



Trial suggests unblocking veins not beneficial for MS

28th March, 2017



Canadian researchers have presented preliminary results of a clinical trial that suggests a surgical intervention to unblock the veins draining the brain and spinal cord is not effective in treating MS.

Chronic Cerebrospinal Venous Insufficiency (CCSVI) is a term used to describe a potential reduction in blood flow in the major veins that drain blood from the brain and spinal cord over a prolonged period. The condition was first described as being a possible contributor to MS by Dr Zamboni in Italy in 2009.

His findings raised a great deal of interest and hope amongst people living with MS, but were viewed as controversial by many clinicians and researchers. This lead to a significant global research effort to better understand the relationship between CCSVI and MS.

Veins that drain the brain and spinal cord

This included a project in Australia and also <u>7 large research projects</u> jointly funded by the MS Society of Canada and the National MS Society (U.S.).

Dr Zamboni had found that blockages or narrowing of the veins leading from the brain was very common in the people with MS that he studied. However, other studies subsequently showed that these vein narrowings are relatively common in both healthy people and people with other neurological disorders, leading most researchers to conclude that CCSVI is unlikely to contribute to the development or symptoms of MS.

Nevertheless many people with MS around the world have undergone a surgical procedure, outside of clinical trials, involving inflation of a balloon to stretch open the blockage in the vein (balloon venoplasty) and have reported a range of outcomes. However, clinical trials and reviews of the data relating to this surgery conducted to date have found no clear evidence to support its efficacy in alleviating the symptoms of MS.

To provide more conclusive evidence of the safety and efficacy of this treatment the MS Society of Canada and the Canadian Institutes of Health Research (CIHR) funded a very carefully designed, gold-standard clinical trial, in 2012.

Recruitment for the trial started in 2012 and took two years. People with MS were assessed by both ultrasound and venography to see if they displayed signs of CCSVI and if they did, they were entered the trial to receive the surgery. A total of 104 individuals were randomly assigned to receive either venoplasty or a sham procedure (placebo) and were then monitored for 48 weeks. After this time, the patients were 'crossed-over' to receive the opposite treatment, placebo or venoplasty, and followed for a further 48 weeks. The study was double-blinded in that neither the patients nor the doctors evaluating them knew who was receiving the actual treatment or the sham procedure.





Preliminary results of this trial were presented on 8 March, 2017, at the <u>Society for Interventional</u> <u>Radiology</u> annual scientific meeting in Washington, D.C., USA. They showed no statistical difference in outcomes between the two study groups in terms of MRI measures of lesions, clinical assessments of MS symptoms and patient self-assessments. The research team concluded that venoplasty is ineffective as a treatment for people living with multiple sclerosis.

We understand that the results of this study may be disappointing for some people with MS and may not reflect the personal experiences of some individuals who have undergone the procedure. However, as all medical treatments and procedures carry some risks, it is crucial that well-designed studies such as this are conducted to help us understand what benefits, if any, may be expected from an intervention for most people with MS.

Further information

View further details from the University of British Columbia <u>here</u> View a statement (with links to <u>further resources</u>) from the MS Society of Canada <u>here</u>

Australian research into CCSVI

A clinical trial of venoplasty for CCSVI in people with MS commenced at the Alfred Hospital, Melbourne, in 2012. It is our understanding that recruitment has been completed for this study, but the research is ongoing and the findings have not yet been published. You can read more about this study <u>here</u>. MS Research Australia contributed funds to this trial that were specifically raised for this study by members of the MS community via the state MS societies and MS Australia.

In 2010, MS Research Australia funded a study at the Austin Hospital, Melbourne, to look at the prevalence of CCSVI in people with early MS and people without MS. You can read about the outcomes of this study <u>here</u>