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The ‘miracle cure’

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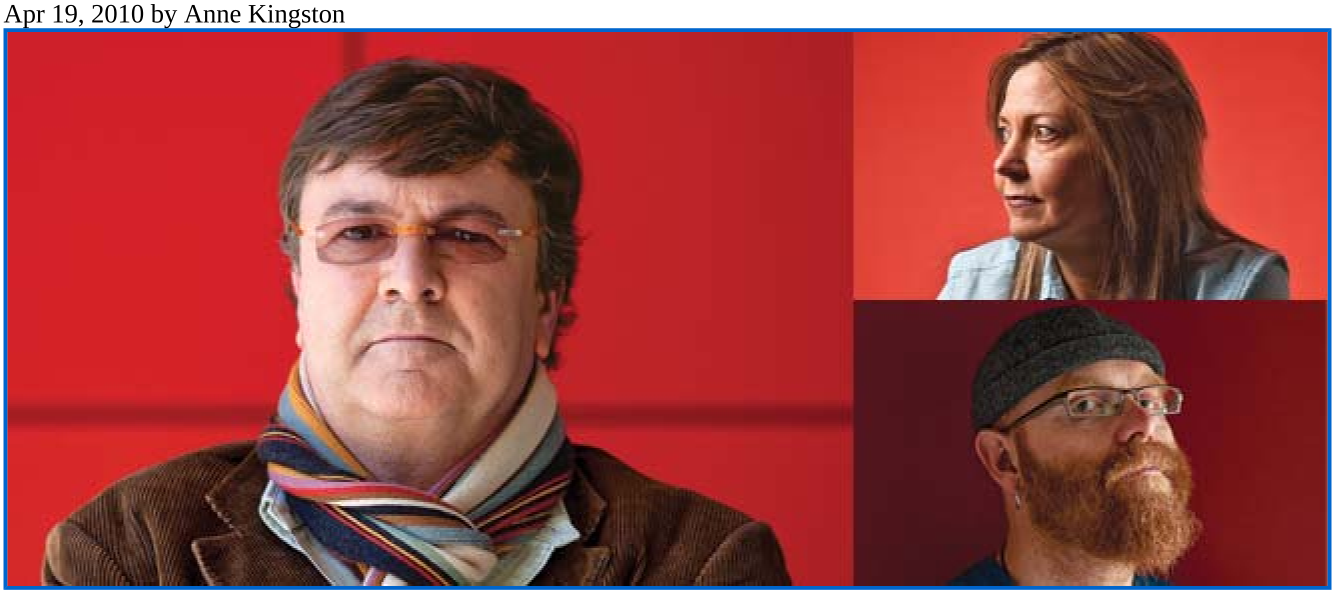

Photographs by Andrew Tolson

Last week, in a traditionally appointed Vancouver living room, Dr. Mark Godley made an announcement that could change the face of Canadian medicine. Addressing a multiple sclerosis support group that had formed on Facebook, the anesthesiologist and medical director of False Creek Healthcare Centre shared “very, very good news”: “A patient in B.C. had the procedure done here in B.C. today,” he said as the dozen people gathered erupted in claps, cheers and enthusiastic calls for details. The group here knows the lingo: “the procedure” is the radical and game-changing “liberation treatment” pioneered and named by Italian vascular surgeon Paolo Zamboni that has dominated MS chat rooms and academic research since it was first reported by media last November. The MS patient in B.C. showed results consistent with Zamboni’s, Godley reports: “He has warmth in his hands, the numbness has gone from his fingers, and for the first time [in years] he’s able to lie flat on his back.”

What’s stunning about Godley’s announcement is that, until now, the “liberation” treatment—a simple surgery that sends a tiny balloon to clear a clogged jugular vein—has been almost entirely unavailable in Canada, where it’s considered “experimental” by health officials. Provincial health care plans won’t fund it; doctors won’t perform it. Instead, Canadians have been flying to private clinics in Poland, Kuwait and India, paying upward of $10,000 for the surgery. In fact, the procedure that Godley describes was performed under the radar in an unnamed B.C. hospital, billed as a routine angioplasty. It was done “very quietly without the hospital knowing what he was really there for,” he says. Soon, though, such stealth will be unnecessary: in May, Godley said, his private clinic will be the first in Canada to openly offer the day surgery. “Wow!” cried out one member of the support group. “What’s the cost?” asked someone else, to which another replied, laughing, “Who cares?”

Such excitement has greeted Zamboni’s research among MS patients, who a year ago couldn’t have imagined a possible cure for the degenerative disease that affects 2.5 million people worldwide. Most are diagnosed at a young age—between age 15 and 40—more of them women than men, and most of Northern European descent. Canada has among the highest incidence of the disease—between 55,000 and 75,000 people, with 1,000 new cases every year. Not only is there no cure, researchers have not found a cause. All that’s known for certain is that the symptoms, which include numbness, loss of mobility, bladder malfunction and paralysis, are devastating.

