The Liberation Treatment: A whole new approach to MS

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Amid the centuries-old castles of the ancient city of Ferrara is a doctor who has come upon an entirely new idea about how to treat multiple sclerosis, one that may profoundly change the lives of patients.

Dr. Paolo Zamboni, a former vascular surgeon and professor at the University of Ferrara in northern Italy, began asking questions about the debilitating condition a decade ago, when his wife Elena, now 51, was diagnosed with MS.

Watching his wife Elena struggle with the fatigue, muscle weakness and visual problems of MS led Zamboni to begin an intense personal search for the cause of her disease. He found that scientists who had studied the brains of MS patients had noticed higher levels of iron in their brain, not accounted for by age. The iron deposits had a unique pattern, often forming in the core of the brain, clustered around the veins that normally drain blood from the head. No one had ever fully explained this phenomenon, considering the excess iron a toxic byproduct of the MS itself.

Dr. Zamboni wondered if the iron came from blood improperly collecting in the brain. Using Doppler ultrasound, he began examining the necks of MS patients and made an extraordinary finding. Almost 100 per cent of the patients had a narrowing, twisting or outright blockage of the veins that are supposed to flush blood from the brain. He then checked these veins in healthy people, and found none of these malformations. Nor did he find these blockages in those with other neurological conditions.

"In my mind, this was unbelievable evidence that further study was necessary to understand the link between venous function and iron deposits on the other," Zamboni told W5 from his research lab in Ferrara.

What was equally astounding, was that not only was the blood not flowing out of the brain, it was "refluxing" reversing and flowing back upwards. Zamboni believes that as the blood moves into the brain, pressure builds in the veins, forcing blood into the brain's grey matter where it sets off a host of reactions, possibly explaining the symptoms of MS.

"For me, it was really unbelievable to understand that iron deposits in MS were exactly around the veins. So probably, it is a dysfunction of drainage of the veins," Zamboni said.

"This is very important, because iron is very dangerous, because it produces free radicals, and free radicals are killers for cells. So we need to eliminate iron accumulation."

Zamboni dubbed the vein disorder he discovered CCSVI, or Chronic Cerebrospinal Venous Insufficiency, and began publishing his preliminary research in neurology journals.

He soon found that the severity of the vein blockages were located corresponded to the severity of the patient's symptoms. Patients with only one vein blocked usually had milder forms of the disease; those with two or more damaged veins had more severe illness.

Zamboni found blockages not only in the veins in the neck directly beneath the brain -- the jugular veins -- but in a central drainage vein, the azygos vein, which flushes blood down from the brain along the spine. Blockages here, he found were associated with the most severe form of MS, primary progressive, in which patients rapidly deteriorate. For this form of MS, there currently is no effective treatment.

As for how these vein abnormalities form, Zamboni isn't sure. He believes, though, that congenital defects, problems that likely formed before birth, can be blamed for most of the problems, though this has not been conclusively proven.

Most neurologists Zamboni initially approached with his findings dismissed them. But one specialist, Dr. F. Salvi, at Bellaria Hospital in Bologna, was intrigued by the concept. He began sending Zamboni MS patients for CCVIS testing, to see if what he was finding was correct. The images of narrowed or blocked veins, called "strictures," were irrefutable for Salvi.

Focus on a treatment

But Dr. Zamboni had an even more important idea. If key veins of MS patients were blocked, perhaps he could open them and restore normal blood flow?

Taking a page from standard angiography, in which doctors use balloons to open up blocked arteries that feed blood from the heart, he enlisted the help of vascular surgeon Dr. R. Galeotti, also at the University of Ferrara and Santa Anna Hospital. Three years ago, the team began a study in which they treated 65 MS patients to see if endovascular surgery would restore flow in these vessels and lessen MS symptoms.

The study detailing those results will be published in the Journal of Vascular Surgery on Nov. 24. But preliminary results, already released, show patients had a decrease in the number of new MS attacks, a big reduction in the number of brain lesions that define MS, and improved quality of life. The only time symptoms returned for the patients was when the veins re-narrowed.

Because the surgery freed the blood flow, the team dubbed the procedure "The Liberation Treatment."

Zamboni's sense is that the earlier patients are diagnosed and treated, the more function they will preserve,

and the less damage the improper blood flow will do to the brain.

"Because MS is a progressive disease and strikes young people, if we lose time, there are a lot of young people that will progress without possibility to get back. This is very heavy for me," he says.

Zamboni has also been studying the prevalence of CCSVI with a team at the University of Buffalo in New York, in collaboration with Dr. Robert Zivadinov. That study, to be published in January, has looked at 16 MS patients, including eight from the U.S and eight from Italy. All have been found to have blocked veins of CCSVI, just as Zamboni described, and all eventually underwent the Liberation Treatment.

Relief for patients

One of those patients was Buffalo resident Kevin Lipp. Lipp had MS for over a decade, and as part of the study, discovered he had five blocked veins in his neck. After undergoing the Liberation Treatment 10 months ago, he says he hasn't had a single new MS attack.

