Device May Lower Atrial Fib Stroke Risk by 60%

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VANCOUVER, B.C. — Percutaneous occlusion of the left atrial appendage appears to reduce stroke risk by about 60% in high-risk patients with atrial fibrillation, Horst Sievert, M.D., said at a meeting sponsored by the International Academy of Cardiology.

"Catheter closure of the left atrial appendage is feasible and safe. Randomized trials should be done. This may become an alternative treatment strategy for patients with atrial fibrillation who are at increased risk for ischemic stroke in whom long-term anticoagulation with warfarin is contraindicated," added Dr. Sievert of the CardioVascular Center Frankfurt (Germany).

He presented an interim analysis of data from the European Percutaneous Left Atrial Appendage Transcatheter Occlusion (PLAATO) registry.

The project, a nonrandomized feasibility study, recently completed its planned enrollment of 173 patients, to be followed for 2 years post procedure.

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Dr. Sievert reported on the first 99, with a mean of 10 months follow-up. Their mean age was 70 years. All of them had nonrheumatic atrial fibrillation (AF) and at least two additional stroke risk factors, and they were unable to take warfarin.

The PLAATO device is a catheter-delivered, self-expanding nitinol cage covered with polytetrafluoroethylene anchored by hooks that stabilize the occluder in the left atrial appendage (LAA).

The rationale for this novel form of device therapy lies in the well established observation that more than 90% of all thrombi in patients with nonrheumatic AF originate in the LAA.

The mean procedure time was 73 minutes. Patients were placed on aspirin and clopidogrel (Plavix) for at least 1 month afterward.

The PLAATO device was implanted in 94 of the 99 patients. Three patients had an LAA that was too large to fit the device, which comes in diameters of 15-32 mm and can close LAAs up to 29 mm in diameter. In two other patients the device wasn't implanted because of other anatomic considerations.

Two strokes have occurred, one at 1 month and the other on day 457, for an annual incidence of 2.4%. The expected incidence of stroke, based upon the CHAD2 risk factor scoring system, was 6.3%.

"That's a 60% stroke reduction, equivalent to what we can expect with warfarin," Dr. Sievert said.

Complications within 30 days of the procedure included three cases each of tamponade and pericardial effusion. Two of these patients required no treatment; the other four were successfully treated with pericardiocentesis. There were no sequelae, he said.

Routine transesophageal echocardiographic follow-up at 3 months revealed thrombus on the occluder in one patient, which resolved without incident, Dr. Sievert reported.

Session cochair Nasser Lakkis, M.D., of Baylor College of Medicine in Houston, indicated that he found the acute complication rate troubling, adding that it compares unfavorably with historical event rates in untreated high-risk atrial fibrillation patients.

"You're right. This is a concern, and we have to work on that," Dr. Sievert replied. "But again, there were no sequelae from the pericardial effusion or tamponade; it was not a serious problem. And we could show, I think, that we are able to reduce stroke."

That's a key finding, he added, because more than 50% of all AF patients are unable to take warfarin long term for various reasons.

Atrial fibrillation is an enormously important risk factor for stroke. Beyond age 80 years, 30% of all strokes are the result of AF.

The European registry is funded by ev3 Inc., which has taken over Appriva Medical, the company that initially developed the PLAATO device. ■