Medtronic News

Meta-Analysis Shows Medtronic's Solitaire(TM) Stent Retriever Device Improves Functional Outcomes for Acute Ischemic Stroke Patients; Reduced Mortality in Patients 80+

SEER Pooled, Patient-Level Analysis of SWIFT PRIME, EXTEND-IA, ESCAPE and REVASCAT Shows Safety and Efficacy of Solitaire Device

DUBLIN - February 18, 2016 - A meta-analysis published online today in *Stroke* and presented at the International Stroke Conference (ISC) in Los Angeles, Calif., found that the addition of Medtronic plc's (NYSE: MDT) Solitaire(TM) stent retriever to current pharmaceutical treatment (IV-tPA) significantly improves functional outcomes in patients suffering stroke. Safety and Efficacy of Solitaire Stent Thrombectomy - Individual Patient Data Meta-analysis of Randomized Trials (SEER) also showed a significant reduction (20% vs. 40%, adjusted OR 3.7(1.3-10.6), p=0.01) in mortality for patients over the age of 80.

SEER assessed four global clinical trials published last year in the *New England Journal of Medicine* (NEJM): SOLITAIRE(TM) FR With the Intention For Thrombectomy as PRIMary Endovascular Treatment for Acute Ischemic Stroke (SWIFT PRIME), Endovascular Revascularization With Solitaire Device Versus Best Medical Therapy in Anterior Circulation Stroke Within 8 Hours (REVASCAT), EXtending the Time for Thrombolysis in Emergency Neurological Deficits - Intra-Arterial (EXTEND-IA) and Endovascular Treatment for Small Core and Proximal Occlusion Ischemic Stroke (ESCAPE). SEER is the first patient-level global meta-analysis of the four randomized trials and examined data from a total of 787 patients. The analysis showed that patients experiencing an acute ischemic stroke and treated with the Solitaire stent retriever, when eligible, had significantly improved independent functional outcomes (mRS 0-2) at 90 days than patients treated with IV-tPA alone (54% vs. 31.5%, p<0.0001). The analysis also found that patients over the age of 80 and in good health had a clinically and statistically significant 20 percent absolute reduction in mortality. Further, the analysis showed a strong significance in the numbers needed to treat (2.5) to reduce disability (i.e., for every 2.5 patients treated with the Solitaire device plus IV-tPA, 1 patient showed improved functional outcomes).

"The SEER analysis confirms the overall benefits of the Solitaire stent retriever device and provides important insights into clinical subgroups where the benefits were not clear cut in the individual trials," said Bruce Campbell, BMedSc, MBBS (Hons), FRACP, PhD, University of Melbourne. "The meta-analysis showed that patients over the age of 80 clearly benefited with significantly reduced mortality. Patients with contraindications to IV-tPA, as well as those with more challenging blocked arteries in both the neck and brain, also show a clear benefit from Solitaire."

The study showed a time-benefit relationship for treatment of patients with acute ischemic stroke, with decline in the probability of independent functional outcome with longer time from symptom onset to reperfusion.

"Treatment with the Solitaire stent retriever was very successful with extremely low complication rates and low symptomatic intracranial hemorrhage," said Mayank Goyal, MD, FRCPC, University of Calgary. "The pooled data represents a broad sample of health-care systems, countries and hospitals and demonstrates applicability in different health systems around the world."

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.

"This analysis confirms the robust treatment benefits of stent retrievers, specifically, the most studied of these devices: the Solitaire stent retriever, across multiple health care systems across the world," said Manish Gupta, senior director, Global Medical Affairs, Medtronic Neurovascular. "Medtronic has a longstanding commitment to proving the value of our innovations through scientific research and it is rewarding to see how our data is helping to spark a revolution in stroke care globally."

In June 2015, the American Heart Association/American Stroke Association (AHA/ASA) published new stroke treatment

guidelines that recommended the use of stent retriever technology - such as the Solitaire stent retriever device - in conjunction with IV-tPA as a first-line treatment for eligible patients.

According to the AHA/ASA, stroke is the fifth leading cause of death in the U.S. and the leading cause of disability.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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