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Tuesday, June 15, 2010

Chair

Mrs. Joy Smith

Subcommittee on Neurological Disease of the Standing Committee on Health

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● (1135)

[*English*]

The Vice-Chair (Ms. Kirsty Duncan (Etobicoke North, Lib.)): Good morning. I'd like to welcome everybody to the Subcommittee on Neurological Disease, a subcommittee of the Standing Committee on Health.

We have many people in the room here in Canada.

With us as witnesses have Dr. Paolo Zamboni, a medical doctor and director of the Vascular Diseases Center at the University of Ferrara in Italy; Dr. Marian Simka, medical doctor, Department of Vascular and Endovascular Surgery, in Poland; and Dr. Robert Maggisano, medical doctor, vascular surgeon, Sunnybrook Health Sciences Centre in Toronto.

Here in Ottawa, we are joined by the president of the Canadian Institutes of Health Research, Dr. Alain Beaudet, and from the Multiple Sclerosis Society of Canada, the assistant vice-president of research, Dr. Karen Lee.

Welcome, everybody.

Each of the witnesses will have seven minutes of testimony. We're going to begin with Dr. Paolo Zamboni.

Dr. Zamboni.

Dr. Paolo Zamboni (Medical Doctor, Director, Vascular Diseases Center, University of Ferrara, As an Individual): Good evening.

Chronic cerebrospinal venous insufficiency is a syndrome characterized by flow blockages of the internal jugular and azygous veins system, with insufficient drainage from the brain. This syndrome has been recently inserted in guidelines in a consensus conference and published in the December issue of *International angiology: a journal of the International Union of Angiology* and vascular medicine. Venous pressure in the blocked and damaged jugular vein and the azygous vein was found to be significantly higher.

There are many other people who have observed this kind of syndrome and have correlated the association of this CCSVI with a neurodegenerative disorder called multiple sclerosis. We describe it in the original group of patients in which we found a very strong association in 100% of people, and in our experience we've found an association of 90%.

Dr. Zivadinov in the United States described an association of 60%, and the presence of CCSVI in 22% of other neurological disorders under normal controls. A group from Jordan described the prevalence of MS in 84% with 0% in controls. Dr. Simka, who is actually listening to us, found an MS prevalence of CCSVI in 90% of cases.

CCSVI was found to be associated with multiple sclerosis in different latitudes and in populations with different genetic backgrounds. I have found that the gold standard is catheter venography. It may very well defeat CCSVI, which is characterized by a narrowing wall malformation, with bypass activated through collateral circles. I have described this in the slide presentation sent two days ago.

As far as diagnosis is concerned, catheter venography is certainly the gold standard, but unfortunately it is an invasive technique. We have developed an echo-colour Doppler protocol, and I believe it is an ideal tool because it is not invasive and it is very useful for screening.

We also performed some tests in order to understand the reproducibility of this echo-colour Doppler protocol. We found it very useful if the physician, technician, or sonographer was trained in this, with some significant differences between trained and untrained operators.

As far as treatment is concerned, we applied simple, conservative angioplasty, and we described the effect of this treatment in a prospective pilot open-label study published last December.

The Vice-Chair (Ms. Kirsty Duncan): Dr. Zamboni, I'm sorry, but could we ask you to suspend for a minute? We're working on interpretation and they're struggling at the moment.

Can we also ask you to take the papers away from the mike, please? That seems to be causing some of the difficulty.

● (1140)

Dr. Paolo Zamboni: Okay.

We described the CCSVI treatment by means of standard balloon angioplasty in a paper published in the *Journal of Vascular Surgery* last December. According to our results, angioplasty was demonstrated to be safe. We never had major vascular complications and patients were discharged from hospital on the same day in the early afternoon.

I sent members of the committee some pictures showing the technique, but this is not really an experimental technique. It's a well-known technique that is simply applied to a new venous segment in which this kind of malformation was not previously described.

We followed up with our patients for 18 months and found a significant reduction in the number of relapses of multiple sclerosis in them, compared to what had happened in the previous two years. We found a significant reduction in so-called active lesions measured by blinded MRI. We also measured a significant improvement in relapsing/remitting multiple sclerosis patients in cognitive and motor functions.

Very importantly, we also found a significant decrease in chronic fatigue. Chronic fatigue is one of the more disabling symptoms in people affected by multiple sclerosis. Until now, there has been no effective treatment for this specific symptom.

The Vice-Chair (Ms. Kirsty Duncan): Dr. Zamboni, can I ask you to wrap it up, please?

Dr. Paolo Zamboni: I will repeat this: chronic fatigue is one of the more disabling symptoms in multiple sclerosis. Following balloon angioplasty, we found significant improvements in this symptom. This is particularly interesting, because until now there have not been effective treatments for chronic fatigue, and chronic fatigue is really disabling for multiple sclerosis patients and is completely orphaned from any effective treatment today.

It is clear that more study is needed, but treatment must not wait for clinical trials. Actually, in Italy, we are starting randomized controlled trials, but I think that this kind of treatment is completely proposable under the umbrella of the ethical committee measuring what exactly happened in the follow-up of patients who undergo this treatment.

We also performed another randomized control study in cooperation with the State University of New York at Buffalo by comparing two groups of patients. In one, the early treatment group, the angioplasty was performed at a baseline. In the second group of patients, angioplasty was delayed for six months. This study demonstrated that balloon angioplasty is safe and well tolerated, thus confirming the safety of this kind of treatment. The rate of restenosis was 29% in the damaged jugular vein, but zero per cent in the azygous vein. Very importantly, we found a significant decrease in the number of T2 lesions blindly measured by the means of MRI, and this also confirmed that this kind of treatment is protective for multiple sclerosis patients.

My conclusions are that CCSVI exists and is a serious obstruction, a major vascular problem, whether a patient has multiple sclerosis or not. CCSVI is significantly related to multiple sclerosis patients at different latitudes and of different genetic background populations. Angioplasty corrects the blood flow from the brain and, really, the correction helps people with multiple sclerosis.

I think it is irresponsible not to proceed with angioplasty treatment of CCSVI in patients with multiple sclerosis under the umbrella of controlled studies, supervised by ethical committees in tertiary hospitals, and with all the capability in interventional radiology and in vascular and endovascular surgery.

Thank you.

● (1145)

The Vice-Chair (Ms. Kirsty Duncan): Thank you, Dr. Zamboni. We appreciate your time and effort.

It was important to hear Dr. Zamboni fully, but to be fair to all the witnesses, we will give 12 minutes to those remaining.

