AMEDS
CENTRUM

MEDICAL REPORT
ON CCSVI TREATMENT

THE PATIENTS

Since 2010 AMEDS Centrum has professionally dealt with the diagnosis and treatment of chronic cerebro-spinal venous insufficiency (CCSVI). This venous system pathology, which has only recently been described by Prof. P. Zamboni, shares a striking similarity with multiple sclerosis (MS).

Our center has treated more than 500 MS patients to date, from Poland and abroad (a majority of patients have come from Canada and the Scandinavian countries), 38% of which have been men. Average age of our patients was 46 years.

The statistical AMEDS Centrum patient has been diagnosed with MS 11 years ago. The majority of patients suffered from secondary progressive MS. Pre-operation, our patients were assessed on the 10 point Expanded Disability Status Scale (EDSS), with the average patient score of 5.5 points.

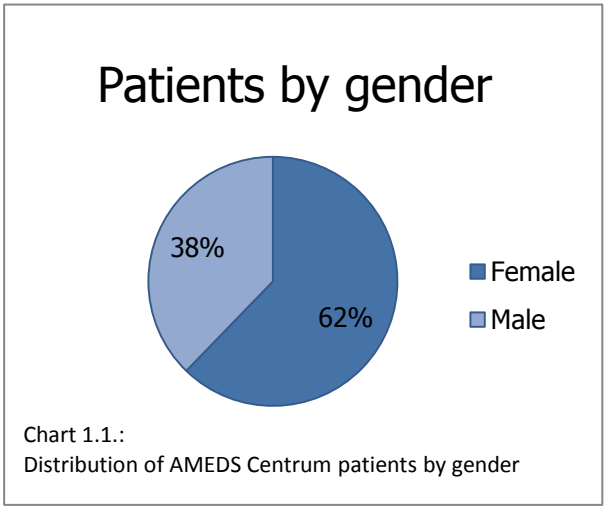


Chart 1.1.:
Distribution of AMEDS Centrum patients by gender

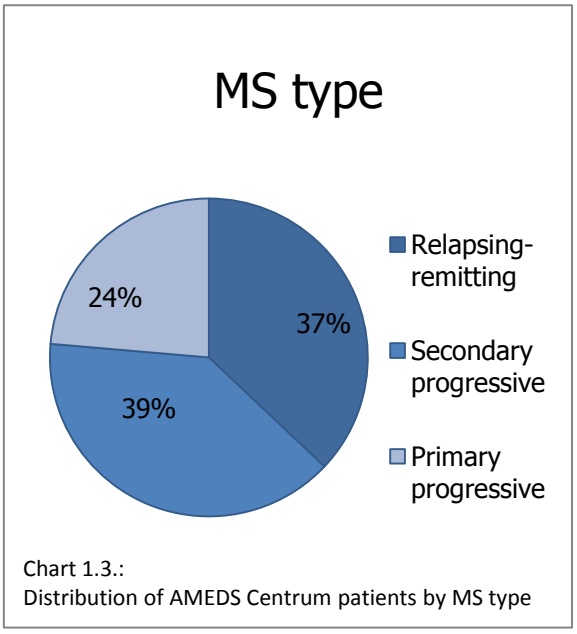


Chart 1.3.:
Distribution of AMEDS Centrum patients by MS type

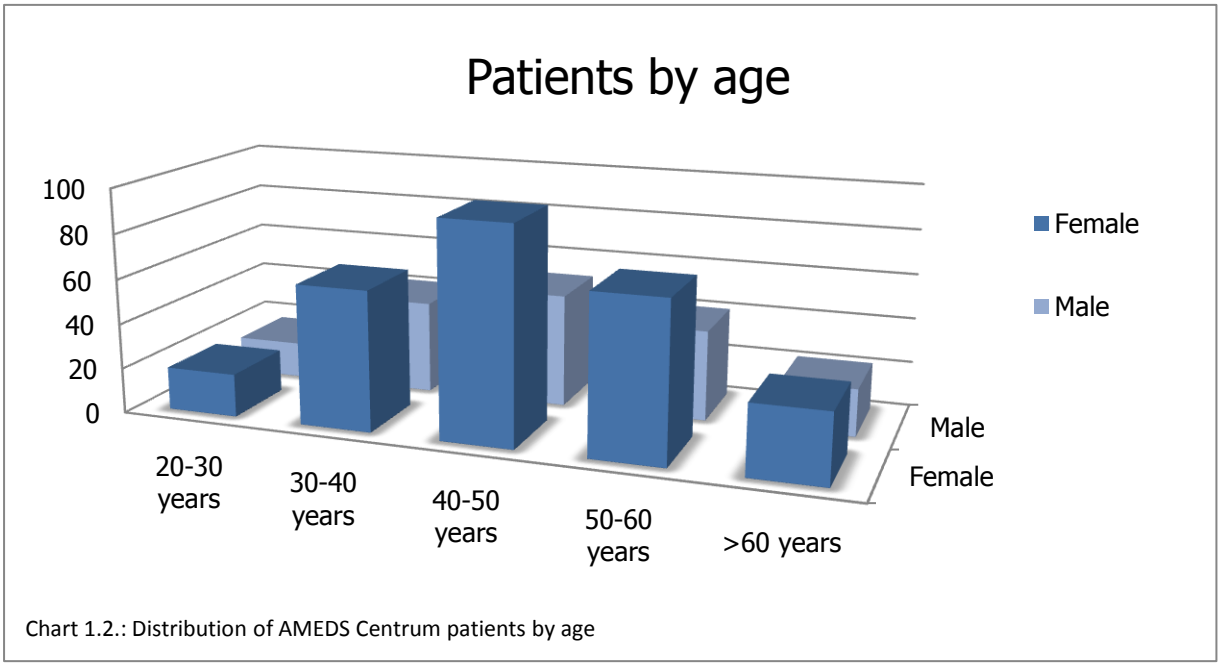


Chart 1.2.: Distribution of AMEDS Centrum patients by age

DIAGNOSIS AND TREATMENT

Ultrasound (Doppler and transcranial)