Conventional thinking is that MS is an autoimmune condition that causes the body to attack and damage the protective covering, or myelin, around nerve cells in the brain and spinal cord, making them slow to emit impulses and move muscles. Zamboni’s findings, published in August 2009, point to the disease having its roots in the vascular system, a theory that dates back to the 19th century. When studying the ultrasounds and MRI results of MS patients, the medical professor at the University of Ferrara discovered that virtually all showed a blockage or a narrowing of veins leading from the brain, a condition he dubbed “chronic cerebrospinal venous insufficiency,” or CCSVI. Such blockages, he posited, could cause blood to flow back to the brain, resulting in toxic iron deposits that in turn could trigger MS symptoms. When he cleared the veins using a balloon angioplasty, Zamboni witnessed remarkable transformations: those in the early stage of the disease had a full recovery; those with severe disabilities showed marked improvement—more energy, renewed sensation and movement in hands and legs, and improved vision. Zamboni’s own wife, Elena Ravalli, who has MS and who inspired his research, has not had another attack since she had the procedure years ago.

As MS patients convened on the West Coast for Godley’s big news, the traditional medical gatekeepers of the disease were gathering in Toronto for the American Academy of Neurology’s annual meeting. Just how much MS has come to dominate the neurological agenda is reflected in the fact some 20 per cent of papers at the convention deal with the disease, a handful of which explore the possible CCSVI connection. Zamboni himself will make a star turn. The notion that MS could be caused by a vascular plumbing problem has turned MS research on its head, or, as a paper given at McMaster in February put it: “Is Multiple Sclerosis really Multiple Stenosis?”, the medical term for narrowed veins.

Many neurologists have yet to be convinced. At the far extreme, there’s professor Alastair Compston, head of the department of clinical neurosciences at the University of Cambridge and one of Britain’s pre-eminent MS researchers, who out-and-out dismisses Zamboni’s findings: “People with MS are unlikely to benefit from treatments that dilate blood vessels,” he said. Others suggest patients’ positive response is a “placebo effect.”

Dr. Amit Bar-Or, a neurologist at McGill University who co-authored a recent paper in the *Annals of Neurology*, takes a more measured approach. He says that Zamboni raises two important questions. Is CCSVI unique to MS patients, or do others have it too? And, if it is unique to MS, then is it a cause or a consequence of the disease? Bar-Or points out that as more research is conducted, there has been less and less conclusive evidence that CCSVI is found only in MS patients. Zamboni’s initial 2006 study showed CCSVI in 100 per cent of MS patients compared to zero in non-MS individuals; subsequent data by Zamboni and later researchers at the University of Buffalo, however, has not been so definitive: the first Buffalo study found 55 per cent of MS patients had CCSVI compared to 22 per cent of non-MS individuals. Then, findings released at the conference this week further showed “an increased prevalence of CCSVI in MS” but lower than Zamboni’s original study. “So what went from clearly distinguishing the illness from the non-illness [is] much more grey,” says Bar-Or

What’s more, if CCSVI isn’t the cause of MS, then liberation surgery may not be much help over the long term, says Bar-Or. “If you open up the vessels that are damaged as a consequence of the disease, you won’t necessarily solve the disease.” And given the “relapse-remission” cycle common in MS patients, it’s difficult to know yet—in the absence of rigorously controlled studies—whether individuals who report relief after liberation surgery are doing better “because of the procedure or in spite of the procedure.” Any neurologist will tell you that one constant in MS is that it’s ever-changing.

Another concern is the risk of using stents in veins (a departure from Zamboni’s balloon protocol), as many offshore clinics do to prevent them from collapsing. Inserting stents in veins, which tend to be floppy and flaccid, is more difficult and risky than inserting them in more rigid arteries. Even so, surgeons have performed angioplasties on veins since the late 1970s, mostly on legs. A CCSVI study at Stanford University was shut down in December after a stent migrated to one patient’s heart, requiring emergency surgery. Another patient died of a post-operative stroke.

The MS Society of Canada has shown reluctance to endorse CCSVI treatment. “This is a cause for real excitement,” president Yves Savoie says. Still, blind, placebo-controlled clinical trials are required. The history of MS research is peppered with purported cures—bee stings to snake venom. “We respect and honour the right of persons with MS to make the decision [about treatment],” Savoie says. “But we do not recommend people seek experimental treatment outside of clinical trials where there are safeguards for patient safety.”

