Original Article

Use of wireless respiratory rate sensor monitoring during opioid patient-controlled analgesia after gynaecological surgery: A prospective cohort study

Address for correspondence:
Dr. Ban Leong Sng, KK Women's and Children's Hospital, 100 Bukit Timah Road, Singapore – 229899.
E-mail: sng.ban.leong@singhealth.com.sg

Submitted: 10-Oct-2020
Revision: 23-Oct-2020
Accepted: 19-Jan-2021
Published: 10-Feb-2021

Access this article online
Website: www.ijaweb.org
DOI: 10.4103/ija.IJA_1262_20
Quick response code

Shang-Ming Cheng[1], Jason Ju In Chan[1,2], Chin Wen Tan[1,2], Enhong Lu[1], Rehena Sultana[3], Ban Leong Sng[1,2]

[1]Department of Women's Anaesthesia, KK Women's and Children's Hospital, [2]Anaesthesiology and Perioperative Sciences Academic Clinical Program, Duke-NUS Medical School, [3]Centre for Quantitative Medicine, Duke-NUS Medical School, Singapore

ABSTRACT

Background and Aims: Respiratory depression is a rare but serious complication during opioid administration. Therefore, early detection of signs of deterioration is paramount. The current standard of care of using manual intermittent respiratory rate (RR) measurement is labour intensive and inefficient. We evaluated a wireless sensor monitor, Aingeal (Renew Health Ltd, Ireland), to continuously monitor RR, heart rate (HR) and temperature compared to standard clinical measurements. **Methods:** Patients who underwent major gynaecological operations and received postoperative opioid patient-controlled analgesia were recruited. Patients were connected to the sensor monitor via a central station software platform. The primary outcome was comparison of RR between sensor and nursing monitoring, with secondary outcomes being HR and temperature between two methods. Feedback from patients and healthcare providers was also collected. Bland-Altman analyses were used to compare the vital signs recorded in sensor against those in patient's electronic record. **Results:** A total of 1121 hours of vital signs data were analysed. Bias for RR was -0.90 (95% confidence interval (CI): -9.39, 7.60) breaths/min between nursing and averaged sensor readings. Bias for heart rate was -1.12 (95% CI: -26.27, 24.03) and bias for temperature was 1.45 (95% CI: -5.67, 2.76) between the two methods. **Conclusion**: There is satisfactory agreement of RR measurements, as well as HR and temperature measurements, by the wireless sensor monitor with standard clinical intermittent monitoring with overall good user experience.

Keywords: Gynaecology, patient-controlled analgesia, postoperative care, respiratory insufficiency, vital signs, wireless technology

INTRODUCTION

Opioid-induced respiratory depression is the most serious complication of opioid patient-controlled analgesia (PCA).[1] The current standard of care for postoperative patients includes intermittent measurement of respiratory rate (RR), but the lack of monitoring between these scheduled intervals may delay detection and treatment of opioid-induced respiratory depression. Furthermore, these patient-nurse interactions may temporarily increase the patient's awareness and RR, thereby masking the true effect of opioid-induced respiratory depression. Frequent manual measurement of RR is labour intensive and reduces healthcare productivity and efficiency.[2]

Since RR, heart rate (HR) and adequacy of oxygenation are part of the important physiological indicators

How to cite this article: Cheng SM, Chan JJ, Tan CW, Lu E, Sultana R, Sng BL. Use of wireless respiratory rate sensor monitoring during opioid patient-controlled analgesia after gynaecological surgery: A prospective cohort study. Indian J Anaesth 2021;65:146-52.

in predicting deterioration of hospital in-patients,[3] clinical outcomes may be improved via early recognition and treatment of patients with deranged RR and HR.[4] A recent study suggested that the use of continuous monitoring (with capnography and oximetry) may improve patient safety. This is especially true for patients who are at high risk of respiratory depression.[5]

Recent advancement in wireless technology allows convenient continuous patient monitoring. The Aingeal (Renew Health Ltd, Ireland), is designed as a wearable ambulatory device to support clinical staff during both direct and indirect patient monitoring. When measuring RR, a previous study on healthy subjects demonstrated comparable performance between the sensor and standard monitoring of within +2.42 and -3.88 breaths per minute, with an average difference of less than 1 breath per minute, implying the similar performance of sensor monitoring to that of standard monitoring, but with portable functionality.[6] A validated wearable monitoring device can provide continuous relevant clinical data, allowing healthcare providers (HCPs) to identify deranged physiologic indicators in real time and apply timely intervention.

