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**NEW STUDY FINDS COMMONLY USED HEART MONITORING SYSTEM OFTEN FAILS
TO DETECT SERIOUS CARDIAC ARRHYTHMIAS, A LEADING CAUSE OF
STROKE AND SUDDEN CARDIAC DEATH**

*Multi-Center, Peer-Reviewed Study to Be Published in March Issue of
Journal of Cardiovascular Electrophysiology Finds
That New Methods Are Needed to Help Save Lives*

PHILADELPHIA AND SAN DIEGO, March 5, 2007 — A recently completed multi-center, peer-reviewed study has found that cardiac arrhythmias, one of the most common yet potentially dangerous heart conditions affecting more than four million Americansⁱ, often go undetected despite medical monitoring, resulting in more than 780,000 hospitalizations and contributing to approximately 500,000 deaths each yearⁱⁱ.

The first of its kind study, to be published in the March issue of the *Journal of Cardiovascular Electrophysiology*, compared the effectiveness of two ambulatory electrocardiographic monitoring systems in detecting arrhythmias, a condition in which a person's heartbeat is abnormal. Three hundred patients presenting with symptoms suggestive of a cardiac arrhythmia and with previous negative or inconclusive 24-hour Holter monitoring or 24-hours of telemetry, were enrolled in the study by 17 cardiology practices. Patients were randomized to either a new technology called Mobile Cardiac Outpatient Telemetry (MCOT) or to a cardiac loop event recorder. The results of the study showed that MCOT was almost three times more effective detecting and diagnosing clinically significant arrhythmias compared to the frequently prescribed cardiac loop event recorder.

MCOT detected clinically significant arrhythmias in 41 percent of patients, compared to the cardiac loop event recorder, which detected arrhythmias in just 15 percent of patients ($p < 0.001$). Furthermore, MCOT detected clinically significant atrial fibrillation in 23 percent of patients, compared to 8 percent by cardiac loop event recorders ($p < 0.001$). In patients that experienced no symptoms (asymptomatic patients) during the study, the cardiac loop event recorders detected no (0%) clinically significant atrial fibrillation, compared to MCOT, which detected clinically significant atrial fibrillation in 17 percent of patients ($p < 0.001$).

Other notable findings of the study:

- In patients with syncope (fainting, passing out) or presyncope (dizziness), MCOT detected clinically significant arrhythmias in 52 percent of patients, compared to 16 percent of cardiac loop event patients ($p < 0.001$).

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- In patients with syncope or presyncope, MCOT detected clinically significant atrial fibrillation in 24 percent of patients compared to 2 percent of cardiac loop event patients ($p < 0.001$). In the same group of patients, MCOT detected asymptomatic atrial fibrillation in 19 percent of patients compared to no (0%) cardiac loop event patients ($p < 0.001$).
- In a sub-group of sites using the auto-detect/auto-trigger cardiac loop event recorders, an arrhythmia was confirmed or excluded as the cause of symptoms in 88 percent of MCOT patients, compared to only 46 percent of cardiac loop event patients ($p = 0.002$).

“These are very compelling findings that for the first time clinically validate the importance and superiority of MCOT—particularly when you consider that a meaningful percentage of patients may not experience easily detectable symptoms,” said Steven A. Rothman, M.D., Mainline Arrhythmia and Cardiology Consultants, Wynnewood, PA, the principal investigator of the study. “Clearly, physicians need to more carefully consider the value of prescribing MCOT as the first-line diagnostic tool when monitoring patients for clinically significant arrhythmias.

“In the diagnosis of patients with symptoms of a cardiac arrhythmia, MCOT provides a significantly higher yield than standard cardiac loop event recorders,” continued Dr. Rothman. “This result was more pronounced in patients presenting with symptoms of syncope or presyncope. MCOT was superior to cardiac loop event recorders for the detection of clinically significant arrhythmias, with a shorter time to diagnosis. The technology reduces patient error, enhances diagnostic accuracy, decreases time to diagnosis, and improves patient care.”

About Cardiac Arrhythmia Monitoring

A cardiac arrhythmia is categorized as a temporary or sustained abnormal heart rhythm that is caused by a disturbance in the electrical signals in the chambers of the heart. Proper administration of electrical signals to the heart is necessary to ensure effective heart function. There are two main categories of arrhythmias: tachycardia, meaning a rapid heartbeat, and bradycardia, meaning a slow heartbeat.

