



*A charity dedicated to finding
the cause of Multiple Sclerosis*

DIRECT - MS

5119 Brockington Rd. NW
Calgary, Alberta
Canada T2L 1R7
Tel: 403-282-0028
email: info@direct-ms.org

May 04, 2010

To whom it may concern,

Direct-MS and CCSVI

I am the president of Canada's second largest MS registered charity, Direct-MS (868267568 RR0001). We fund research and we provide science-based information on MS to help people make informed decisions when it comes to treatment choices.

Our charity was the first MS charity in the world to recognize the great importance of CCSVI for MS and we started supplying information on this to persons with MS in August, 2009. After it became apparent the MS Society of Canada and MS researchers in Canada were not interested in CCSVI, we introduced CTV to the concept of CCSVI. They recognized the great importance of the subject and their subsequent documentary on CCSVI greatly raised awareness throughout the world. This in turn forced the MS Society to acknowledge the importance of CCSVI and to commit to funding research. Furthermore it forced the MS researchers and clinicians to acknowledge the great potential of CCSVI treatment for MS patients.

Direct-MS was also the first charity to actively fund CCSVI research and gave the University of Buffalo CCSVI Phase 1 study \$75,000 USD in 2009. Recently, we gave the same researchers \$50,000 USD for the Phase 2 portion of their key research. Right now the biggest controversy in the world of multiple sclerosis is whether or not persons with MS should get tested and treated for CCSVI as soon as possible. This is the elephant in the room and I hope the subcommittee will tackle this issue head-on.

CCSVI and MS

Introduction

In this brief I want to emphasize that the current scientific data demonstrate beyond a reasonable doubt that CCSVI is associated with MS and is a causal factor of the disease. The current data also indicate it is very likely that CCSVI is a key part of the ongoing MS disease process. Given this, it is therefore reasonable to assume that treatment of CCSVI may well be of considerable benefit. This logical conclusion is being supported every day by new accounts from people who have had CCSVI treated and whom have had substantial improvements in symptoms ascribed to MS. Below I present the data and logical interpretations which spring from such data.

CCSVI as a Causal Factor of MS

The current data demonstrate that CCSVI is associated with MS - that is CCSVI is much more common in persons with MS than in the healthy population and in persons with other neurological disease. The above described association of CCSVI with MS was first demonstrated by the research of Dr Paolo Zamboni and colleagues in Italy. It has been confirmed by the detailed and large scale Phase 1 CCSVI study (500 subjects) at the University of Buffalo.

Data from work in the USA Poland, India and Kuwait have added even more data demonstrating that between 63 and 90% of persons with MS have CCSVI. The variance in the prevalence is due mainly to the sensitivity of the detection methods with the higher numbers coming from centres which used highly sensitive, selective venography and endovascular treatments to detect CCSVI. Lower numbers come from centres using only Doppler Ultrasound which is more operator-dependent and less sensitive. Regardless, it is definite that the majority of persons with MS have CCSVI. No one who is aware of the scientific data is disputing this established association. Of course, mere association does not lead to an interpretation of CCSVI being a causal factor.

The key scientific finding that indicates CCSVI is a causal factor of MS is the determination by vascular researchers at Georgetown University that CCSVI is caused by truncular venous malformations which are undisputedly congenital in origin. Such malformations include the occurrence of malformed valves, webs, septa, missing or poorly formed veins. Vascular researchers from 27 countries have ratified this finding in a recently published scientific paper (Lee et al, International Angiology, Dec. 2009). Thus it is clear that CCSVI precedes the MS disease process which means it must be a causal factor. Any claim that such a coincidence is purely chance cannot be taken seriously.

Importantly, the other supporting evidence that demonstrate CCSVI is a causal factor for MS is that reasonable biological mechanisms which would be part of CCSVI can explain parts of the MS disease process. Furthermore, there is solid data which indicate that these biological mechanisms have occurred in MS patients. Such data include the perivenous nature of all MS lesions and the presence of iron deposits and fibrin cuffs in the parts of the venous walls associated with lesions.

In summary, the simplest and thus best interpretation of all the current data is that CCSVI is an important part of the MS disease process. This interpretation is further supported by the University of Buffalo finding that, the more severe the case of MS, the greater the likelihood CCSVI is present. Thus it appears CCSVI exacerbates the MS disease process such that those with MS and CCSVI progress farther and faster. Given that some of the biological mechanisms of CCSVI, such as the upregulation of adhesion molecules on the endothelial walls, would enhance the autoimmune process of MS, such a finding is completely reasonable and to be expected.