We will now move to Dr. Marian Simka.

Dr. Marian Simka (Medical Doctor, Department of Vascular and Endovascular Surgery, EUROMEDIC Specialist Clinics): Good morning, ladies and gentlemen.

First, I'd like to thank you for the kind invitation to this conference. I represent the Euromedic specialist clinic in Katowice, Poland, which I believe has performed the largest number of endovascular treatments for chronic cerebrospinal venous insufficiency in the world. Although we began those treatments only in October of last year, we currently perform about 20 procedures per week and the total number of people who have been treated is now about 400.

It's important to point out that the interventions for this venous problem in our department have been approved by the bioethical committee of the Regional Silesian Board of Physicians in Katowice, Poland. Because we collect all data regarding patients' history, clinical status, and the characteristics of the venous lesions that have been diagnosed, the analysis of this data set has enabled us to draw some conclusions regarding links between CCSVI and multiple sclerosis and also regarding the safety of the treatment.

First, CCSVI has been found to highly correlate with multiple sclerosis. Only 3% of the multiple sclerosis patients we have seen were not diagnosed with CCSVI, using colour Doppler sonography, magnetic resonance venography, and standard venography.

Secondly, localization and severity of venous lesions have been found to significantly affect the clinical course of multiple sclerosis. For example, injuries to the optic nerves were found more often in the cases with unilateral lesions in the internal jugular veins, while bilateral stenoses in the internal jugular veins correlated with a less frequent ocular pathology. More disabled patients were found to suffer from bilateral and/or severe occlusions of the internal jugular veins and the patients with stenosed azygous vein presented with the most aggressive clinical course of the disease.

These findings, in addition to preliminary observations that a substantial percentage of multiple sclerosis patients improved after endovascular interventions, favour the idea that surgical treatments for those venous obstacles should be an important part of the management of multiple sclerosis.

The most important question regarding treatment for CCSVI, however, regards the safety of such a management of venous outflow blockages. Such a management strategy is actually recommended by the consensus document of the International Union of Phlebology, as has been mentioned by Dr. Zamboni.

However, although similar endovascular procedures for the treatment of other venous pathologies or arterial pathologies are known to carry very low risk, an actual rate of complication related to such treatments for CCSVI remains undetermined, mainly because these procedures are not yet routinely performed in these cases. Moreover, recently in some neurological papers it has been claimed that surgical treatment for CCSVI can be dangerous. Interestingly, those statements were based only on the beliefs of the authors and not on the body of evidence. Contrary to those opinions, in our clinic we have demonstrated that these procedures are safe and are usually well tolerated by the patients.

The group of 347 CCSVI patients with associated multiple sclerosis have undergone a total of over 500 endovascular procedures, including 414 balloon angioplasties and 173 stent implantations. These procedures were performed during 341 interventions. In this group, there were only a few rather minor and occasional complications or technical problems related to the procedures.

Regarding life-threatening complications, there were no deaths, no major hemorrhages, no cerebral strokes, and no migration of the stent. Regarding major complications, there were only two early stent thromboses.

● (1150)

In two cases, there was a false aneurysm in the groin, but this was successfully treated with thrombin injection. In one case it was necessary to open the femoral vein to remove the velum. There were no injuries to the nerves.

Regarding other minor complications, there were some cardiac arrhythmias, some minor bleeding from the groin, some gastro-intestinal bleeding, some lymphatic cysts, and some technical problems. But all of these complications were minor and they did not produce more problems in the future. Therefore, in our opinion, precise preoperative diagnostics should consist of colour Doppler sonography and magnetic resonance venography.

Also, selective use of the stents, if balloon angioplasty is not successful, can make the endovascular management for CCSVI free of significant complications and, in terms of restoring the proper venous outflow, even more efficacious than performing balloon angioplasty in all cases.

However, the actual impact of the endovascular treatments for venous pathology on the clinical course of multiple sclerosis warrants more clinical studies and longer follow-ups.

Thank you.

The Vice-Chair (Ms. Kirsty Duncan): Thank you very much, Dr. Simka. We appreciate your time and your testimony.

I will now move to Dr. Maggisano in Toronto.

Dr. Robert Maggisano (Medical Doctor, Vascular Surgeon, Sunnybrook Health Sciences Centre, As an Individual): I won't reiterate what has been so well elaborated by Dr. Simka and Dr. Zamboni, but I'll try to bring you a perspective on where we are in Canada.

The essence of the problem is an assumption that venous abnormalities to drainage from the brain circulation cause venous hypertension, causing, if you will, dilatation and leakage of fluid and red cells into the brain matter, causing inflammatory reaction—possibly an immune reaction—and that this may be associated with MS. This has been very well described, as you've heard, by two excellent reporters.

I guess the issue for Canada is, where do we go in Canada to test the hypothesis? As you're probably aware, the MS Society has spent $700,000 in funding for studies that are essentially evaluating not the hypothesis of whether or not these lesions and the treatment thereof can improve the MS symptoms; rather, we're spending $700,000 in evaluating the techniques that have been described on how to evaluate stenoses and how the frequency of stenoses in MS patients compare with the frequency of stenoses and venous abnormalities in the normal population.

I put to you that this is very interesting and will give us some interesting academic information, but I'm not really sure that it is relevant to the issue at hand. If one wants to test my hypothesis of a new drug being efficacious in the treatment of a disease disorder, one has to put that medication into the patient and test it compared to a normal cohort that may receive placebo.

In this particular case, I personally know that not everybody with venous outflow obstructions has MS. Probably, if one looks at a general population of normal individuals, there will be significant venous abnormalities found.

We know from the surgery that we do for cancer that we resect the jugular vein not infrequently when we're doing neck dissections. We also know that when we do carotid surgery, we not infrequently ligate venous outflow from the brain and from the face. None of these people develop complications of MS. So probably there is significant venous abnormality noted in the normal population.

That doesn't preclude the notion that in these particular patients who may have some underlying tendency to neurological disorders, their pathology and the venous disease may be correlated with neurological damage.

A case in point here would be in venous disorders of the lower extremity. I've been practising vascular surgery for the last 30 years and routinely, through Doppler ultrasound, I evaluate people with venous insufficiency, both of the deep and the superficial venous system. Infrequently, some of those patients will develop what we call the “postphlebitic leg”, with ulcerations and hemosiderin deposits, which reflects what Dr. Zamboni was talking about: the iron deposits noted in the brain of MS patients.

