Respiratory rate measurement: a comparison of methods

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Abstract

The value of monitoring respiratory rate as a key vital sign to detect early changes in the health status of critically ill patients has been well documented. However, although pulse oximetry has been a major advance in bedside monitoring, it has not been demonstrated to be an indicator of serious illness. Arterial blood oxygen saturation appears to be poorly understood by hospital staff and lacks specificity as a monitoring tool. Therefore, the primary objective of this study was to demonstrate an equivalence between the respiR8™ respiratory rate monitor and manual counting methods, defined as a difference within ±2 breaths per minute. Secondary objectives of this study were to assess the respiR8™ performance from the end-user perspective, analysing respiR8™ alarm activations, corresponding pulse rate and SpO2 readings (sub-group), and to assess repeatability of both manual and digital readings using a Bland-Altman analysis (describe).

Key words

■ Respiratory rate ■ Measurement ■ Pulse rate

A new monitor has been developed to allow continuous monitoring of respiratory rate for patients requiring oxygen given by a face mask. The respiR8 (Anaxsys) has already been shown to reliably record respiratory rate in volunteers and has good correlation with the respiratory rate measured by both clinical counting and capnography. The value of monitoring respiratory rate, as a key vital sign to detect early changes in the health status of critically ill patients, has been well documented (Sage and Gough, 1998; Folke et al, 2003; Cretikos et al, 2008). Previous studies have demonstrated that:

- Respiratory rates above 27 breaths per minute are an important predictor of cardiac arrest
- Respiratory rate is more discriminatory between stable and unstable patients than pulse rate
- Patients with a respiratory rate of 25–29 breaths per minute had a mortality rate of 21%.

Despite the proven value of respiratory rate monitoring, a survey undertaken by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) (2005) stated that:

> **'It is clear that pulse and blood pressure and temperature were most frequently recorded and that respiratory rate was the least recorded variable. This is especially worrying, as respiratory rate has been shown to be an early and sensitive indicator of deterioration.'**

Though pulse oximetry has been a major advance in bedside monitoring, it has not been demonstrated to be an indicator of serious illness. Arterial blood oxygen saturation appears to be poorly understood by hospital staff (NCEPOD, 2005 Cretikos et al, 2008) and lacks specificity as a monitoring tool. Despite this, arterial saturation is recorded more often than respiratory rate by junior doctors and staff nurses who are not trained in pulse oximetry, lack knowledge of basic principles, and make serious errors in interpretation of readings.

Current respiratory rate monitors tend to be based on measuring impedance (ratio of the voltage phasor to the electric current phasor) across the chest, for example, electrocardiographs. However, such measurements are often inaccurate, since movement by the patient and obstruction of the respiratory tract gives erroneous results.

Furthermore, though capnography (monitoring of the concentration or partial pressure of carbon dioxide (CO_2) in the respiratory gases) also provides an assessment of respiratory rate, the equipment is often limited to intensive care units and operating theatres. Therefore, respiratory rate monitoring remains largely dependent on manual observations.

Since it is recognized that the recovery phase after surgery and anaesthesia is a time of increased health risk to patients (Hök et al 1993) continuous monitoring of respiratory rate is of value in assessing the usability of the respiR8 respiratory counter in this setting and as a surrogate for other applications. The primary objective of this study is to demonstrate equivalence between the

'manual' and 'digital' methods, defined as a difference within ±2 breaths per minute. The value of ±2 breaths was based on the results of the volunteer study.

The secondary objectives of this study were to assess the respiR8 performance from the end-user perspective to analyse respiR8 alarm activations, corresponding pulse rate and SpO_2 readings (sub-group) and to assess repeatability of both manual and digital readings using Bland-Altman analysis (Bland and Altman, 1986)

Methods

This study was an open-label, multi-centre, non-randomized medical device use study designed to compare the respiR8 counter with manual respiratory rate counts in postoperative recovery patients. Four study centres participated in the UK:

- University Hospital of North Staffordshire
- Papworth Hospital NHS foundation trust
- Russells Hall Hospital
- Ashford and St Peter's Hospital NHS Trust

Patients consented for preoperative analyses and actively entered the study post-operatively, when the oxygen mask was applied.

