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NEWS RELEASE

## First Blinded Study of Venous Insufficiency Prevalence in MS Shows Promising Results

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BUFFALO, N.Y. -- More than 55 percent of multiple sclerosis patients participating in the initial phase of the first randomized clinical study to determine if persons with MS exhibit narrowing of the extracranial veins, causing restriction of normal outflow of blood from the brain, were found to have the abnormality.

The results were reported today by neurology researchers at the University at Buffalo.

When the 10.2 percent of subjects in which results were border line were excluded, the percentage of affected MS patients rose to 62.5 percent, preliminary results show, compared to 25.9 percent of healthy controls.

These preliminary results are based on the first 500 participants in the Combined Transcranial and Extracranial Venous Doppler Evaluation (CTEVD) study, which began at UB in April 2009. Investigators are planning to examine 500 additional subjects, who will be assessed in the second phase of the study with more advanced diagnostic tools. Complete data on the first 500 will be presented at the American Academy of Neurology meeting in April.

Robert Zivadinov, MD, PhD, UB associate professor of neurology and principal investigator on the study,

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A study by neurologist Robert Zivadinov has shown that the narrowing of extracranial veins is, at the very least, an important association in multiple sclerosis.

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says he is "cautiously optimistic and excited" about the preliminary data. Zivadinov directs the Buffalo Neuroimaging Analysis Center (BNAC), located in Kaleida Health's Buffalo General Hospital, where the study is being conducted.

"The data encourage us to continue on the same course," he says. "They show that narrowing of the extracranial veins, at the very least, is an important association in multiple sclerosis. We will know more when the MRI and other data collected in the CTEVD study are available." The analyses are being conducted by an independent statistician.

The investigation is the first step in determining if a condition called chronic cerebrospinal venous insufficiency (CCSVI) is a major risk factor for MS. CCSVI is a complex vascular condition discovered and described by Paolo Zamboni, MD, from Italy's University of Ferrara. Zamboni's original investigation in a group of 65 patients and 235 controls showed CCSVI to be associated strongly with MS, increasing the risk of having MS by 43 fold.

Zamboni and Zivadinov hypothesize that this narrowing restricts the normal outflow of blood from the brain, resulting in alterations in the blood flow patterns within the brain that eventually cause injury to brain tissue and degeneration of neurons.

The first 500 patients, both adults and children, were grouped based on their diagnosis: MS, clinically isolated syndrome (CIS) and "other neurologic diseases" (OND), in addition to healthy controls.

All participants in the first phase underwent ultrasound (Doppler) scans of the head and neck in different body postures to view the direction of venous blood flow. MS subjects also underwent MRI scans of the brain to measure iron deposits in lesions and surrounding areas of the brain, using a method called susceptibility-weighted imaging. Iron findings on these images will be related to subjects' disability and neuropsychological symptoms.

Of the total participants, 97.2 percent were adults, with the 280 MS patients comprising the largest disease cohort examined in the study to date. The majority of MS subjects were diagnosed with the relapsing-remitting form of MS. There were 161 healthy controls. Doppler scan results were reported on five specific criteria that affect venous blood flow. Patients who met at least two of the criteria were considered to have CCSVI. More detailed analysis of specific Doppler criteria and their association to disease status is underway.

When the 10.2 percent borderline subjects were included in the "normal" category (no venous insufficiency), the CCSVI prevalence was 56.4 percent in MS subjects and 22.4 percent in healthy controls.

In this large MS cohort, the presence of CCSVI did suggest an association with disease progression, a finding that was not shown in Zamboni's smaller cohort, Zivadinov notes.

The finding that 22.4 percent of healthy controls also met two CCSVI criteria requires continuing investigation, he says.

Bianca Weinstock-Guttman, MD, UB associate professor of neurology in the UB School of Medicine and Biomedical Sciences and a co-principal investigator on the study, notes that the results of the CTEVD research will pose new and provocative questions about the CCSVI theory.

Murali Ramanathan, PhD, associate professor in the Department of Pharmaceutical Sciences, UB School of Pharmacy and Pharmaceutical Sciences, and Ralph Benedict, PhD, UB professor of neurology and psychiatry, also are major contributors to the study.

The University at Buffalo is a premier research-intensive public university, a flagship institution in the State University of New York system and its largest and most comprehensive campus. UB's more than 28,000 students pursue their academic interests through more than 300 undergraduate, graduate and professional degree programs. Founded in 1846, the University at Buffalo is a member of the Association of American Universities.