Therefore, in this study, our primary outcome was to validate the use of Aingeal sensor monitor by comparing the RR measurement accuracy of the device against standard intermittent clinical nurse monitoring in postoperative gynaecological patients receiving intravenous morphine PCA. The secondary outcomes were the comparisons of HR and temperature between the two methods. We also examined the feasibility (installation and deployment) of using the sensor within a post-operative in-patient setting and determined user acceptance by HCPs and patients.

METHODS

This study was reviewed and approved by the SingHealth Centralised Institutional Review Board (Ref: 2018/2223) and registered on Clinicaltrials.gov (NCT03750318). Written informed consent was obtained from all recruited patients. Female patients of American Society of Anesthesiologists (ASA) I-III, aged 21-70 years old, undergoing gynaecological surgery and requiring postoperative analgesia via intravenous PCA were recruited. This prospective cohort study was conducted at our institution between January and May 2019 and adhered to the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines.

As per standard practice, data from intermittent clinical monitoring were recorded using the hospital electronic nurse charting system and postoperative analgesia was managed by the acute pain service. We excluded patients who had active implantable devices (e.g., a pacemaker or implantable cardiac defibrillator); any skin conditions or injuries affecting electrode placement; who were pregnant; or who were, in the opinion of ward staff, not suitable to participate.

The Surveillance System comprised two main components: A United States Food and Drug Administration (FDA)-approved and European conformity (CE)-marked patient-worn wireless vital signs sensor monitor (Aingeal) that transmits data over Wi-Fi to a central station software platform (Surveillance Station) [Figure 1]. The sensor device measures single lead electrocardiogram (ECG), HR, RR, respiration waveform and skin temperature. Snapshots of data were transmitted by the devices intermittently using a Wi-Fi link (Institute of Electrical and Electronics Engineer (IEEE) 802.11.b/g, in the 2.4 GHz frequency band) via a secure server to the Surveillance Station, enabling data visualisation at the Surveillance Station and vital signs plotting. Pre-defined high and low limited were individually set for each patient, and an alert would be raised in the event of HR, RR or skin temperature derangement. A standalone Wi-Fi network was set up to facilitate system use for the purposes of the evaluation.

HCPs were trained on the use of the Surveillance System and were asked to use the system during routine patient care until completion of the study. Standard care and monitoring were continued as per hospital practice and remained unchanged by the study activities.

Monitoring commenced upon admission to the ward. Duration of opioid therapy for postoperative patients

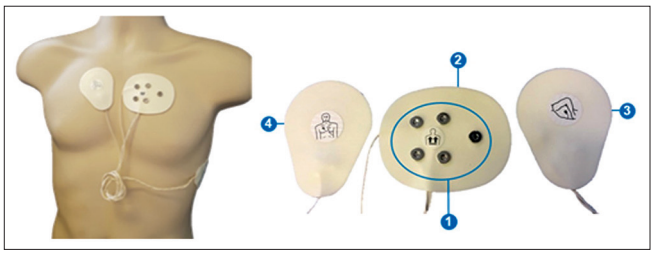

Figure 1: Diagram of Aingeal system. 1: Magnetic connection studs. 2: Studded electrode patch. 3: Left electrode patch. 4: Right electrode patch. Images provided with permission from Renew Group Private Limited

ranged from one to three days. Upon cessation of opioid therapy, sensor monitoring was stopped. De-identified log files were extracted from the Surveillance Station and re-processed to produce counts of the number of alarms raised during the monitoring period. Vital sign trend graphs were produced.

Anonymous data recorded by the sensor monitor device during the evaluation were compared against standard intermittent monitoring data extracted from electronic nursing records. If adverse events were noted, HCPs were asked to record the patient's sensor device serial number and the date, time and duration of the adverse event. HCPs were also asked to provide feedback on their experiences with the system, which was reviewed with ward management, of which the feedback was performed in a 5-point Likert scale: (1) Strongly disagree; (2) Disagree; (3) Neither agree nor disagree; (4) Agree; (5) Strongly agree. Considerations were given to the clinical utility of the system, ease of use, patient and nurse acceptance and integration with existing workflow. Patients who had worn the device were invited to complete a feedback questionnaire.

The sample size of 35 was based on the assumption of a mean difference of RR between the two methods as 5 breaths/min, standard deviation (SD) of the difference as 2.5 breaths/min with maximum allowed difference between the methods as 12 breaths/min, level of significance $\alpha = 5\%$, powered at 80% and using paired t–test; we planned to recruit 35 adult in-patients. Hence, a total of 35 in-patient postoperative adult women on opioid therapy were recruited to wear the sensor device to facilitate a proof-of-concept evaluation of the surveillance system as part of an integrated monitoring with opioid delivery system in the ward setting.