The ability to diagnose or rule out a cardiac arrhythmia as the cause of a symptom or cardiac condition is important both to treat those patients with serious arrhythmias, as well as to identify those patients that may not require further medical attention. The problem is that the most commonly prescribed diagnostic method, the Holter monitor (first developed in the late 1940s and generally worn by a patient for 24-48 hours), rarely finds infrequent but nonetheless serious arrhythmias in many patients. *Circulation*, a publication of the American Heart Association, reported as early as 2003 that the “principal limitation of Holter recordings is that the sampling period is usually too short to allow capture of an infrequent arrhythmia.” Similarly, a 2004 Frost & Sullivan study reported that Holter monitors have been found to be effective in diagnosing cardiac arrhythmias only 10 percent of the time.

When Holter monitoring fails to detect an arrhythmia, physicians often place the patient on a portable cardiac loop event recorder, which patients wear for 30 days, but the recorder only stores a limited amount of data, typically about 10 minutes. Additionally, in most cases, cardiac loop event recorders require that the patient activate the device when they feel symptoms, an inherent limitation as patients may or may not experience symptoms.

The most recent advancement in ambulatory arrhythmia monitoring is CardioNet MCOT, whereby patients wear three chest leads attached to a small portable sensor that continuously detects every heartbeat and transmits the ECG data in real-time to a pocket-sized monitor. If the algorithms in the monitor detect an abnormal heartbeat, the monitor automatically transmits the patient's ECG data to the CardioNet Monitoring Center using wireless communications. CardioNet MCOT offers several advantages to physicians, payors, and patients, including: real-time, continuous ECG data detection; 96 hours of memory; increased compliance through technology and reduced patient interaction; reflection of real-life cardiac activity; symptom correlation; detection of arrhythmias where symptoms are not experienced; minimization of data artifacts or “noise”; two-way wireless capabilities for transmission, remote programming and data retrieval; and the ability to tailor the system to physicians’ needs.

CardioNet MCOT is available today in 25 states and growing rapidly. In some other states where reimbursement has been lagging, payors have been waiting for clinical data to prove the efficacy of the new service. Jim Sweeney, Chairman and CEO of CardioNet, said that he now expects more insurance companies to reimburse for MCOT as a result of the findings of this study. “It is far better to cover the cost of an effective monitoring technology than to incur the cost of ongoing testing and treatment of patients who are left undiagnosed, and who may ultimately be hospitalized because of stroke or other serious heart conditions.”

Methodology

A 300-patient, 17-center, randomized study evaluated patients who had previous 24-hour Holter monitoring or 24-hours of telemetry with negative or inconclusive results. Patients were randomized to use either CardioNet MCOT or cardiac loop event recorders for a 30-day period due to symptoms thought to be due to an arrhythmia.

Journal of Cardiovascular Electrophysiology

The *Journal of Cardiovascular Electrophysiology* (JCE) informs readers about the latest developments in the study and management of arrhythmic disorders. JCE contains peer-reviewed research, original investigations, scholarly reviews, editorials and case reports. Articles are published online ahead of the print publication.

About CardioNet

CardioNet (<http://www.cardionet.com>) is a leading provider of ambulatory, wireless, real-time arrhythmia monitoring, and has provided services to over 65,000 patients. The company has invested over \$84 million and seven years developing its medical devices and 24-hour monitoring service center. Of that amount, it has invested over \$40 million developing its proprietary integrated patient monitoring platform that incorporates a wireless data transmission network, internally developed software, and FDA cleared algorithms. CardioNet’s initial efforts are focused on the diagnosis and monitoring of cardiac arrhythmias (heart rhythm disorders) and drug-therapy titration, with a solution providing heartbeat-by-heartbeat monitoring on a continuous basis. Since its inception, CardioNet has been able to secure reimbursement with Medicare, and by contracting with over 143 commercial insurance companies, allowing access to over 142 million individuals in the United States. CardioNet was recently named one of “50 medical companies to watch” by *Medical Device and Diagnostic Industry* magazine.

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ⁱ Mayo Clinic

ⁱⁱ American Heart Association