

Solitaire™ FR Revascularization Device

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I. INTRODUCTION

STROKE is the 4th leading cause of death in the United States and the leading cause of disability. Stroke is caused by the occlusion of the cerebrovasculature due to a thrombus or embolus. The Solitaire FR Revascularization Device is an advancement in the endovascular treatment of acute ischemic stroke. The Solitaire device is used by interventional radiologists to recanalize the major cerebrovascular arteries that become occluded during a stroke leading to infarct of brain tissue distal to the thrombus.

II. RECOGNITION OF STROKE SYMPTOMS

The most important determinant to a patient's outcome from stroke is time. The treatments available today only allow for medical intervention to reestablish circulation in the blocked vessel up to 8 hours after the onset of symptoms. After this time window for the risk outweighs the benefit of any active treatment and the patient could face severe morbidity or mortality. For these reasons fast recognition of stroke symptoms and response to these symptoms has been a major public health initiative over the last several years. The mnemonic F.A.S.T. has become the mantra for educating the public about the signs of stroke. F.A.S.T stands for Face, Arm, Speech and Time. Drooping of one side of the face, weakness in one arm and slurring of speech are the hallmark signs someone is having a stroke. Time is the key component to saving brain function and is emphasized as "Time lost is brain lost". Recognizing the symptoms and reacting fast give the patient the best chance of a good outcome.

III. TREATMENT OPTIONS

For patients who suffer a major stroke treatment options to reverse the damage caused to the infarcted areas of the brain are limited to the first eight hours after symptom onset. Drug treatment is available up to 4.5 hours after symptom onset and for those who either fail drug treatment or are not candidates for drug treatment, mechanical thrombectomy by endovascular intervention may be an option up to 8 hours after symptom onset. The Merci Retriever, which uses a corkscrew like device to engage and remove the clot has been the standard of care for mechanical thrombectomy. In 2012 the Solitaire FR Revascularization Device was approved by the FDA based on the strong results of the SWIFT Trial. The Solitaire device is threaded through the clot over a guidewire and then is deployed from the center of the clot, expanding outward, ensnaring the clot for removal.



The Solitaire Clot Retrieval System deployed in an occluded middle cerebral artery.

IV. RESULTS

The results of the SWIFT trial which compared patients undergoing mechanical thrombectomy for treatment of acute ischemic stroke randomized to either the Merci Retriever or the Solitaire device. The results showed the successful recanalization rates of the Solitaire device and the Merci retriever were 61% and 24% respectively, good neurological outcomes at 90 days was 58% vs 33% in favor of the Solitaire device and mortality at 90 days was also in favor of the Solitaire device at 17% vs 38% .

V. DISCUSSION

Stroke continues to be one of the leading causes of morbidity and mortality in the US and worldwide. Despite its prevalence the treatment options for stroke remain limited and only available within a relatively short window. Recognition of stroke symptoms by the public and getting patients to the hospital quickly are key to the outcomes of stroke patients. While the treatment options are limited the Solitaire FR Revascularization Device represents an important advancement in treatment. The superior recanalization rates and morbidity and mortality outcomes show that a novel design to an existing mode of treatment can produce a large impact on public health.

REFERENCES

- [1] "Solitaire FR Revascularization Device" Covidien. 27 Feb 2013 <<http://www.ev3.net/neuro/intl/flow-restoration/solitaire-fr-revascularization-device.htm>>
- [2] Saver, JL Jahon R, Levy EI. Solitaire flow restoration device versus the Merci Retriever in patients with acute ischaemic stroke (SWIFT): a randomized, parallel-group, non-inferiority trial. *The Lancet*, 380(9849), 1241-1249 2012.
- [3] "About Stroke" American Stroke Association. 27 Feb. 2013 <http://www.strokeassociation.org/STROKEORG/AboutStroke/About-Stroke_UCM_308529_SubHomePage.jsp>