



Research Article

A Quality Assurance Study of Respiratory Rate Measurements on Obese Patients with a Novel Monitoring Technology

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Abstract

Background: Many practical challenges exist when caring for Obese patients, with the obesity epidemic being a global problem. Overweight and obese individuals are more likely to have respiratory symptoms than individuals with a normal BMI, even in the absence of demonstrable lung disease [1]. For example, it is known that respiratory system compliance is reduced in obese individuals [2] with the net effect on pulmonary function being rapid, shallow breathing patterns. Several techniques may be used for the continuous assessment of adequate oxygenation and ventilation in obese patients. Pulse oximetry is a reliable estimate of oxygenation, but detection of hypoventilation or airway obstruction as evidenced by arterial oxygen saturation can be delayed [2], manual counting of respiratory rate is inaccurate, even when implemented by trained health care professionals, and leaves respiratory rate unmonitored for long periods of time in the general ward. Contactless systems are limited by the fact that they cannot move with the patient as the patient moves through the hospital system. Capnography, the gold standard, provides adequate monitoring of respiratory rate. However, this monitoring technique may be affected by changes in dead-space, cardiac output and breathing patterns related to obesity [1]. RespiraSense™ is a novel, non-invasive, wireless, body worn, motion-tolerant and continuous respiratory rate monitor which provides a viable solution to the monitoring of respiratory rate in individuals across the BMI spectrum. **Aim:** We aimed to demonstrate equivalence of RespiraSense at measuring respiratory rate in obese patients in comparison to the gold standard method of capnography. **Methods:** RespiraSense measures respiratory rate and transmit signals wirelessly to a tablet device. We measured respiratory rate in a total of 19 outpatients of an Integrated Complex Obesity Clinic in the UK. Patients were observed for one (1) hour and the measurements from the capnograph and RespiraSense were compared. Qualitative data were collected to assess the comfort and usability of the device. **Results:** Data from 11 patients was evaluated. For all patients with a BMI > 35, a mean RR of 17.01 (SD 5.42) for capnograph measurements compared to a mean RR of 17 (SD 4.2) with RespiraSense were recorded. The mean RR measurement for all patients was less than the defined normal RR of 20 breaths per minute. For the five (5) patients with a BMI in the range of 35-49 a mean RR of 16.56 (SD 2.42) for capnograph measurements compared to a mean RR of 17.3 (SD 4.03) with RespiraSense were recorded. For the five (5) patients with a BMI > 50, a mean RR of 18.5 (SD 6.09) for capnograph measurements compared to a mean RR of 19 (SD 3.5) with RespiraSense were recorded. All comparative measurements were within the pre-defined limits of error. **Conclusion:** continuous measurement of RR with RespiraSense in obese patients is a feasible and reliable alternative to existing methods.

Keywords: Respiratory rate; Wearables; Digital health; Early warning score; Respiratory failure; Respiratory compromise

Introduction

Background

According to the National Institute for Health and Care Excellence “respiratory rate is the best marker of a sick patient and is the first observation that will indicate a problem or deterioration in condition”. Accurate measurement and interpretation of this vital sign is therefore essential in ensuring best possible patient outcomes. However, despite the awareness of its importance, clinical staff find it is not efficient in a busy clinical setting [2] and have very low confidence in the reliability of recordings [3]. This lack of faith is resulting in essential clinical information not being used or indeed misleading clinical care [3]. It has been found from a 2015 systematic review of continuous monitoring methods that their implementation cannot yet be supported as results are inconclusive and the methodological quality of the studies included was questionable [4]. Despite its limitations manual counting of respiratory rate is seen as the industry standard whereas capnography is recognised as the gold standard measurement.

Aim

We aimed to demonstrate equivalence of RespiraSense at measuring respiratory rate in comparison to the gold standard method of capnography in obese patients [5].

Methods

Study Design

This was a single centre, prospective, controlled, exploratory investigation designed to validate that RespiraSense is effective in monitoring respiratory rate in obese patients in comparison to the gold standard method capnography [6,7]. The primary endpoint was the agreement between respiratory rates measured with RespiraSense averaged over a rolling 15-minute window compared to average respiratory rate measured with capnography. Measurements for the primary endpoint were taken for one (1) hour.

Recruitment

Patients were recruited from the Integrated Complex Obesity Clinic of Queen Alexandra Hospital, Portsmouth, UK from the 28th July 2017 to the 23rd March 2018.

Patient had to fulfill the following inclusion criteria: Age ≥ 18 years, have a BMI ≥ 35 and be willing to voluntarily sign a

statement of informed consent.

Patients with the following criteria were excluded:

Allergic to medical grade skin adhesive, continuous long term oral steroid use, under the influence of substance abuse (drug or alcohol) and any disorder [8], including cognitive dysfunction, which would inhibit their ability to accurately complete questionnaires and freely give informed consent.

