Medtronic News

Study Shows Longer Arrhythmia Detection Window Reduces Shocks for Medtronic Implantable Defibrillator Patients

Late-Breaking Clinical Trial Validates Medtronic Proprietary Device Algorithms

MINNEAPOLIS & BOSTON--(BUSINESS WIRE)--May. 10, 2012-- Medtronic, Inc. (NYSE: MDT) today announced results from the first and only clinical trial to show that Medtronic cardiac devices can safely extend detection time before triggering therapy in primary and secondary prevention patients. The ADVANCE III study, presented today as a late-breaking presentation at Heart Rhythm 2012, the Heart Rhythm Society's 33rd Annual Scientific Sessions, evaluated patients with implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy with defibrillation (CRT-D), and found devices programmed with longer duration (increased number of intervals) to detect arrhythmias provided therapy (shocks and anti-tachycardia pacing, ATP) only when needed and without increased risk to patients.

Patients in the study were randomized to two groups: an extended detection (30/40 intervals) and the standard detection interval (18/24 intervals). The study met its primary endpoint by demonstrating a 37 percent reduction in ICD/CRT-D therapies, including all-cause shocks and ATP, in the extended detection patient group. Additionally, mortality and arrhythmic syncope (fainting) were low and not significantly different between the two patient groups.

"These findings are significant, as they provide solid evidence confirming earlier studies demonstrating that this longer detection window is safe and effective for ICD recipients, including, for the first time, secondary prevention patients," said Maurizio Gasparini, MD, study investigator, IRCCS Istituto Clinico Humanitas, Rozzano-Milano, Italy. "Optimizing implantable defibrillator programming to utilize shock and anti-tachycardia pacing only when needed for all ICD patients will ultimately result in improved quality of care and patients' experience with their implanted device."

Implantable defibrillators are designed to provide lifesaving shocks or painless pacing to stop potentially deadly fast or irregular heart rhythms, known as ventricular arrhythmias, in primary prevention patients considered at high-risk of experiencing an arrhythmia and in secondary prevention patients with previously documented arrhythmias. These life-threatening heart rhythms can lead to sudden cardiac death, which kills more people each year than lung cancer, breast cancer and HIV/AIDS combined.1, 2Medtronic estimates more than 70,000 lives have been saved worldwide by implantable defibrillators over the past five years.3

"For the last 20 years, Medtronic has been the market leader in developing innovative shock-reduction technology and providing a broad portfolio of scientific research to help physicians deliver the best therapy and quality of care to their patients," said Marshall Stanton, M.D., Vice President and General Manager, Implantable Defibrillator Business, Cardiac Rhythm Disease Management at Medtronic. "We look forward to continuing to build upon our unique, clinically advanced, proprietary features to reduce shocks and improve patient survival and quality of life."

Medtronic continues to provide the broadest portfolio of scientific research in the area of shock reduction, having supported eight major clinical trials to date involving more than 5,500 patients worldwide—more than any other device manufacturer. Medtronic pioneered ATP in its implantable defibrillators, and is the only company to offer ATP During Charging™, available since 2005, which automatically uses pacing pulses to painlessly stop fast, dangerous heartbeats, while concurrently preparing to deliver a shock if needed, with no delay. As evidenced with the ADVANCE III data, the combination of extended intervals with ATP During Charging on Medtronic devices further reduces ICD therapies, offering painless arrhythmia termination initially, without delaying a shock if ultimately needed.

Medtronic's proprietary technologies, including the exclusive SmartShockTM technology available on its PROTECTATM family

of implantable defibrillators, can dramatically reduce the incidence of inappropriate shock, with 98 percent of patients predicted to be free of inappropriate shock at one year. 4 In head-to-head comparisons with similar products from Boston Scientific and St. Jude Medical, third-party research has demonstrated a significantly reduced risk of inappropriate shock5 with Medtronic ICDs, as well as an improved ability to avoid inappropriate therapies6, confirming Medtronic leadership in shock reduction.

About the ADVANCE III Trial

The prospective, randomized, multicenter trial included 1,902 patients implanted at 94 medical centers throughout Europe, South Africa, Asia and Russia over a two year period. A total of 948 patients were randomized to the longer 30/40 number of intervals to detect (NID) arm, while 954 patients were included in the shorter 18/24 standard NID arm; patient demographics across both arms were similar. Patients in both arms had the Medtronic-exclusive feature ATP During Charging programmed “ON.” Approximately 75 percent of patients were considered primary prevention, while 25 percent were classified as secondary prevention. Patient mortality (6.3% pts/yr in the 18/24 group vs. 5.5% pts/yr in the 30/40 group, HR: 0.87 (0.57-1.32), p=0.504) and arrhythmic syncope rates (2.2 pts/yr vs. 1.1 pts/yr, IRR=1.91, p=0.21) were low and not significantly different between arms (30/40 vs. 18/24).

In collaboration with leading clinicians, researchers and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias.

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.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic’s periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

1American Cancer Society. Cancer Facts and Figures. 2006.

2 CIA. The World Fact Book – Rank Order – HIV/AIDS – deaths. Available at http://www.cia.gov.

3 Medtronic data on file. 2012.

4 Volosin et. al. “Virtual ICD: A Model to Evaluate Shock Reduction Strategies.” Heart Rhythm. Vol. 7, N. 5, May supplement 2010. (PO3-125).

5 Gold, et. al. “Prospective comparison of discrimination algorithms to prevent inappropriate ICD therapy: Primary results of the Rhythm ID Going Head to Head Trial.” Heart Rhythm Society. doi:10.1016/j.hrthm.2011.10.004.

6 Gold, et. al. “Head-To-Head Comparison of Arrhythmia Discrimination Performance of Subcutaneous and Transvenous ICD Arrhythmia Detection Algorithms: The START Study.” Journal of Cardiovascular Electrophysiology. doi: 10.1111/j.1540-8167.2011.02199.

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