Summaries of patient and HCP acceptability, demographics and reason for admission were produced. In general, categorical data were summarised using frequency counts with percentages, and continuous data were summarised using means with SDs, or medians with ranges. Bland-Altman analyses were used to compare heart and respiration rates as recorded in sensor device against the vital signs data recorded in the patient's electronic record. For each parameter, this involved plotting the difference in the counts against the mean of the two absolute counts. The 95% and 99% limits of agreement, equivalent to 2 times SD and 3 SD were plotted. Statistical Analysis System (SAS) version 9.4 software (SAS Institute; Cary, North Carolina, USA) was used for all the analyses.

RESULTS

We enroled and analysed 35 women [Table 1], with the majority undergoing total abdominal hysterectomy with bilateral salpingo-oophorectomy (n = 20), followed by open myomectomy or cystectomy (n = 7) and others (n = 8).

A total of 1121 hours of vital signs data from the sensor [Figure 1] were analysed. Figure 2a illustrates the primary outcome of RR measurement over time. Of note, there was interpersonal variation in RR being

Table 1: Patient demographic and characteristics (*n*=35)

	Summary
Age (years)	46.7±9.0
Race	
Chinese	24 (68.6)
Malay	8 (22.9)
Indian	0 (0.0)
Others	3 (8.5)
Weight (kg)	69.0±16.8
Height (cm)	156.5±7.0
BMI (kg/m^2)	28.1±6.3
ASA status	
I	12 (34.3)
II	19 (54.3)
III	4 (11.4)

Data reported as mean±SD or number (%). ASA – American Society of Anesthesiologists; BMI – Body mass index; SD – Standard deviation

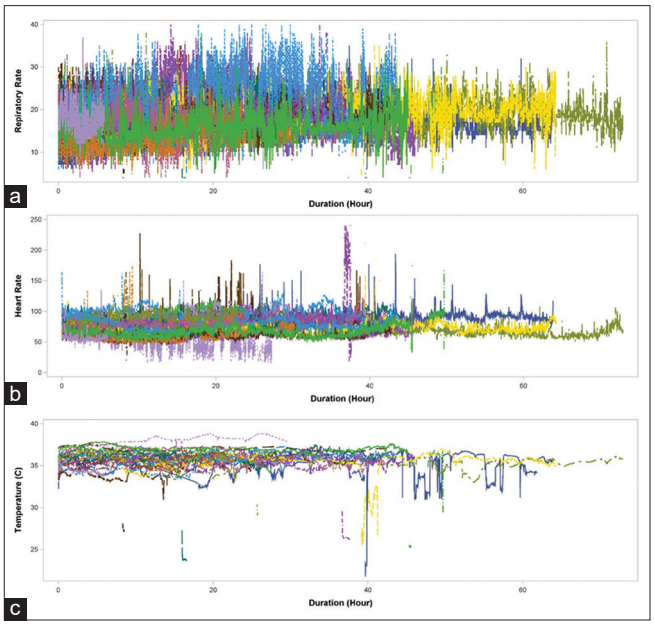

Figure 2: Graphs of (a) respiratory rate (breaths per minute); (b) heart rate (beats per minute); and (c) skin temperature; against time. Each colour represents one patient

observed, with some measurements above the normal range. The Bland and Altman plot for RR as measured in 1-minute interval [Figure 3a] showed a bias between standard intermittent measurements and averaged sensor measurement of -0.90 (95% CI -9.39, 7.60) breaths/min. The bias was -1.04 ± 4.0 (95% CI -8.96 to 6.88) breaths/min when the filter was set to 5-minute intervals [Figure 3b].

Figure 2b shows HR measurement with time. The majority of measurements were within the range of 60 and 120 beats/min with occasional HR measurements that were out of the normal range. Figure 3c represents the Bland and Altman plot for HR at 5-minute intervals. The bias between standard intermittent measurement and averaged sensor reading was -1.12 (95% CI: -26.27, 24.03) beats/min.

Figure 2c shows limited variation of temperature among the tested subjects during the trial period. There were occasional sudden drops in temperature recordings. The Bland and Altman plot for temperature at 5-minute intervals showed a bias between intermittent measurements and the averaged sensor readings of -1.45 (95% CI: -5.67, 2.76) ºC/min [Figure 3d].