The basic method used in the diagnosis of patients with chronic cerebro-spinal venous insufficiency (CCSVI) is a Doppler ultrasound. It is a safe and completely non-invasive diagnosis of the vascular system. The equipment we use at AMEDS Centrum is the "MyLabVinco" from the Italian company Esaote, designed for both extra and intracranial testing. 3D Doppler technology is used to determine the hemodynamic severity of venous insufficiency.

The following parameters are assessed during diagnosis:

- The presence of venous stenosis
- Circulatory disorders and reversed blood flow (reflux)
- Flow change in extra-cranial veins dependent on body position
- The presence of valvular disease

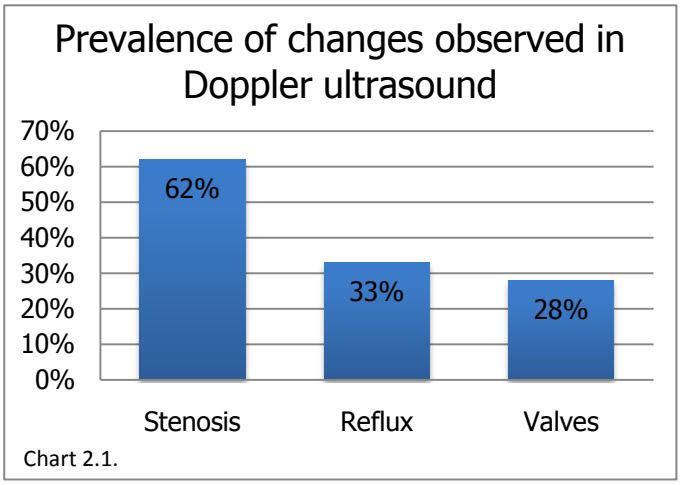
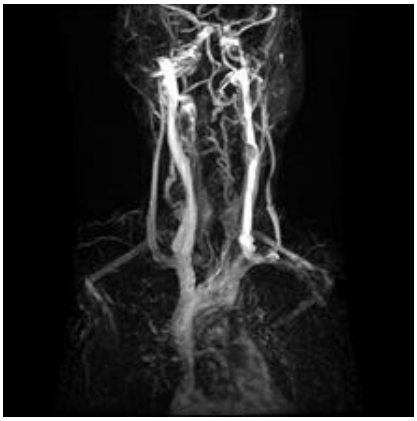


Chart 2.1.

The above chart shows the prevalence of abnormalities that were discovered in patients who underwent Doppler examination.

Magnetic Resonance Imaging (MRI)



MRI of the brain and neck has two main purposes:

- The assessment of brain activity in the context of determining the presence and location of demyelinating lesions, as well as the possible presence of other abnormalities.
- Evaluation of venous outflow, in particular the jugular and azygos veins. The analysis includes: symmetry of venous outflow, width and patency of the veins, as well as an assessment of any stenosis or vein modeling caused by adjacent anatomical structures.

