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MIST STUDY EXPLORES LINK BETWEEN MIGRAINES AND HOLE IN HEART

Can Fixing the Heart Fix the Head?

ATLANTA, GA (March 13, 2006)—A study presented today during the American College of Cardiology's inaugural *Innovation in Intervention: The i2 Summit 2006* in Atlanta, Ga., will answer intriguing questions about whether repairing a hole in the heart known as a patent foramen ovale (PFO) can ease the pain of severe migraine headaches. Innovation in Intervention: i2 Summit is an annual meeting for practicing cardiovascular interventionalists sponsored by the American College of Cardiology in partnership with the Society for Cardiovascular Angiography and Interventions.

The Migraine Intervention with STARFlex Technology (MIST) trial will answer that question. It is the first study to evaluate the effectiveness of PFO closure for the sole purpose of relieving migraines.

"Many patients with migraines suffer tremendously," said Peter Wilmshurst, M.D., co-principal investigator of the MIST trial and a consultant cardiologist at Royal Shrewsbury Hospital, Shrewsbury, England. "If we can cure migraines with a simple procedure that takes less than an hour, that will have a considerable benefit for patients."

A hole in the wall separating the two upper chambers of the heart is essential in a developing fetus, as it allows blood to circulate throughout the body without being diverted to the lungs. After birth, the hole usually closes on its own. However, in a small percentage of adults, a large PFO remains—and about half of those patients have severe migraine headaches with aura.

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Dr. Wilmshurst was among the first researchers to observe improvement in migraine headaches in patients who, for other medical reasons, had a procedure to seal the PFO.

To definitively determine whether PFO repair can eliminate migraines, the MIST trial studied 147 patients with severe, frequent migraines and a medium-to-large PFO, randomly assigning them to PFO closure or a sham intervention. Fifteen medical centers participated in the study.

PFO closure is accomplished by threading a catheter through a femoral vein in the groin and into the right side of the heart. The catheter—mounted with a pair of spring-loaded, umbrella-like patches—is then passed into the left atrium through the PFO. After the first umbrella is opened, the catheter is pulled back into the right atrium. Then the second umbrella opened, and the two patches come together, forming a tight seal.

All patients in the MIST study had general anesthesia and transesophageal echocardiography before randomization to determine the presence and size of the PFO. Patients who were assigned to the sham intervention woke up from anesthesia with a cut in the groin just as treated patients did. To further avoid the possibility of a placebo effect or bias in determining the effect of PFO closure on migraine frequency and severity, all patients were evaluated at monthly intervals over six months by neurologists unaware of which group the patients had been assigned to. If PFO closure works as hoped, it could help an estimated one in three patients with severe migraine, Dr. Wilmshurst said.

Dr. Wilmshurst and co-principal investigator Dr. Andrew Dowson, director of the Headache Service at King's College Hospital, London, England, will present the results of the MIST trial at a Late Breaking Clinical Trials session on Monday, March 13, at 9:00 a.m.

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The American College of Cardiology (www.acc.org) represents the majority of board certified cardiovascular physicians in the United States. Its mission is to advocate for quality cardiovascular care through education, research, promotion, development and application of standards and guidelines- and to influence health care policy. ACC.06 and the ACC inaugural i2 Summit, the first-ever meeting for interventional cardiologists, will bring together more than 30,000 cardiologists and cardiovascular specialists to share the newest discoveries in treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.

Innovation in Intervention: i2 Summit is an annual meeting for those practicing coronary and non-coronary interventions. Sponsored by the American College of Cardiology, in partnership with the Society for Cardiovascular Angiography and Interventions and other professional associations, i2 Summit 2006 offers late-breaking interventional clinical trials, peripheral, vascular, coronary and valvular education, live cases from Europe, Asia and the United States, emerging technology / state-of-the-art lectures, expert simulation demonstrations, interactive *Laptop Learning* and general cardiovascular education at ACC.06, held concurrently with i2 Summit, for a dynamic, complete cardiovascular educational experience. i2 Summit consolidates all clinical, educational, practical and community needs into one event and delivers unsurpassed needs-based learning with true objectivity.