

# Detection of Postoperative Vital Signs Abnormalities on a Surgical Ward using Conventional and Remote Automated Monitoring

Michael H McGillion RN PhD<sup>1,2</sup>, Maura Marcucci MD MSc<sup>1,2</sup>, Flavia K Borges MD PhD,<sup>1,2</sup> David Conen, MD MPH<sup>1,2</sup>, Brenda Coleman RN PhD<sup>1</sup>, Krysten Gregus RN<sup>2</sup>, Saman Parvaneh PhD<sup>3</sup>, Amal Bessisow MD MSc<sup>4</sup>, Ameen Patel MD<sup>1</sup>, Prathiba Harsha MSc<sup>5</sup>, Carley Ouellette RN MSc<sup>1</sup>, Sandra Ofori MD<sup>1,2</sup>, Dan Sessler MD<sup>6,2</sup>, P.J. Devereaux MD PhD<sup>1,2</sup>

<sup>1</sup>McMaster University, Faculty of Health Sciences, Hamilton, Ontario, Canada; <sup>2</sup>Population Health Research Institute, Hamilton, Ontario, Canada; <sup>3</sup>Philips Research North America, Cambridge, Massachusetts; <sup>4</sup>McGill University Health Centre, Division of General Internal Medicine, Montreal, Quebec; <sup>5</sup>Hamilton Health Sciences, Hamilton, Ontario; <sup>6</sup>Cleveland Clinic, Cleveland, Ohio

Corresponding Author: Michael McGillion: [mmcgill@mcmaster.ca](mailto:mmcgill@mcmaster.ca)

Submitted: 22 November 2021; Accepted: 7 February 2022; Published: 24 February 2022

DOI: <https://doi.org/10.22374/cjgim.v17iSP1.591>

## Abstract

**Background:** The true incidence of abnormal vital signs on post-surgical wards may be seriously underestimated based on nurse obtained conventional measurement. We sought to determine the incidence and severity of postoperative tachycardia, bradycardia and hypoxemia detected by continuous remote automated monitoring (RAM) versus the incidence of these vital sign abnormalities detected during routine nursing care.

**Methods:** We conducted a prospective cohort proof-of-concept study of 121 patients aged  $\geq 45$  years recovering from orthopedic surgery. Eligible patients were at risk of postoperative myocardial injury and had a planned hospital stay  $\geq 48$  hours. Philips' IntelliVue MX40 wearable RAM technology was used to continuously monitor patients' heart rate and pulse oximetry up to 72 hours following surgery. In addition, study personnel obtained vital signs collected during routine nursing care from participants' medical charts. Clinically meaningful tachycardia, bradycardia and hypoxemia were defined as heart rates  $>100$ ,  $<55$ , and blood oxyhemoglobin saturation ( $SpO_2$ ) of  $<90\%$  for  $>15$  contiguous minutes, respectively.

**Results:** Continuous RAM identified clinically meaningful episodes of tachycardia in 42 of 121 patients [34.7%] versus 7 patients [5.8%] identified by routine nursing care, for an absolute difference 28.9% (95% confidence interval [CI] 20.8, 37.0;  $p=0.001$ ). RAM also detected bradycardia in 14 of 121 patients [11.6%] versus 6 patients [5.0%] detected by routine care, for an absolute difference 6.6% (95% CI 2.2, 11.0;  $p=0.07$ ). RAM detected hypoxemia in 25 of 107 patients [23.3%] compared with 1 patient [0.9%] detected through routine monitoring, for an absolute difference of 22.4% (95% CI 14.5, 30.3;  $p=0.001$ ).

**Conclusion:** Most clinically meaningful episodes of vital signs abnormalities detected by continuous RAM were missed by nurses through conventional periodic monitoring. Continuous RAM technologies have the

potential to improve patient outcomes through early identification of physiological abnormalities on surgical wards.

## Résumé

**Contexte:** La fréquence réelle des signes vitaux anormaux dans les unités de soins postopératoires peut être grandement sous-estimée sur la base des mesures classiques obtenues par le personnel infirmier. Nous avons cherché à déterminer la fréquence et la gravité de la tachycardie, de la bradycardie et de l'hypoxémie postopératoires détectées par une surveillance automatisée à distance (SAD) en continu par rapport à la fréquence de ces anomalies des signes vitaux décelées pendant les soins infirmiers courants.

**Méthodologie:** Nous avons mené une étude prospective de validation de concept auprès de 121 patients âgés de 45 ans ou plus se remettant d'une intervention chirurgicale orthopédique. Les patients admissibles présentent un risque de lésion myocardique postopératoire et leur séjour prévu à l'hôpital est d'au moins 48 heures. Le moniteur portable IntelliVue MX40 de Philips issu de la technologie de SAD a été utilisé pour surveiller en continu la fréquence cardiaque et l'oxymétrie de pouls des patients pendant 72 heures après l'intervention chirurgicale. En outre, le personnel de l'étude a pu obtenir les mesures des signes vitaux recueillies lors des soins infirmiers courants à partir des dossiers médicaux des participants. La tachycardie, la bradycardie et l'hypoxémie d'importance clinique ont été définies comme étant respectivement une fréquence cardiaque supérieure à 100 pour la tachycardie et inférieure à 55 pour la bradycardie et une saturation pulsée en oxygène (SpO<sub>2</sub>) inférieure à 90 % pendant plus de 15 minutes consécutives.

**Résultats:** La SAD en continu a relevé des épisodes d'importance clinique de tachycardie chez 42 des 121 patients (34,7 %) comparativement à 7 patients (5,8 %) dans le cas des soins infirmiers courants, soit une différence absolue de 28,9 % (intervalle de confiance [IC] à 95 % de 20,8 à 37,0; P = 0,001). La SAD a également détecté une bradycardie chez 14 des 121 patients (11,6 %) comparativement à 6 patients (5,0 %) dans le cas des soins courants, soit une différence absolue de 6,6 % (IC à 95 % de 2,2 à 11,0; P = 0,07). La SAD a détecté une hypoxémie chez 25 patients sur 107 (23,3 %) comparativement à 1 patient (0,9 %) dans le cas des soins courants, la différence absolue étant de 22,4 % (IC à 95 % de 14,5 à 30,3; P = 0,001).

**Conclusion:** La plupart des épisodes d'importance clinique d'anomalies des signes vitaux détectés par la SAD en continu ont été manqués par les infirmières lors de la surveillance périodique classique. Les technologies de SAD en continu peuvent améliorer l'évolution de l'état de santé des patients grâce à une détection précoce des anomalies physiologiques dans les services de chirurgie.

