PFO Closure With Implant Tested for Migraine

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ATLANTA — Patent foramen ovale closure with a septal repair implant gave a modest benefit to patients with migraine and PFO, according to preliminary results of a study with 163 patients.

The enrollment phase of the study also showed that right-to-left cardiac shunts occurred in 60% of the patients with migraine who were screened, Dr. Peter Wilmshurst reported at the annual meeting of the American College of Cardiology.

This prevalence is "very, very high," commented Dr. David O. Williams, director of interventional cardiology at Rhode Island Hospital in Providence. "The usual prevalence [in the general population] is about 15%-20%," he said.

Insertion of a STARFlex septal repair implant provided complete migraine relief in 3 of 74 patients (4%) during 6 months of follow-up, the same rate as in the 73 patients who received a sham procedure. Thus the device, developed by NMT Medical Inc. (which also sponsored the study), failed to achieve the primary end point of complete headache relief.

"However, using more conventional migraine trial end points, significant differences were found," noted study investigator Dr. Andrew Dowson, a headache specialist at King's College Hospital in London. Overall, 42% of patients receiving the implant had a 50% reduction in headache days, compared with 23% of sham-treated patients, a statistically significant difference.

The Migraine Intervention with STARFlex Technology (MIST) trial was a randomized, placebo-controlled, double-blind study that initially screened 432 individuals with migraine. The study was done in 2005 at 13 centers in the United Kingdom. Patients were aged 18-60 years, with a minimum 1-year history of migraine with an age at onset no later than 50 years, frequent migraines (at least 5 days per month but at least 7 headache-free days per month). The study was restricted to those with migraine with aura, because previous studies showed an association between PFO and these types of migraines, Dr. Dowson said.

Contrast transthoracic echocardiograms showed that 72 patients had small shunts (atrial and pulmonary), 22 had large pulmonary shunts, 3 had atrial septal defects, and 163 had large patent foramen ovales (PFOs), for a total of 260 shunts, said Dr. Wilmshurst, a coinvestigator and cardiologist at Royal Shrewsbury (U.K.) Hospital.

The 163 patients with large PFOs were targeted for the study, and after 16 were excluded 147 patients were randomized to receive either PFO closure or a sham operation. Patients underwent a 3-month healing phase after surgery, followed by a 3-month analysis phase in which migraine occurrences were continually monitored.

Patients continued their prophylactic migraine medication, but those who overused migraine medication were excluded from the study. Other exclusion criteria included prior stroke or transient ischemic attack, and cardiac contraindications.

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Handheld Device Can Spot Brain Hematomas

An investigational near-infrared imaging technology in a handheld device can detect brain hematomas soon after trauma.

The Infrascanner detects hematomas based on the differential near-infrared light absorption of hemoglobin in the bleeding versus the nonbleeding area of the brain.

"The user-friendly device that maps out the location of the hematoma with graphics on a PDA screen can assist paramedics and emergency room personnel in attending to those injured in traffic and sports accidents, falls, and on the battlefield," said Banu Onaral, Ph.D., director of the school of biomedical engineering, science, and health systems at Drexel University in Philadelphia.

The scanner unit is a handheld device based on a PDA platform with a wireless probe. The signal from the probe is digitized and transmitted by wireless link to the handheld unit.

Multicenter clinical trials are underway. Pending approval by the Food and Drug Administration, the device could be available by the end of the year.

—Kerri Wachter