Zamboni emphasizes that the Liberation Treatment does not make people in wheelchairs walk again. Rather, it seems to stop the development of further MS attacks, and in some cases, improves movement and decreases the debilitating fatigue that are the hallmarks of MS.

The foundation that has sponsored Zamboni's research, the Hilarescere Foundation, also urges cautious restraint.

"We can't give the illusion to patients that this is a guaranteed treatment and it is easy. This is not right. And we have never done this," says Hilarescere President Fabio Roversi-Monaco. "We don't say this is a cure for M.S. We only say that research is advancing, and there is encouraging data but we are waiting for more conclusions."

Dr. Zivadinov in Buffalo is now starting a new study, recruiting 1,600 adults and 100 children, half of them MS patients. He plans to use ultrasound and MRI scans to confirm if those with MS also have CCSVI and if their family members have the abnormalities too.

Prof. Mark Haake, a neuro-imaging scientist at McMaster University and Wayne State University in Detroit is also intrigued by Zamboni's findings. He has long been seeing iron deposits in the brains of MS patients using a specialized MRI analysis called SWI - specific weighted imaging. When he saw Zamboni's initial publications, he immediately contacted the Italian doctor and began collaborating.

Population studies under way

Haake too is initiating a study, asking neurological centres across North America and Europe to take some extra MRI scans of the neck and upper chest of MS patients. The scans can then be electronically sent to his research team for analysis. He believes this grassroots approach could spur larger and more in depth studies. He's hoping he can engage MS specialists and vascular surgeons, interventional radiologist around the world to study the theory and then move to diagnosing and treating MS patients quickly.

"I think patients do play a role, because there are millions and millions of dollars donated to MS Societies and a lot of money set aside by the government to study MS research and right now, 99.9 per cent of that money goes somewhere else," he told W5.

"So the patients need to speak up and say 'We want something like this investigated, at least at an early stage, to see if there is credence to this theory.' Even if it is 10 or 20 per cent of these people who can be helped, that needs to be investigated," says Haacke.

Haake's research is being done with no funding; he's unwilling to wait the nine months to a year needed to get formal research funding applications approved. Urgency, he says, is needed in finding the answer to the question of whether Dr. Zamboni is right.

"Certainly, I continue my battle because I am fully convinced that this is the right thing for the patient," he says.

The MS Societies of Canada and the U.S. are reticent to support Zamboni's theories. They maintain that: "Based on results published about these findings to date, there is not enough evidence to say that obstruction of veins causes MS... It is still not clear whether relieving venous obstructions would be beneficial."

Interest in CCSVI growing

But CCSVI has become a subject of intense interest among MS patients who are texting and emailing details of Zamboni's work, locating the few centres around the world that have started to work on studies on CCSVI and the Liberation Treatment.

Zamboni says every day, MS patients hear about his theory and either write, email or call him asking for treatment he can't yet provide. Still, some surgeons in the U.S. are now offering the surgery Zamboni's team has pioneered.

Jeff Beal, an L.A-based, Emmy-Award-winning musical director has already paid to have the surgery procedure. After he was diagnosed with MS five years ago, he was left unable to work a full day and worrying he would spend the rest of his life in a wheelchair. Unable to come to terms with the diagnosis, his wife, Joan, set to find new treatments and eventually came upon Zamboni's work. Unable to get her husband treated in Italy, she convinced a Californian vascular surgeon who already performs similar surgery on leg veins to look at Zamboni's work and test Jeff for CCSVI. Jeff was diagnosed with two blocked jugular veins and treated with the Liberation Treatment. (with a slightly different procedure than the italan one..using Stents) He now says he has much more energy and none of the chronic fatigue that used to limit his activity.

"I reached what I would call sort of a higher plateau, in the sense of the most debilitating symptom, which is

the fatigue. So, I still have fatigue every day, I still battle it; it's still one of my symptoms. But in terms of the total reservoir of energy, it's much greater than it used to be. And that's a huge gift, especially to my family," Beal told W5.

His wife Joan was delighted with the surgery's results.

"Suddenly, he's helping Henry with his homework and he's playing trumpet duets with Henry and he's awake. And there's this presence in the house that hadn't been there for two years," she said.

Joan has now become a "cheerleader" of Zamboni's work on MS chat sites, urging other patients to show their neurologists the material being published by the Italian team and to ask them to consider setting up a study in other MS clinics.

Among all of Zamboni's success stories and the patients who sing his praises is his wife Elena. Her MS caused her to lose her vision for a time and develop what she called "violent" attacks. She had difficulty walking and was losing her balance and feared a life in a wheelchair unable to care for herself. Elena became one of her husband's first ultrasound test patients and was found to have a complete closure of the azygos vein in her central chest. She was one of the first to be liberated almost three years ago. After having regular debilitating MS attacks for nearly a decade before, Elena has been symptom-free ever since. An elegant, intelligent woman, she now has a quick walk, with no sign of disability. Her husband couldn't be happier.

"What I think is this is probably the best prize of the research," says Zamboni.