Materials

RespiR8 is a medical device comprising of a monitor which connects to a disposable oxygen mask, fitted with a sensor which measures moisture in exhaled breath (*Figure 1*). The respiR8 monitor displays the current respiratory rate and has a trend screen that shows respiratory rate over time.

Selection of study population

At the time of entry into the study, patients had to be over 12 years of age, admitted for elective surgery, received general anaesthesia, able to communicate effectively with the investigator and required postoperative oxygen via an adult-sized mask.

Compliance

Investigators were trained for participation in this study and in the use of the respiR8. The respiR8 mask was applied within 10 minutes of the patient being admitted to recovery and the time was recorded. Respiratory rates outside the lower and upper limits, and reasons for alarm activation were recorded. Upper and lower respiR8 alarm limits were set according to recovery ward protocols.

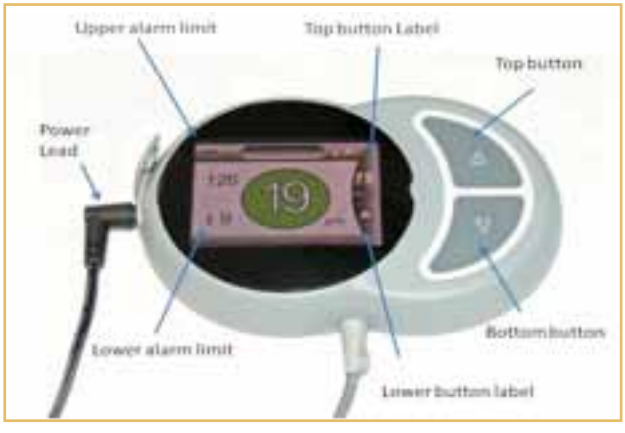

Figure 1: The respiR8 monitor

Data collection

Two health professionals (HCP1 and HCP2) conducted the study. HCP1 took respiratory rate counts by placing a hand on the patient's chest and counting chest excursions for 1 minute. This was done out of view of the respiR8 monitor. HCP2 recorded the respiR8 monitor readings simultaneously with the manual count. RespiR8 readings were recorded at 15, 30, 45 and 60 second marks. HCP2 also recorded corresponding SpO_2 and pulse rate readings for those times.The process was repeated after approximately 10 minutes, collecting a total of two data sets for each patient.

Assessment questionnaire

Participating HCPs were asked to fill in feedback forms comprising of 19 questions to assess the respiR8 counter's performance and ease of use.

Analysis of performance data

All analyses were performed using SAS version 9.2. Statistical analyses were performed using all data from subjects who had the respiR8 mask applied (Safety Set), subjects with at least one performance evaluation (Full Analysis Population) and using data from a user questionnaire. All data were analysed using standard statistics.

The primary analysis involved a comparison of respiratory rates from the respiR8 and the manual methods using the approach of Bland and Altman (Bland and Altman, 1986). Further analyses were performed to examine the degree of correlation between the manual count and respiR8 results, and between the first and second readings. In addition, association and subgroup analyses were performed to identify variables and factors to explain the variability in the difference between the respiR8 and manual methods.

Results

Of the 270 patients recruited for the study, there were 12 screen failures and 38 patients were missed in recovery. Therefore, 220 patients completed the study.

Primary endpoint: performance

A positive correlation (r=0.70; P<0.001) between the two respiR8 counter readings was found. Similarly, a positive correlation (r=0.67; P<0.001) between the two manual readings were found.

The difference between respiR8 reading 1 and manual reading 1 versus differences between respiR8 reading 2 and manual reading 2 comprised a weak correlation (r=0.27) but was statistically significant (p<0.001). Therefore, first and second readings were not combined.

In addition, there was a strong correlation (r=0.84; P<0.001) between respiR8 counter reading 1 and manual counting reading 1 (*Table 1*).