But the point is that not all patients with venous insufficiency develop these complications, so there's obviously a predisposition in some patients to develop iron deposits that could lead to inflammation and the immune response known to be involved in MS patients.

From the point of view of Canada, we obviously don't have a lot of experience in the treatment of the venous blockages that have been identified in patients with MS. We've done a few anecdotal cases—I haven't, but friends of mine have—that are reporting, again, anecdotal improvement in the symptomotology.

● (1155)

But the question begs to be asked that if we are going to evaluate the notion, the hypothesis, that CCSVI and its treatment is related to and can benefit patients with MS, I think we have to do a proper, randomized, blinded, and controlled study to test the hypothesis, and not do what the MS Society in Canada is proposing or has funded, which is really to fund the best means of investigating venous abnormalities and how the MS population and the normal population relate to one another in the frequency of this disease process.

● (1200)

The Vice-Chair (Ms. Kirsty Duncan): Would you like to continue or have you finished, Dr. Maggisano?

Dr. Robert Maggisano: No. I'm finished.

The Vice-Chair (Ms. Kirsty Duncan): We thank you for your testimony.

Now we will move to Dr. Alain Beaudet, who is the president for the Canadian Institutes of Health Research.

Dr. Alain Beaudet (President, Canadian Institutes of Health Research): Thank you, Madam Chair.

It is with great pleasure that I appear before you today in my role at the Canadian Institutes of Health Research to discuss the important issue of multiple sclerosis research in Canada.

Your committee is holding important hearings on the matter, and I'm happy to share this time with other witnesses, including Dr. Zamboni, whose new therapeutic approach for chronic cerebrospinal venous insufficiency gives hope to patients and their loved ones who face the burden of this debilitating disease every day.

Let me first share with you what CIHR is doing in the area of MS.

[*Translation*]

The CIHR is determined to move our knowledge of multiple sclerosis forward and to speed up research into the prevention, diagnosis and treatment of this terrible disease. Our strategic plan, developed as recently as 2009, speaks to our commitment, as we have made reducing the burden of chronic diseases one of its five priorities.

Multiple sclerosis is a key element in this priority, because Canada has one of the highest rates of this disease in the world. Multiple sclerosis is the most common neurological disease affecting young adults, especially young women, and, every day, three people in Canada are diagnosed with the disease.

[*English*]

CIHR's commitment to MS research is reflected in the funding it has made in this area. CIHR has invested over $45 million directly in MS-related research. In addition, CIHR has provided important investments in the area of neurosciences, with over $120 million in 2008-09 alone, and a further $38 million in stem cell research, both of which will help researchers pursue potentially useful therapies for the treatment of diseases such as multiple sclerosis.

The studies supported by this funding have provided significant new insights into the pathological mechanisms underlying MS.

While the recently developed CCSVI treatment opens new potential therapeutic avenues for some of the patients suffering from MS, it is critical, as was said previously by my colleagues, to ensure that these avenues are explored through research conducted according to the highest standards of scientific excellence to assess if the treatment is both safe and effective. Indeed, evidence-based practice is the cornerstone of our health care system here in Canada.

It is for these reasons that CIHR, as one of its top priorities, has decided to invest in patient-oriented care in Canada to improve the uptake of clinical results in actual practice. We call this our strategy on patient-oriented research.

[*Translation*]

This strategy for patient-oriented research is built on the principle that there is a growing need to conduct intervention studies in order to address important clinical issues, as is the case with the clinical trials on multiple sclerosis that we are discussing today. These studies involve large numbers of patients who are receiving health-care services in many settings across the country. The results from such trials provide the basis for clinical practice providing accurate patient diagnosis, prognosis and treatment.

[*English*]

It is clear from the present hearings and the extraordinary hope that has arisen from the early results of Dr. Zamboni's procedure that research into clinical treatment of MS has to be accelerated.

What is critical, however, is to ensure that we invest in research wisely, in well-designed studies that are safe for patients and that are likely to yield scientifically valid results. In this context, CIHR will be convening, in collaboration with the MS Society of Canada, a meeting of top Canadian and international researchers in the field.

This meeting is to be held in August and will focus on how best to accelerate research and innovation in MS, with a focus on potential links between neurovascular issues and MS, including CCSVI. These researchers will review current international efforts and research gaps focused on neurovascular research related to MS. The expected outcome will be a richer understanding of clinical research priorities regarding potential innovations related to diagnosis and treatment of MS.

In the meantime, CIHR and the MS Society of Canada are working together on a daily basis, and I urge researchers interested in better understanding the linkages between MS and CCSVI to apply for CIHR's funding opportunities.

Thank you, Madam Chair.

● (1205)

The Vice-Chair (Ms. Kirsty Duncan): Thank you, Dr. Beaudet.

We appreciate your time today.

I'd now like to turn to Dr. Karen Lee, who's the assistant vice-president of research for the Multiple Sclerosis Society of Canada.

Dr. Karen Lee (Assistant Vice-President, Research, Multiple Sclerosis Society of Canada): Thank you, Madam Chair and subcommittee members.

Thank you for the opportunity to speak today about CCSVI and its relationship to MS. I am speaking as a representative of the MS Society of Canada with previous experience as a basic researcher, with a focus in multiple sclerosis.

For 60 years, the MS Society has journeyed with tens of thousands of Canadians who have lived with this devastating disease called MS. With them, we sense the despair that MS can bring and grasp the desire and hope that one day the answers to this disease might appear. We fully appreciated how excited people affected by MS were when the news of CCSVI came onto the public stage.

As an organization that cares deeply for the well-being of all people affected by MS, we want to ensure people have genuine hope. Dr. Zamboni's hypothesis on CCSVI has stimulated conversation about multiple sclerosis worldwide. As with any new hypothesis, many questions remain, and early results need to be replicated and validated in well-designed, controlled studies.

While the pace of research seems frustratingly slow, it is critical to produce evidence that can be used to make reliable therapeutic decisions. As Dr. Zamboni and his colleagues have stated, today and before now, the results of the pilot study warrant a subsequent randomized controlled study.

In November 2009, the MS Society issued a request for research operating grants to study the relationship between CCSVI and multiple sclerosis and to identify what treatment potential it may offer to people living with MS. This past Friday, we announced, in collaboration with our U.S. counterparts, the National Multiple Sclerosis Society, a $2.4 million commitment to CCSVI and MS research. This will fund seven research projects in North America.

All of the Canadian research projects that were recommended for funding by a review panel of non-conflicted international experts, comprised of interventional radiologists, vascular surgeons, imagers, and neurologists, will be funded by the MS Society of Canada. The MS Society has committed $700,000 to these four projects.

