Claret Medical treats first patient in SENTINEL Trial, on path to approval

By Omar Ford
Staff Writer

Claret Medical (Santa Rosa, California) has been gaining a lot of attention as of late, first from results from CLEAN-TAVI ,and now the company is reporting that the first patient has been treated in its SENTINEL Trial in the U.S., a multicenter pivotal trial of the Sentinel Cerebral Protection System (CPS).

The first patient was treated at New York and Presbyterian Hospital/Columbia University Medical Center (New York) by Susheel Kodali, a national co-principal investigator for the trial. The SENTINEL Trial will evaluate up to 284 patients at up to 15 centers nationwide.

"This is a very big study both for the company and for the cardiovascular field as a whole in that this is the first study that is testing the efficacy of a device that is intended to protect the brain from ischemic lesions during cardiovascular procedures – in this case specifically the TAVR procedure," Tony Fields, COO, Claret, told *Medical Device Daily*.

Claret Medical said that it expects enrollment to take between seven to nine months.

The primary endpoints for the SENTINEL Trial are the reduction in total new lesion volume as determined by diffusion-weighted magnetic resonance imaging (DW-MRI) and major adverse cardiac and cerebrovascular events (MACCE). A number of secondary endpoints, such as neurocognitive and histopathological outcomes during TAVR, will be compared in the study arms with and without cerebral protection.

"The goal of the study is to elucidate the benefit of capturing debris during this procedure, and we feel strongly that we'll show a difference between not using the device and using the device in terms of lesions of the brain," he said. "These lesions of the brain have been shown in numerous studies to lead to greater incidents in stroke longterm. Our desire and goal is that this will become the standard of care in the U.S., but it's very hard to predict that."

Stroke continues to be a devastating complication of TAVR procedures, occurring in around two to eight percent of procedures according to published literature. Recently, new ischemic brain lesions, or "silent" infarcts, have been shown to occur in more than 90% of TAVR patients. These lesions have been associated with adverse neurologic and cognitive consequences, and dementia. They have also been shown to increase the risk of stroke by two to four times in future years, according to population-based studies published in the 2013 American Stroke Association/American Heart Association consensus guidelines.

Fields said that the device is simple to use an implant in patients.

"Our device goes in prior to the start of the TAVI procedure and comes out just following it," he said. "It's a six french catheter that goes right in the radial artery of the right arm and its threaded up through that vessel and deployed in each of the two carotid vessels leading to the brain. The

idea is to filter any debris that is released through the TAVR procedure, capture it and remove it from the body."

At last month's Transcatheter Cardiovascular Therapeutics (TCT) meeting, 30-day results from the CLEAN-TAVI randomized, controlled trial studying Claret Medical's cerebral protection system were presented as a Late Breaking Clinical Trial session. The results strongly supported the use of the technology.

Results show that there was 53% reduction in the total volume of new brain lesions and 60% reduction in the number of new brain lesions two days after the TAVR procedure when the Claret Medical cerebral protection system was used; 24% incidence of the neurological symptoms of ataxia in the control group as compared to nine percent in the treatment group protected with the Claret Medical system in a "Per Protocol" analysis at two days, which reached statistical significance; observed neurological deficit in 28 percent of all control patients at two days post-procedure when evaluated by a NIHSS (National Institute of Health Stroke Scale) trained specialist in an "Intent to Treat" analysis, demonstrating that prospective assessment pre- and post-procedure can identify more neurological effects than has been reported to date

"Any occurrence of stroke is one too many, and results from this clinical trial may give us the evidence needed to make cerebral protection a standard of care during TAVR, as it is in carotid artery stenting," said Samir Kapadia, director of the **Cleveland Clinic's Sones Cardiac Catheterization Laboratories** and a national co-principal investigator for the study. "By both capturing and removing embolic debris released during TAVR, the Sentinel CPS may offer a unique neuroprotective benefit. We expect the device to demonstrate a similarly significant reduction in the number and size of lesions in the brains of TAVR patients when cerebral protection is used as was recently reported in the CLEAN-TAVI trial."

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