## Introduction

Worldwide about 100 million adults  $\geq 45$  years of age have major noncardiac surgery annually and 25% of these patients will suffer a major postoperative complication (e.g., myocardial infarction/injury, sepsis, bleeding) in the first 30 days following surgery.<sup>1-3</sup> These complications can result in death, substantial morbidity, prolonged hospitalization, and increased health service utilization and patient costs. Few patients die or sustain complications in the operating room; most adverse events occur after surgery when patients are on a surgical ward.<sup>3</sup>

Perioperative alterations in patient hemodynamics (i.e., blood pressure, heart rate) and oxygenation have been associated with cardiovascular complications and mortality.<sup>4-10</sup> Most of the existing studies focus on intraoperative hemodynamic compromise; however, hemodynamic compromise

also occurs after surgery and is more strongly associated with adverse outcomes.<sup>11</sup> Moreover, on post-surgical wards patients' vital signs are not monitored continuously as is the case in the operating room. Instead, patients' vital signs are typically monitored by nurses every 4 to 12 hours, as dictated by institutional policies.<sup>12,13</sup> This routine approach to patient monitoring can increase the risk that abnormal vital signs remain undetected or that they are detected after substantial delays, leaving patients vulnerable to sustained hemodynamic compromise and related organ damage.<sup>12,13</sup> Data suggests that myocardial ischemia/injury after noncardiac surgery is most often due to a myocardial oxygen supply-demand mismatch, triggered by altered oxygenation and hemodynamics.<sup>14</sup> Episodes of tachycardia and bradycardia can be clinically important antecedents to myocardial injury (including infarction) and death.<sup>4,15,16</sup> Similarly,

postoperative hypoxemia is a well-established indicator of patient instability, myocardial injury/infarction, and other serious adverse events.<sup>17–22</sup>

The true incidence of abnormal vital signs on post-surgical wards can be seriously under-estimated based on routine nursing measurements.<sup>23</sup> Continuous remote automated monitoring (RAM) technologies have the potential to revolutionize postoperative patient surveillance. Continuous RAM refers to systems featuring wearable sensors that collect continuous vital signs data from patients.<sup>12</sup>

In this prospective cohort study of patients at higher risk of postoperative cardiac injury who were undergoing noncardiac [orthopedic] surgery, we sought to determine the incidence and severity of postoperative tachycardia, bradycardia and hypoxemia detected by continuous RAM versus the incidence of these vital sign abnormalities detected during routine nursing care.

## Methods

We conducted a prospective cohort proof-of-concept study of patients aged  $\geq 45$  years recovering from noncardiac surgery at the Juravinski Hospital and Cancer Centre in Hamilton, ON, Canada. Patients were eligible if they had  $\geq 2$  risk factors for postoperative myocardial injury (i.e., history of coronary artery disease, stroke, transient ischemic attack, diabetes, peripheral vascular disease, or congestive heart failure, or had preoperative creatinine  $>175$   $\mu\text{mol/L}$ ); were undergoing noncardiac surgery with a general or regional anesthetic; and had a planned hospital stay  $\geq 48$  hours. Recruitment was restricted to the orthopedic surgery ward for feasibility reasons (i.e., the management, application, and cleaning of RAM equipment worn by patients). The study received ethics approval before enrolment began (Hamilton Integrated Research Ethics Board #14-215).

Research personnel screened the preoperative assessment clinic patient list to determine eligibility. Patients were enrolled as soon as possible after surgery. After written informed consent, staff collected demographic, medical history, and type of surgery from participants and their medical chart and applied the RAM device to participants. Staff followed participants daily to postoperative Day 3 or discharge, whichever occurred first, to review compliance and issues with the RAM monitors.

Philips' IntelliVue MX40 wearable RAM technology (Figure 1) was used to continuously monitor patients' heart rate and pulse oximetry. The MX40 can collect data on heart



**Figure 1.** The Philips IntelliVue MX40 wearable patient monitor.

rate, electrocardiography, blood pressure, and  $\text{SpO}_2$  from ambulatory patients. The device is a Food and Drug Agency-approved patient wearable monitor, inclusive of heart rate and  $\text{SpO}_2$  ranges of 15–300 BPM for adults patients (accuracy of 1% of the range) and 0–100% (accuracy root mean square of 2–3.5 % depending on utilized reusable sensor), respectively (please see Supplement for the MX40 Instructions for Use C.01 [courtesy of Royal Philips] document). Participants started wearing this RAM technology in the post anaesthesia care unit before transfer to the surgical ward. Patients and healthcare providers were blind to measurement results from the RAM technology. Nurses continued to measure vital signs as per standard of care (i.e., 4-to-12-hour intervals) or as instructed by the most responsible physician.<sup>12,13</sup> Nurse-collected vital signs were abstracted from participants' medical charts after patient discharge by research staff blind to the RAM data. The cumulative number of minutes of clinically meaningful episodes of tachycardia, bradycardia and hypoxemia were estimated from chart data and recorded by postoperative day.

These analyses were restricted to patients with data collected on the post-surgical ward (i.e., starting postoperative Day 0, after discharge from the post-anesthesia care unit) and for whom there were a minimum of 45 minutes of contiguous RAM data on any given patient-day. Patient-day was defined as any postoperative day (i.e., days 0 to 3), or part thereof, in which there were both RAM and nurse-collected vital signs data available on a given patient.

Clinically important bradycardia was defined as a heart rate of  $<55$  beats per minute (bpm)<sup>24</sup> for at least 15 contiguous minutes. Clinically meaningful tachycardia was defined as a heart rate of  $>100$  bpm<sup>25</sup> for at least 15 contiguous

minutes and/or a heart rate of >140 bpm for at least 5 contiguous minutes, regardless of rhythm. Clinically meaningful hypoxemia episodes were defined as SpO<sub>2</sub> readings of <90%<sup>26</sup> for at least 15 contiguous minutes and/or ≤80% for at least 5 contiguous minutes. RAM heart rate records of <30 or >220 bpm and oxygen saturation levels of <65% or >100% were deemed out-of-range and excluded from these analyses. A comparison of the duration of episodes using raw and smoothed (uniformly weighted moving average) data found no statistically significant differences. As such, durations of episodes were reported using raw data.

Comparisons were limited to days for which the patient had both RAM and vital signs data collected by nurses. Absolute differences between the percent of patients with at least one clinically meaningful episode of bradycardia, tachycardia or hypoxemia detected by RAM versus nurses were assessed by Chi square or Fischer’s exact tests. These data were also used to calculate the number needed to monitor (1/absolute difference). Analyses were conducted in Stata SE, version 16.1 (College Station, Texas, USA).

