Randomized penumbra 3-D trial of next generation stent retriever meets primary endpoints

July 27 2016

Today during the Society of NeuroInterventional Surgery's (SNIS) 13th Annual Meeting, SNIS President Donald Frei, MD, announced that the Penumbra 3D Trial successfully met the primary trial endpoints, demonstrating non-inferiority in safety and efficacy of Penumbra 3D Revascularization Device, when used with Penumbra System aspiration devices compared to Penumbra System aspiration devices alone.

Results showed non-inferior revascularization rates according to the FDA-defined primary effectiveness measure of TICI 2-3 in the Penumbra 3D Revascularization Device with Penumbra System aspiration devices arm (3D+aspiration device arm) compared to the Penumbra System aspiration devices only arm (aspiration device-only arm) (88.5 percent vs. 85.9 percent). In addition, the more strictly defined revascularization measure, TICI 2b/3, showed non-inferiority between the 3D+aspiration device arm and the aspiration device-only arm (83.9 percent vs 74.1 percent). The primary safety endpoints - device-related serious adverse events (SAEs) and procedure-related SAEs - were not statistically different between the two arms ($p=1.0$ and $p=0.4920$, respectively).

Dr. Frei served as lead investigator of the study and is also the director of NeuroInterventional Surgery at Radiology Imaging Associates/Swedish Medical Center in Englewood, Colorado.

"This study shows that we can achieve excellent revascularization with good clinical outcomes in aspiration alone as well as with aspiration plus stent retriever thrombectomy," said Dr. Frei. "As endovascular technology continues to advance, we can help more patients with emergent large vessel occlusion (ELVO) achieve independence."

Patients in both arms experienced similar rates of return to functional independence (mRS ? 2 at 90 days): 41.6 percent in the 3D+aspiration device arm and 48.8 percent in the aspiration device-only arm (p=0.4260). These clinical outcomes were obtained without the benefit of selecting patients using imaging techniques designed to detect viable brain tissue.

Provided by Society of NeuroInterventional Surgery