

## **Integrating intraoperative diagnostic information: lessons learned from the PREMISE trial**

*Authors & Affiliation:* Yuval Karmon<sup>1,2</sup>, Robert Zivadinov<sup>3</sup>, Bianca Weinstock-Guttman<sup>2</sup>, Karen Marr<sup>3</sup>, Vesela Valnarov<sup>3</sup>, Kresimir Dolic<sup>3</sup>, Cheryl Kennedy<sup>3</sup>, Ellen Carl<sup>3</sup>, L. Nelson Hopkins<sup>1</sup>, Elad I. Levy<sup>1</sup>, Adnan H. Siddiqui<sup>1</sup>

<sup>1</sup>Department of Neurosurgery, <sup>2</sup>The Jacobs Neurological Institute, and the<sup>3</sup>Buffalo Neuroimaging Analysis Center, State University of New York, Buffalo, NY

Recently, a condition named chronic cerebrospinal venous insufficiency (CCSVI) has been described in patients with multiple sclerosis (MS) (1). It is characterized by multiple intraluminal stenosing malformations of the principal pathways of extracranial venous drainage, particularly in the internal jugular veins (IJVs) and the azygous vein (AZY), that impedes the normal blood outflow from the brain (1-4). Its diagnosis was mainly based on non-invasive Doppler sonography (DS) for IJV imaging (1, 3) and invasively on using selective venography (SV) for the depiction of both Azygus and IJV stenosis (1,2). Based on the findings, treatment of stenotic lesions with balloon angioplasty was proposed to have a presumable therapeutic potential.

Despite being the “gold standard” for assessing and quantifying vascular problems, arterial/venous angiography only provides a luminography (a contrast shade of the lumen boundaries) with little or no data on the vessel's wall, or intraluminal structures thus limiting the ability to detect lesions such as atheroma, intraluminal valves, septa, and flaps. Intravascular sonography, has an advantage over angiography because it provides images from within the vessel, has greater resolution without having to penetrate the extravascular soft tissues, and provides 3D assessments (20). Because of its higher spatial resolution and the fact that it enables analysis of the insides of vessel walls, IVUS provides a more reproducible and accurate measurement of disease severity than angiography (10).

In this study we used IVUS as a complementary tool during SV in order to delineate better details of endoluminal structural abnormalities.

As there were some reports of serious adverse events (SAE) during or after some of the SV performed, the initial part of the study was conducted mainly as a safety phase for the endovascular procedure.

This pilot study investigated possible complimentary new ways to detect both the mechanical impediments (DS and IVUS) to cranial blood drainage and it's the resultant deranged flow.