Medtronic News

Medtronic Study Reveals Significant Heart Rhythm Disorders Occurring in Patients Undergoing Hemodialysis

Data Presented at Kidney Week 2014 Find Irregular Heartbeats Occur Frequently Around Hemodialysis Sessions

MINNEAPOLIS and PHILADELPHIA - Nov. 13, 2014 - Medtronic, Inc. (NYSE: MDT) today revealed the results of a new study which found that atrial fibrillation (AF) and bradycardia-two common heart rhythm disorders-occurred at higher than expected, and clinically significant, rates in patients with end-stage renal disease (ESRD) undergoing hemodialysis. Moreover, these worrisome rhythm disorders appeared to correlate with patients' dialysis cycles, occurring immediately before, during and after their dialysis sessions. The irregular heartbeats were found in the Monitoring in Dialysis (MiD) Study using the Medtronic Reveal® XT Insertable Cardiac Monitor (ICM). The data were presented at Kidney Week 2014: the American Society of Nephrology 47th Annual Meeting.

"It has been known that patients with end-stage renal disease are at significant risk for cardiac arrhythmias and sudden death. While it has been assumed that fluid and electrolyte imbalances are key contributors to the development of arrhythmias, other factors, including ventricular hypertrophy and cardiac fibrosis, also may exacerbate the underlying risk," said study co-author James A. Tumlin, M.D., FASN, professor, Renal Division at the University of Tennessee College of Medicine. "The data presented today underscore the high prevalence of arrhythmias in ESRD patients, as demonstrated by this technology, and suggest a need for intensive monitoring."

The MiD Study monitored arrhythmias in 50 hemodialysis ESRD patients at eight sites during a six-month period using the Reveal XT ICM, a cardiac monitoring device inserted under the skin of the chest that tracks the heart's activity for up to three years. The preliminary analysis found that:

- Heart arrhythmias were strongly associated with the hemodialysis schedule: Patients' risk for cardiac rhythm problems peaked during the 12-hour interval beginning with each session, decreased for the next 12 hours, and then gradually increased during the remainder of the interdialytic interval (the interval between dialysis sessions).
- Atrial fibrillation is commonly experienced by these patients: In the study, 52 percent of patients experienced AF. A total of 1,640 AF episodes of six minutes or longer were detected in 22 of 50 patients, and the rate of AF events was nearly four times higher in the 12 hours following dialysis.
- Bradycardia (slow heart rates) occurred more frequently than ventricular tachycardia (abnormal and dangerous rapid or chaotic heart rhythms): In the study, 19 of 50 patients had at least one bradycardia episode (with a rate of 26 bradycardia events per patient month); there were only two sustained ventricular arrhythmia episodes during the follow-up. To date, five patients have received pacemakers following the detection of their bradycardia.

ESRD is the final stage of kidney failure, when the kidneys lose the ability to filter wastes and extra fluids from the body. Because ESRD is permanent, patients require a transplant or ongoing dialysis treatment, where a machine acts as the kidney filter.

"The MiD study shows how nephrologists and cardiologists can work together to treat patients who are undergoing dialysis," said Ven Manda, vice president of Medtronic Renal Care Solutions. "The study results give us crucial insight on the timing, frequency and types of abnormal heart rhythms experienced by these patients - especially as it relates to the delivery of dialysis - and these findings may affect how dialysis treatments are delivered in the future."

About Arrhythmias and Long-Term Monitoring

AF is an irregular quivering or rapid heart rhythm in the atria, and is one of the most common and undertreated heart rhythm disorders in America.1 Failure to recognize and treat AF can lead to strokes. With bradycardia, the heart may beat fewer than 60 beats per minute.2

As abnormal heart rhythms often have no symptoms and may occur infrequently, they may be difficult to detect. Current standard of care for cardiac monitoring - including electrocardiograms and Holter monitors - can only detect arrhythmias

occurring during the limited time of monitoring. Insertable Cardiac Monitors are designed for long-term use and can help physicians determine the causes of infrequent, unexplained arrhythmias by continuously monitoring a patient's heart activity for up to three years.

"The Reveal XT device used in the MiD study is a long-term monitor that offers a new approach to managing patients on hemodialysis by identifying clinically-significant abnormal heart rhythms - when they occur - so that patients can receive appropriate treatment," said Nina Goodheart, vice president and general manager of the Diagnostics and Monitoring Business at Medtronic. "Effective cardiac monitoring can lead to better patient outcomes, and may lead to even more efficient delivery of care with economic benefits."

Earlier this year, Medtronic introduced the Reveal LINQ(TM) ICM System, the newest generation of ICM and the smallest cardiac monitor available (~1 cc, or one-third the size of a AAA battery). Like its predecessor, this even smaller device is placed under the skin of the chest and its battery allows for up to three years of monitoring. In addition, the Reveal LINQ device communicates wirelessly with a new patient bedside monitor which uploads device data to the Medtronic CareLink network.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

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.

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1 Columbia Heart. Atrial fibrillation and arrhythmia center. http://www.columbia-heart.com/services/atrial-fibrillation-arrhythmia-center/index.html. Accessed on October 31, 2014.

2 American Heart Association. Bradycardia: slow heart rate. http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/Bradycardia-Slow-Heart-Rate_UCM_302016_Article.jsp. Accessed on October 31, 2014.

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