Paolo Zamboni – a Q&A

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The following is the transcript of the interview with Paolo Zamboni, conducted by The Globe's Siri Agrell. The Italian medical professor turned the multiple sclerosis community on its head by suggesting that MS – long regarded as an autoimmune disease – might be caused by chronic cerebro-spinal venous insufficiency (CCSVI).

What's your reaction to the death of Mahir Mostic [the Ontario man who died last month after undergoing an angioplasty in a Costa Rican clinic]?

There are thousands of procedures done all over the world. I cannot control what happens in any way. My academic activities cannot control what happens in the world.

Do you feel bad that your name is connected to these types of deaths?

We have thousands of requests for visits, consultations. But I never reply because it's not possible. I work 12 hours a day on this kind of research. I am not a consultant and I do not perform any activity related to the business of CCSVI at all.

What are you researching now?

It's going very well. I think that in the next six months we'll publish several publics, some in co-operation with other universities around the world. In one month, I believe we'll get final approval for a big, double blinded, randomized control trial on the value of balloon angioplasty in MS treatment. This may be the only study to help us understand the role of CCSVI treatment. It will involve approximately 15 centres in Italy and double blinded and randomized in order to avoid any residual doubt on the so-called placebo effect. There will be an objective measurement, not just the subjective clinical assessment of a neurologist, but also by using the proper device for measuring motor activity, balance, and neural activity.

When will that study be completed?

Two years. The observation will be 15 months. But you have to get all the data from all the centres and the analysis will require time.

If you find that the procedure is not helpful, do you think people will stop getting the procedure done?

I don't think so. My recommendation at this particular moment, from a scientific point of view –which is the only point of view interesting for me – is that we do not have enough

data to recommend surgery in MS. But individuals, both physicians and patients, are completely free to do what they want. I cannot control this. I do not want to control this. But certainly, the message is that we are not ready in this moment to recommend surgery.

Are you monitoring other studies around the world?

Yes, I was in New York last week at a big vascular meeting and had a lot of exchanges from colleagues from all over the world. And I understand that there is the intention to submit different ethical, quality-controlled studies for approval regarding diagnosis and treatment. I think this is very interesting. This is fantastic to me because of the [studies'] non-profit status.

Why do you think so many countries have been reluctant to endorse the CCSVI treatment?

The Canadian situation can be transported to other countries. There is very big opposition on behalf of the neurology community usually involved in MS research. They prefer at this moment to perform epidemiological studies. But I think that this can be considered a parallel track. Because information coming from the correction of CCSVI is also very important and cannot be postponed in my opinion.

So you think that both avenues should be studied?

Yes, I think both are very important. And there are many other prospective models: in vitro, genetics. All these studies can be carried out contemporaneously and give us a lot of information in a reduced time. Because that is very important for people.

Do you think news of CCSVI complications and deaths is setting back your research?

Yes, because what I saw in the last month is that the treatment of CCSVI is, in the majority of cases, investigated with the wrong methodology and protocols as opposed to what we proposed. And this is contributing to big confusion. It will be negative in confirming our data, but the point is that nobody used the gold standard.

Do you think doctors are being irresponsible by performing the procedure?

I don't think so. But I think it is very important to divide what is speculation for business from what is a good activity. There are centres in the United States, Italy and other countries that [are doing the intervention] without big publicity and have highly qualified people capable of managing the complications. So this is very important.

Does it upset you that people are traveling far from home and paying to have this done?

I cannot control what happens. I know there are a lot of centres in the world stating that they are in contact with me or use my methodology or are formally trained by me. But really I do not know them. So I understand there is a lot of speculation and it is very difficult to defend people. The only right defence, in my opinion, is a clear action from the government. I think it's very important that the government understands this kind of non-profit treatment research is very important and needs to be done urgently for ethical protection of the patient. That's my message.

So you think governments need to step in and say we're going to do this treatment in a controlled fashion?

Absolutely. I cannot understand why a country like Canada with a very good public-health system refuses to support a treatment study on 500 people. I think that is not a good thing. It's not the correct answer.

Do you think it would save lives if they stepped in?

I think that a study like this, using the proper, conservative, safe treatment with ethical protection and the possibility of managing the event of a complication, can be very useful for people.

You've said you never recommended the use of stents in the procedure. Why do you think people keep getting them?

I think this is not a very responsible thing in this particular moment. We need to be conservative. The risk of migration is very high, as is thrombosis. I have shown that managing CCSVI with two balloon angioplasty, you may have a perfect result. So I prefer to use two approaches rather than just one in a dangerous way.

Are lots of people with MS contacting you for advice?

Yes, we have hundreds of calls and e-mails every day. This is very difficult to manage, of course.

Do you reply to all of them?

We have a website with a FAQ, we have an answer line open three hours daily with possibility for people that call with the possibility to speak English or French or another language.

Do you feel overwhelmed by the attention?

Oh yes, absolutely. All the patients have a personal story to tell. There are thousands of procedures done all over the world. I cannot control what happens in any way. My academic activities cannot control what happens in the world.

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