Final results from the RESPECT study reported

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Final results from the RESPECT trial found that percutaneously closing a patent foramen ovale (PFO) using the Amplatzer PFO Occluder was superior to medical management in the prevention of recurrent ischemic stroke in patients who previously had a cryptogenic stroke.

Findings were reported today at the 28th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine. The U.S. Food and Drug Administration (FDA) recently approved the device for recurrent stroke prevention in patients with a PFO and history of cryptogenic stroke on the basis of these data.

A PFO is a small hole between the atria that did not close completely early in life and which can allow a venous system clot to enter the left atrium and travel to the brain causing a stroke. Current guidelines call for medical management with anticoagulants or antiplatelet drugs for patients with PFO following a cryptogenic stroke. The RESPECT study examined the use of a device that closes the hole percutaneously versus medical management. From 2003 to 2011, a total of 980 subjects between 18 and 60 years of age were randomized to PFO Closure (N=499) or medical management (N=481) at 69 sites in the United States and Canada. The newest study results further extended follow-up, analyzing data from August 2003 through May 2016 for outcomes of recurrent ischemic strokes and recurrent ischemic strokes of unknown mechanism.

The mean follow-up for the PFO group was 6.3 years and 5.5 years for the medical management group [total patient years: 3,141 (PFO) and 2,669 (medical management)]. Key findings showed that in the intention-to-treat cohort, there was a 45% relative risk reduction [HR 0.55 (95% CI: 0.305, 0.999) Log-rank 2-sided P-value: 0.046] in recurrent ischemic stroke for the PFO group and a 62% risk reduction [HR 0.38 (95% CI: 0.18, 0.79) Log-rank 2-sided P-value: 0.007] from recurrent ischemic stroke of unkown mechanism. An additional sensitivity analysis of all-cause stroke in patients under age 60 showed a 58% relative risk reduction [HR 0.42 (95% CI: 0.21, 0.83) Log-rank 2-sided P-value=0.010).

Technical success (delivery and release of the device) of the PFO closure was 99.1% and procedural success (implantation without in-hospital serious adverse event) was 96.1%. In addition, there were no intra-procedural strokes, device embolization, device thrombosis or device erosion. Major vascular complications (0.9%) and device explants (0.4%) were also low.

"The long-term results of the RESPECT trial show that PFO closure was more beneficial than medical management alone in reducing recurrent stroke," said David E. Thaler, MD, PhD, Chairman of the Department of Neurology, Tufts Medical Center and Tufts University School of Medicine, Associate Professor of Neurology, Tufts University School of Medicine and Director of the Comprehensive Stroke Center at Tufts Medical Center. "PFO closure can be considered an appropriate treatment option for patients with cryptogenic stroke to reduce their risk of recurrent stroke, but collaboration between a cardiologist and neurologist is important for proper patient selection."

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