New Guidelines Support Use of Cardiac Monitoring for Patients with Unexplained Fainting

March 24, 2017 8:00 AM CT

Medtronic

American College of Cardiology, American Heart Association and Heart Rhythm Society Jointly Issue First-Ever Syncope Guidelines that Reinforce Benefits of Continuous Cardiac Monitoring

DUBLIN - March 24, 2017 - Newly published guidelines from the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society (HRS) recommend the use of cardiac monitors for evaluating patients with unexplained fainting, called syncope. The "2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients with Syncope," was recently published online in the *Journal of the American College of Cardiology*, *Circulation and* HeartRhythm.[1]

Syncope is a sudden loss of consciousness that occurs when blood pressure drops and not enough oxygen reaches the brain, affecting 1.5 million people worldwide each year. Some causes of unexplained fainting are harmless; however, heart-related causes, including abnormal heart rhythms, are common and among the most serious causes of syncope. Left untreated, cardiac syncope doubles the risk of death and carries a six-month mortality rate of greater than 10 percent.[2]

Medtronic offers cardiac monitors for patients based on the frequency of symptoms or the nature of the syncope events. The Medtronic SEEQ(TM) MCT System is a wireless, continuous, external heart monitor that can be worn for up to 30 days to detect any irregular heartbeats. The Reveal LINQ(TM) ICM with TruRhythm(TM) Detection allows physicians to continuously and wirelessly monitor a patient's heartbeat for up to three years; one-third the size of an AAA battery (~1 cc), it is placed just beneath the skin through a small incision of less than 1 cm in the upper left side of the chest using a minimally invasive procedure. For the evaluation of syncope patients, the device offers exclusive algorithms that result in a 95 percent reduction in false bradycardia (slow heartbeat) episodes and a 47 percent reduction in false pauses (brief absence of cardiac activity) episodes when compared with its predecessor, the Reveal LINQ(TM)ICM.[3]

"The causes of syncope can be difficult to diagnose as episodes are usually infrequent and unpredictable," said David Benditt, M.D., professor of medicine and co-director of the Cardiac Arrhythmia Center at the University of Minnesota. "Detection with short-term monitoring techniques is often unsuccessful and, as a result, patients may see several different specialists and undergo multiple tests without receiving a conclusive diagnosis. When the cause of syncope is unclear, continuous long-term cardiac monitoring has become the standard of care, particularly in early stages of evaluation."

The new guidelines, intended to drive better informed clinical decisions and improved patient outcomes, support the use of cardiac monitoring in patients with unexplained syncope with the strongest endorsement, stating: "The choice of a specific cardiac monitor should be determined on the basis of the frequency and nature of the syncope events." Both external and implantable cardiac monitors are recommended based on symptom frequency in the new guidelines. Implantable cardiac monitors have a stronger recommendation as a result of the strong evidence and randomized controlled trials that support the use of ICMs in unexplained syncope patients.

The benefits of long-term cardiac monitoring with a Reveal® ICM in syncope patients are supported by clinical evidence that demonstrates superiority compared to conventional tests. As evidenced by the PICTURE (Place of Reveal In the Care Pathway And Treatment of patients with Unexplained Recurrent SyncopE) study, long-term cardiac monitoring with Reveal ICMs led to diagnosis and specific treatment for 78 percent (170 of 218) of patients who experienced recurrent syncope. Of those diagnosed, 75 percent of patients were shown to have had a cardiac cause of their syncopal event. In addition, the study found that patients were evaluated by an average of three different specialists for managing their syncope and underwent a median of 13 inconclusive tests before a Reveal ICM was implanted.[4] The Reveal LINQ ICM may help reduce costs associated with these inconclusive diagnostic tests while providing effective diagnoses for these patients. [5]

"Medtronic is committed to bringing meaningful innovations that help patients lead healthier lives, while providing clinicians with the best tools so that they can efficiently and effectively diagnose and treat their patients," said Nina Goodheart, vice president and general manager of the Patient Monitoring & Diagnostics business at Medtronic.

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 of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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. http://www.onlinejacc.org/content/early/2017/03/10/j.jacc.2017.03.002

2. Soteriades ES, et al. *N Engl J Med*. 2002;347:878-885.

3. TruRhythm Detection Algorithms. Medtronic data on file. 2017.

4. Edvardsson N, Frykman V, van Mechelin R, et al. Use of an implantable loop recorder to increase the diagnostic yield in unexplained syncope: results from the PICTURE registry. *Europace.* February 2011;13(2):262-269.

5. Edvardsson N, Wolff C, Tsintzos S, Rieger G, Linker NJ. Costs of unstructured investigation of unexplained syncope: Insights from a micro-costing analysis of the observational PICTURE registry. *Europace*. July 2015;17(7):1141-1148.

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