## Results

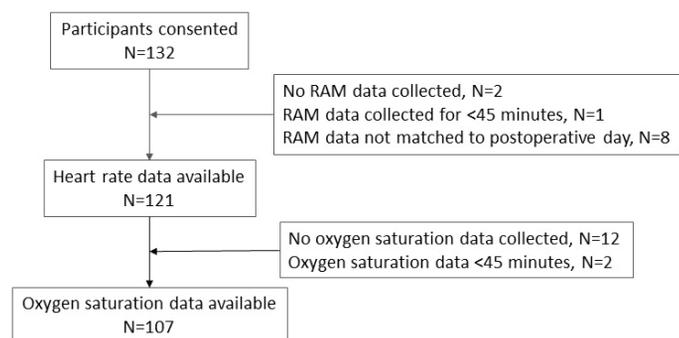
One hundred thirty-two patients undergoing orthopedic surgery were enrolled between September 22, 2014 and September 8, 2015. As shown in Figure 2, 121 participants had RAM heart rate data and 107 had SpO<sub>2</sub> data corresponding to their postoperative ward stay. Reasons for exclusion are listed in Figure 2. As shown in Table 1, there were fewer participants with a history of chronic obstructive pulmonary disease in the analysis groups than in the overall study population, but the groups were otherwise similar. The median age of the analyzed population was 67 years and just over

**Table 1.** Characteristics of participants in the pilot study and those with RAM device data available for postoperative days of follow-up

	Full cohort (N=132)	Analyzed sample (N=121)
Age, median years (IQR)	67.5 (61.2, 74.1)	67.2 (61.2, 74.3)
Female	73 (55.3)	65 (53.7)
Male	59 (44.7)	56 (46.3)
Ethnicity, European	71 (53.8)	66 (54.5)
South Asian	60 (45.1)	54 (44.6)
Black	1 (0.8)	1 (0.8)
Baseline measures		
Tachycardia (>100 bpm)	7 (5.3)	6 (5.0)
Bradycardia (<55 bpm)	2 (1.5)	2 (1.6)
History of tobacco use	69 (52.3)	61 (50.4)
Medical conditions, history at enrolment		
Atrial fibrillation	1 (0.8)	1 (0.8)
Coronary artery disease	9 (6.8)	9 (7.4)
Deep vein thrombosis/pulmonary embolism	7 (5.3)	6 (5.0)
Stroke	4 (3.0)	4 (3.3)
Sleep apnea	17 (12.9)	15 (12.2)
Chronic obstructive pulmonary disease	6 (4.5)	4 (3.3)*
Diabetes	70 (53.0)	63 (52.1)
Type of surgery		
Major hip/pelvic surgery	39 (29.5)	38 (31.4)
Knee arthroplasty	93 (70.5)	83 (68.6)
Type of anesthetic		
General	33 (25.0)	31 (25.6)
Spinal	99 (75.0)	90 (74.4)
Intensive care unit admission	2 (1.5)	2 (1.6)
Duration of surgery, median minutes (IQR)	104 (94, 115)	103 (94, 115)
Length of stay, median days (IQR)	3 (2, 4)	3 (2, 4)

\*p<0.05

bpm: beats per minute; IQR: interquartile range



**Figure 2.** Flow chart of participants in pilot cohort study for post-surgical patients 45 years of age or older

50% were female. Two participants (1.6%) were admitted to the intensive care unit following surgery for 2 nights each, precluding collection of RAM data on those postoperative days.

Across the 121 participants with RAM heart rate data, the duration of recordings ranged from 50 minutes to 72 hours per participant, with a median of 23 hours total (see Table 2). The daily duration of follow-up ranged from 8.0 to 20.2 hours per patient. Of the 107 patients with SpO<sub>2</sub> data, the median overall duration of readings was 9.2 hours, with median daily durations of 4.2 to 5.1 hours per patient.

**Table 2.** Number of post-surgical patients and median number of RAM readings by participant for heart rate and oxygenation (SpO<sub>2</sub>), by patient-day

	Postoperative Day 0	Postoperative Day 1	Postoperative Day 2	Postoperative Day 3	Overall Days 0–3
<b>Heart rate</b>					
Number of patients with readings	114	106	46	13	121
Median hrs of RAM/patient (range)	8.0 (0.8–11.3)	20.2 (2.0–24.0)	10.1 (1.4–24.0)	8.3 (2.8–17.8)	23.1 (0.8–72.4)
<b>SpO<sub>2</sub></b>					
Number of patients with readings	95	92	37	9	107
Median hrs of SpO <sub>2</sub> /patient (range)	4.3 (0.5–8.5)	5.1 (0.9–15.9)	4.5 (0.1–11.8)	4.2 (0.6–5.9)	9.2 (0.7–31.9)

SpO<sub>2</sub>: oxyhemoglobin saturation; hrs: hours

**Table 3.** Number of post-surgical patients with at least one episode of clinically significant tachycardia, bradycardia, or hypoxemia recorded by RAM device and nursing staff, by patient-day and overall

	Postoperative Day 0	Postoperative Day 1	Postoperative Day 2	Postoperative Day 3	Overall <sup>1</sup> Day 0 to 3
<b>Tachycardia (&gt;100 bpm &gt;15 min)</b>					
RAM: # of patients	26 (22.8%)	22 (20.7%)	14 (30.4%)	5 (38.5%)	42 (34.7%)
Median # of min (range)	219 (26–538)	94.5 (19–875)	91 (31–426)	66 (18–153)	215.5 (18–875)
Nurse: # of patients	2 (1.7%)	5 (4.7%)	1 (2.2%)	0	7 (5.8%)
Median # of min (range)	165 (120–210)	660 (330–1018)	300 (NA)		350 (120–1018)
<b>Bradycardia (&lt;55 bpm &gt;15 min)</b>					
RAM: # of patients	5 (4.4%)	10 (9.4%)	2 (4.4%)	0	14 (11.6%)
Median # of min (range)	112 (61–134)	174.5 (22–816)	117 (108–126)	0	152.5 (22–816)
Nurse: # of patients	4 (3.5%)	3 (2.8%)	0	0	6 (5.0%)
Median # of min (range)	47.5 (30–123)	255 (240–570)			181.5 (35–570)
<b>SpO<sub>2</sub> (&lt;90% &gt;15 min)<sup>2</sup></b>					
RAM: # of patients	10 (10.5%)	15 (16.3%)	9 (24.3%)	2 (22.2%)	25 (23.3%)
Median # of min (range)	49 (16–197)	146 (16–457)	142 (16–600)	48.5 (24–73)	146 (16–600)
<b>SpO<sub>2</sub> (&lt;80% ≥5 min)<sup>2</sup></b>					
RAM: # of patients	1 (1.0%)	2 (2.2%)	2 (5.4%)	0	4 (3.7%)
Median # of min (range)	38 (NA)	196.5 (36–357)	168 (29–307)		190.5 (29–357)

1. Total number of patients with at least one episode during post-operative days 0–3; does not sum across row because patients could have an episode on more than one post-operative day (see Table 2 for number of patients with RAM data per day)

2. One patient was identified during monitoring by nurses with SpO<sub>2</sub> < 90% but no information was available about the SpO<sub>2</sub> level nor duration.