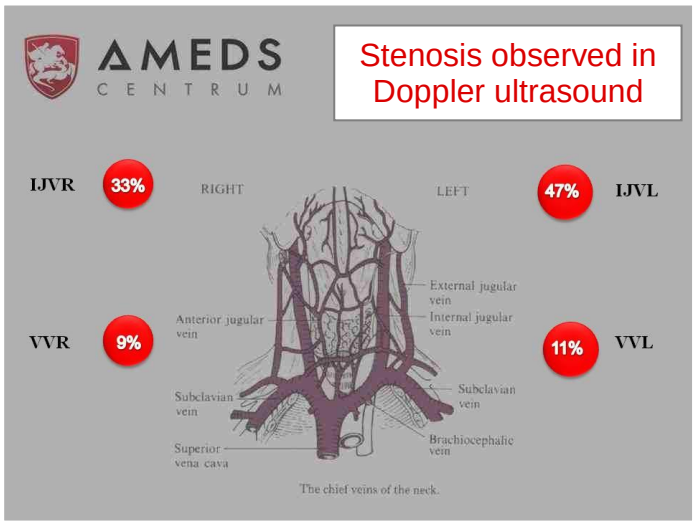
The examination of the venous system is made using modern techniques with the use of a contrast agent (which allows for optimum picture clarity): Multi-phase MRI venography as well as a T1-weighted 3D GRE sequence of very high resolution, which guarantees very high quality images.

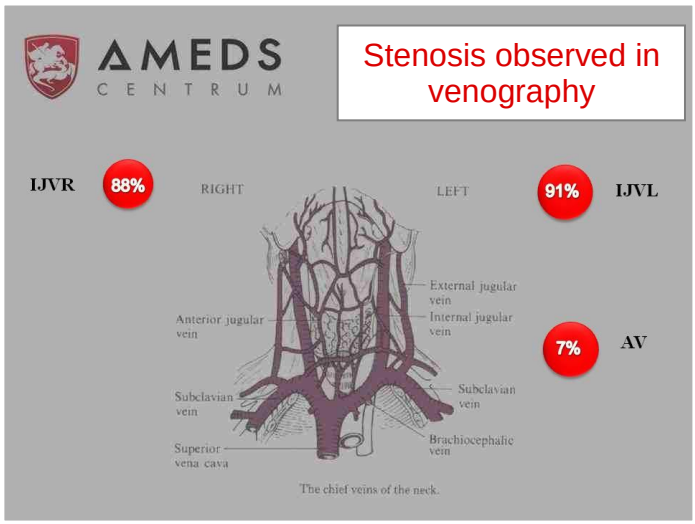
The contrast agents used are paramagnetic and result in negligible, mild side effects (headaches, hot flashes, extremely rare allergic reactions). The MRI contrast agent we use has been rated by the European Society of Urogenital Radiology as one of the safest agents available. Moreover, this contrast agent contains a higher concentrations of paramagnetic media than other contrast agents, and also improves relaxation times – these traits guarantee an optimal level of contrast enhancement in MR Venography, which in turn permits a more accurate evaluation to be performed.

DIAGNOSIS AND TREATMENT

VENOGRAPHY

The final step in the diagnostic process is a venography, which produces the most reliable diagnosis of abnormalities in the venous system. It consists of the administration of a contrast agent into the vein via a catheter (inserted in either the femoral or subclavian vein). This allows the most accurate visualization of vascular lesions. This procedure is invasive and therefore entails a risk of complications. Venography precedes any intra-vascular operations. The venography procedure allows for an exact examination and imaging of the venous system, which provides an excellent method of verifying and confirming the presence of any abnormalities detected by Doppler or MRV. The below drawings show the prevalence of stenosis detection using Doppler ultrasound and venography (IJVR – right internal jugular vein; IJVL – left internal jugular vein; VVR – right vertebral vein; VVL – left vertebral vein; AV – azygos vein).





VENOUS ANGIOPLASTY

Venous angioplasty, also known as balloon angioplasty, is the basic method of treatment applied to CCSVI patients at AMEDS Centrum. In rare instances, when necessary, stents are inserted.

Venous angioplasty is a procedure performed for widening the constricted vein with the use of a special catheter placed in the vein via percutaneous access (the catheter is introduced in the groin area, into the femoral vein). A balloon is then inserted into the constricted vein and inflated with gas.

