‘Encouraging’ Early Findings With Embolic Protection in TEVAR, Suggests Small Pilot Study

By Michael O’Riordan

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Hollywood, FL—The use of an embolic protection device in thoracic endovascular aortic repair (TEVAR) is feasible and appears to reduce silent infarcts to the brain, according to the results of small feasibility study.

In findings presented yesterday at International Symposium on Endovascular Therapy (ISET) 2016, embolic protection with the Sentinel Cerebral Protection System (Claret Medical) appeared to reduce the number and volume of cerebral lesions as assessed by MRI.

“At the moment, there is no embolic protection used in TEVAR, anywhere,” lead investigator Gagandeep Grover, MBBS, of Imperial College (London, England), told TCTMD. “But what we have noticed is that there is data emerging now from ours and other units that there is a cerebral embolization rate and a stroke risk associated with TEVAR. There is also a silent cerebral infarction rate, just as there is in TAVR. Based on that data, we asked how can we mitigate that risk?”

At their clinical center, Grover said the rate of silent cerebral infarction with TEVAR was previously shown to be 68%, while the rate of overt stroke was 13%. In line with these data, a neuroimaging study from Germany reported that the rate of silent cerebral infarction was 63% in 19 patients who underwent TEVAR. These silent “insults” are caused by microembolization—valve tissue, calcification, thrombus, or other materials—that can occur when wires and devices are passed within the diseased aorta. These infarcts, said Grover, have been documented to increase the future risk of stroke by 2- to 4- fold and are associated with dementia, depression, and neurocognitive decline.
Grover pointed to CLEAN-TAVI, a 100-patient study presented in 2014 showing that the Claret Montage embolic protection device (Claret Medical) significantly reduced the number and volume of cerebral lesions in high-risk TAVR patients who underwent treatment with the filter. Using the same principle, the researchers have tested the system in just 4 patients to date as part of a pilot study but so far the results are promising, according to investigators.

“We have started to see encouraging results,” said Grover. “We’re doing pre- and post-MRI and neurocognitive testing. . . . Two patients had no lesions in the brain on MRI, and 2 patients had very small-volume lesions. It is very early data but hopefully when we complete the pilot study—just like the CLEAN-TAVI did—we can perform a randomized trial to determine if there is a true benefit.”

Patients in the pilot study were emergency hospital admissions for acute aortic syndrome but stable enough for recruitment. Senior investigator Mo Hamady, MBChB, also of Imperial College, told TCTMD the device consists of a 6–Fr-compatible catheter with 2 deployable filters delivered via the brachial or radial artery from the patient’s right side. The device uses a proximal embolic filter in the brachiocephalic artery and a distal embolic filter delivered to the left common carotid artery.

In timing the deployment and retrieval of the device, Grover said the first case took 16 minutes while their last case took 2 minutes. “It’s a very rapid learning curve,” she said.

Regarding the neurocognitive findings, Grover said the data to date are preliminary, but testing has not revealed deficits in any the patients. As for the clinical need, she told TCTMD that the number of TEVAR cases is increasing in the United Kingdom, and with the emergence of TEVAR over open surgery, older patients are undergoing treatment. Older patients tend to be particularly vulnerable to cognitive deficits—loss of memory or executive function, for example—after the procedures. “If we’re treating a wider population and an older age group, we should start thinking about how we can protect longer-term neurocognitive decline,” Grover stressed.

Disclosures:
Grover and Hamady report no conflicts of interest.

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