

# Curing MS with a Simple Operation: Fact or Fiction?

**Research by an Italian doctor indicating that multiple sclerosis (MS) can be treated with a simple surgical procedure has caused a stir among those who study the condition.**

According to Dr Paolo Zamboni of the University of Ferrara in Italy, MS may be the result of poor vascular circulation in the brain, calling the long-held theory that it is an autoimmune disease into question.

Dr Zamboni's theory is that abnormal flow through the azygous and jugular venous systems results in a build-up of iron in the brain. The excess iron damages blood vessels and allows the metal, as well as other substances, to cross the blood-brain barrier.

*MedPage Today* reported that the hypothesis had immediate clinical implications. First, if narrowed or obstructed veins are the cause of the condition, people might easily be screened for MS long before symptoms appear. Secondly, a simple surgical procedure - a percutaneous

transluminal angioplasty - could open the veins and perhaps halt or reverse the course of the disease.

However, Dr Zamboni's theory has not been proven yet and experts have cautioned that more research is needed to overthrow the reigning paradigm. In particular, they warned patients against seeking vascular surgery before a full-scale, randomised blinded controlled trial has been conducted to test the hypothesis.

"Most experts regard it as a long shot that needs to be studied," Dr John Richert, the executive vice president for research and clinical programmes at the National Multiple Sclerosis Society in the US told *Medpage Today*.

However, Zamboni told a Canadian newspaper recently that he was confident that 'this could be a revolution for the research and diagnosis of MS'.

Researchers at the Buffalo Neuroimaging Analysis Center in the US are currently trying

to determine whether people with MS are more likely to have what has been dubbed 'chronic cerebrospinal venous insufficiency'.

They are enrolling 1100 patients diagnosed with possible or definite MS, 300 age- and sex-matched normal controls, and 300 patients with other autoimmune and neurodegenerative diseases.

"If we can prove our hypothesis that cerebrospinal venous insufficiency is the underlying cause of MS," the researchers said in a statement, "it is going to change the face of how we understand MS."

The investigators are following up a small pilot study, as well as one conducted by Dr Zamboni and colleagues and reported late last year in the *Journal of Neurology, Neurosurgery & Psychiatry*.

In that study, Zamboni and colleagues looked at venous outflow in 65 patients with clinically defined MS and 235 controls, using transcranial and extracranial Color-Doppler high-resolution examination.

The MS patients were 43 times more likely to have abnormalities than the controls, they reported.

The Buffalo researchers found a similar result in their small pilot study of 16 patients with relapsing-remitting MS and eight healthy controls: all the patients, but none of the controls, had chronic insufficient blood flow from the brain.

In a report in a recent issue of the *Journal of Vascular Surgery*, Dr Zamboni and colleagues also offer results of a study in which they surgically treated 65 MS patients with abnormal cerebral venous outflow.

The effect of the surgery on MS symptoms was compared with rates of symptoms during the two years before the procedure.

According to published reports (the final paper is not yet available) half of the patients with the remitting-relapsing form of the disease had no attacks during the 18 months following surgery. The corresponding rate before surgery was 27%.

In addition, the proportion of patients with active gadolinium-enhanced lesions seen on MRI scanning fell from 50% to 12%.

While the results seem promising, they fall well short of proof, according to Dr Richert. "This is something that requires a well-controlled, blinded prospective study," he said.

One danger is that patients may jump the gun, Dr Richert warned. "There are a number of patients who may be expecting that they can just go to a vascular surgeon and get this done," he said.

He added that the results of Dr Zamboni's surgical trial - while good science - aren't enough yet to overturn the existing paradigm.

Among other things, Richert said, it's possible that the apparent benefit was a long-lasting placebo effect.

He noted that in clinical trials with a placebo, the group on placebo 'reproducibly and consistently did better on the trial than they did prior to entering the trial'.

Dr Zamboni and colleagues measured MS symptoms in patients before and after the procedure, rather than comparing surgical and control groups.

The changes that they saw, Richert said, are similar to those 'that we tend to see in placebo groups in major drug trials'.

He added that the society is 'anticipating' proposals for a randomised trial of the surgery by next month.

## Simple Steps to Safe Surgery

**Each year, more than 234 million people worldwide undergo surgical treatment to alleviate disabilities and reduce the risk of death from traumatic injuries, cancers, cardiovascular disease and other common conditions.**

While surgical procedures are intended to save lives, surgical care can result in complications that affect morbidity and mortality rates. According to the World Health Organisation (WHO), mortality from general anaesthesia alone is reported to be as high as one in 150 patients in parts of sub-Saharan Africa.

Best Care...Always! - a collaborative initiative by private hospitals, funders and clinical leadership organisations designed to improve the quality of care in SA's public and private hospitals - aims to reduce hospital-acquired infections through the implementation of a simple series of treatment protocols.