Patients expressed high satisfaction regarding the use of sensor device, although a few patients reported discomfort or skin itchiness upon application [Table 2]. Some of them also had difficulties with self-application especially after showering. HCPs also responded favourably to the Surveillance System, but occasional loss of readings were also observed [Table 3]. In the survey, several HCPs expressed that training sessions should be required to improve their confidence on the application and care of device during its deployment. In some cases, HCPs also observed difficulties in detecting HR and RR for high BMI patients.

Table 2: Patient feedback (*n*=35)

	Median (range)
Adequate information	4 (3-5)
Comfort all the time	4 (2-5)
No skin irritations	4 (2-5)
Able to continue with daily activities	4 (2-5)
Comfortable applying the device independently	4 (2-5)
Comfortable having HR and RR monitored	4 (2-5)
Comfortable having monitored remotely without nurses' presence	4 (2-5)
Feel more secure with continuous monitoring than with periodic checks	4 (2-5)
Keen to continue remote monitoring if warded again	4 (2-5)

HR – Heart rate; RR – Respiratory rate. The feedback was performed in a 5-point Likert scale: (1) Strongly disagree; (2) Disagree; (3) Neither agree nor disagree; (4) Agree; (5) Strongly agree

Table 3: Healthcare providers feedback (*n*=35)

	Median (range)
Easy to set patients up on the Surveillance Monitoring Central Station	4 (4-5)
Easy to apply onto patient	4 (4-5)
Did not appear to increase patient's discomfort	4 (2-5)
Loss of readings (vital signs) from device was uncommon	2 (2-2)
Able to view and monitor vital signs on Surveillance Monitoring Central Station easily	4 (4-5)
Could use without special training	2 (2-4)
Meets clinical needs	4 (4-5)
Safe for clinical use	4 (4-5)
Easily integrated with ward routine	4 (4-5)
Enhances patient care in the ward	4 (4-5)

The feedback was performed in a 5-point Likert scale: (1) Strongly disagree; (2) Disagree; (3) Neither agree nor disagree; (4) Agree; (5) Strongly agree

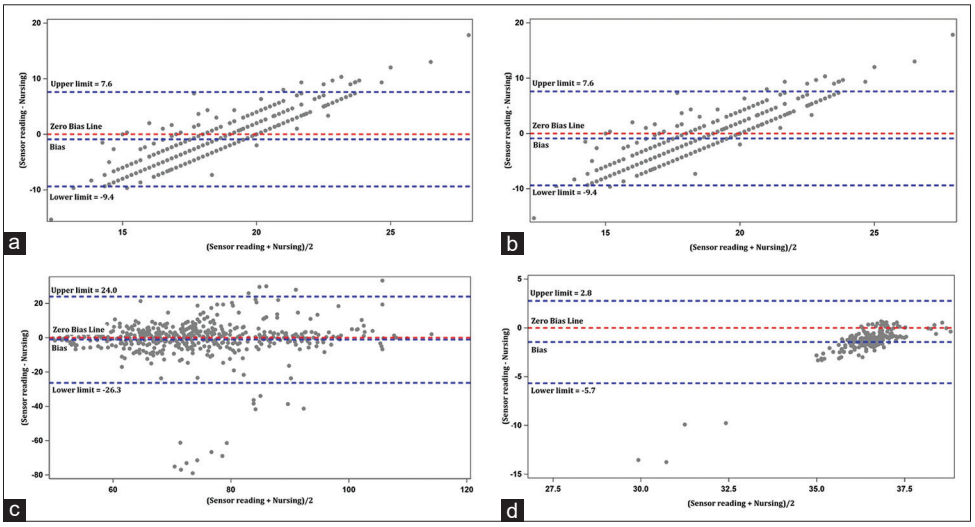

Figure 3: Bland and Altman plots for (a) respiratory rate at 1-minute interval; (b) respiratory rate at 5-minute interval; (c) heart rate at 5-minute interval; and (d) temperature at 5-minute interval

DISCUSSION

In this single-centre, prospective cohort study, RR measurements recorded by the study sensor monitoring were comparable to standard intermittent nursing measurements. HR and temperature also showed similarities between the sensor readings and nursing measurements. HCPs and patients expressed satisfaction with the application and comfort of the study sensor monitoring.

Monitoring of RR using manual intermittent measurement is labour intensive and time consuming. Intermittently recorded RR is an estimated or 'spot' measurement,[7] may not accurately represent the dynamic nature of RR and the HCPs may not be able to timely detect obstructive apnoeic episodes.[8] The importance of dynamic continuous RR measurement may be particularly relevant to the use of modified early warning systems (MEWS) which are reliant on timely and accurate vital signs measurements. The additional feature of wireless monitoring device overcomes the bulkiness of standard monitoring systems, which could be useful in further improving the continuous monitoring of patients, especially in isolation room settings.

