



57th Annual Scientific Session
MARCH 29 – APRIL 1 • CHICAGO

EMBARGOED FOR RELEASE
Tuesday, April 1, 2008
8:30 a.m. CDT

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‘TRENDS’ STUDY BEGINS TO DEFINE STROKE RISK IN THOSE WITH LOW BURDEN OF INTERMITTENT ATRIAL FIBRILLATION

CHICAGO, IL — Atrial fibrillation (AF) is the most common of all heart arrhythmias. It is usually diagnosed when a patient has palpitations, but can be diagnosed at the time of fatigue or shortness of breath. AF is known to be a cause of stroke from blood clots from the heart going to the brain, and patients take warfarin to prevent such strokes. What isn't clear is the risk of stroke posed by occasional brief bouts of intermittent AF.

The TRENDS Study: Is There a Critical Value of Daily Atrial Tachyarrhythmia Burden from Device Diagnostics That Raises Stroke Risk?, presented today at the American College of Cardiology's 57th Annual Scientific Session, suggests that one predictor of stroke risk is the amount of AF detected by implanted devices. ACC.08 is the premiere cardiovascular medical meeting, bringing together cardiologists and cardiovascular specialists to further breakthroughs in cardiovascular medicine.

Sustained AF is known to be associated with increased stroke risk and is a major cause of stroke, particularly in older individuals. The TRENDS Study is a prospective, observational study evaluating the relationship between device-detected AF and risk of thromboembolic events (TEs). According to investigators, the newer implantable medical devices are extremely sensitive and can comprehensively detect events in the heart never seen before. The goal is to determine how to take this information and use it to give patients the best care.

More than 3,000 patients were enrolled in The TRENDS Study from 116 sites, of which 2813 met inclusion criteria and 2486 had device data available for analysis. Inclusion criteria were implantation of a cardiac rhythm device capable of monitoring atrial tachycardia (AT)/AF burden and ≥ 1 stroke risk factor (heart failure, hypertension, age ≥ 65 y, diabetes, or prior stroke). The mean age was 71 years, patients were moderate-to-high risk (mean CHADS₂ risk score = 2.2), 21 percent were on warfarin and 62

percent were on aspirin therapy at baseline. The patients' physicians directed antithrombotic therapy.

AT/AF burden was defined as the longest total duration of AT/AF in hours on any given day during a 30-day rolling window before the first TE or end of follow-up. Time-varying burden for each window was divided into 3 groups: zero burden, and burden below (low burden: <5.5 h on each day/window), or above (high burden: ≥ 5.5 h on at least 1 day/window) the median value for all non-zero windows.

2-2-2/ TRENDS Study

During an average follow-up of 1.4 years (3382 patient-years), device data were retrieved every three months. In total, 12 percent of windows had high burden, 12 percent had low burden, and 76 percent had zero burden. Forty TEs were included in the analysis. The TE rate for the zero AT/AF burden group was 1.1 percent per year compared to 1.7 percent per year for any AT/AF burden; subdivided as high burden (2.4% per year) and low burden (1.1% per year). Compared to zero burden, the hazard ratios in the low and high burden groups were 0.98 (p=0.97) and 2.20 (p=0.06), respectively.

“Overall, we found a surprisingly low rate of stroke in these patients with moderate clinical stroke risk, particularly when compared to previous studies of AF patients with similar risk profiles. Our results suggest that device-detected AT/AF burden greater than 5.5 hours on any day during the preceding 30 days may double the risk for thromboembolism independent of known risk factors and antithrombotic therapy,” said Taya Glotzer, MD, Clinical Assistant Professor of Medicine, University of New Jersey School of Medicine and Dentistry, Hackensack University Medical Center and lead study author. “Further study is needed to precisely identify the AT/AF burden threshold that merits medical intervention.”

Dr. Glotzer will present “The TRENDS Study: Is There a Critical Value of Daily Atrial Tachyarrhythmia Burden From Device Diagnostics That Raises Stroke Risk?” in the ACC.08 Late-Breaking Clinical Trials II session, Tuesday, April 01, 2008, 10:00 a.m. - 11:30 a.m., McCormick Place, North Hall B1.

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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.08 is the largest cardiovascular meeting, bringing together cardiologists and cardiovascular specialists to share the newest discoveries in the treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.