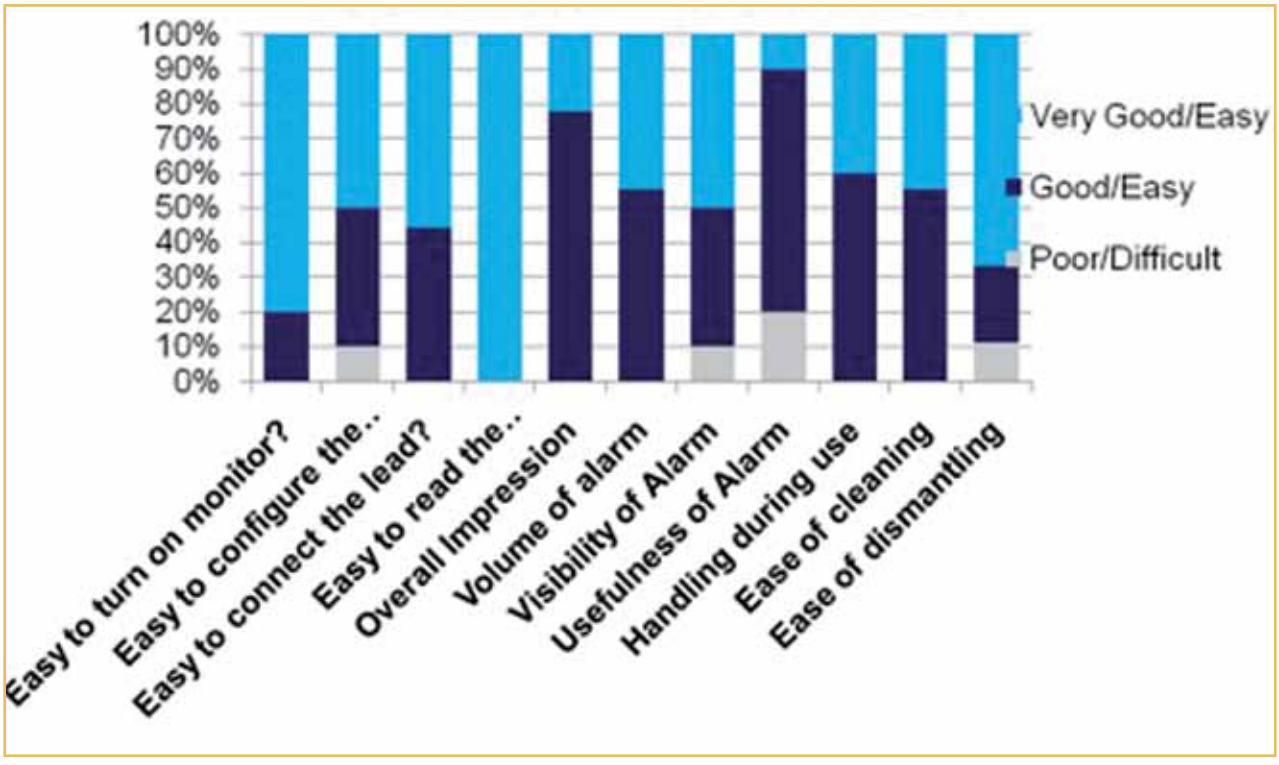

Figure 2: Graph

Primary endpoint

Counts from the first respiR8 readings were compared in a pair-wise manner with manual counts. For the first set of readings, 95% of the respiR8 data lay within +4 and -6 breaths per minute of the first set on manual count data. These results are outside the pre-defined protocol limits of agreement of 95% of reading being within ±2 breaths per minute for the two methods of counting.

On comparing the second readings by Bland-Altman analysis, the differences were less variable when compared with the first readings. For the second set of readings 95% of the respiR8 data lay within +3 and -4.5 breaths per minute of manual count data. Although less variable than the first readings, the second readings were also outside the pre-defined protocol limits of agreement of 95% of the data within ±2 breaths per minute (*Table 2*).

The difference in the mean value of the respiratory rates for the two methods was -0.86 (mean manual rate 14.32, mean respiR8 rate 13.46).