Subjects could withdraw from the clinical investigation at any time without any rationale and without compromising their future medical care. Subjects could also be removed from a clinical investigation by their physicians if they felt it to be in the best interest of the subject.

Potential subjects were identified through a database search. Once identified research participants were contacted via letter which contained the Patient Information Leaflet (PIL) and Informed Consent Form (ICF). A message was also posted to the closed peer-to-peer group on the Integrated Complex Obesity Clinics social media page (Facebook).

Measurements

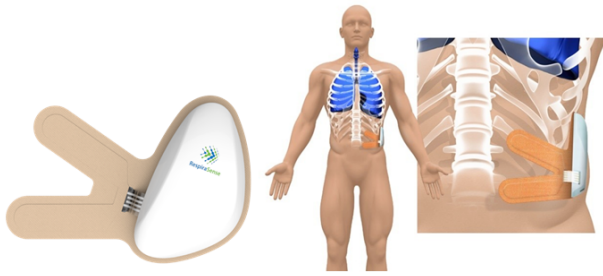
We collected gender, age, height, weight, waist (cm), hip (cm), demographic data, RespiraSense measurements and capnography measurements [9,10]. Body mass index was calculated from height and weight.

The capnograph measurement was performed using the Nonin Life Sense Model LS1-9R. The monitor uses sidestream non-dispersive infrared (NDIR) spectroscopy to continuously measure respiratory rate. Calibration was performed as per manufacturer’s instructions one to two weeks before the commencement of this investigation. The Nonin Life Sense utilizes a sample line (a single use disposable tubing) that attaches into the patient’s nose and connects to the monitor’s moisture trap. The cannula is inserted into each nostril and tubing placed behind the ears.

During this investigation, the RespiraSense sensor was attached to the patient’s skin, straddling their chest and left side, using medical grade adhesive. Each subject’s participation was monitored for one hour.

RespiraSense

RespiraSense is a CE-marked device and as such has been deemed safe to use with no expected interactions with most concomitant medical treatments. As per the Instructions for Use (IFU) RespiraSense is not to be used during defibrillation, Magnetic Resonance Imaging, X-Ray or other medical imaging procedures.



The Lobe and Sensor, RespiraSense™ are transmitted to the mobile application via Bluetooth.

RespiraSense™ is a non-invasive, wireless, body worn, motion-tolerant and continuous respiratory rate monitor. The system consists of a RespiraSense™ Lobe, a single-use Sensor and a Mobile Application. The Lobe and Sensor – ‘RespiraSense™’ - are assembled together and placed onto the patient for the purpose of monitoring respiratory rate. RespiraSense™ utilizes a generic sensory technology called piezoelectric films which are assembled into an array. This piezoelectric array is able to measure small deformations in the relative angles of the thoracic and abdominal surfaces that occur during breathing and convert these changes into an electrical signal. The rate of these changes corresponds to respiratory rate. On-board accelerometers and discriminatory algorithms in the device means that the system is tolerant to movement artefacts such as coughing, talking and walking.

Respiratory rate data collected by RespiraSense™ are transmitted to the mobile application via Bluetooth. This data can then be transmitted via Wi-Fi to the most appropriate location in the hospital, be that a nurse’s station or the Electronic Health Record (EHR).

Statistics

The primary endpoint was analyzed using a Bland Altman (BA) analysis to measure limits of agreement between methods. The BA analysis was corrected for repeated measures within each subject if required. In addition, a Deming regression was performed on the collected data. The pass criteria for the study were defined as: The limits of agreement of the Bland Altman analysis to not contain +3 bpm or -3 bpm, with the 95% CI on the Deming regression intercept containing 0 and the 95% CI on the Deming regression slope containing 1.

The sample size was calculated based on previous analysis of RespiraSense versus capnograph, the expected standard deviation in difference in average RR over a 15-minute window between RS and Capnography was estimated to be 1.1 bpm. A 2-sided 95% CI for the mean of the differences between methods were constructed with a maximum length of 2 bpm. Assuming a dropout rate of 10% and at least 1 usable data point per patient, this required the recruitment of 21 patients.

All data were summarized with descriptive statistics including mean, standard deviation (SD), median, minimum, maximum, first and third quartiles for interval scales and number and frequency for categorical variables.

Results

Recruitment

Data was collected from 28th July 2017 to the 23rd March 2018. 19 patients met inclusion criteria, of these 19 agreed to consent. In all, 19 patient’s measurements were completed. Data from 11 patients was included in the analysis. 6 (54%) patients were male and the mean age of patients was 62 years (SD 22). 1 patient was unable to stand for measurements and was excluded from BMI reporting. 5 patients had a BMI of between 35 and 50 whilst five (5) patients had a BMI of greater than 50.

Respiratory Rate Measurements

The results of the measurements are presented in the BA plots below (Fig). Bland Altman analysis was corrected for repeated measures within subjects. Agreement of measurements was within pre- defined limits for capnograph versus RespiraSense.