These projects are blinded in randomized controlled studies that are looking at imaging techniques and the prevalence of stenosis in patients with MS. As well, these studies will look at various populations such as children and families, where they'll use twins to look at genetic linkages. These studies are also studying linkages to MS pathology, as well as how iron deposits may be linked to CCSVI and multiple sclerosis.

The goal of funding controlled trials is to evaluate outcomes in the most objective way possible. Many neurologists and researchers have shown scientific curiosity in regard to the concept of CCSVI and are assessing it on the basis of evidence, as they would with any other issue. We hope the studies we fund will resolve conflicting data from previous research.

For example, Dr. Zamboni's research team suggests that blood drainage is impeded by venous restriction. However, a research group working in Germany and the U.K. recently published a study suggesting that cerebral venous drainage in patients with MS is not restricted. It is because of the differing data that they and many other clinicians and researchers agree that investigation of neck vein abnormalities needs further assessment.

By funding research into MS and CCSVI, the MS Society joins other MS societies and governments around the world to ensure that the answers about CCSVI are found as quickly as possible. If evidence is found that treatment of CCSVI is a valid therapeutic treatment option for MS, the MS Society will advocate vigorously to make testing and treatment widely accessible for people with MS.

Because of our long association with Canadians affected by MS, the MS Society recognizes the hope that Dr. Zamboni has brought to people with MS. We certainly understand how people might wish this proposed treatment to be available to them immediately.

It is important to recognize that the barrier to accessing treatment is the lack of data supporting the hypothesis both for diagnosis and for intervention. This data is required by provincial governments, physician organizations, and hospitals in order to make evidence-based decisions as to whether CCSVI should be treated in people with MS.

● (1210)

This is why the MS Society is funding research into CCSVI. This is also the reason we are advocating for additional research to be funded by the federal government to ensure this evidence is available as soon as possible.

The Vice-Chair (Ms. Kirsty Duncan): Thank you very much, Dr. Lee.

I know there are a lot of questions around the table. We'll begin with the Honourable Dr. Bennett. This will be a seven-minute round for all questioners.

Hon. Carolyn Bennett (St. Paul's, Lib.): Thanks very much.

Thanks to all of you.

I'd like to begin with Dr. Zamboni's conclusions, which I think are worth repeating because they inform a lot of where a lot of the people in the room feel we need to go. They are as follows:

> CCSVI exists and is a serious obstruction, whether the patient has MS or not.
>
> CCSVI is significantly related to MS.
>
> Angioplasty corrects the blood flow from the brain.
>
> That correction helps people with MS.
>
> It is irresponsible not to proceed with angioplasty treatment of CCSVI in patients with MS, under the umbrella of clinical studies supervised by ethical committees.

In terms of the patients who may end up in a wheelchair next week or lose their lives to MS, I'm asking why the first piece of research wouldn't be to capture the people who have neurological disease, well-documented by their specialists across the country, and who have gone elsewhere to get their procedure and then have come back to Canada. Why would that not be the first piece of research you would do in this population that exists right now, so that you could very quickly figure out whether or not this works?

I think Dr. Maggisano was very clear that the narrowness of the project being funded by the MS Society is not going to get us where we want to go as quickly as the people and the patients require. So I—

[*Applause*]

Hon. Carolyn Bennett: So I guess I would like Dr. Beaudet to tell us what is the nature of the research that will be funded by CIHR. And obviously we would like the $16 million that was mentioned in the previous testimony of the minister to go there, but how do we get you more money so you can capture what exists already?

So I'd like to know, I guess firstly, from Dr. Beaudet, what is the proposal you've put out there? You said it was very broad. I'm not sure that's what people want to hear. I think they want to hear that it is about CCSVI.

Secondly, who is on the panel? And are some of the people with experience doing this procedure, like Dr. Zamboni and Dr. Simka, or the partners in Buffalo, on the panel? Because there has been concern, as you know, that as Dr. McDonald said, asking for an electrician for permission to go and do a plumbing job has not been satisfactory up until now.

And then I guess I would say to Dr. Maggisano, you've have said you want double-blind trials, but how would you suggest that CIHR move forward such that all of the people who are being discriminated against because they happen to have MS...? How would you capture them, in what...? It looks like an echo colour Doppler, as was said in Dr. Zamboni's testimony, would be an ideal tool for a non-invasive screening, such that these people could actually start there.

So what's the call for papers that you've done, Dr. Beaudet?

● (1215)

Dr. Alain Beaudet: You have several questions. I think I will start by thanking you for making it clear that you believe that any treatment should be based on evidence and for having the confidence that CIHR can provide that evidence.

Now obviously we can only fund proposals that are submitted to us, and I'll start with Dr. Maggisano. I think his last sentence was equally important: we need proper, randomized, blinded clinical trials.

What I'm asking is for Canadian researchers to propose a protocol for a proper, randomized, blinded clinical trial on the effect of this treatment, this therapeutic approach. And we are open to that: as you know, we do fund clinical trials. Our next competition has a deadline of mid-August for registration and we are open to receiving proposals for clinical trials.

That won't give you an answer in one month, but I think it is the way to go to get true evidence as to whether or not.... And it's the recommendation and it's also the last sentence of Dr. Zamboni's paper. As he says, the results of this pilot study warrant a subsequent randomized controlled study. But we need proposals from Canadian researchers and physicians for such a trial to be funded.

Hon. Carolyn Bennett: Can you tell me who is on the panel that will be reviewing it?

Dr. Alain Beaudet: That's another piece to we're trying to do to accelerate the research in that area. For accelerating research in that area, we have to see the whole picture and put this proposal in the broader context of the relationships between cerebrospinal venous insufficiency and venous congestion, but also other cerebrovascular issues and MS.

For that, we've conveyed experts, experts not only from the neurology side but also from the vascular surgery side—

Hon. Carolyn Bennett: Vascular surgeons with experience in this?

Dr. Alain Beaudet: Not necessarily with experience in treating patients with MS, but with experience in angioplasty, yes. So we need people with experience in imaging for diagnosing venous insufficiency, neurologists with experience with MS, and, of course, surgeons with experience with angioplasty. We want these people to have an unbiased look at what's the evidence out there, what's going on, what are the ongoing trials, and what are the most promising avenues broadly.

Hon. Carolyn Bennett: Has there been an analysis of the international work to date?

