Medtronic News

Medtronic Announces Preliminary PRODIGY Results: a Global Study to Identify Patients at High Risk for Opioid-Induced Respiratory Compromise

Groundbreaking Microstream(TM) Capnography Study Provides Easy-to-Use Risk Prediction Tool
Study Found Greater Than 40 Percent of Patients on Hospital General Care Floor Experience Opiod-Induces Respiratory Depression

DUBLIN and SAN DIEGO - February 17, 2019 - Medtronic plc (NYSE:MDT) today announced preliminary results from PRODIGY, a Medtronic-sponsored, prospective, multi-center study to identify people at high risk for opioid-induced respiratory depression (OIRD), a form of respiratory compromise.

Study results demonstrated that investigators were able to develop an easy-to-use risk prediction tool to identify patients at high risk of developing respiratory compromise, a potentially life-threatening condition causing a progressive inability to breathe adequately. In addition, results showed that more than 40 percent of patients on the general care floor experienced OIRD, which is significantly higher than previously reported in clinical literature.

One goal of the study was to develop and internally validate an accurate risk assessment scoring tool - the PRODIGY score. The PRODIGY score identifies adults on the hospital general care floor receiving opioid medication who are at increased risk for OIRD. Variables used to develop the risk assessment score included age, gender, sleep disorders, chronic heart failure and opioid naïvety. The PRODIGY score performed well, identifying 76 percent of patients with confirmed respiratory depression (AUC=0.7620). Publication of full results is expected in 2019. The study, presented at the Society of Critical Care Medicine's (SCCM) 48th Critical Care Congress in San Diego, California, was selected for the Star Research Achievement Award recognizing excellence in research.

"Clinical evidence shows that acute and unexpected respiratory compromise on the general care floor is increasingly common. Until now, we have not been successful in predicting which patients are at high risk when recovering on the general care floor," said Ashish K. Khanna, M.D., primary study investigator and an associate professor of anesthesiology and intensivist at the Wake Forest School of Medicine. "These data validate an easy-to-use OIRD risk prediction tool to identify patients at the highest risk and guide early intervention using continuous capnography-based monitoring. Early identification and intervention in these high-risk patients has the potential to improve patient safety and decrease the economic and clinical burden of unplanned ICU admissions."

The PRODIGY (PRediction of Opioid-induced respiratory Depression In patients monitored by capnoGraphY) study included 1,496 patients across 16 sites in the U.S., Europe and Asia. This is the largest known study using continuous capnography and oximetry. The initial study publication, "Seeking Answers from the PRODIGY Trial," in the Journal of Critical Care, reviewed respiratory compromise on the general care floor and the study methodology.1 Continuous capnography and pulse oximetry data were collected using Medtronic Microstream(TM) and Nellcor(TM) monitoring technology. Data presented by Dr. Khanna at SCCM showed OIRD occurred in 46 percent of patients. Additionally, all patients experiencing these events were reviewed and confirmed by an independent clinical event committee of physicians with expertise in perioperative respiratory medicine.

"The PRODIGY study reflects our commitment to improving solutions for respiratory compromise - a common, costly and deadly but preventable condition," said Vafa Jamali, senior vice president and president of the Respiratory, Gastrointestinal & Informatics business, which is part of the Minimally Invasive Therapies Group at Medtronic. "We are encouraged by the data demonstrating the use of the PRODIGY OIRD risk prediction tool. It can help clinicians prioritize resources by identifying those patients at highest risk on the general care floor who should be continuously monitored with capnography and pulse oximetry."

For additional information about monitoring for respiratory compromise with capnography in the post-operative and general care

settings, please visit: medtronic.com/respiratorycompromise

About Respiratory Compromise

Respiratory compromise is a potentially life-threatening, progressive condition negatively impacting a person's ability to breathe adequately to maintain oxygenation and carbon dioxide removal. Patients with OIRD may experience shallow, slow or no breathing after opioid administration which undetected can lead to cardiopulmonary arrest and death.2 This condition is rapidly becoming the third-most costly hospital inpatient expense in the U.S., and dramatically increases the likelihood of adverse patient outcomes and cost of patient care.3 Not only is respiratory compromise common and dangerous, it has been very difficult to predict.4-6

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 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 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.

-end-

1. Khanna AK, Overdyk FJ, Greening C, Di Stefano P, Buhre WF. Respiratory depression in low acuity hospital settings - seeking answers from the PRODIGY trial. J of Crit Care 2018,

https://www.jccjournal.org/article/S0883-9441(18)30217-X/fulltext. Accessed June 18, 2018.

2. Morris TA, Gay PC, MacIntyre NR, et al. Respiratory compromise as a new paradigm for the care of vulnerable hospitalized patients. Respir Care. 2017 Apr;62(4):497-512. doi: 10.4187/respcare.05021.

3. Wier LM, Henke R, Friedman B. Diagnostic groups with rapidly iCosts, by payer, 2001-2007: statistical brief #91. Healthcare Cost and Utilization Project (HCUP) Statistical Briefs. Rockville MD2010.

4. Belcher AW, Khanna AK, Leung S, et al. Long-acting patient-controlled opioids are not associated with more postoperative hypoxemia than short-acting patient-controlled opioids after noncardiac surgery: a cohort analysis. Anesth Analg. 2016;123(6):1471-9.

5. Khanna AK, Sessler DI, Sun Z, et al. Using the STOP-BANG questionnaire to predict hypoxaemia in patients recovering from noncardiac surgery: a prospective cohort analysis. Brit J Anaesth. 2016;116(5):632-40.

6. Sun Z, Sessler DI, Dalton JE, et al. Postoperative hypoxemia is common and persistent: a prospective blinded observational study. Anesth Analg. 2015;121(3):709-15.

Contacts:

John Jordan

Public Relations

+1-508-452-4891

Ryan Weispfenning

Investor Relations

+1-763-505-4626

---

https://news.medtronic.com/2019-02-17-Medtronic-Announces-Preliminary-PRODIGY-Results-a-Global-Study-to-Identify-Patients-at-High-Risk-for-Opioid-Induced-Respiratory-Compromise