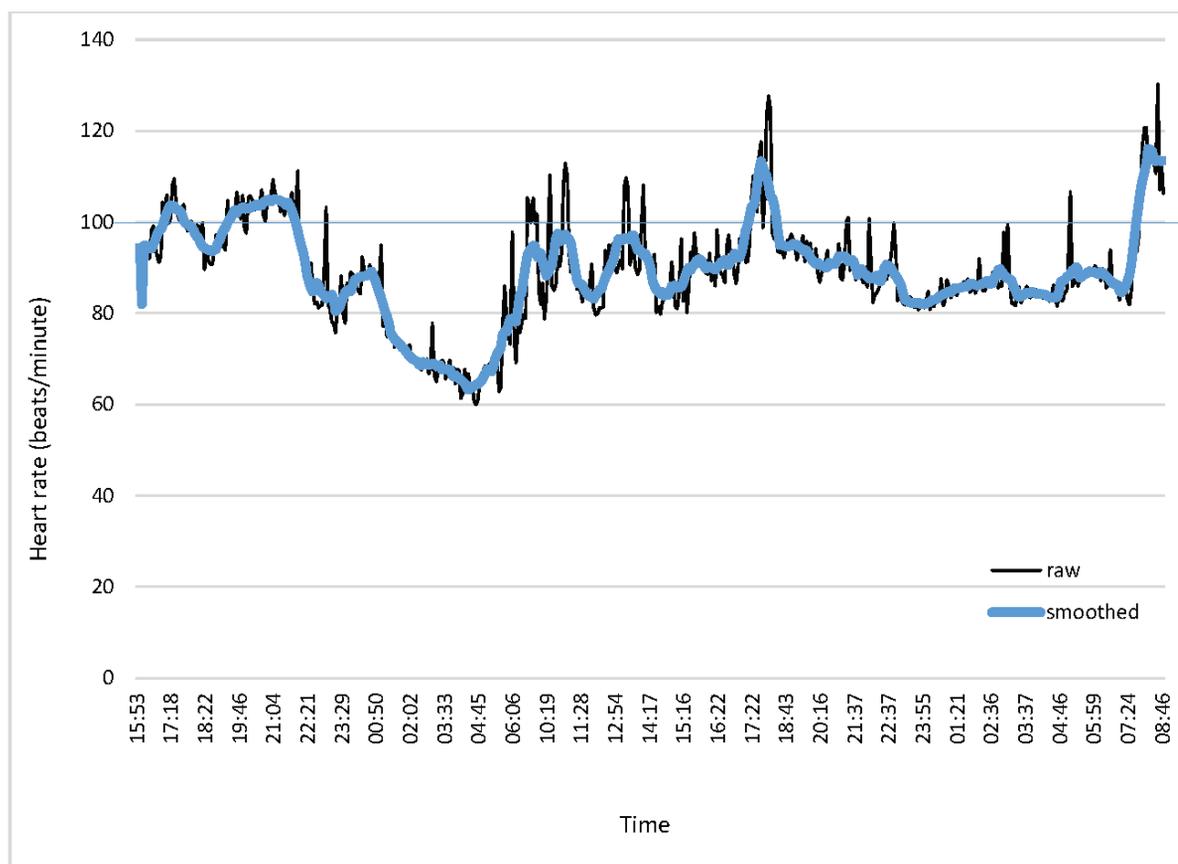
bpm: beats per minute; min: minutes; N: number of episodes; SpO<sub>2</sub>: oxyhemoglobin saturation; RAM: remote automated monitoring

### Tachycardia

According to the RAM heart rate data, there were 67 (of 276 available) patient-days with at least one episode of clinically meaningful tachycardia (i.e., >100 bpm, lasting longer than 15 minutes). The median duration across patient-days was 215.5 (IQR 92–333) minutes (see Table 3). Across post-operative Days 0 to 3, the highest heart rates recorded by RAM ranged from 145 to 177 bpm. In contrast to RAM, nurse-recorded data reflected a total of 8 patient-days with at least one episode of clinically meaningful tachycardia. The estimated median duration of nurse-detected tachycardia was 350 minutes per patient-day (IQR 300–990). The highest heart rates recorded in the patient charts were lower than those recorded by RAM, i.e., 110 to 114 bpm and were recorded on postoperative Days 0 to 2.

Of 121 patients with data, 42 (34.7%; 95% confidence interval (CI) 26.2, 43.2) had at least one episode of clinically

meaningful tachycardia detected by RAM that occurred across postoperative days 0 to 3. In comparison 7 patients (5.8%; 95% CI 1.6, 9.9; p=0.001) had tachycardia detected through intermittent vital signs monitoring by nurses (see Table 3). The absolute difference was 28.9% (95% CI 20.8, 37.0) which corresponds to a number needed to monitor of 4. In other words, for every 4 patients monitored by RAM, one additional patient with tachycardia would be detected compared with conventional nurse monitoring. Nurses detected clinically meaningful tachycardia in one participant with no clinically meaningful tachycardia recorded by RAM. According to RAM, this participant did have 3 episodes of tachycardia (10–14 minutes each), but none of these episodes met the study criteria for clinical significance. Figure 3 demonstrates an example of raw and smoothed RAM data collected for one patient with clinically meaningful episodes of tachycardia. This patient had 4



**Figure 3.** Raw and smoothed (moving average) RAM heart rate data collected for one participant experiencing clinically meaningful episodes of tachycardia (>100 beats/minute for >15 minutes)

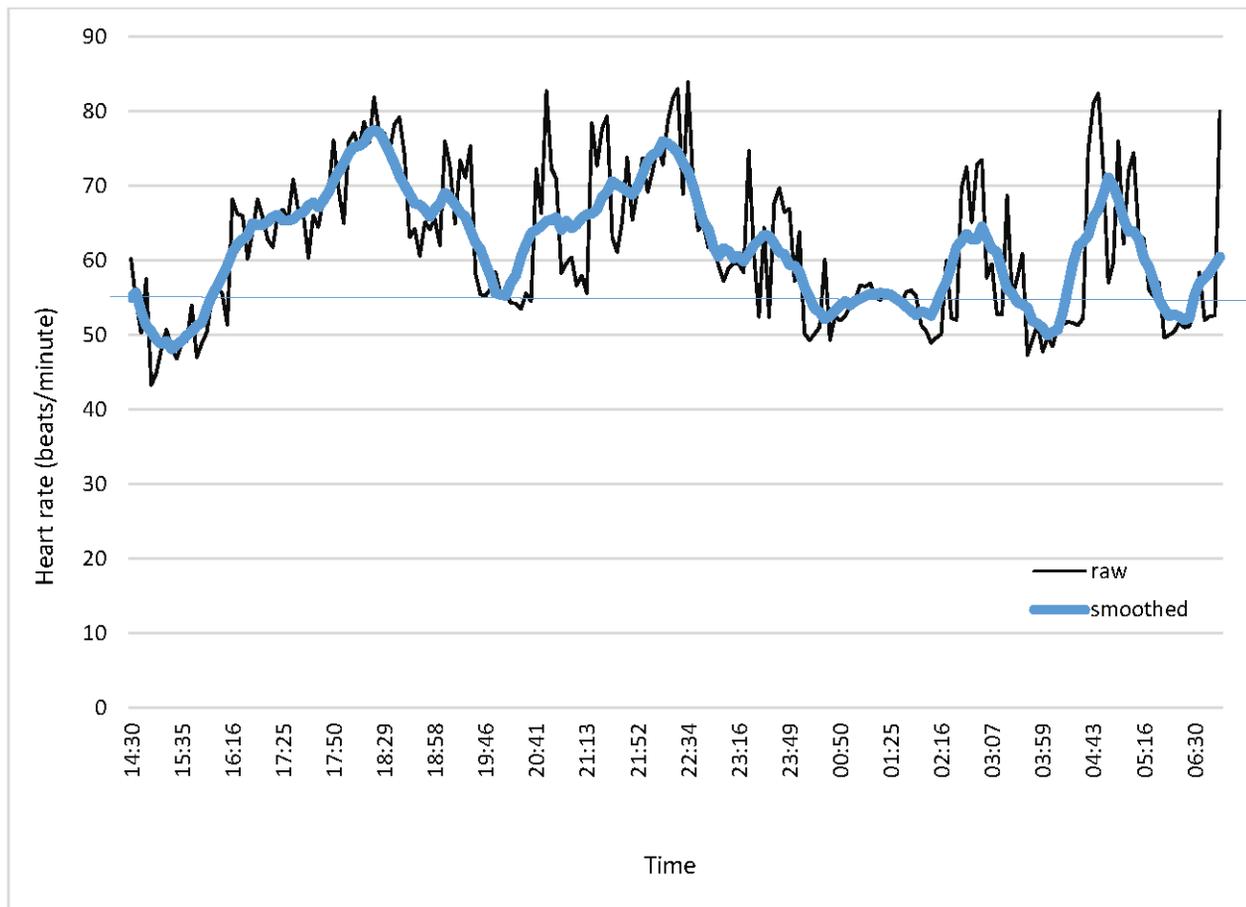
clinically meaningful episodes of tachycardia that occurred on postoperative Day 1 (58 and 2 hours 52 minutes’ duration, respectively; averaging 104 bpm) and Day 2 (47 and 56 minutes’ duration, respectively; averaging 113 bpm). RAM observation stopped during the second episode on Day 2.

