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Product bulletin

Stryker announces publication of the DAWN™ Trial results in the New England Journal of Medicine

Kalamazoo, Michigan, USA – November 13, 2017 –The New England Journal of Medicine published the results of the DAWN Trial, the first to provide compelling evidence in treating late window and wake-up stroke patients with mechanical thrombectomy. Currently, less than one in 10 patients suffering from an ischemic stroke receives thrombectomy, due in part to a lack of scientific evidence supporting treatment beyond six hours. The results shown in the DAWN trial have the potential to fundamentally change the paradigm of care for stroke patients globally.

According to Dr. Tudor Jovin, co-principal investigator from the University of Pittsburgh Medical Center, “By quadrupling the size of the therapeutic time window, the consequence of DAWN is that many more patients with large vessel occlusion stroke have the potential to be treated with mechanical thrombectomy. DAWN validates the physiological, rather than time-based approach to patient selection for endovascular therapy.”

“Time alone should no longer be a disqualifier for thrombectomy but rather only a source of urgency. We hope this new treatment paradigm will benefit a large proportion of patients who were previously deemed untreatable,” commented Dr. Raul Nogueira, Professor of Neurology, Neurosurgery and Radiology at Emory University School of Medicine and Director of Neuroendovascular Service, Marcus Stroke & Neurosciences Center, Grady Memorial Hospital and co-principal investigator on the study.

“The results of the DAWN Trial offer the first level-one evidence of significant reduced disability in patients who present in the late time window,” said Mark Paul, president of Stryker’s Neurovascular division. “However, best outcomes are achieved when patients are treated as quickly as possible, requiring increased patient awareness, EMS outreach and hospital infrastructure to be in place.”

The DAWN Trial reflects Stryker’s commitment to clinical leadership and focus on patient pathway development. Sponsored by Stryker, the trial was designed to evaluate functional outcomes at 90 days in stroke patients treated with mechanical thrombectomy using the Trevo® Retriever compared to those receiving medical therapy alone. Patients were screened for inclusion in the trial if they had a stroke that started within six to 24 hours, or a stroke with an unknown time of onset—a significantly longer treatment window than the currently cleared thrombectomy indication.

About the Trevo Retriever

Stryker's Trevo Retriever is a tiny stent-shaped medical device that is attached to a thin wire. In a minimally invasive procedure that utilizes X-ray, the physician navigates the retriever from the femoral artery (located in the upper leg) to the blocked blood artery in the brain. The retriever is designed to ensnare the blood clot and remove it from the body. Originally cleared by the FDA in 2012 for the revascularization of patients experiencing ischemic stroke, the Trevo Retriever has been used in thousands of patients worldwide. The retriever's indication within the DAWN Trial, for use in patients treated six to 24 hours after last seen well, is currently under an Investigational Device Exemption (IDE) only. The Trevo Retriever was the only mechanical thrombectomy device used in the DAWN Trial.

An animation and Important Safety Information of Stryker's Trevo Retriever is available here:

<https://youtu.be/PxcERzyl67I>

About ischemic stroke

An ischemic stroke occurs when an artery in the brain becomes blocked by a blood clot or other substance such as plaque, a fatty material. Blood vessels carry blood, oxygen and nutrients throughout the body and to the brain. When the brain is deprived of blood and oxygen, it fails to work properly. Depending on the severity of the stroke and the area of the brain affected, loss of brain function or death may occur. According to the World Heart Federation, ischemic stroke contributes to 6 million deaths around the globe.¹

About Stryker

Stryker is one of the world's leading medical technology companies and, together with its customers, is driven to make healthcare better. The company offers innovative products and services in Orthopaedics, Medical and Surgical, and Neurotechnology and Spine that help improve patient and hospital outcomes. More information is available at www.stryker.com.

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1. <http://www.worldstrokecampaign.org/learn.html>. Accessed September 19, 2017.