Medtronic News

Medtronic-Sponsored Study Indicates Bi-Ventricular Pacing Superior to Right Ventricular Pacing in Avoiding Cardiac Enlargement

Early Results Show Preserved Heart Size in Pacemaker Patients with Normal Left Ventricles

MINNEAPOLIS & ORLANDO, Fla.--(BUSINESS WIRE)--Nov. 15, 2009-- Pacing the two lower chambers of the heart, or bi-ventricular pacing, prevented cardiac enlargement as compared to only pacing the right ventricle in pacemaker patients with normal pumping hearts, according to results presented today from the Pacing to Avoid Cardiac Enlargement (PACE) trial, a clinical study supported by Medtronic, Inc. (NYSE: MDT). Bi-ventricular pacing is proven to reduce symptoms, extend survival and reduce heart size in symptomatic heart failure patients; however, it is not currently approved for use with pacemaker patients with normal pumping hearts. PACE data were presented today as a late-breaking clinical science session at the Scientific Sessions 2009, the annual congress of the American Heart Association in Orlando, Fla. and published online in the *New England Journal of Medicine*.

Meeting its primary objective, PACE results showed that after one year of pacing, patients with pacing in both right and left ventricles (bi-ventricular) had no significant changes in left ventricle size while patients paced only in the right ventricle developed enlarged left ventricles. Adverse changes in patients paced only in the right ventricle included:

- A significant increase of 6.3 milliliter on average in the size of the left ventricle at the end contraction, and
- A decrease of 6.8 percent in the ejection fraction, or the amount of available blood pumped from the left ventricle.

“These early results show bi-ventricular pacing may be superior to pacing only in the right ventricle to preserve the heart’s normal left ventricle size and pumping ability for these pacemaker patients,” said Cheuk-Man Yu, M.D. professor of medicine at Prince of Wales Hospital, The Chinese University of Hong Kong in China and PACE lead investigator. “As the first randomized study with this patient population, these initial results suggested that ensuring synchrony of the ventricles can help maintain patient health.”

“Clinical evidence shows delivering pacing only when and where patients need it is important to improving the care of pacemaker patients,” said Marshall Stanton, M.D., vice president of clinical research for the Cardiac Rhythm Disease Management business at Medtronic. “With the Medtronic-exclusive pacing mode MVP®, Managed Ventricular Pacing, which is the only technology available that reduces unnecessary right ventricular pacing by 99 percent, and the ongoing BLOCK-HF bi-ventricular pacing study, Medtronic is dedicated to offering physicians the latest tools and clinical evidence to help physicians deliver appropriate care to their pacemaker patients.”

About PACE

The PACE study is a prospective, randomized, double-blind, parallel study enrolling 177 patients at four hospitals in Asia. Patients had a Medtronic Insync® III cardiac resynchronization therapy-pacemaker (CRT-P), or bi-ventricular pacemaker without defibrillation, and had no prior history of heart failure with normal left ventricle function and ejection fraction greater than or equal to 45 percent. Patients were evaluated at one, three, six, nine and 12 months.

About Cardiac Resynchronization Therapy

Cardiac resynchronization therapy (CRT), also known as bi-ventricular pacing, is a treatment for heart failure that uses an implantable device to improve the pumping efficiency of the heart. A cardiac resynchronization therapy-pacemaker (CRT-P), is a stopwatch-sized device implanted in the upper chest to resynchronize (without defibrillation) the contractions of the ventricles by sending tiny electrical pacing impulses to the heart muscle to help the heart pump blood throughout the body more efficiently and reduce symptoms. Cardiac resynchronization therapy is intended to complement standard drug treatment, and dietary and lifestyle modifications.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology – alleviating pain, restoring health and extending life for millions of people around the world.

Caution: The CRT-P devices used in the PACE trial are investigational for the patient population studied; their use is limited by federal (or United States) law to investigational use for this indication.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's Annual Report on Form 10-K for the year ended April 24, 2009. Actual results may differ materially from anticipated results.

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