Bland Altman	
Bias15	0.1652
Stdev15	1.4351
Upper95_15	2.9780
Lower95_15	-2.6476
R-squared	0.9381

Table 1: Bland Altman results.

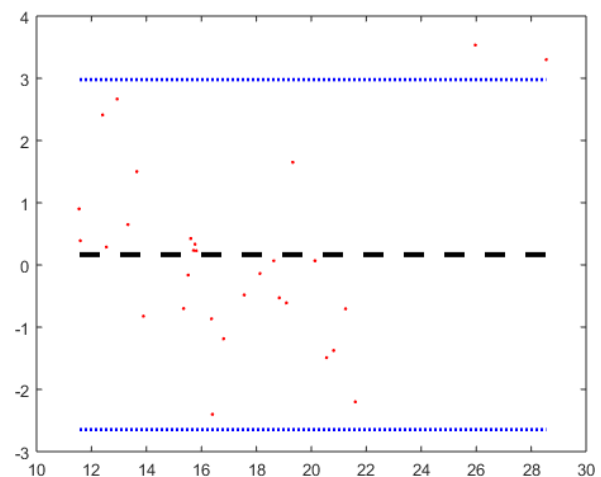


Figure 1: Bland-Altman. Y-axis shows difference between methods and X-axis shows average.

15 Minute Deming Analysis	
Bias	0.34
Bias 95CI upper	4.70
Bias 95CI Lower	-4.03
Bias CI contains 0?	TRUE
Slope	0.97
Slope 95CI upper	1.24
Slope 95CI lower	0.70
Slope CI contains 1?	TRUE

Table 2: Deming plot results.

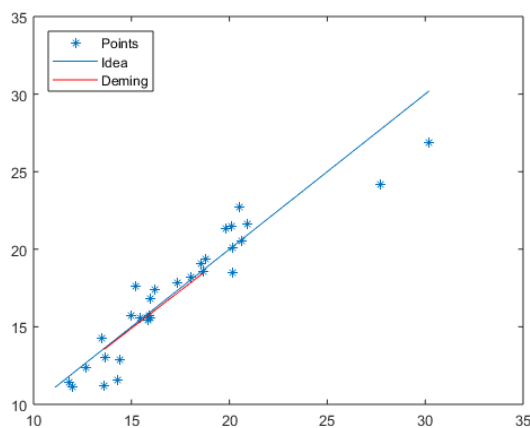


Figure 2: Deming plot of data from first 9 subjects.

Discussion

What we have shown

In the present study we have shown that RespiraSense delivers a high quality measurement of respiratory rate compared to gold standard in obese patients. Respiratory rate was measured within the pre-defined level of agreement both at rest and during movement and reliability of measurements was independent of gender, BMI and age.

What others have shown

Respiratory rate is a key measurement for risk stratification of cardiac and respiratory conditions and trauma. Despite this it has been called the ‘neglected’ vital sign. Documented measurements often diverge from accurately counted ones. Previous studies (Lee, Subbe) have shown that RespiraSense can accurately and reliably measure respiratory rate in patients that are in the Normal BMI range when the patient is at rest and when moving.

Strength and Weaknesses

This was a prospective study powered to show the reliability of respiratory rate measurements in a clinical environment on obese patients. The comfort of the device and the ease of

application was assessed. While the present study is a single centre study we believe that physiology is sufficiently universal to allow extrapolation of the results to other hospitals or countries.

Clinical Implications

RespiraSense measures the movement of the chest and abdomen during ventilation to derive respiratory rate. Increased compliance and shallow breathing patterns that are evident in obese individuals present technological challenges for respiratory monitoring technologies. This study has demonstrated that RespiraSense can accurately and reliably measure respiratory rates for obese patients.

The choice of the ‘right respiratory rate’ for risk stratification will therefore require further thoughts. Given that the movement centre was able to reliably identify movement it would be possible to restrict measurements to period of rest only. The duration of battery life make the unit potentially suitable for short admissions to hospital, intensive monitoring to elicit improvement or deterioration in patients in whom an admission could be averted after a short period of assessment, periods of acute deterioration on general wards or monitoring in step-down units with limited length of stay.

Implications for Research

RespiraSense measures the movement of the chest and abdomen during ventilation to derive respiratory rate. Increased compliance and shallow breathing patterns that are evident in obese individuals present technological challenges for respiratory monitoring technologies, including SPO2. Patients who are obese commonly develop hypoventilation and sleep apnoea syndromes which contribute to hypoxemia, pulmonary hypertension and a progressively worse disability. Further research should be conducted to determine if RespiraSense can be used to identify hypoventilation patterns or sleep apnoea events in obese individuals.

Ethics

RespiraSense is a CE-marked product that was being used within its intended purpose. The investigational study was performed in accordance with the ethical requirements defined in the Declaration of Helsinki and to the principles set out in the ISO 14155 international standard and with national regulations. The study was approved by the research ethics committee on the 04/04/2017 (REC reference 225890).

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