Only one patient was identified as having a clinically meaningful episode of tachycardia with a heart rate exceeding 140 bpm for 5 minutes or longer; it was detected by RAM, with no episodes of heart rates exceeding 140 bpm recorded by nursing staff. The episode occurred on postoperative Day 3, averaged 157 bpm, and lasted 2 hours 13 minutes. It occurred in the early morning hours (01:52 to 04:05). This observed tachycardia was preceded by two other clinically meaningful episodes of tachycardia (i.e., >100 bpm for longer than 15 minutes); each of these episodes occurred the previous evening (postoperative Day 2), and ranged from 100 to 111 bpm, lasting for 54 and 74 minutes, respectively. These two episodes were detected by RAM but not recorded by nurses.

**Bradycardia**

RAM detected clinically meaningful bradycardia over 17 patient-days with a median duration of 152.5 minutes (IQR 111–459) (see Table 3). The slowest heart rates recorded by RAM were 30 to 36 bpm as recorded on postoperative Days 0 to 2. Bradycardia was recorded by nurses on 7 patient-days with a similar total duration of 181.5 minutes (IQR 60–255) per patient-day. The slowest heart rates recorded by nurses were higher than those recorded by RAM: 48 to 52 beats per minute on postoperative Days 0 to 2.

Across postoperative days 0 to 3, 14 of 121 patients (11.6%; 95% CI 5.9, 17.3) had clinically meaningful bradycardia recorded by RAM while 6 patients (5.0%; 95% CI 1.1, 8.8; p=0.07) had it recorded by ward nurses (see Table 3) for an absolute difference of 6.6% (95% CI 2.2, 11.0), and a number needed to monitor of 15. Nurses identified 3 patients not recorded by RAM as having clinically meaningful bradycardia. For 2 of these patients, bradycardia was detected by RAM, but the durations of the episodes were each less than 15 contiguous minutes (i.e., not meeting our definition of clinical meaningfulness).



**Figure 4.** Raw and smoothed (moving average) RAM heart rate data collected for one participant experiencing clinically meaningful episodes of bradycardia (<55 beats/minute for >15 minutes)

See Figure 4 for an example of raw and smoothed RAM data collected for one patient with clinically meaningful episodes of bradycardia. This patient had 5 clinically meaningful episodes of bradycardia: 1 on Day 0 (1 hour 38 minutes in duration; averaging 51 bpm) and 4 on Day 1 (48–56 minutes' duration; averaging 52 bpm). Standard monitoring of vital signs by nurses did not detect bradycardia in this patient.