Dr. Alain Beaudet: Well, that's exactly...it's part of what we're asking this committee of experts: to analyze what's out there and what are the contradistinctions. As you saw, there are contradictions out there in the literature. We have to understand these contradictions, look at what's out there, and look at what's needed in terms of further studies and why these contradictions—

The Vice-Chair (Ms. Kirsty Duncan): Dr. Beaudet, thank you. We have to move on.

Monsieur Malo.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Thank you, Madam Chair.

[*English*]

Dr. Robert Maggisano: Madam Chair, I think I was asked to reply to the comment.

The Vice-Chair (Ms. Kirsty Duncan): Oh, yes, Dr. Maggisano, absolutely.

Dr. Robert Maggisano: May I?

The Vice-Chair (Ms. Kirsty Duncan): Yes, of course.

Dr. Robert Maggisano: May I have one minute?

Mr. Luc Malo: *Prenez le temps que vous voulez pour répondre.*

Dr. Robert Maggisano: I'm sorry?

The Vice-Chair (Ms. Kirsty Duncan): Yes, please, Dr. Maggisano. Go ahead.

Mr. Luc Malo: For as long as you wish.

Dr. Robert Maggisano: All right.

Thank you very much to Dr. Beaudet for his input.

I think we all know that what is lacking, at least in Canada, through all the research and all the commentary that has been made, is that we need a treatment arm to test the hypothesis. Unfortunately, the $2.4 million that has gone out from the MS Society in Canada and in the U.S. does not go in the direction of testing the hypothesis that treatment will or will not improve the outcome of the neurological symptoms.

These are people who are basically living in a terrible situation of chronic and progressive disability and without any real treatment available to them. I think that both Dr. Zamboni and our colleague from Poland have suggested that this is not new treatment for us. We treat veins and arteries with angioplasty routinely. It has a low-risk and a very minimally invasive component to it. Most of these treatments are outpatient treatments.

So I would really urge the committee members, the government, and the appropriate funding agencies to look towards funding the definitive study that will answer the question, which is not whether MS has or does not have associated venous disease, but rather, does treatment of the venous outflow obstruction, as reported by Dr. Zamboni, improve the neurological outcome? This is very analogous to any drug that neurologists are asked to test. If you don't test the drug to the patient and investigate the outcome, you will never know whether that drug improves the outcome or not.

What we're doing with our funding, for some reason that is very difficult for me to understand, is that we're running around and saying, well, do people with MS have venous obstruction? Do they have anomalous venous drainage? We're wasting time and money, and we're certainly not helping our people who are going overseas to get treatment when we should be able to do the studies in a blinded fashion within Canada.

What we need is teamwork among vascular surgeons and neurologists who are competent in MS and who can independently assess the efficacy of the treatment. But we need to get going on this, so that within a year or two we can let our MS population know the answer.

[*Applause*]

● (1220)

The Vice-Chair (Ms. Kirsty Duncan): Thank you, Dr. Maggisano.

Now we're going to go to Monsieur Malo.

[*Translation*]

Mr. Luc Malo: Madam Chair, before I ask my questions, I have to say that I completely understand the emotions of those who are in the room.

But I must point out that we are not on a television set, we are in a committee room. Witnesses may be present for the debate, of course, but you must understand that there are rules to be followed and decorum to be maintained. So I would encourage witnesses to curb their enthusiasm, just so that the committee can conduct its work as efficiently as possible.

Voices: Oh, oh!

[*English*]

The Vice-Chair (Ms. Kirsty Duncan): Mr. Malo, please go ahead with your questions. We're looking forward to what you have to say.

[*Translation*]

Mr. Luc Malo: Thank you very much, Madam Chair.

I completely understand that what I have just said does not go over well with the witnesses. But if that kind of reaction were permitted in all committees, we could easily lose control of the proceedings. It is a rule, that's all. Perhaps the incident would be considered closed if the clerk could confirm the rule.

But I will ask my questions right away.

Dr. Zamboni, you said in your presentation that clinical trials could be conducted under the control of ethics committees. Could you please give us some more details on how you consider ethics committees could monitor or supervise clinical trials?

I would also ask our other witnesses for their opinion on the effectiveness of a process like that and on whether the approach is in common use.

[*English*]

Dr. Paolo Zamboni: In Italy, we are now carrying out a randomized control study with the following characteristics. It's blinded so that you may take away any doubt about the placebo effect, because the untreated arm will have the same surgery, and the treated arm conventional angioplasty. We also need independent assessors measuring the clinical outcome as well as conventional MRI measures.

I want to underline that until now there are no treatments capable of having a real and serious primary end point for treatment regarding a neurodegenerative disease, because until now, the viable treatment can simply reach an MRI and radiological end point and not a clinical end point, because disability cannot be prevented at all by the actual treatment. The challenge with this supervised randomized control double-blind study is to try to investigate if the additional benefits of the angioplasty and the eventually associated treatment of a major vascular problem may also lead to the prevention of disability.

● (1225)

Dr. Robert Maggisano: I think I can answer the question, because in most of the university centres across Canada, we have been evaluating disease processes for the last 20 years. We did this with coronary artery angioplasty and with peripheral arterial angioplasty. We've done it with carotid disease. We're doing it with the discovery of whether or not carotid angioplasty is better than surgery. So we have tremendous expertise across the country in evaluating and monitoring the efficacy of novel and new treatments for all disease processes.

So I don't think it's an issue of how our ethics committees would be structured to oversee the process of intervention of the venous lesions described by Dr. Zamboni. I think we have tremendous talent across the country to do that—and within the academic centres.

[*Translation*]

Mr. Luc Malo: Thank you.

[*English*]

Dr. Paolo Zamboni: We know this—

[*Translation*]

Mr. Luc Malo: It is just...

Dr. Paolo Zamboni: We know this very well.

An hon. member: There is a delay in the audio feed.

[*English*]

The Vice-Chair (Ms. Kirsty Duncan): Monsieur Malo, would you like to ask a question or would you like Dr. Zamboni to answer?

[*Translation*]

Mr. Luc Malo: Dr. Zamboni can answer, of course, but first, I would like to ask Ms. Lee a question.

Twice during his remarks, Dr. Maggisano clearly indicated that, in his opinion, the research process that the Multiple Sclerosis Society of Canada is undertaking is not adequate.

I would like her to respond, because I believe that what Dr. Maggisano said is quite important.

[*English*]

Dr. Paolo Zamboni: I'm sorry. Probably I don't understand very well, but the idea of Dr. Magissano is perfect, because any time you have new—

The Vice-Chair (Ms. Kirsty Duncan): Sorry, Dr. Zamboni, but I am going to rudely interrupt you for a minute to allow Dr. Lee to respond to a question.

