

Stroke patients experience superior outcomes with intra-arterial treatment vs. tPA

17 December 2014

Penumbra, Inc., the market leader in intra-arterial stroke treatment, announced that an independent study published online today in the *New England Journal of Medicine* found that intra-arterial stroke treatment, including the company's clot extraction technology, was shown to be significantly more effective than medical management with tissue plasminogen activator (tPA), which is the current standard of care. The findings of this randomized, controlled comparative effectiveness trial of stroke treatment have the potential to change the standard of care and improve functional independence for the 15 million stroke patients worldwide who currently have few treatment options.

Intra-arterial treatment, also called endovascular or interventional treatment, involves working inside the artery to remove the clot. In the MR CLEAN (Multicenter Randomized Clinical trial of Endovascular treatment for Acute ischemic [stroke](#) in the Netherlands) comparative effectiveness study, intra-arterial treatment improved the rate of good functional outcome by 71 percent over treatment with medical management with tPA alone. Of patients who received intra-arterial treatment, 32.6% achieved a clinically defined positive stroke outcome compared with 19.1% of those who received medical management. Intra-arterial treatment was beneficial for all ages (18+), including the elderly (80+) - a population for whom intervention was previously thought to be risky.⁽¹⁾ The trial began enrolling in 2010 and participating physicians used earlier generation intra-arterial technology. Currently available technology continues to improve upon the baseline set by MR CLEAN.

"Despite being the number one cause of long-term adult disability, stroke has been one of the most undertreated and devastating diseases in the

world," said Albert J. Yoo, M.D., director of Acute Stroke Intervention in the Division of Interventional Neuroradiology/Endovascular Neurosurgery at Massachusetts General Hospital, assistant professor at Harvard Medical School and study author of MR CLEAN. "Now that intra-arterial treatment has been proven to provide significant benefits for stroke patients of all ages, we have a golden opportunity to dramatically improve the lives of stroke victims and, at the same time, help reduce costs in our healthcare system by returning patients to functional independence."

MR CLEAN also demonstrated:

- Intra-arterial treatment was effective for patients with the most common and devastating form of stroke, LVO (large vessel occlusion), for which tPA is less effective.
- Intra-arterial treatment is effective up to 6 hours after stroke onset vs. 3 to 4.5 hours for tPA.
- Both treatments were safe, with no differences relating to hemorrhage or mortality.

"With the results of MR CLEAN, we have the needed evidence to support [endovascular treatment](#) in the fight against stroke, and the results are truly astounding," said Michael J. Alexander, MD, FACS, Director of the Neurovascular Center, Professor of Neurosurgery at Cedars-Sinai and past president of the Society of NeuroInterventional Surgery. "They show that endovascular treatment can benefit a broad population of patients - not just younger patients as previously thought but older patients as well if treated early."

"The MR CLEAN study results provide evidence to support intra-arterial treatment in the fight against

stroke and have the potential to change the standard of care," said Adam Elsesser, chief executive officer, director and founder, Penumbra. "Penumbra is proud to have supported the MR CLEAN trial, and these important results will aid our efforts to improve access to intra-arterial treatment for the millions of stroke patients around the world."

Penumbra provided an unrestricted grant for the trial, and its devices were among those included in the protocol. Companies providing grants had no influence over the trial's design or execution. Penumbra's newest intra-arterial treatment, which was not available at the time MR CLEAN was conducted, is the ACE™, a next generation clot extraction system that uses aspiration alone to engage and remove blood clots causing an [acute ischemic stroke](#). Results with the Penumbra ACE system continue to improve upon the baseline set by MR CLEAN.

STROKES IN THE U.S.

affect **800,000** Americans per year

cost **\$73.7 B** in 2010

#1 cause of disability

#4 cause of death

Intra-Arterial Treatment is More Effective

Pharmaceutical	Intra-Arterial
Tissue Plasminogen Activator (tPA) Helps Dissolve Clot to Restore Blood Flow	Blood Clot Removed Using Minimally Invasive Vacuum Inside the Artery
Up to 3 TO 4½ Hours	Up to 6 Hours
19.1%	32.6%

From The New England Journal of Medicine
Intra-Arterial More Effective than tPA in Improving Outcomes¹

Call 911 + Fast Treatment

Critical to Reduce Risk of Long-Term Disability or Death

Find Your Nearest Advanced Stroke Center

900 Stroke Centers in U.S.

Only 50% Offer Intra-Arterial Treatment

www.Quest25topStroke.com

Penumbra

¹ Berkhemer OA, Fransen PSS, Soumar D, et al. A randomized trial of intra-arterial treatment for acute ischemic stroke. N Engl J Med. In Press.

Stroke is the leading cause of disability in the United States, affecting 800,000 people each year. Fast, effective treatment is essential to achieve the best possible outcome from a stroke. Before making a decision about treatment for yourself or a loved one, learn the comparative facts about both drug and intra-arterial treatments -- and which one is more effective at helping you or a loved one regain mobility and functional independence. Credit: Penumbra, Inc.

Provided by Merryman Communications

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