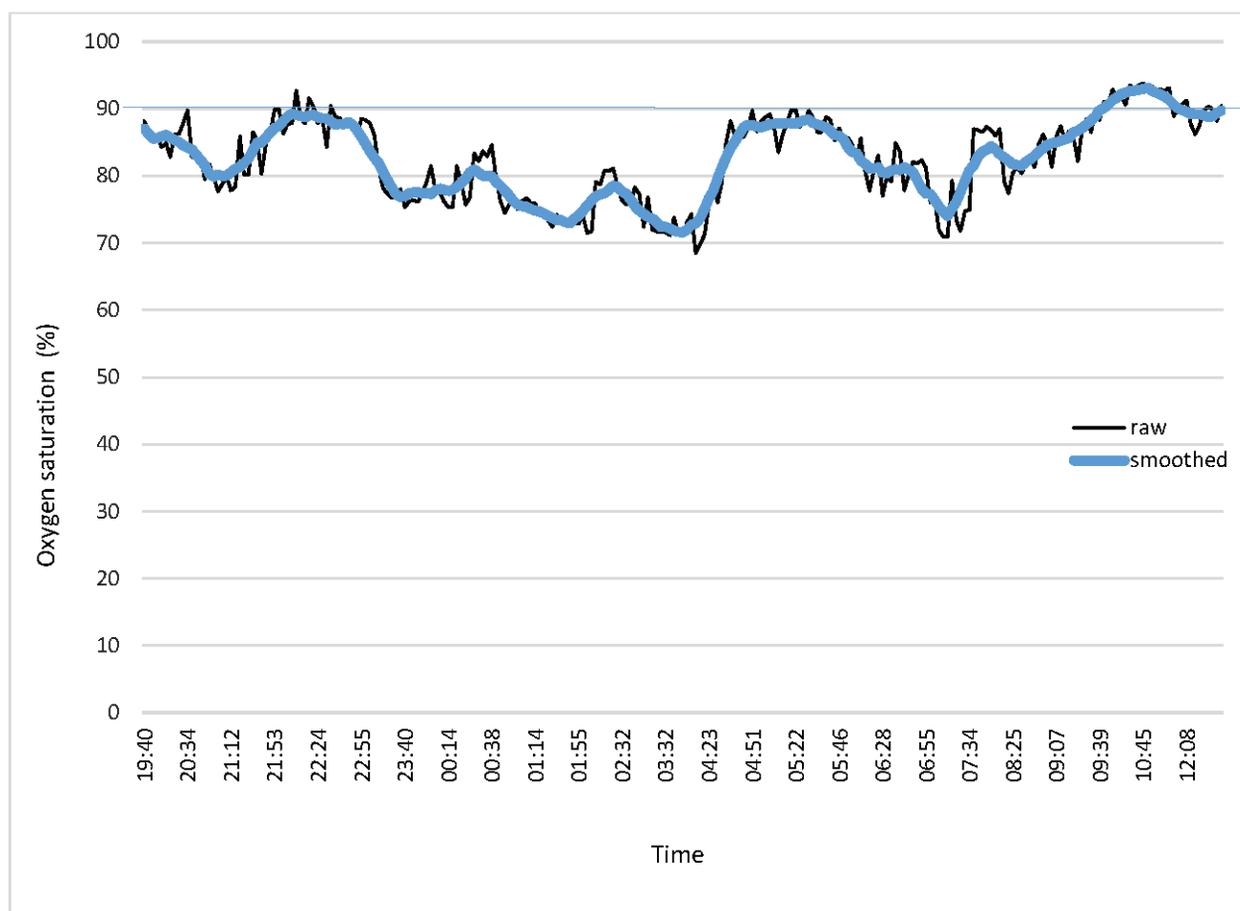
### Hypoxemia

RAM detected 36 patient-days (of 233 available) with clinically meaningful episodes of hypoxemia (i.e., <90% for >15 minutes). The median duration of these episodes was 146 minutes (IQR 64–305) (see Table 3). Five of these patient-days included hypoxemic episodes of SpO<sub>2</sub> <80% for 5 minutes or longer (median duration 190.5 minutes; IQR 32.5–351). The lowest SpO<sub>2</sub> levels recorded by RAM were 68.5–73.4%, across postoperative Days 0 to 3.

Clinically meaningful episodes of hypoxemia occurred in 25 of 107 patients (23.3%; 95% CI 15.3, 31.4) and 4 (3.7%;

95% CI 0.1, 7.3) with SpO<sub>2</sub> readings of <90% and <80%, respectively (see Table 3). Nurses identified one participant as having low SpO<sub>2</sub> (0.9%; 95% CI -0.9, 2.8; p=0.001) for an absolute difference compared with SpO<sub>2</sub> readings of <90% of 22.4% (14.5, 30.3) and a number needed to monitor of 5. No information was available about the level or duration of hypoxemia in the medical records and there were no readings from RAM indicating hypoxemia in this participant. However, this patient's RAM SpO<sub>2</sub> recordings were intermittent, with several gaps of up to 8 hours duration.

Figure 5 displays raw and smoothed RAM data collected for one patient with clinically meaningful episodes of hypoxemia. The patient highlighted in the figure had one episode of hypoxemia on postoperative Day 1 that was 4 hours 18 minutes in duration with an average SpO<sub>2</sub> of 84%. This episode extended into Day 2 for 9 hours 39 minutes with an average SpO<sub>2</sub> of 80% followed by a brief (1 hour 20 minute) set of readings above 90% before dipping to <90% again (for 21 minutes) before RAM was discontinued. As noted



**Figure 5.** Raw and smoothed (moving average) RAM oxygen saturation data collected for one participant experiencing clinically meaningful episodes of hypoxemia (<90% for >15 minutes)

above, this patient’s clinical records did not note low oxygen readings.

### Interpretation

Of the 121 postoperative patients in this prospective study, we found an absolute difference of 28.9% between RAM and nurse-detection in the percentage of patients with clinically meaningful tachycardia detected within 3 days of surgery. The absolute differences were 22.4% in the percentage of patients with hypoxemia detected and 6.6% in the percentage with clinically meaningful bradycardia detected. These absolute differences correspond to numbers needed to monitor of 4, 5, and 15, respectively. These data demonstrate that nurses did not detect substantial numbers of clinically meaningful vital signs abnormalities through episodic workflows that were detected using continuous RAM.

This proof-of-concept study reflected the early experience of our group with continuous RAM technology. Our data corroborate the results of other prospective studies using RAM. Sun *et al.*<sup>26</sup> reported that 37% of patients (>44 years of age) undergoing noncardiac surgery had  $\geq 1$  hour of SpO<sub>2</sub> of <90% postoperatively recorded by RAM technology (i.e., Nellcor OxiMax N-600x, Covidien [Dublin, Ireland]). The patients were followed from the time they left the post-anesthesia or intensive care unit for up to 48 hours or discharge, whichever occurred first. Of note, nurses missed 90% of the episodes of hypoxemia recorded by RAM. Similarly, Brown *et al.*<sup>27</sup> reported that 80% of postoperative patients had hypoxemia ( $\leq 90\%$ ) detected by continuous pulse oximetry, while intermittent vital signs observations detected hypoxemia in only 4% and 6% of patients at 5 and 30 minutes postoperatively, respectively. These reported estimates are somewhat higher than what we observed in the present study where RAM detected SpO<sub>2</sub> levels of <90% that persisted for

longer than 15 minutes in 23% of patients, with nurses missing all of these episodes. Collectively, these studies demonstrate that episodes of hypoxemia are easily unnoticed using standard, episodic nursing vital signs workflows. Continuous monitoring of oxygen levels has been shown to reduce the need for transfer to intensive care units and ‘rescue’ interventions due to earlier recognition of the problem.<sup>28,29</sup>

A chart review of adult patients (18 years or older) who underwent lobectomies in 2009–2011 found that 11.8% of the 20,695 patients had a record of postoperative tachycardia; the method of detection was not noted.<sup>30</sup> In a study employing 24-hour ambulatory electrocardiogram, the prevalence of ventricular tachycardia, in a group of adults 60 years or older, was 10–11%.<sup>31</sup> In the present study, the incidence of postoperative tachycardia detected by RAM was 34.7%, which was significantly higher than the 5.8% reported by nursing staff. Detection of heart rate abnormalities can have important implications for patient safety outcomes. For example, Sigmund *et al.*<sup>32</sup> reported that adults 18 years of age or older who had hip or knee arthroplasty were at significantly increased risk of pulmonary embolism (odds ratio [OR]: 9.39) or elevated troponin (OR: 4.71) if they had heart rates of >110 bpm in the first 4 days following surgery.

In addition to showing that nurses missed vital signs abnormalities detected by RAM, our data also suggest that nurses, through episodic vital signs workflows, missed more extreme abnormal vital signs abnormalities. This finding further illustrates the importance of automation to facilitate constant patient surveillance. Even in the context of conventional, episodic vital signs monitoring, scheduled patient observations (i.e., every 4 to 12 hours) are often missed. In a large hospital-based study (658 628 nursing shifts across 24 069 ward days) in the United Kingdom, Redfern *et al.*<sup>33</sup> reported that 17% of routine vital sign observations to be taken on patients, as dictated by institutional policy, were missed and another 31% were significantly delayed because nurses were busy attending to pressing patient-related matters and emergencies.

Moving forward, future studies should focus on implementation of continuous RAM both on the surgical ward and into the patient’s home to support recovery. Continuous RAM technology is evolving. New, more advanced technologies are capable of continuously monitoring multiple patient biometrics, simultaneously. Ideally, along with multiparameter sensing, studies of advanced forms of continuous RAM should also focus on integrating real-time, automated early alert systems to forewarn clinicians of impending patient deterioration and inform preventative interventions.