Dr. Karen Lee: Thank you.

We understand that there's an urgency today from our clients who are wanting the treatment right now and to be tested. At the MS Society, we want to be responsible, to ensure that this treatment is safe and effective. In order to do this, we need to ensure that there is enough data out there. Right now, I know that Dr. Zamboni has presented his work and is presenting data on this. Also, however, Dr. Zivadinov is showing some differing data. And right now a new paper has come out that shows people with MS have zero blood flow drainage issues.

So with those different data in mind, we have to ensure that first steps are correctly looked into. Therefore, we have funded, with our American counterparts, $2.4 million towards further understanding the relationship between CCSVI and multiple sclerosis.

● (1230)

The Vice-Chair (Ms. Kirsty Duncan): Thank you, Dr. Lee.

I will respectfully ask all our visitors to maintain decorum so that we can continue with the committee.

Thank you, Monsieur Malo.

Now we will go to seven minutes for Ms. Hughes.

Mrs. Carol Hughes (Algoma—Manitoulin—Kapuskasing, NDP): Thank you very much.

I greatly appreciate your testimony and your comments today.

With the amount of procedures that you have done currently—and I'm asking this of the physicians who are with us today—I'm just wondering, have there been some negatives? I know that you've talked about some of the negative impacts, but how much of this has actually helped the patients?

People with MS have a condition. They get this procedure. How many of them have had zero....

A voice: Benefits.

Mrs. Carol Hughes: Yes. Benefits: that's the word I'm looking for. Thank you.

How many of them have had zero benefits from it?

The Vice-Chair (Ms. Kirsty Duncan): Is this question to...?

Mrs. Carol Hughes: This is a question to the doctors: Dr. Zamboni, Dr. Simka, and Dr. Magissano.

Dr. Marian Simka: May I answer the question?

Mrs. Carol Hughes: Yes.

Dr. Marian Simka: Our results are very preliminary because we began the treatments on the larger group of patients in January of this year, so we have only some months of experience on the bigger group of patients. I think we will have full data in the autumn, after the half-year, after the treatment.

But what I can say now about what we are seeing after one or two months of the treatment is that about 80%, 90%, of the patients experience improvement, and many of the patients are progressive multiple sclerosis patients with no options for treatment. Many of them have no possibility to have effective pharmacological treatment. For these patients, it's really a big thing, but of course, as I said, our data is very incomplete and primary.

Dr. Robert Maggisano: We have not done any angioplasties at our institution because we refuse to do them outside of a proper protocol. But Dr. Sandy McDonald, as I'm sure you're aware, has done seven cases, all of whom have shown improvement. I'm cautious here, in that the improvement was not identified by a blinded independent observer, which is what's necessary to do a proper study.

I have to comment on Dr. Lee's comment that they are evaluating the safety of the procedure. I beg to differ. What they are testing and funding testing of is not the procedure that is being advocated; rather, they're researching and funding research to see if venous disease is associated with MS. So if you're going to evaluate the efficacy and the safety of a procedure, you can't do it outside of actually doing the procedure and seeing whether it is safe.

Mrs. Carol Hughes: Dr. Zamboni, do you have any comments with respect to the benefits for the patients, what the percentage has been?

Dr. Paolo Zamboni: Yes. I began this treatment in 2007. We had 50 relapsing-remitting patients who completed three years of follow-up. The result was that 75% of the relapsing-remitting patients did not have more relapses or more active lesions on the MRI and increased their quality of life. This was in three years.

● (1235)

Mrs. Carol Hughes: I think the word is that the quality of life.... I mean, for these patients, for these people, this is the important part. They understand that this is not a cure, but it's an opportunity to relieve some of the symptoms they have and maybe prevent other medical problems from occurring.

So I have a question for Ms. Lee and Mr. Beaudet. There is some talk about.... Dr. Maggisano talked about the evaluating of the technique. What appears to be lacking is testing hypothesis; that's also what he's mentioned.

So here's my question. We were at a time where people were actually getting the procedure in Canada and the testing, so while we're waiting for you to get yourselves organized in order to decide how the research is going to be done for this, there's an opportunity for all of these people to actually have access to a treatment that will provide them with some relief, even if it's just a little bit of relief—whether their feet will no longer be cold, whether they will be able to go to the washroom on their own, anything.... It would be something they don't have right now.

So my question is this: is it not possible? We talk about a blinded study. I don't think we need to be blind about the fact that we saw Mr. Garvie walk in here as opposed to being in his wheelchair.

The Vice-Chair (Ms. Kirsty Duncan): Ms. Hughes, you have 30 seconds left, if you want to ask your question.

Mrs. Carol Hughes: I'm just wondering, is it not possible to be able to do the study with respect to having the procedures done in conjunction with the doctors performing them to provide you with the information you need? It would save us a lot of money as well and your study would go a lot further and a lot longer.

[*Applause*]

The Vice-Chair (Ms. Kirsty Duncan): Before we go to Dr. Beaudet, I'll just respectfully ask that we all.... This is emotional for everybody in the room.

We'll allow the witnesses to respond.

Dr. Alain Beaudet: So again, I think we agree here that our health care system is based on evidence-based practice. We do not submit patients to treatments for which we don't have proof that it works and that the benefits outweigh the risks. That's the first thing.

The second thing is what you're proposing actually is putting patients on protocols, i.e., to carry out proper randomized clinical trials to determine, in an unbiased fashion, whether or not the treatment works. What we are saying is that we urge researchers to come with a proposal to put patients on protocols to actually look at whether or not the procedure is actually efficient.

Now, I think this ties in very well with the studies that the MS Society has just started to fund, because you will agree with me that we could not really ethically carry out angioplasty on patients without first demonstrating that, indeed, there's insufficient or improper venous drainage in those patients; hence the importance of developing methods to determine whether or not there's proper venous drainage. Because you wouldn't do an angioplasty to improve venous drainage if there's no problem with the venous drainage, you would agree with me.

So that, I think, is a very important part of the puzzle: demonstrating that the hypothesis is right and justifying ethically the clinical studies using angioplasty.

The Vice-Chair (Ms. Kirsty Duncan): Thank you, Dr. Beaudet.

I think Dr. Maggisano wanted to get in on this. I'll allow him to answer before we go to Mr. Brown.

● (1240)

Dr. Robert Maggisano: I don't disagree with the proposal for randomized studies. I have an issue with what's currently being funded. It's lacking the treatment arm necessary to answer the question that you just said needs to be answered.

