

Results of the RESPECT trial presented at TCT 2012

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A clinical trial indicates that using an investigational medical device to close a PFO, or "hole in the heart," may be superior to medical management alone in the prevention of a repeated stroke. Results of the RESPECT trial were presented at the 24th 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.

A PFO (patent foramen ovale) is a flap-like opening between the left and right upper chambers (atria) of the heart, which typically fuses shut after birth. In approximately one in four people, the opening does not fuse shut and in some cases, a blood clot may pass through the PFO and potentially travel to the brain causing an ischemic stroke. It is estimated that PFO rates are three times higher in the patient population with [cryptogenic stroke](#), or stroke without an overt source. However, to date, no [randomized clinical trial](#) has demonstrated superiority of PFO closure over standard [medical therapy](#) for secondary [stroke prevention](#), despite there being observational data suggesting a possible benefit.

RESPECT was a prospective, randomized (1:1), multi-center trial designed to evaluate whether PFO closure with the AMPLATZER PFO Occluder is superior to the current standard medical treatment in the prevention of [recurrent stroke](#) (a second stroke). Made of wire mesh, the investigational device is inserted into the PFO through a catheter to seal the passageway between the left and right atria.

A total of 980 patients were enrolled over eight years. Patients diagnosed with a cryptogenic stroke and PFO (age 18-60) were randomized to either the investigational device group or the medical therapy group within 270 days of the stroke. Forty-nine percent of the patients had a large stroke as the qualifying stroke event. The average age in the study was 46 and patients were otherwise generally healthy.

Statistics from the RESPECT trial:

- Two year events rates were low in both the device and medically treated groups
- 1.6 percent vs. 3.0 percent respectively
- All primary events were non-fatal, recurrent ischemic strokes
- The clinical risk reduction of stroke using the device ranged from 46.6 percent to 72.7 percent compared to medical management alone, depending on the analysis population being assessed
- Among the intent-to-treat analysis population, this reduction achieved borderline statistical significance
- In per-protocol and as-treated analyses, the reductions were statistically significant
- Serious adverse event (SAE) rates did not differ between the device and medical groups
- 23.0 percent vs. 21.6 percent respectively
- Medical therapy included one of four regimens:
 - Warfarin (25.2 percent)
 - Aspirin (46.5 percent)
 - Clopidogrel (14.0 percent)
 - Aspirin combined with dipyridamole (8.1 percent)
 - Aspirin combined with clopidogrel (6.3 percent)
- The total incidence of atrial fibrillation was not significantly different between the device and medical group
- 3.0 percent vs. 1.5 percent respectively

- No device related thrombus, erosion, or embolization was observed
- There were no study-related deaths

"In patients between 18 and 60 years old with cryptogenic ischemic stroke and PFO, the totality of evidence from RESPECT demonstrates that PFO closure with the AMPLATZER PFO Occluder provides evidence of benefit over medical management alone, with very low device and procedure-related risks," said lead investigator John D. Carroll, MD. Dr. Carroll is Professor of Medicine, Co-Director of the Cardiac and Vascular Center, and Director of Interventional Cardiology at the University of Colorado.

"The optimal secondary prevention strategy following a cryptogenic ischemic stroke in patients who are found to have a PFO has been unknown. This need to know is particularly intense for young stroke patients who have no or minimal traditional risk factors for [ischemic stroke](#), yet face a risk of recurrent [stroke](#) for many decades. RESPECT makes progress in both removing the "unknown" or cryptogenic cause of some strokes and providing high quality data from a large, long-term randomized trial."

Provided by Cardiovascular Research Foundation

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