The Need for CCSVI Testing and Treatment Sooner Rather than Later

As mentioned at the start of this brief, the biggest controversy in the world of multiple sclerosis is whether or not persons with MS should get tested and treated for CCSVI as soon as possible. Given, that CCSVI is a causal factor of MS and contributes to the disease process, there can be

little doubt that CCSVI testing and treatment needs to become available in Canada within the year.

It is completely unreasonable to delay such testing and treatment until major research studies determine that CCSVI is a key part of the MS disease process and that relief of CCSVI will be of benefit. The MS research community has publicly acknowledged that such research will take between 5-10 years at best. If we use the time it takes for similar research of a drug therapy, the time may well be 10-15 years. Given that we already know that CCSVI is a key part of the MS disease process, it is reasonable to assume that CCSVI treatment has a reasonably good chance of being of benefit. This is all we need to know for a proper decision to be made regarding the timing of treatment availability. I would further note that there are numerous accounts of substantial improvements in persons who have had the treatment. Such data cannot be ignored.

The chart below presents the decision-making choices in regards to the timing of CCSVI treatment.

MS Patient's Perspective on CCSVI Treatment		
	CCSVI Relief Is of Significant Value for MS	CCSVI Relief Is Not of Significant Value for MS
CCSVI Treatment Available Soon	Major Gain	Minor loss
CCSVI Treatment Notably Delayed and/or Denied	Major Loss	No loss/gain

If CCSVI treatment becomes available soon and it is very effective (a reasonable assumption as

described above), the MS patients will enjoy a major gain with a significant lessening of disabilities or, in some cases, a complete resolution of the disease process. If the treatment proves to be of little value, they will suffer only a small loss of time and minor side effects. I would emphasize that the venous angioplasty treatment recommended for CCSVI is very safe and entails no more risk than standard angioplasty treatment for arterial problems. Any views to the contrary have no scientific support, and angioplasty for arterial problems is done hundreds of times a day across Canada.

In contrast to this, if treatment is substantially delayed and the treatment eventually is shown to be very effective, then persons with MS will have suffered a huge loss represented by all the preventable, additional disabilities accumulated during the delay in treatment introduction. If the treatment has little to no benefit, then persons with MS will not be affected by the delay.

Thus we have potential outcomes for the two options of treatment timing, soon or delayed. The option of CCSVI treatment becoming available soon is the obvious, correct option to take assuming the health of persons with MS is paramount. This path offers outcomes of either major gain or minor loss. The path of delayed CCSVI treatment holds either major loss or no loss/gain for persons with MS. Any claim that MS patients would be better off if they chose the major loss or no loss/gain path versus a major gain/minor loss path is clearly absurd. I am hopeful the subcommittee members can readily understand the above logic and why there is no doubt that Canada must institute the availability of treatment of CCSVI as soon as possible.

Conflicts of Interest

I would note that various factions have been strongly advocating for substantially delayed treatment (i.e. 5 -10 years). I would further note that these factions have a major conflict of interest in that they have strong financial ties to the pharmaceutical industry that stands to lose billions of dollars if CCSVI treatment is effective. I can only ask that the subcommittee take into account such a major and blatant conflict of interest when any organization or individual, who in the past has received funding from the pharmaceutical industry, lobbies for delayed

treatment. As shown above, such delayed treatment would clearly not be in the best interests of the physical health of persons with MS, although it certainly would be in the best interests of the financial health of the pharmaceutical industry and all those it funds.

Summary

The current scientific data clearly demonstrate that, because CCSVI is both associated with MS and precedes it, CCSVI must be a causal factor of MS. Data also indicate that CCSVI is a key part of the MS disease process and that CCSVI treatment is very safe and has a very good chance of being of benefit.

A logical decision making process shows that the health of persons with MS would be much better served by having CCSVI treatment available sooner rather than later. Views to the contrary seem to be affected by a major conflict of interest.

I am hopeful that Canada will do what is in the best interests of persons with MS and make CCSVI testing and treatment available throughout Canada in 2010.

Sincerely,

Dr Ashton F Embry

President and Research Director, Direct-MS