So of course it's important to know how to evaluate it and of course it's important to know how to image, but in the absence of a treatment arm in the protocols that the MS Society is funding for $2.4 million, we're not going to get an answer to the question. And the real issue is, will treatment of the lesions that we're going to learn how to identify...? And it's very easy to learn how to identify them. If one takes a trip to Ferrara, Dr. Zamboni will be more than happy to teach our techs and doctors how to properly evaluate for the hypertension and the decrease in blood flow. We're not used to these kinds of evaluations in Canada. I run vascular labs and my techs do not know how to do the study because we have not ever evaluated this in our country.

But what needs to happen is a change in paradigm. Let us go over to Ferrara. Let us learn what the proper technique is for evaluating MS, both by ultrasound and MR venography, and bring it back and then put to the test the hypothesis of whether or not treatment is efficacious.

If we don't do that, if we're going to focus on the evaluation of the disease process of the venous drainage over the next two years, we won't get to answer the question for four to five years. If we put the treatment arm with the studies concurrently to what is happening, then it's conceivable that we might have an answer within 18 months or 24 months, which will help the MS population a lot.

The Vice-Chair (Ms. Kirsty Duncan): Thank you, Dr. Maggisano.

Dr. Paolo Zamboni: May I answer?

The Vice-Chair (Ms. Kirsty Duncan): Dr. Zamboni, be very quick, please, as we have to get to Mr. Brown.

Dr. Paolo Zamboni: Okay. Very, very quickly, I want to underline that the gold standard in medicine to detect a stenosis or a narrowing in a vessel is gold standard angiography. I formally invite members of the committee to visit us, and I will be pleased to show you, in the computer system of our university hospital, 130 consecutive cases of this narrowing.

So this proof is completely undebatable, and probably if you follow other paths to demonstrate that this does not exist, it will certainly be the wrong way of confronting the problem, because the consensus conference on venous malformations inserted CCSVI in the official guidelines of the medical vascular society.

The Vice-Chair (Ms. Kirsty Duncan): Thank you very much, Dr. Zamboni.

I will now go to Mr. Brown for seven minutes.

Mr. Patrick Brown (Barrie, CPC): Thank you, Madam Chair.

Thank you for all the excellent testimony and information today.

Dr. Zamboni, thank you in particular for training Dr. Sandy McDonald. He has told me and members of this committee, I know, that your techniques are what allowed him to successfully treat the patients he has in Barrie, Ontario.

I hail from Barrie, Ontario, and I know that everyone in Barrie views Sandy as a physician who is of unquestioned integrity. That's one of the reasons why I'm a big believer in your work: because I know that Sandy would never do anything that he didn't unequivocally believe in. I know that in our community he has put himself at exposure, at risk, and he spent his own money to help treat patients because he believes in your work so much.

We all talk about evidence. What I'm curious about is how we can move this yardstick forward and what evidence is required. I was quite disheartened when the Royal Victoria Hospital had to discontinue Dr. McDonald's work.

I had a conversation with the CEO of RVH. She said that there was a variety of reasons that this treatment couldn't take place at RVH. One was that there were certain protocols with the College of Physicians and Surgeons. There's also the Ontario health technical advisory committee. And RVH wasn't going to be the lone wolf in the province of Ontario.

Here's what I wanted to know. The MS Society talked about providing evidence to provincial governments and I've heard mention of the treatment arm. What do we need to provide? Has anyone had conversations with various provincial bodies?

I think we all have the same end goal. If we believe in this, the end goal would be to see this in provincial health plans, so that someone doesn't have to spend $10,000 to go to Bulgaria. What is it going to take to get it to that point, to see this on OHIP, for example, in Ontario, so that Doctor Sandy McDonald and others wouldn't be putting themselves in tremendous legal exposure simply to help patients? I spoke to him this morning. That's what he asked me: how do we find a way through this minefield?

This is my question for the MS Society. Have you been given any information from provincial health ministries and what is required to have it added to the list of treatments?

For Mr. Beaudet, in the research that the minister talked about last night, the minister said that they are eagerly looking for applications for MS and specifically this new CCSVI. Is there going to be clinical research that involves treatment in that? What are the restrictions on the research that is being currently asked for?

● (1245)

Dr. Karen Lee: I'll start first.

So what we do understand in the scientific world is that you do need to provide further evidence. So right now, Dr. Zamboni's group has provided evidence in terms of CCSVI in MS; however, it's a very small group of people, so it's a pilot study, as Dr. Zamboni has stated, and it was not randomized. Many of the provincial governments will look and analyze for those data, so unfortunately, therefore, they don't have enough data right now.

They need bigger populations. They need more randomized controls. That is why the MS Society is funding the initial phase of these, basically almost replicating what Dr. Zamboni has done, in order to further understand if there is a relationship between CCSVI and MS and to do randomized and controlled studies in larger populations. So that's the first step.

Mr. Patrick Brown: How can the CIHR complement that in the expeditious fashion that we all hope for?

Dr. Alain Beaudet: Well, as I said already, and I'm sorry that I'm repeating myself, we're really anxious to receive a proposal for a randomized clinical trial, with treatment, to look at the possibility of funding a study, if it's deemed scientifically acceptable and methodologically sound, to look in a unbiased fashion and in a larger number of patients across the country at the efficiency of the treatment.

This being said, we do not make decisions as to the accessibility of treatment. What we do is fund the best possible research that we believe will provide solid scientifically sound evidence that the treatment is safe and efficacious. That's our goal.

Mr. Patrick Brown: Now there's one thing that has been repeated. I'm sorry to make you repeat yourself, but I think it's important to get it out. One thing that has been said is that there is no treatment arm of this research. So in this clinical research, randomized treatment would be part of it—

Dr. Alain Beaudet: There would be a treatment arm.

Mr. Patrick Brown: Okay. So that's very important to state, because obviously that's going to be something that's required to convince provincial governments that it's high time to have this as part of health insurance. So it's very encouraging to hear that.

Just as a friendly suggestion, I understand from Dr. Maggisano, who is from Sunnybrook.... I know that Sunnybrook has done partnerships before with the Royal Victoria Hospital in Barrie on cancer care. When I spoke to the CEO at RVH, I know that she mentioned they'd be eager to do partnerships with a senior hospital, a teaching hospital, and possibly on this MS. So maybe that's a possible application.