The risk of complications connected with the procedure is estimated to be less than 3%, with the risk of serious events staying below 1,5%.

	ANGIOPLASTY	STENTS
Left internal jugular vein	**401**	**32**
Right internal jugular vein	**389**	**15**
Azygos vein	**37**	**7**

Treatment results – neurological state

Fatigue Severity Scale (FSS)

In two thirds of patients with multiple sclerosis, chronic fatigue is an accompanying symptom of the disease and always a big problem for the patient. The FSS scale helps in assessing fatigue levels. The scale is from 1 to 7, with higher scores reflecting higher fatigue levels (scores above 5.5 signify severe fatigue). Our patients have been observed to experience a marked improvement in the incidence of fatigue (a reduction of 35% on the FSS scale!) and a dramatic increase in strength and energy.

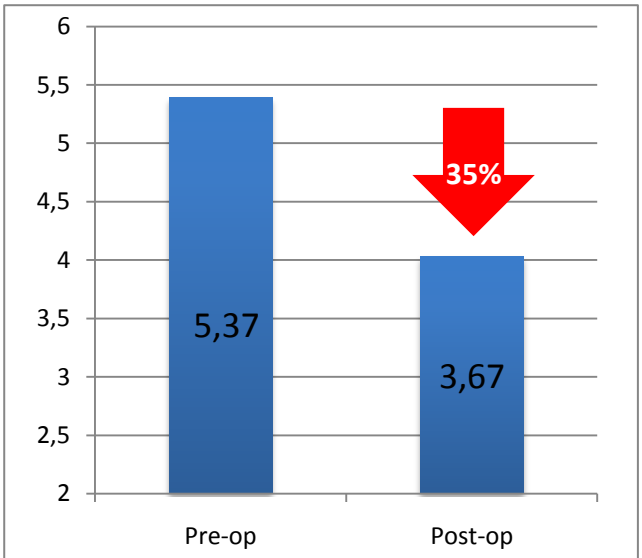


Chart 3.1.: Fatigue Severity Scale

Multiple Sclerosis Impact Scale 29 (MSIS-29)

Multiple Sclerosis Impact Scale 29 (MSIS-29) is a proven and reliable scale for measuring the quality of life in patients with MS. The patient answers 29 questions (20 regarding physical state, coordination and mobility and 9 about mental state). After the score is calculated we obtain a result on a scale of 0-100, where the higher the score, the worse the state of health of the patient. AMEDS Centrum patients who have undergone treatment display a noticeable improvement in mental and physical health – shown below – with a corresponding reduction of points on the MSIS-29 scale.