Our study has some limitations. The RAM data were not consistently available for the full period of participants’ hospital stay and were collected intermittently for several patients. This scenario likely led to underestimates of the number of patients and patient-days with clinically meaningful episodes of tachycardia, bradycardia, and hypoxemia. Another limitation was that the duration of clinically meaningful episodes, as noted by nursing staff, was based on discrete vital signs readings—the duration of clinically meaningful vital signs abnormalities was extrapolated by study personnel based on these clinical chart data. This extrapolation method likely led to over-estimates of the duration of the nurse-detected clinically meaningful episodes of tachycardia, bradycardia, and hypoxemia. Furthermore, our analysis was limited to values reported by Philips’ RAM devices with raw waveforms (e.g., electrocardiography) unavailable for more in-depth analysis of captured events (e.g., tachycardia). Finally, this proof-of-concept study was restricted to a single orthopedic surgery ward and patients at higher risk of postoperative myocardial injury, thereby limiting generalizability.

Our study found that meaningful vital signs abnormalities were missed by clinicians but were detected with continuous RAM. Continuous RAM technologies are available and the science of RAM implementation in the postoperative context is evolving. Beyond proof-of-concept, pragmatic clinical trials focused on continuous RAM implementation and evaluation are needed. Attention should be given to the facilitation of timely clinician response to vital signs abnormalities and early intervention to prevent patient deterioration and postoperative adverse events.

## Author Contributions

A Bessissow, D Sessler, K Gregus, and P.J. Devereaux procured the data. B Coleman, M Marcucci, MH McGillion, and P.J. Devereaux conceptualized the analysis plan, analyzed the data, and drafted the manuscript. All authors conducted a critical, substantive review of the manuscript and contributed to revisions.

## Acknowledgements

Regarding the MX40 Instructions for Use in the Supplement to the article, Philips Healthcare (“Philips”) hereby gives

permission, until further notice, to the Canadian Journal of General Internal Medicine (CJGIM), to make use in its regular course of business of the Philips' proprietary and/or copyrighted material attached hereto, subject to the CKGIM mentioning "courtesy of Royal Philips" in connection with such use. MH McGillion holds the Heart and Stroke Foundation/Michael G. DeGroot Chair in Cardiovascular Nursing at McMaster University.

## Funding

The IntelliVue MX40 wearable RAM technology for this study was provided by Philips.

## Conflict of Interests

MH McGillion and P.J. Devereaux are members of a research group with a policy of not accepting honorariums or other payments from industry for their own personal financial gain. They do accept honorariums/payments from industry to support research endeavours and costs to participate in meetings. MH McGillion has been a member of trusted advisor panels for Philips (unpaid) about RAM and other healthcare technologies. Based on study questions, P.J. Devereaux has originated and grants he has written, he has received grants from Abbott Diagnostics, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol-Myers-Squibb, CloudDX, Coviden, Octapharma, Philips Healthcare, Roche Diagnostics, Siemens and Stryker. P.J. Devereaux has participated in advisory board meetings for GlaxoSmithKline, Boehringer Ingelheim, Bayer and Quidel Canada. He attended an expert panel meeting with AstraZeneca and Boehringer Ingelheim and he was Consultant for a call with Roche Pharma. He has also been invited as a speaker with Bayer Inc and Novartis Pharma Canada. D Conen has received consultant fees from Roche Diagnostics; and speaker fees from Servier and BMS/Pfizer, outside of the current work. D Sessler has grants from GE and Masimo to study ward monitoring. Sotera provides ward monitoring systems to the Department of Outcomes Research. He is a paid consultant for Sensifree. S Parvaneh was an employee of Philips Research North America, Cambridge, Massachusetts at the time of data procurement. He is currently an employee of Edwards Lifescience, Irvine, California. FK Borges, B Coleman, P Harsha, M Marcucci, S Ofori, A Patel: None.

## References

1. Weiser TG, Regenbogen SE, Thompson KD, Haynes AB, Lipsitz SR, Berry WR, et al. An estimation of the global volume of surgery: A modelling strategy based on available data. *Lancet*. 2008;372(9633):139–44. [http://dx.doi.org/10.1016/S0140-6736\(08\)60878-8](http://dx.doi.org/10.1016/S0140-6736(08)60878-8)
2. Devereaux PJ, Sessler DI. Cardiac complications in patients undergoing major noncardiac surgery. *New Engl J Med*. 2015;373(23):2258–69. <http://dx.doi.org/10.1056/NEJMra1502824>
3. VISION study investigators. Association between complications and death within 30 days after noncardiac surgery. *CMAJ*. 2019;191(30):e830–7. <http://dx.doi.org/10.1503/cmaj.190221>
4. POISE Study Group, Devereaux PJ, Yang H, Yusuf S, Guyatt G, Leslie K, et al. Effects of extended-release metoprolol succinate in patients undergoing non-cardiac surgery (POISE trial): A randomised controlled trial. *Lancet*. 2008;371(9627):1839–47. [http://dx.doi.org/10.1016/S0140-6736\(08\)60601-7](http://dx.doi.org/10.1016/S0140-6736(08)60601-7)
5. Cegarra-Sanmartin V, Paniagua-Iglesias P, Popova E, de Nadal CM, Alonso-Coello P, Plou P, et al. [Perioperative acetylsalicylic acid and clonidine in noncardiac surgery patients (POISE-2 trial)]. *Rev Esp Anesthesiol Reanim*. 2015;62(5):270–4.
6. Walsh M, Devereaux PJ, Garg AX, Kurz A, Turan A, Rodseth RN, et al. Relationship between intraoperative mean arterial pressure and clinical outcomes after noncardiac surgery: Toward an empirical definition of hypotension. *Anesthesiology*. 2013;119(3):507–15. <http://dx.doi.org/10.1097/ALN.0b013e3182a10e26>
7. Bijker JB, Persoon S, Peelen LM, Moons KGM, Kalkman CJ, Kappelle LJ, et al. Intraoperative hypotension and perioperative ischemic stroke after general surgery: A nested case-control study. *Anesthesiology*. 2012;116(3):658–64. <http://dx.doi.org/10.1097/ALN.0b013e3182472320>
8. Abbott TEF, Pearse RM, Archbold RA, Ahmad T, Niebrzegowska E, Wragg A, et al. A prospective international multicentre cohort study of intraoperative heart rate and systolic blood pressure and myocardial injury after noncardiac surgery: Results of the VISION study. *Anesth Analg*. 2018;126(6):1936–45. <http://dx.doi.org/10.1213/ANE.0000000000002560>
9. Aronson S, Varon J. Hemodynamic control and clinical outcomes in the perioperative setting. *J Cardiothorac Vasc Anesth*. 2011;25(3):509–25. <http://dx.doi.org/10.1053/j.jvca.2011.01.018>
10. Bartels K, Kaizer A, Jameson L, Bullard K, Dingmann C, Fernandez-Bustamante A. Hypoxemia within the first 3 postoperative days is associated with increased 1-year postoperative mortality after adjusting for perioperative opioids and other confounders. *Anesth Analg*. 2020;131(2):555–63. <http://dx.doi.org/10.1213/ANE.0000000000004553>
11. Roshanov PS, Rochweg B, Patel A, Salehian O, Duceppe E, Belley-Côté EP, et al. Withholding versus continuing angiotensin-converting enzyme inhibitors or angiotensin II

