RANDOMIZED CONTROLLED TRIAL OF CONTINUOUS PULSE OXIMETRY AND WIRELESS CLINICIAL NOTIFICATION POST-SURGERY: THE VIGILANCE STUDY

Matthew A. Chong[1], James E. Paul[2], Norman Buckley[2], Toni Tidy[2], Diane Buckley[2]
[1]Department of Anesthesia and Perioperative Medicine, Western University, London, ON, Canada; [2]Department of Anesthesia, McMaster University, Hamilton, ON, Canada

Schulich MEDICINE & DENTISTRY

Western

Introduction:

- Respiratory depression is a serious perioperative complication
- Recently, technology has become available to continuously monitor patients on regular surgical wards with pulse oximetry and wireless clinician notification with alarms
- The clinician is notified via a pager and may intervene earlier to prevent further clinical deterioration
- To date, no randomized controlled trial (RCT) has evaluated this technology on a regular surgical ward [1]

Hypothesis/Aim:

- To perform a pilot study to evaluate the feasibility and tolerability of implementing a wireless respiratory monitoring system in post-surgical patients
- Feasibility will be measured by average patient recruitment per week
- Tolerability will be defined as % of patients completing the course of monitoring

Methods:

- Ethics approval received
- Study conducted on two regular surgical wards at a McMaster University affiliated teaching hospital
- Population:
  - Adult surgical patients with expected length of stay of 1 day or more
- Intervention:
  - Standard care versus standard care plus wireless respiratory monitoring
  - The monitor was set to notify the patient's nurse via pager if his or her S_pO_2 decreased below 90%
- Randomization sequence was computer-generated
- Allocation managed by a 24-hour call-in center
- Blinding was deemed unfeasible given the nature of the intervention.
- All data were extracted onto standardized digital study forms via electronic data capture (RedCAP, Vanderbilt University) [2]

Primary outcomes

- Feasibility: average patient recruitment per week
- Tolerability of the monitoring system
- Anticipated sample size for full clinical trial with the reported event rate of 2% and assuming a 50% reduction with the intervention [3] was 2319 patients or 16 patients per week

Secondary outcomes

- Respiratory events defined as a composite of naloxone administration for respiratory depression, transfer to ICU, or cardiac arrest team activation
- Number of alarms per week, the type of alarms, and the response to the alarm by the nursing staff
- Data were analyzed by intention-to-treat

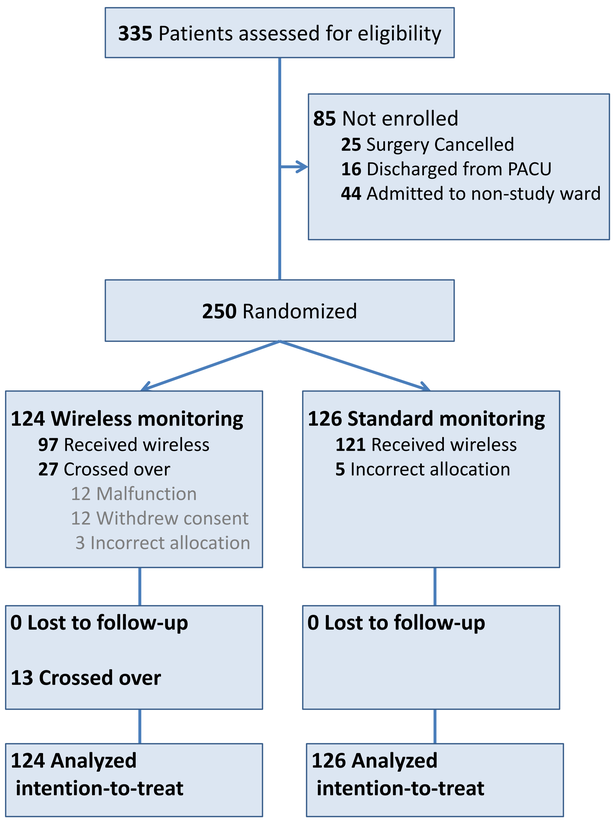

Figure 1: Consort Flow Diagram

Results:

- Of the 335 patients screened for eligibility, 250 were enrolled and randomized into the study (Figure 1)
- Baseline demographics and ASA class was similar between the groups, with the exception of slightly more female patients in the wireless monitoring group that received gynecologic surgery (Table 1).

Primary Outcomes

- Average patient recruitment per week was 13.6 patients (95% CI 12.0-16.2)
- The wireless monitoring was very tolerable with 86.6% of patients completing the course of monitoring.

Secondary outcomes

- The composite respiratory event rate was low with only 1 event in the wireless group and none in the standard group (Table 2; p=0.50)
- There were 4.0 (95% CI 1.6-6.4) alarms per week
- The response to alarms is shown in Table 3

Table 1: Baseline demographics

	Standard Monitoring	Wireless Monitoring
Total (n)	126	124
Age (years)	57.5 (15.8)	58.0 (13.9)
Sex (female)	78 (61.9%)	94 (75.8%)
ASA Class	2.93 (0.61)	2.93 (0.63)
BMI	27.5 (5.9)	28.6 (7.0)
OSA (n)	6 (4.8%)	4 (3.2%)
Type of Surgery		
General surgery	72 (57.1%)	46 (37.1%)
Urology	12 (9.5%)	12 (9.7%)
Gynecology	41 (32.5%)	65 (52.4%)
Orthopedics	0 (0%)	1 (0.81%)
Plastics	1 (0.79%)	0 (0%)
Type of Anesthesia		
General	89 (70.6%)	83 (66.9%)
General and Regional	30 (23.8%)	37 (29.8%)
Regional	7 (5.6%)	4 (3.2%)

Table 2: Secondary outcomes

	Standard Monitoring	Wireless Monitoring
Composite primary outcome	0	1
Naloxone use for respiratory depression	0	0
Respiratory depression	0	0
ICU transfer	0	1
Cardiac arrest team activation (Code Blue)	0	0

Table 3: Alarm Responses

	n	(%)
Applied oxygen or increased F_iO_2	62	66.0
Roused patient or encouraged deep breathing and coughing	29	30.8
Called physician	3	3.2
Total	94	

Conclusions:

- This pilot study demonstrated adequate patient recruitment and high tolerability of the wireless respiratory monitoring system
- No difference detected in the respiratory event rate, but this pilot trial was not powered nor intended to detect differences in that outcome
- A large RCT is warranted to resolve the clinical equipoise surrounding the usage of wireless respiratory monitoring in the regular surgical ward setting for the prevention of post-operative respiratory events

References:

[1] Pedersen, T. et al. (2014) Pulse oximetry for perioperative monitoring. The Cochrane database of systematic reviews 3:CD002013.
[2] Harris, P. et al. (2009) Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 42(2):377-81.
[3] Shapiro, A. et al. (2005) The frequency and timing of respiratory depression in 1524 postoperative patients treated with systemic or neuraxial morphine. J Clin Anest. 17:537-542.

Acknowledgements:

We thank Covidien for providing the wireless respiratory monitoring system free of charge. They played no role in the design, conduct, analysis, or decision to publish/disseminate the results of this research. We thank the CIHR for recognizing Dr. Matthew Chong with a Health Professional Student Research Award for his work with the project.

McMaster University

CIHR IRSC Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

REDCap