Despite the comparable agreement of the study sensor monitoring with standard intermittent measurement, posture changes and motion may introduce artefacts into measurements made using impedance pneumography, which the study sensor used. Furthermore, obstructive apnoeic episodes may also be missed.[9] On inspection of the raw data, we noted variations in RR for one patient. Similar observations were reported in other continuous monitoring studies utilising impedance pneumography,[10,11] but may be improved with future software improvement.[12]

The study sensor monitor calculates HR from electrocardiogram (ECG) signals and demonstrated good agreement with standard intermittent measurements. The sensor utilised a minimalistic ECG lead design, complex front-end filtering and microcontroller processing algorithms to minimise motion artefacts.[13] ECG interpretation was not included in this study analysis. If utilised, it may have an added benefit of continuous cardiac monitoring. The temperature measurements recorded by the sensor have been shown to have agreement with the tympanic temperature. The design of the sensor ECG patch included an adhesive foam that provides insulation and creation of a microclimate around the skin temperature sensor to reduce environmental heat influence.[14]

Several small trials have looked into clinical feasibility of utilising wearable remote vital signs monitors.[10,11,15,16] Hernandez-Silveira *et al*. showed an overall satisfactory agreement between the study patch HR and RR readings and clinical observation, although the respiratory data were more frequently rejected as artefacts.[10] Downey *et al*. found that their study patch did not reliably provide HR readings consistent with intermittent measurements for post-operative patients and the accuracy of RR and temperature were outside of acceptable limits.[11] Instead of impedance pneumography, in some devices, RR was estimated using a combination of two ECG-derived respiratory signals (the respiratory sinus arrhythmia and the QRS-amplitude) and the accelerometer signal.[15] Breteler *et al*. tested one such device on 25 post-operative patients with good accuracy measuring HR. However, the accuracy for RR was outside acceptable limits.[16]

Recent developments in mobile technology and network connectivity allow us to utilise continuous wearable sensor monitoring devices to monitor various physiological parameters.[17] Remote surveillance technologies have great potential to change the ways we manage and monitor patients in the perioperative setting.[18,19] Even with increased ward monitoring and rapid response teams, there is still delayed recognition of deteriorating physiological parameters.[20] Continuous physiological sensor monitoring may facilitate earlier identification of deranged physiological parameters and timely intervention.[21] Further work is needed to establish the clinical benefit, cost effectiveness and development of implementation strategies for such continuous sensor monitoring systems.[19] Despite current advocation for multimodal opioid sparing strategies, opioid PCA would remain an important part of postoperative analgesic control.[22,23] Future work could incorporate sensor monitoring with PCA devices to further enhance patient safety and minimise the risk of opioid-induced respiratory depression.[24]

Because of the small sample size, the study was not powered to detect adverse events, including opioid-induced respiratory depression. However, the aim of this study was to study the agreement of RR, HR, and temperature measured using a sensor monitor against standard intermittent measurements.

As our study subjects were limited to Asian females, future studies should include a larger sample size and different surgical procedures. User feedback suggested there could be challenges in monitoring patients with high BMI. Further larger studies should include verification of difficult monitoring in those with high BMI. Our study also had wide range of durations (2.5 hours to 60 hours) of application. The current evidence also suggests that monitoring up to seven days should be continued to avoid chances of apnoea-hypopnoea, especially on the third night after surgery.[25] It may be clinically relevant to extend the monitoring period in future studies. There is limited evidence on comparing the performance of this wireless study sensor monitor with other devices (e.g., wired impedance pneumography, capnography), hence comparison can be considered in future studies.

CONCLUSION

In conclusion, there is satisfactory agreement of RR measurements, as well as HR and temperature measurements, by the wireless study sensor monitor, Aingeal, with standard clinical intermittent monitoring. There is good overall user experience. Future refinement of the device and software may further improve the vital signs monitoring.

Acknowledgements

We would like to thank Ms. Sing Zhi Kee (Clinical Research Coordinator), Ms. Dora Xinping Gan (Clinical Research Coordinator), and Ms. Agnes Teo (Senior Clinical Research Coordinator) for their administrative support in this work. We would also like to acknowledge Dr Ming Jian Lim and Dr John Song En Lee on their help in the recruitment.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patients have given their consent for their clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

This clinical trial received research funding and Renew's surveillance monitoring system and Aingeal devices from Renew Group Private Limited. The sponsor company was not involved in the design of the study, data collection, data analysis, interpretation of data and in scientific writing of the manuscript.

Conflicts of interest

There are no conflicts of interest.

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