Medtronic Focuses on a Preventable Patient Safety Issue: Respiratory Compromise

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Medtronic

New Data Presented at ANESTHESIOLOGY® 2015 Demonstrates the Value of Integrated Pulmonary Index™ and Microstream™ Capnography

SAN DIEGO - October 28, 2015 - Medtronic plc (NYSE: MDT) today announced findings from two clinical studies, the first validating the clinical utility of the Integrated Pulmonary Index(TM) (IPI) in the post anesthesia care unit (PACU) to identify respiratory adverse events (RAE) and the second, a study on the cost-effectiveness of capnography in gastrointestinal (GI) sedation. The study results highlight the need for clinicians to actively monitor for respiratory compromise following general anesthesia and procedural sedation with both pulse oximetry and capnography. These data were presented at the ANESTHESIOLOGY® 2015 annual meeting in San Diego.

Respiratory failure is the second-most frequently occurring preventable safety adverse event[1] causing higher mortality rates, longer hospital and intensive care unit stays, and billions of additional healthcare dollars spent each year.[2, 3] It is rapidly becoming the third most costly hospital inpatient expense in the U.S.[2] Respiratory Compromise, which consists of respiratory insufficiency, failure and arrest, dramatically increases the likelihood of adverse outcomes and cost of patient care. Currently, 13 million patients use patient-controlled analgesia each year and up to 678,000 of these patients experience life-threatening, opioid-induced respiratory depression.[4]

"The findings presented today demonstrate the clinical benefits and potential cost savings capnography can provide across a broad spectrum of patients," said Michael Tarnoff, MD, vice president and chief medical officer, Minimally Invasive Therapies Group at Medtronic. "These studies underscore Medtronic's commitment to reducing the growing burden of respiratory compromise across clinical settings to improve the health and care of patients."

Abstract #3024: Integrated Pulmonary Index Can Predict Respiratory Adverse Events in Postoperative High-Risk Hypoventilation Patients at Post-Anesthesia Care Unit

A prospective observational study found using Medtronic's IPI in the PACU can help predict respiratory adverse events, also referred to as respiratory compromise, more effectively than pulse oximetry alone. The study evaluated 163 patients at high-risk for hypoventilation (breathing at an abnormally slow rate) in the PACU following general surgery, enrolled at two hospitals in Japan between October 2014 and February 2015. Patients at high-risk for hypoventilation were defined as having a body-mass index of more than 28 (considered obese) or were more than 75 years old. At both PACUs, these patients were monitored with electrocardiography and for blood pressure as well as Medtronic's Capnostream(TM) 20 patient monitor, which measured pulse oximetry, pulse rate, respiratory rate and end-tidal carbon dioxide for the IPI. The study investigated onset of RAE defined as a respiratory event with prolonged stay in PACUs or transfer to intensive care units due to airway narrowing, hypoxemia, wheezing and apnea.

Of the 163 patients enrolled in the study, 7 percent (11 patients) had an RAE. The study found that the initial IPI of the RAE patients was lower compared to the non-RAE patients (6.5 ± 2.5 vs. 9.1 ± 1.3; $p<0.0001$) and the initial SpO_2 of the RAE patients was lower than the non-RAE patients ($96.6 \pm 4.4\%$ vs. $98.3 \pm 1.9\%$; $p=0.0147$). Importantly, the authors concluded that the sensitivity and specificity of IPI was better than that of SpO_2 for onset of RAE.

"It is critical that patients who are administered any type of sedation, from general anesthesia to procedural sedation, be carefully monitored for signs of respiratory compromise," said Hiroshi Morimatsu, MD, PhD, director, Anesthesiology and Resuscitology Department at Okayama University Hospital in Japan. "Capnography monitoring can detect subtle changes in respiratory status and provide the earliest indication of airway compromise. The findings from this study provide further evidence of the necessity to use capnography, along with the Integrated Pulmonary Index, for postoperative patients, especially those with high risk of hypoventilation."

To monitor the respiratory status of patients and identify early changes in a patient's breathing, Medtronic developed the IPI, an algorithm that incorporates four real-time vital signs (end-tidal CO_2, pulse oximetry, respiratory rate and pulse rate) into a single number. Microstream™ capnography plays a critical role in the PACU to monitor for respiratory compromise, providing the earliest indication of a change to a patient's breathing by measuring levels of exhaled carbon dioxide.

Abstract #4163: Modeling the Cost Effectiveness of Capnography Monitoring During Procedural Sedation for Endoscopy

A cost-efficacy modeling study of capnography during procedural sedation for endoscopy was also presented at ANESTHESIOLOGY® 2015. The study found that Microstream™ capnography was likely to be cost-effective and may have important applications to patient safety during endoscopy. Based on the cost-efficacy model assuming 8,000 patients in one year and a capnography cost of $4,000 per monitor, study researchers found capnography was estimated to prevent nine procedure terminations, two unplanned hospital admissions and an anesthesiologist intervention. The study also found the use of capnography for endoscopy reduced adverse events, resulting in a savings of $123 per procedure after one year.

"Capnography monitoring is considered the standard of care during deep sedation administered by anesthesiologists," said John Vargo, MD, MPH, chair, Gastroenterology Department of the Digestive Disease Institute at the Cleveland Clinic. "Our study results concluded that capnography can be cost effective when used during endoscopic sedation practices where a mixture of deep and moderate sedation is employed."

About Respiratory Compromise

Respiratory compromise is a critical complication that dramatically increases the likelihood of adverse outcomes and the cost of patient care. Current monitoring strategies for early detection of postoperative respiratory compromise may be inadequate. A comprehensive and continuous patient monitoring strategy encompassing respiratory rate, pulse oximetry and capnography has the potential to reduce the incidence and severity of postoperative respiratory compromise, improve patient outcomes and reduce the cost of care.

For additional information about respiratory compromise, please visit http://aemprod.covidien.com/covidien/clinical-solutions/respiratory-compromise or http://www.respiratorycompromise.org/. Medtronic is also interested in supporting research projects around respiratory compromise. To learn more, please visit http://aemprod.covidien.com/covidien/support/investigator-sponsored-research.

Multimedia Release

A multimedia version of this release, with video and downloadable graphics can be found at:
https://medtronicmediacap.gcs-web.com/medtronic-focuses-preventable-patient-safety-issue-respiratory-compromise

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 85,000 people worldwide, serving physicians, hospitals and patients in more than 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] Healthgrades website, "Quality Matters: Tackle the Top 3 Patient Safety Issues." https://www.hospitals.healthgrades.com/index.cfm/customers/e-newsletters/april-2013/quality-matters-tackle-the-top-3-patient-safety-issues/, Accessed October 20, 2015.

[2] Wier LM, Henke R, Friedman B. Diagnostic Groups with Rapidly Increasing Costs, by Payer, 2001-2007: Statistical Brief #91. Healthcare Cost and Utilization Project (HCUP) Statistical Briefs. Rockville MD2010.

[3] Kelley SA, Agarwal S, Parikh N, Erslon M, Morris P. Respiratory insufficiency, arrest and failure among medical patients on the general care floor. *Crit Care Med*. 2012;40(12):764.

[4] Stoelting R. (President, Anesthesia Patient Safety Foundation). Presentation at the Patient, Safety Science & Technology Summit in January 2013.

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