

Consistently Good Acute Stroke Outcomes and Device Safety With The Penumbra System™ Again Confirmed In NIH-Funded Study

The Associated Press

ALAMEDA, Calif.--(BUSINESS WIRE)--Feb 13, 2013--Last week Joseph Broderick, MD, Principle Investigator of the Interventional Management Of Stroke III (IMS III) Trial, announced the overall results and major subgroup analyses at the International Stroke Conference (ISC) in Honolulu, Hawaii. Thomas Tomsick, MD, Principle Investigator and Primary Interventional Investigator announced results comparing outcomes by intra-arterial approach.

The IMS III Trial was a prospective, randomized trial comparing two different treatment approaches—combined intravenous (IV) and intra-arterial (IA) therapy, and standard IV r-tPA (clot-busting drug)—to restoring blood flow to the brain. The primary goal was to determine if individuals with ischemic stroke treated using a combined IV/IA approach to recanalization started within 3 hours of onset are more likely to have a better outcome than individuals treated with standard IV r-tPA alone. IMS III began enrolling in 2006.

In the device-based IA intervention subset, The Penumbra Aspiration Thrombectomy System showed 84.6% TICI 2-3 revascularization of ICA and/or M1 occlusions vs. 72.8% for the Retriever category overall (72.7% for the Merci Retriever and 75% for the Solitaire Stent Retriever.) Penumbra Aspiration Thrombectomy also achieved 33.3% of patients living independently with a good clinical outcome* vs. 23.5% for the Retriever category overall (23.4% for the Merci Retriever and 25% for the Solitaire Stent Retriever.) The study clearly showed that the proportion of good clinical outcomes increased with greater reperfusion rates.

The safety record of the Penumbra System also fared very well when compared to the Retriever category devices. Mortality among patients with ICA and/or M1 occlusions treated with the Penumbra System was very low at 17.9% verses 33.3% for Retrievers (33.8% for the Merci Retriever and 25% for the Solitaire Stent Retriever). Embolization to New Territory (ENT) when using the Penumbra System occurred only 3.7% of the time verses 23.0% of the time when Retrievers were used in any treated vessel (22.1% for the Merci Retriever and 40% for the Solitaire Stent Retriever.) The study demonstrated that a stroke patient's chance of achieving functional independence was very poor when ENT occurred. Without ENT, 30.2% of patients made a good recovery.* When ENT occurred, only 17.9% of patients made a good recovery.

"I'm not surprised that the Penumbra System data is better than the other interventional techniques in the IMS III Trial," said Blaise Baxter, MD, FRCPC, Director of Interventional Services at Erlanger Hospital in Chattanooga, Tennessee. "The newest devices in the Penumbra System armamentarium, like the 5MAX

Reperfusion Catheter, allow us to stay at the site of occlusion using direct aspiration to make sure we remove all of the clot and prevent any embolization to otherwise unaffected territories.” J Mocco, MD, MS, Associate Professor of Neurological Surgery, Vanderbilt University Medical Center in Nashville, Tennessee and Principle Investigator for the prospective, randomized THERAPY Trial of acute stroke intervention said, “The IMS III trial did not use an imaging-based patient selection criteria to screen patients for enrollment. In fact, over 20% of patients enrolled in the IA arm of IMS III did not even receive IA therapy. The vast majority of these were because the patient was deemed to have no significant brain artery blockage.” “Moving forward it is critically important to identify those patients that have a high potential for benefit from IA intervention, meaning those with a treatable brain occlusion, as well as those hypothesized to have a low likelihood of improving with IV tPA alone. The THERAPY trial uses a very easy to implement clot length criteria which we believe will identify exactly this patient group. The ease of determining clot length, and its ability to define a large treatment effect for endovascular therapy, has now been shown in two large trials, one out of Germany, and another recently presented by Albert Yoo, MD, et. al. from Massachusetts General Hospital here at the ISC,” Dr. Mocco continued.

“A growing consensus among top stroke hospitals was achieved during a packed meeting at the International Stroke Conference. This consensus points toward a trial design that includes both appropriate imaging-based screening criteria, and the use of the most modern and advanced technologies including Direct Aspiration, and clot capture devices like the Penumbra 3D. THERAPY’s design, and its inclusion of the latest technologies, is strongly supported by data from large, NIH-funded studies such as IMS III and MR Rescue. We owe a huge debt to the work of those pioneering investigators in helping to point the way forward,” concluded Dr. Mocco.

* Modified Rankin Score (mRS) of 0-2 at 90 days Solitaire is a trademark of Covidien, Inc. and Merci is a trademark of Stryker, Inc.

ABOUT THERAPY

The THERAPY Trial is a landmark randomized-control trial designed to demonstrate the effectiveness of aspiration thrombectomy for stroke patients with large vessel occlusions. The Therapy Trial has the potential to change the standard of care for stroke by studying a focused patient population that is most likely to benefit from interventional treatment. THERAPY employs a novel, state-of-the-art imaging-based patient selection algorithm that has the potential to define a population of patients particularly resistant to intravenous clot-busting drug, but particularly responsive to aspiration-based clot removal. This unique trial design, combined with the latest innovations in thrombectomy tools, may provide high quality evidence of the benefit of inside-the-artery clot removal treatment for patients suffering an acute stroke. Patients will be assigned to either IV r-tPA therapy alone or a combined IV r-tPA therapy and intra-arterial (IA) treatment with the Penumbra System. THERAPY will enroll up to 692 patients at up to 75 sites around the world. ClinicalTrials.gov Identifier: NCT01429350 ABOUT Penumbra Penumbra, Inc. (www.penumbrainc.com) is an independent medical device company committed to delivering clinically beneficial products that help patients suffering from stroke and other vascular diseases. Penumbra’s global headquarters is located in Alameda, California with

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