Studies Show New Promise for Stroke Victims

Two global trials published online in *The New England Journal of Medicine* (*NEJM*) and presented at the European Stroke Organisation Conference found that the addition of the Solitaire™ device stent thrombectomy procedure to current pharmaceutical treatment significantly reduced disability in patients suffering stroke. These trials confirmed the findings of three previous trials also published in *NEJM*.

Both the SOLITAIRE™ FR With the Intention For Thrombectomy as Primary Endovascular Treatment for Acute Ischemic Stroke (SWIFT PRIME) and Endovascular Revascularization With Solitaire Device Versus Best Medical Therapy in Anterior Circulation Stroke Within 8 Hours (REVASCAT) trials assessed if patients experiencing an acute ischemic stroke (AIS) and treated with the Solitaire device in addition to current medical therapy, including IV-tPA when patients were eligible, had less stroke-related disability than patients treated with IV-tPA or medical therapy alone. SWIFT PRIME was sponsored by Medtronic plc and REVASCAT was supported by an unrestricted grant from Medtronic.

“SWIFT PRIME showed that treatment with the Solitaire device is safe, technically successful and substantially reduces long-term disability levels,” said Jeffrey L. Saver, M.D., FAHA, FAAN, FANA, professor of Neurology, Geffen School of Medicine at the University of California, Los Angeles (UCLA) and director, UCLA Comprehensive Stroke Center. “This treatment marks the beginning of a new era in stroke care.”

Similarly, REVASCAT (206 patients) showed that patients treated with the Solitaire device in addition to medical therapy (which included IV-tPA in eligible patients that comprised 70 percent of subjects enrolled) up to eight hours

from onset of symptoms, experienced a statistically significant improvement in the rate of return to functional independence (43.7 percent vs. 28.2 percent) in favor of patients treated with the Solitaire device when compared to medical therapy alone.

Both SWIFT PRIME and REVASCAT confirmed the findings of Extending the Time for Thrombolysis in Emergency Neurological Deficits–Intra-Arterial (EXTEND-IA), Endovascular Treatment for Small Core and Proximal Occlusion Ischemic Stroke (ESCAPE) and Multi-center Randomized Clinical trial of Endovascular treatment for Acute ischemic stroke in the Netherlands (MR CLEAN), global trials also published in *NEJM*. All of these trials have shown that the amount of time to treatment has a significant impact on outcomes. SWIFT PRIME demonstrated dramatic improvements in workflow (the complete cycle of care from diagnosis through treatment) compared to previous trials. The trial was conducted at 39 centers across seven countries, demonstrating broad applicability in different health systems and the achievability of fast, efficient stent thrombectomy care.

REVASCAT was conducted at four comprehensive stroke centers in Catalonia, Spain, covering a population of 7.5 million people. In looking at the overall population, 85 percent of the population of protocol-eligible patients were enrolled in the trial. The broad eligibility criteria and the high enrollment achieved in the REVASCAT trial, therefore, make the positive results of the Solitaire device highly generalizable to a sizable majority of those who suffer strokes in Catalonia.

“We now have five global trials that provide an overwhelming body of clinical evidence in support of Solitaire stent thrombectomy,” said Antoni Davalos, M.D., director, Department of Neurosciences, Hospital Universitari Germans Trias i Pujol. “Based on these findings, it is time for the stroke community to come together to re-evaluate stroke treatment guidelines and to look for systems to facilitate the access of treatable

patients to specialized centers.”

The Solitaire device uses a micro-sized catheter to access arteries in the brain affected by stroke through an incision in the leg. Once delivered, the Solitaire device helps to immediately restore blood flow and remove the blood clots causing the stroke.

“These findings are bringing the global stroke treatment community together to rethink how we provide stroke care,” said Brett Wall, president of the Neurovascular business, which is part of the Restorative Therapies Group at Medtronic. “Improving patient access to the proven Solitaire device stent thrombectomy procedure is an important objective for all of us who are committed to fighting stroke. We support the revision of guidelines and the benefit that this will drive to patients, health systems and our broader society.”

According to the World Stroke Organization, stroke is the fifth leading cause of death worldwide and contributes to nearly 6 million deaths around the globe.

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