We heard from the Minister of Health last night that she's eager to see applications. We've heard from Mr. Beaudet that he's eager to see applications. So let's start seeing those applications roll in, because that's going to be a key step in this.

Is that something you might be interested in? I'm sorry to prod you on something that's obviously Sunnybrook's decision, but I thought I would mention RVH as a suggestion.

● (1250)

Dr. Robert Maggisano: Yes. We have been very interested in putting forth a proposal. It would require gathering a team, which obviously involves neurologists or MSologists. The barrier we've had to date is getting that team to collaborate to put forth a proposal. Perhaps after today, and if I go back to my neurological colleagues after being a witness here, they might reconsider and will consider putting together a proper randomized protocol study that hopefully will be funded, and we'll definitely get working on that as soon as possible with Sandy.

The Vice-Chair (Ms. Kirsty Duncan): Thank you, Mr. Brown.

Would the committee allow me to ask a few questions before we move to the five-minute round?

Mr. Patrick Brown: It's 12:52. We're not going to have time for any five-minute rounds, are we? Maybe we could just have four quick questions.

The Vice-Chair (Ms. Kirsty Duncan): Would the committee be willing to allow me to ask some questions?

An hon. member: *Oui*.

The Vice-Chair (Ms. Kirsty Duncan): Thank you.

I guess what I'm struggling with this morning is that we've heard that it's a small number of people who have actually had diagnosis and treatment and it was referred to just Dr. Zamboni's work. The number is upward of a thousand people now. I think Dr. Maggisano was clear in saying that let's not just do an interesting academic exercise, that we do have to test.

Why did the MS Society's announcement of research spending a few days ago aim exclusively at finding a statistical association of CCSVI in MS patients and not at allocating a single cent to actual treatment of CCSVI when all studies done to date have found that association?

Dr. Karen Lee: The MS Society heard from our clients in November when Dr. Zamboni's work was on the public stage. We expedited a process for a research grant, which we normally don't do at the MS Society, because we heard the need for CCSVI and MS research. At that stage, we crafted a request for operating grants specifically to look at the relevance to MS, so CCSVI and MS, so we invited those applications in. At this time, we are announcing funding for $2.4 million to further understand that evidence, that initial work that Dr. Zamboni has done.

The Vice-Chair (Ms. Kirsty Duncan): I think we have to be clear that there is more than Dr. Zamboni's work that has been done. We've heard today that Dr. Simka alone has done 400 patients.

Dr. Beaudet, I tried to ask this earlier today in the health committee. We have heard from the government that $16 million is going to be available to CIHR. The MS Society has asked for $10 million for research. What I asked for before was that the research occur with diagnosis and treatment. Let's diagnose and treat the people. Then you can follow them.

Of that $16 million, I'd like to know not how much is related to MS, but how much is actually allocated to CCSVI.

Dr. Alain Beaudet: Out of that $16 million, which, as you know, was money provided to us by the federal government as an increase over our base budget to address a number of priorities, one of these priorities was to increase the funding for clinical trials. That's exactly what we're talking about today. It's not to increase clinical trials specifically on that topic, but clearly if we receive a solid application to look at this very important issue, it will be considered and hopefully found acceptable for funding. That's all I can tell you.

The Vice-Chair (Ms. Kirsty Duncan): Will the people who—

Dr. Alain Beaudet: If you're asking whether the $16 million will be entirely devoted to MS research, the answer is no.

● (1255)

The Vice-Chair (Ms. Kirsty Duncan): Do we have any idea how much will? The MS Society has asked for $10 million and I have yet to hear if that money is going to be forthcoming to do diagnosis and treatment and follow the people.

Dr. Alain Beaudet: What I'm telling you is that we haven't yet received formal approval from Treasury Board as to how we're going to spend this money, so I cannot give you exact figures. But we have asked for a significant portion of that money to be put in our open grants competition so we can fund clinical trials, and I do hope we will have a successful application in that area.

The Vice-Chair (Ms. Kirsty Duncan): Thank you, Dr. Beaudet.

I would like to ask one last question. Then I'll ask if any of the other committee members would like to ask questions.

It's going to be really important going forward, if we're going to have review of these grant applications, that we have vascular surgeons as part of the review committee. These are the experts in the area. Can we be assured there will be vascular surgeons as part of the review committee?

Dr. Alain Beaudet: We always make sure that every aspect of an application has an expert reviewer to look at it. If the application looks like what I think it will look like, there will be vascular aspects, so we'll have an expert in vascular surgery involved. We need them. We'll also have an expert on MS. We'll need them as well.

The Vice-Chair (Ms. Kirsty Duncan): Thank you, Dr. Beaudet.

I think we have about three minutes left for a quick question.

Monsieur Malo.

[*Translation*]

Mr. Luc Malo: I would just like to try to see how we can decide whether this procedure is safe. In his brief, Dr. Simka told us that he has examined 400 cases and his conclusion is that the procedure is safe.

Dr. Beaudet, in answer to Mr. Brown's question, you said that studies would need to be done to determine if the procedure is safe.

I am just wondering if we can believe that what Dr. Simka said is scientifically recognized as safe or, as you seem to be suggesting, if something else needs to be done to determine if the procedure is safe.

Dr. Alain Beaudet: Mr. Malo, you are putting a balloon into a blood vessel, a vein with a weak wall, and enlarging that vein. Is the procedure 100% safe? I know of no procedure, even eating natural food, that is 100% safe.

The question we must ask ourselves with any procedure is whether the benefits outweigh the risks. That is what we want to find out. We want to make sure that the benefits associated with this procedure significantly outweigh the risks inherent in any procedure. That is evidence-based practice.

[*English*]

The Vice-Chair (Ms. Kirsty Duncan): Would Dr. Simka, Dr. Maggisano, or Dr. Zamboni like to respond? And then, I think, we're going to have to say thank you to everybody.

Dr. Robert Maggisano: Venoplasty has been used in our hospitals in Canada as a treatment modality probably for the last 25 years. As was suggested, no treatment is 100% safe, but it's a minimalistic type of procedure that we use routinely, both in the arteries and in the veins.

I think if the issue is the potential benefit against the potential risk, there's minimal, minimal risk to venoplasty and/or venous stenting from a medical perspective, compared to the potential benefit for a chronic MS patient who would have improved life quality.

The Vice-Chair (Ms. Kirsty Duncan): Thank you, Dr. Maggisano.

First of all, I'd like to thank all of our experts, particularly those who are available from overseas and from Toronto, for their testimony and for their time and effort.

And I'd like to thank everybody who came here today.

The meeting is adjourned.

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