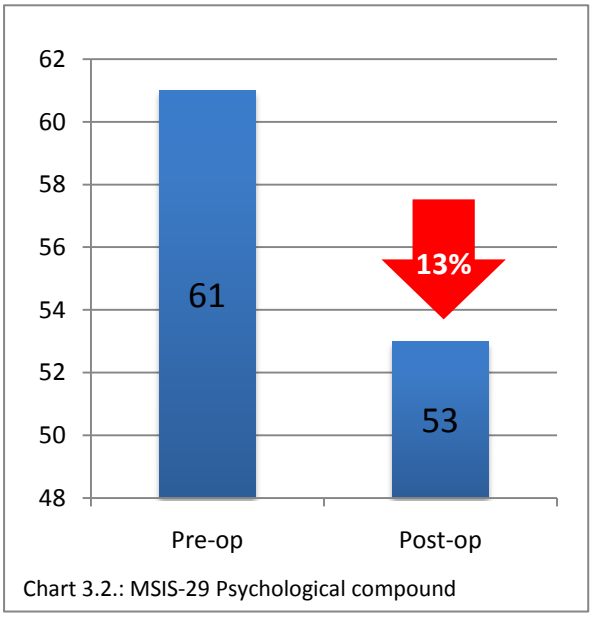


Chart 3.2.: MSIS-29 Psychological compound

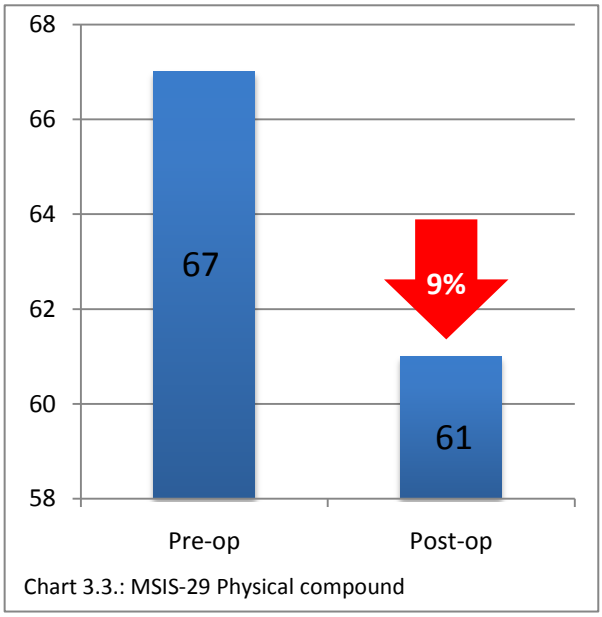
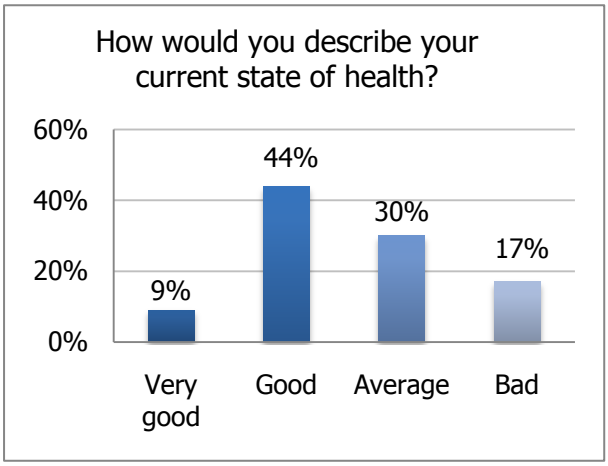
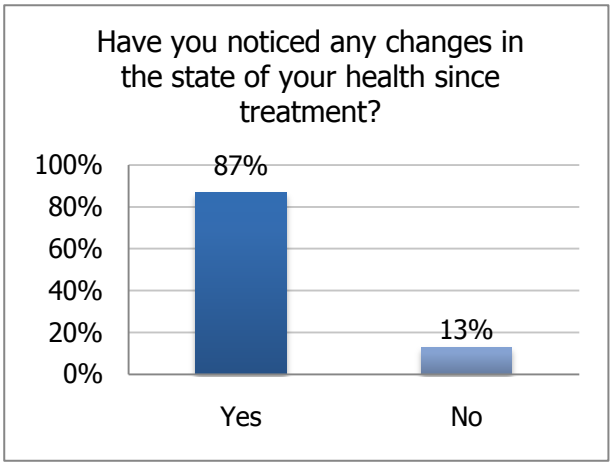