"By working together, the surgical team can improve patient outcomes and safety by reducing infections and other postoperative complications," said Estelle Jordaan, nursing executive at Medi-Clinic.



Medi-Clinic nursing executive, Estelle Jordaan

Modelled on similar international campaigns, but adapted to the South African environment, Best Care...Always! addresses the safety of surgical care through the execution of a small number of condition- or procedure-specific clinical tasks known as 'bundles'. When consistently performed together, these clinical protocols have been shown to be highly effective in reducing patient safety events, such as infections, to very low levels.

The surgical site infection bundle involves four elements:

- Ensuring that appropriately selected prophylactic antibiotics have been administered before the procedure begins;
- Ensuring that the appropriate hair removal process has been followed;
- Maintaining postoperative glucose levels; and
- Maintaining postoperative normothermia.

"The consistent adherence to these four elements has been shown to reduce mortality

and improve outcomes, especially in complex procedures such as cardiothoracic and colorectal surgery," said Andrea Haakestad, nursing process specialist at Medi-Clinic.

In some hospitals, the Surgical Safety Checklist, which is part of the WHO's Safe Surgery Saves Lives campaign, has been adapted to incorporate key elements of the surgical site infection bundle. This checklist requires the surgical team's pausing to verify that key steps have been performed prior to the administration of anaesthesia, commencement of surgery and then prior to the patient leaving the operating theatre.

"Each member of the surgical team is required to play a role in this checking procedure, including the anaesthesiologist, surgeon and nursing practitioners," said Haakestad.

The co-ordinator confirms that the patient's identity has been verified, as well as the surgical site and side, type of procedure and consent. The process also includes checking for allergies and whether there is an increased risk of aspiration or excessive blood loss.

"It's often taken for granted that these checks and balances are done in the normal course of surgery, but a formal procedure, including a written form, not only improves quality, but ensures proper record keeping as well," said Haakestad.

Prior to the skin incision, the team checks whether the surgical site infection bundle is applicable and whether the appropriate antibiotics, if indicated, have been given. "Ensuring that prophylactic antibiotics were administered within the correct window period, for example, can limit the chances of postoperative infections," Haakestad explained. Before the patient leaves the operating theatre, a further series of checks is completed.

The surgical site infection bundle will be rolled out in over 100 South African private hospitals in the next few months. The public sector is included in this initiative but planning is still taking place. Training material is being developed to assist hospitals in implementing and measuring the effects of the surgical site infection bundle.

"By focusing attention on these simple interventions, we hope many lives will be saved," said Jordaan. "Ultimately, the key to the success of the surgical site infection bundle rests on the collaboration between the hospital, doctors, nurses and funders."

## IPR Act to Offer Protection for Traditional Medicines

**The Department of Science and Technology (DST) has thrown its full weight behind research and development initiatives aimed at exploring the value of indigenous and traditional medicines in SA for the benefit of all South Africans.**

Speaking at a recent conference on intellectual property rights, science and technology minister, Naledi Pandor, emphasised the contribution of the recently signed Intellectual Property Rights Act from Publicly Financed Research (IPR) Act towards protecting traditional and indigenous knowledge, and allowing it to be used to promote innovation in SA.

But she said much more needed to be done to assist the custodians of the country's rich indigenous knowledge system to transform it into a productive and profitable mainstream science.

"We need to modernise indigenous knowledge by supporting both the ownership and development of this knowledge in the country," Pandor said.

She said contact with those who utilise indigenous knowledge, including traditional healers, has convinced her of the possible benefits SA might accrue in the pharmaceutical field by

exploring remedies that 'most of us have no interest in or knowledge of'.

But in many communities, efforts to protect this knowledge have come too late as the plants needed to manufacture the traditional remedies have been obliterated by some pharmaceutical companies intent on using these herbs for profit and not for science, Pandor said.

Through its Farmer to Pharma programme, the DST has started to promote and coordinate the commercial use of SA's plant resources and related indigenous or traditional knowledge in its bid to create a viable bio-economy in the country. According to Pandor, the department is now looking at partnering with communities to grow these medicinal plants for 'perpetuity', while researchers at the Medical Research Council are investigating the efficacy and properties of herbs identified for medicinal purposes.

She also called on the local pharmaceutical industry to become more proactive in the research and development of new drugs aimed specifically at relieving South Africa's disease burden.

"The question should be asked why SA is spending over R11bn buying antiretrovirals from other countries. It is our pandemic. We should be responding to it here," Pandor said.

She added that local companies should use IP to make SA a leader in innovation.

"We have brilliant institutions and very bright scientists but we are not investing sufficiently in innovation and R&D," Pandor said.



Science and Technology Minister, Naledi Pandor, speaking at the recent intellectual property rights conference held in Johannesburg