- receptor blockers before noncardiac surgery: An analysis of the vascular events in noncardiac surgery patients cohort evaluation prospective cohort. *Anesthesiology*. 2017;126(1):16–27. <http://dx.doi.org/10.1097/ALN.0000000000001404>
12. McGillion MH, Duceppe E, Allan K, Marcucci M, Yang S, Johnson AP, et al. Postoperative remote automated monitoring: Need for and state of the science. *Can J Cardiol*. 2018;34(7):850–62. <http://dx.doi.org/10.1016/j.cjca.2018.04.021>
  13. McGain F, Cretikos MA, Jones D, Dyk SV, Buist MD, Opdam H, et al. Documentation of clinical review and vital signs after major surgery. *Med J Aust*. 2008;189(7):380–3. <http://dx.doi.org/10.5694/j.1326-5377.2008.tb02083.x>
  14. Sheth T, Natarajan MK, Hsieh V, Valettas N, Rokoss M, Mehta S, et al. Incidence of thrombosis in perioperative and non-operative myocardial infarction. *Br J Anaesth*. 2018;120:725–33. <http://dx.doi.org/10.1016/j.bja.2017.11.063>
  15. Kusumoto FM, Schoenfeld MH, Barrett C, Edgerton JR, Ellenbogen KA, Gold MR, et al. 2018 ACC/AHA/HRS guideline on the evaluation and management of patients with bradycardia and cardiac conduction delay: A report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines and the Heart Rhythm Society. *Circulation*. 2019;140(8):e382–482. <http://dx.doi.org/10.1161/CIR.0000000000000628>
  16. Correction to: 2018 ACC/AHA/HRS guideline on the evaluation and management of patients with bradycardia and cardiac conduction delay: A report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines and the Heart Rhythm Society. *Circulation*. 2019;140(8):e506–8. <http://dx.doi.org/10.1161/CIR.0000000000000721>
  17. Rosenberg J, Kehlet H. Postoperative mental confusion—Association with postoperative hypoxemia. *Surgery*. 1993;114(1):76–81.
  18. Aakerlund LP, Rosenberg J. Postoperative delirium: Treatment with supplementary oxygen. *Br J Anaesth*. 1994;72(3):286–90. <http://dx.doi.org/10.1093/bja/72.3.286>
  19. Rosenberg-Adamsen S, Lie C, Bernhard A, Kehlet H, Rosenberg J. Effect of oxygen treatment on heart rate after abdominal surgery. *Anesthesiology*. 1999;90(2):380–4. <http://dx.doi.org/10.1097/0000542-199902000-00008>
  20. Rosenberg J, Rasmussen V, von Jessen F, Ullstad T, Kehlet H. Late postoperative episodic and constant hypoxaemia and associated ECG abnormalities. *Br J Anaesth*. 1990;65(5):684–91. <http://dx.doi.org/10.1093/bja/65.5.684>
  21. Goldman MD, Reeder MK, Muir AD, Loh L, Young JD, Gitlin DA, et al. Repetitive nocturnal arterial oxygen desaturation and silent myocardial ischemia in patients presenting for vascular surgery. *J Am Geriatr Soc*. 1993;41(7):703–9. <http://dx.doi.org/10.1111/j.1532-5415.1993.tb07457.x>
  22. Gill NP, Wright B, Reilly CS. Relationship between hypoxaemic and cardiac ischaemic events in the perioperative period. *Br J Anaesth*. 1992;68(5):471–3. <http://dx.doi.org/10.1093/bja/68.5.471>
  23. Van Leuvan CH, Mitchell I. Missed opportunities? An observational study of vital sign measurements. *Crit Care Resusc*. 2008;10(2):111–5.
  24. Sessler DI, Meyhoff CS, Zimmerman NM, Mao G, Leslie K, Vásquez SM, et al. Period-dependent associations between hypotension during and for four days after noncardiac surgery and a composite of myocardial infarction and death: A substudy of the POISE-2 Trial. *Anesthesiology*. 2018;128(2):317–27. <http://dx.doi.org/10.1097/ALN.0000000000001985>
  25. Olshansky B, Sullivan RM. Inappropriate sinus tachycardia. *Europace*. 2019;21(2):194–207. <http://dx.doi.org/10.1093/europace/euy128>
  26. Sun Z, Sessler DI, Dalton JE, Devereaux PJ, Shahinyan A, Naylor AJ, et al. Postoperative hypoxemia is common and persistent: A prospective blinded observational study. *Anesth Analg*. 2015;121(3):709–15. <http://dx.doi.org/10.1213/ANE.0000000000000836>
  27. Brown LT, Purcell GJ, Traugott FM. Hypoxaemia during postoperative recovery using continuous pulse oximetry. *Anaesth Intensive Care*. 1990;18(4):509–16. <http://dx.doi.org/10.1177/0310057X9001800417>
  28. Taenzer AH, Pyke JB, McGrath SP, Blike GT. Impact of pulse oximetry surveillance on rescue events and intensive care unit transfers: A before-and-after concurrence study. *Anesthesiology*. 2010;112(2):282–7. <http://dx.doi.org/10.1097/ALN.0b013e3181ca7a9b>
  29. Ochroch EA, Russell MW, Hanson WC 3rd, Devine GA, Cucchiara AJ, Weiner MG, et al. The impact of continuous pulse oximetry monitoring on intensive care unit admissions from a postsurgical care floor. *Anesth Analg*. 2006;102(3):868–75. <http://dx.doi.org/10.1213/01.ane.0000195583.76486.c4>
  30. Giambrone GP, Wu X, Gaber-Baylis LK, Bhat AU, Zabih R, Altorki NK, et al. Incidence and implications of postoperative supraventricular tachycardia after pulmonary lobectomy. *J Thorac Cardiovasc Surg*. 2016;151(4):982–8. <http://dx.doi.org/10.1016/j.jtcvs.2015.11.057>
  31. Aronow WS, Ahn C, Mercado AD, Epstein S, Kronzon I. Prevalence and association of ventricular tachycardia and complex ventricular arrhythmias with new coronary events in older men and women with and without cardiovascular disease. *J Gerontol A Biol Sci Med Sci*. 2002;57(3):M178–80. <http://dx.doi.org/10.1093/gerona/57.3.m178>
  32. Sigmund AE, Fang Y, Chin M, Reynolds HR, Horwitz LI, Dweck E, et al. Postoperative tachycardia: Clinically meaningful or benign consequence of orthopedic surgery? *Mayo Clin Proc*. 2017;92(1):98–105. <http://dx.doi.org/10.1016/j.mayocp.2016.08.005>
  33. Redfern OC, Griffiths P, Maruotti A, Recio Saucedo A, Smith GB. The association between nurse staffing levels and the timeliness of vital signs monitoring: A retrospective observational study in the UK. *BMJ Open*. 2019;9(9):e032157. <http://dx.doi.org/10.1136/bmjopen-2019-032157>