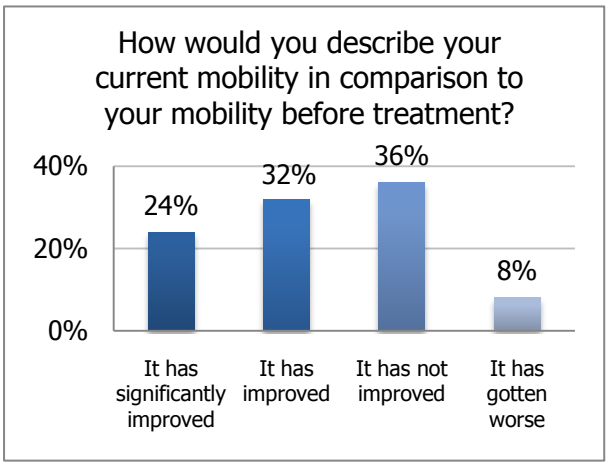
Chart 3.3.: MSIS-29 Physical compound

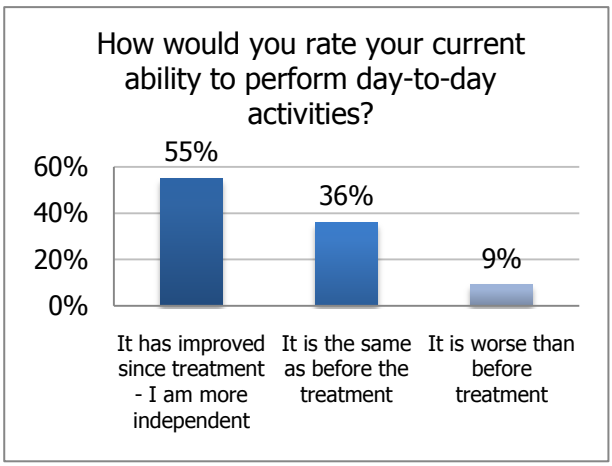
Treatment results – quality of life

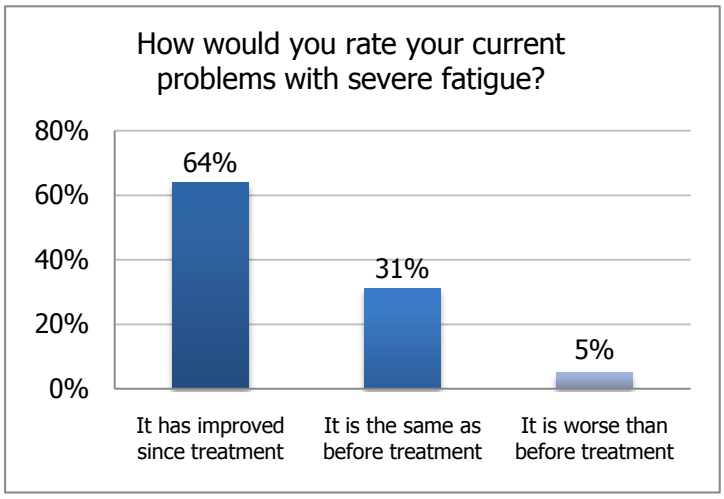
In order to assess the influence that treatment at AMEDS Centrum has on the quality of life and level of improvement in different aspects of functioning, we have devised a special survey for our patients. Within 4-6 months of treatment we asked our patients to answer the questions found in our survey. Below are the results of a couple of selected questions:











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Summary

We have performed over **500** venous angioplasty to date at AMEDS Centrum. The positive effects of treatment of MS patients are noticeable both in the objective assessment of the patients' quality of life as per the MSIS-29 system, as well as in our own assessment. Based on the scale for measuring fatigue levels, improvements reach up to 35%. After 4-6 months, more than half of our patients report a positive change in mobility and daily activity.

In addition to the services currently offered, the staff of AMEDS Centrum plans to conduct clinical trials into the efficacy and safety of angioplasty in CCSVI patients. We also actively participate in international scientific conferences (CCSVI Congress Glasgow, October 2010, Venous Endovascular Forum Katowice, March 2011, ISNVD&CNR Congress Bologna, March 2011) where we present our own experiences and keep abreast of progress in the field.

Dr. Maciej Zarębiński, AMEDS Centrum Medical Team Leader, would like to thank all our patients for placing their trust in us and for sharing (by answering our survey) their opinions on the treatment they received at AMEDS Centrum.

Maciej Zarębiński, MD, PhD

Prof. Jerzy Kotowicz

Professor Jerzy Kotowicz, MD, PhD is a prominent neurologist, specialist and authority on multiple sclerosis. He is the author of more than 80 scientific papers in the Polish and international medical literature. Since 2006 he has served as chairman of the Review Committee of the Polish Clinical Neurophysiology Association, he is the vice-president of the Advisory Board to the Polish Multiple Sclerosis Society. He has served two terms as the vice-president of the Polish Clinical Neurophysiology Association.

"The existence of CCSVI, its relation to MS and the legitimacy of performing balloon angioplasty is the source of much controversy among – and is dismissed by many – neurologists. This state of affairs is the result of unfamiliarity with CCSVI, an attachment to their theory of immuno-inflammatory disease, as well as a conviction that procedures using stents (which are rarely used) are dangerous. Reports presented at two international symposia devoted to CCSVI in Katowice and Bologna in March, 2011 confirm the association of CCSVI with MS. As a result of venous re-canalization after angioplasty, it has been objectively confirmed that the levels of venous oxygen saturation do improve. The reports emphasized the positive influence balloon angioplasty has on the quality of life of patients, on their fatigue levels, on bladder disorders, balance disorders, vision problems, sensory problems and, to a lesser degree, mobility issues. Improvement was also noted in cognitive abilities (memory, concentration, attention).

At present, results are not yet in regarding the clinical trials conducted on the basis of "good medical practice" and "evidence based medicine" which were begun in the middle of 2010, and no long-term results of venous angioplasty are known. The results of these studies will only become available in the future and settle the question of this treatment's effectiveness. The desire of the patient for treatment is highly understandable, though, especially in light of the disease's progress and the lack of effectiveness of other treatments available."

Professor Jerzy Kotowicz, MD, PhD

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