Such caution is to be expected. It took Australian researchers a decade to gain acceptance for their research that proved ulcers were caused by a bacterium, not stress and lifestyle.

Geologist Ashton Embry, the founder of Direct-MS, Canada’s second largest MS charity, isn’t surprised by the skepticism. He experienced it first-hand as an early proponent of vitamin D in treating MS. “It’s finally starting to be accepted,” he says. “But if those people had been taking the proper amount of vitamin D for those 10 years it would have made an enormous amount of difference in their lives. That’s when I learned they didn’t give a damn about anything that wasn’t drugs.” And the market for MS pharmaceuticals is massive, with some estimates pegging revenues at $8 billion in 2009 and exceeding $12.5 billion by 2015. The battle comes down to competing interests, Godley says: “You have neurologists in the research communities that rely on corporate donations, large pharmaceutical companies that have a vested interest in maintaining or promoting the use of pharmaceutical agents.”

MS patients should be patient, Bar-Or says: “If this really is a cure then it ought to cure them in a year or two when we really will know more and will be much more able to endorse this as an approach.” But MS patients don’t have the luxury of time, says Godley: “If I put myself in the shoes of a patient with MS, I would want this done tomorrow. Not in six months—because I may be blind in six months. I may have no bladder control in six months. I may not be able to stand in six months.”

In Canada, MS patients and a handful of rogue doctors aren’t waiting for clinical trials or hypotheses to be proven. Dr. Sandy McDonald, a cardiac-vascular-thoracic surgeon in Barrie, Ont., has seen the benefits of CCSVI treatment first-hand. In what is believed to be the first informal liberation treatment trial, he performed six balloon angioplasties pro bono on MS patients in a limited trial earlier this year. One of his patients was able to give up his walker; a teenage boy could walk up and down stairs for the first time in years. Zamboni’s initial study intrigued him, McDonald says. He travelled to Italy to be taught Zamboni’s neuro-scanning protocol. And he weighed the ethical concerns.

“You look at the risk-benefit balance,” he says. “And, in this case, the risks are pretty darn small.” Using balloon angioplasties to clear jugular veins isn’t common, he says. But other “off-label” procedures (using medical devices in a manner they weren’t originally designed for) is routine. Venous angioplasty using stents is used to deal with renal failure all the time, McDonald says. “Are there controlled studies for that? No, but we’re doing it every day.” Cosmetic surgery is another off-label procedure, he notes: “It’s okay to get bigger breasts or a facelift, yet patients with MS, a debilitating, degenerative disease, have to wait for double-blind studies. Welcome to Canada.”

Gianfranco Campalani, a vascular surgeon in Belfast, Northern Ireland, who was diagnosed with MS in 1986, is even more blunt: “It’s unethical to prolong clinical trials when the procedure has been demonstrated amply that the risks are minimal or non-existent,” he says. Campalani had CCSVI treatment in Italy in 2006, administered by Zamboni. “The results were amazing,” he says. “My back was stronger; I could walk. Other functions not working 100 per cent came back.” His girlfriend cried the first time she saw him after surgery. Last year, when scans revealed a re-narrowing of the veins, he had another balloon angioplasty in Northern Ireland.

Campalani believes it’s scientifically acceptable that clinical trials of drugs be rigorous and safe and long given their potentially dangerous side effects. But CCSVI is different, he says: “If there are anomalies in the vascular system and you can demonstrate them, then forget about MS. You are not treating MS; you are treating a vascular condition,” he says. “And even an idiot knows that an open vessel is better than a narrowed or colluded vessel.” In some cases it may not improve symptoms, he allows: “But you have an open vessel instead of a closed one.” He has been asked to become involved in a private CCSVI clinic opening in the U.K. but wants nothing to do with it. The procedure should be publicly funded, he says, as it now is in Kuwait. Just last week the Kuwaiti government gave interventional radiologists the go-ahead to begin treating patients.

CCSVI brings with it a new public health care arithmetic. According to the Canadian Institute for Health Information, the estimated annual total cost of MS to the Canadian economy is $1 billion, more than that devoted to all infectious diseases combined. The overall direct costs of caring for and treating Canadians with MS is currently estimated by CIHI at $139 million annually, with drugs accounting for almost half of that. Meanwhile, the cost of a scan and angioplasty in a public hospital setting, according to McDonald, runs $1,500.

As dramatic as the economic reality is, the true cost of the disease has nothing to do with money, says Dr. Ian Rodgers of McMaster University, who’s coordinating a major CCSVI research project testing Zamboni’s findings. “The impact on quality of life is so catastrophic, there’s a very high emotional component to this. If there is a glimmer of hope that reversing these strictures in veins gives definitive improvement to people with MS, then absolutely it’s a necessary intervention.”

