suffering from the disease. Saskatchewan, the province with the highest incidence of MS, is funding clinical trials, though they don't include treatment. Newfoundland and Labrador have also committed to observational studies of post-treatment patients. Earlier this month, Ontario announced it would set up a medical panel to investigate after-care for CCSVI patients, though the group won't be assessing the merits of CCSVI treatment.

The small Canadian contingent at the ISNVD included some of this country's most vocal CCSVI advocates, including Dr. Bill Code, who saw his career as an anesthesiologist cut short after his MS diagnosis 16 years ago. Since then, the Vancouver Island resident has written several books on living with MS that focus on an anti-inflammatory diet, nutrition and adopting an integrative medical approach. After Code received CCSVI treatment in California last fall, many of his symptoms—headaches, balance and bladder problems, fatigue—disappeared, he reports. "I have no doubt CCSVI is the real deal," he says.

Other doctors also participated in the program. Mark Godley, the medical director of Vancouver's False Creek Medical Centre, who has been stymied in his quest to offer the procedure at the private clinic, acted as a chairperson for the Congress committee and moderated several panels. Godley likens the flight offshore for CCSVI treatment to the black market created for alcohol during Prohibition—and a sign of a broken Canadian health-care model.

Vascular surgeon Sandy McDonald, the only Canadian doctor to conduct clinical treatment trials of CCSVI, sat on the faculty that established a standardized CCSVI screening protocol. Last year, the Barrie, Ont.

resident conducted a pro bono trial on six MS patients—all of whom he claims experienced salutary results—before it was shut down by the College of Physicians and Surgeons. McDonald, whose Barrie clinic now sees people from around the world for CCSVI scanning, was impressed with the quality of the research—and the caliber of minds present. “The first reported North American trial indicates significant improvement in quality of life and reductions in MS symptoms, physical health decreased fatigue and improvement in balance, cognitive function, coordination, heat intolerance and memory loss,” he says, adding: “All in all, an amazing meeting. I can only hope that several Canadian ‘experts’ were in attendance.”

Indeed, a few people in a position to influence policy were there: Julian Spears, co-director of the neurovascular program at Toronto’s St. Michael’s Hospital, who will sit on the Ontario after-care committee; the MS Society of Canada sent Karen Lee, assistant vice-president of research and programs. What they took away from the conference is unknown, at least publicly. Both declined to be interviewed by Maclean’s.

Zamboni expresses surprise that his procedure has become so politicized. It was never his intent that CCSVI cut neurologists out of the equation. “No. They want to take care of one aspect of this complex disease.”

Resistance to any new approach is predictable, particularly in medicine, he says: “It’s very difficult when you produce something so different. You need time—digestive time.” Of course, time is something MS patients don’t have—as witnessed by the once-unthinkable spectre of Canadians flocking to Bulgaria for medical treatment to restore blood flow. The ISNVD’s next annual meeting is scheduled for Miami this time next year. It’ll be fascinating to see where we are then.