And that’s what is galvanizing a new tribe of warrior “MSers,” as they call themselves, who’ve united online—educating themselves on “Doppler scans” and sharing news and personal stories on *ThisisMS.com*. Facebook support groups are proliferating—forwarding online petitions and posting videos of their meeting: within hours of the Vancouver gathering where Godley broke his big news, a video of it was posted on *UStream.com*.

The power of the Internet and social media has changed the patient-physician dynamic, says Godley. “It’s put physicians who think that they can be guardians of our care in the place that they belong, and they need to become humbled.” An emboldened self-diagnosing patient has emerged. Sandra Birrell, a 51-year-old Victoria MS patient who organized the Godley meeting, represents the new patient-as-clinician mindset: “We’ve almost moved beyond our neurologists now to say we need to get our veins addressed,” she says, arguing that her CCSVI and her MS are separate conditions.

Heroes have emerged, like Dr. Marian Simka, a vascular specialist who operates a clinic in Katowice, Poland, where’s there’s a two-year wait list. Since the clinic’s opening last October, doctors have performed 224 procedures, 18 of them on Canadians. Canadian doctors have visited, too, says Simka, who travelled to Vancouver this year to meet with Godley at False Creek.

These people are on a pilgrimage, in search of healing, literally. One, a man in his late forties from southern Ontario, travelled to Poland last month. It was his last hope. In June 2009, he was diagnosed with primary progressive MS, the most aggressive form of the disease, for which there are no drugs.

“The neurologist gave me nothing—zero talk of exercise or diet,” he says. “I felt they did everything but give me the plans for a wheelchair ramp for my house.” He was hesitant to travel across the world to get an experimental treatment, given that he could walk and even do push-ups. The risk of stent migration worried him: “But the wheelchair was more of a certainty.”

After the one-hour procedure, he felt clearheaded for the first time in months. “My wife couldn’t believe my colour,” he says. “It’s like a new life. I’m sleeping through the night; my leg is good. My balance is better. When I get up I feel great.” He says he doesn’t know how he’ll feel in six months. But the hope the liberation surgery has given him has been life-changing: “From getting diagnosed and the devastation of that, this was the best thing that has ever happened to me because now I’ve been given a gift.”

A visit to Simka’s clinic last month turned 45-year-old Calgary realtor Ginger MacQueen, diagnosed with MS in 2000, into a CCSVI militant. When she first heard about the Zamboni research, she was leery, asking her husband to scan chat rooms. Spending hours every day, seven days a week, reading blogs and medical research, turned her into a believer. MacQueen’s account of her surgery, which she describes on her “I hate MS” blog, sounds like an infomercial. “I’m walking now; all the numbness and tickling is gone from my body; the spasms are gone; I’m not limping, my foot drag is gone. I’ve got so much more energy.”

The day after her surgery, she and her husband walked for hours: “Usually I would have to stop every 10 to 15 minutes but I kept motoring.” Yet it was not her own experience but that of a 29-year-old man from Holland that had the greatest impact. “He arrived with impaired speech and his mouth looked like he’d had a stroke,” she says. A few nights later at dinner, he was a changed man: no slur, no facial disfiguration and he was talking about moving out of his parents’ house. “That’s when I got really furious,” she says. “To me it’s manslaughter if you don’t do something to help.”

Last week, MacQueen organized a protest outside of the MS clinic at Calgary’s Foothills hospital, agitating for CCSVI treatment to be available in Canada. Birrell, who plans on having the surgery, shares the sentiment: “It’s my first choice because I want to get follow-up care.” That’s also the hope of Dion Oxford, a 40-year-old MS patient who was diagnosed with CCSVI this week. Finding out he was eligible for surgery was an emotional moment, he says: “I went from inability to stop smiling to inability to stop sobbing.” Oxford, the director of Toronto’s Gateway Men’s Shelter, was diagnosed with relapsing-remitting MS 13 years ago. Last month, he was re-diagnosed with progressive MS. His decision to have CCSVI testing forced him to confront the new commercialization of the MS market: it cost US$4,500 in Buffalo, $2,700 at False Creek and $1,250 in Montreal. He ended up going to Barrie, where he was tested for free by McDonald, who is working to set up a CCSVI trial with Zamboni. Oxford hopes he will be a part of that, but research funding is required. To that end, he plans to donate the proceeds from his annual 190-km bike-ride MS fundraiser. He’s been doing it for six years and has raised more than $60,000 for the MS Society. This year, for the first time, he’ll ride for himself.

Tags: CCSVI, Dr. Mark Godley, False Creek Healthcare Centre, MS, Multiple Sclerosis, Paolo Zamboni
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