Repeatability of counting methods

The differences between the first and second pairs of readings are highly variable with 95% of the data lying between +8 and -6 breaths per minute (Bland and Altman, 1986). Further analysis to characterize the distribution of the primary endpoint (difference between the respiR8 counter and the manual count) was performed. The frequency (percentage) of differences within a range of limits, for example, within ±1 breath per minute, was produced. In total, 48% of first readings and 53% of second readings were within 1 count, and 69% of first readings and 76% of second readings were within 2 counts (*Table 3*).

Overall, 95% of patients (n=209) had respiR8 readings that were within 5 breaths per minute of the manual

Table 1. Primary measurements

Variable	N	Median	Mean (SD)	Min, max
Manual rate	220	14	14.32 (4.13)	6, 31
R8 counter rate	220	13	13.46 (4.57)	0, 31
Difference	220	-1	-0.86 (2.51)	-10, 13

Table 2. Physiological endpoints

Variable	N	Median	Mean (SD)	Min, max
Pulse	219	76	79.02(16.97)	40, 125
SpO_2	220	100	98.99(1.68)	89, 100
Stratified SpO_2 no alarm	95	99	98.78(1.82)	89, 100
Stratified SpO_2 alarm	125	100	99.15(1.56)	93, 100
Stratified pulse no alarm	94	78	80.04(17.69)	40, 116
Stratified pulse alarm	125	76	78.25(16.44)	45, 125

Table 3. Frequency of differences between limits (beats per minute)

Limits	First reading (*n* (%))	Second reading (*n* (%))
Within +/- 1 BPM	105 (48%)	116 (53%)
Within +/- 2 BPM	152 (69%)	168 (76%)
Within +/- 3 BPM	188 (85%)	198 (90%)
Within +/- 4 BPM	200 (91%)	212 (96%)
Within +/- 5 BPM	209 (95%)	214 (97%)
Within +/- 6 BPM	210 (95%)	217 (99%)

count, and in the second set of readings, 97% of patients (*n*=214) had respiR8 readings that were within 5 breaths per minute of the manual count.

Secondary endpoints

In total, 125 patients triggered the respiR8 alarm during use. There was no difference in the pulse rates or SpO_2 levels of patients who triggered the alarm and those that did not have an alarm incident recorded. The alarm population was a mixture of patients who triggered the upper and lower alarm limits.

Counts when alarm triggered

Pulse rates were higher in patients who triggered the alarm at the high limit (mean=83.7, standard deviation (SD) =19.6) and lower in those who triggered the alarm at the low limit (mean=71.7, SD=15.1), compared with patients who did not trigger the alarm (mean=79.8, SD=17.8). This difference was significant ($p < 0.001$). SpO_2 levels were more variable in patients who triggered the alarm at the high limits. There was no obvious difference between the low group (mean=99.4, SD=1.3) and those who did not trigger the alarm (mean=98.8, SD=1.8). Overall, the difference in variability between groups was also significant (*P*< 0.001).

Analysis of association between rates

Analyses of the associations between the respiR8 count rate and other covariates, body mass index (*r*=0.1576; *P*=0.02696) and pulse (*r*=0.2720; *P*≤0.0001) show these were positively and significantly correlated with respiratory rate. Thus, as body weight increases, so does respiratory rate.

In addition, SpO_2 was negatively correlated (*r*=-0.148; *P*=0.02712) with respiratory rate, indicating low SpO_2 is associated with higher breathing rates. There was also a difference in breathing rates in patients with shallow breathing compared to those who did not have shallow breathing (*P*=0.02132). There was a positive trend (*P*=0.0779) between SpO_2 levels and the difference between the respiR8 and manual measurements. Low levels of SpO_2 were related to larger negative differences between the two counting methods.

Variability

Exploratory analyses to understand the variability in the difference between the respiR8 and manual counts were performed. The frequency and percentage of differences within a range of limits, such as within ±1 breath per minute were produced. It was found that:

- 48% of first readings and 53% of second readings were within 1 count
- 69% of first readings and 76% of second readings were within 2 counts.

For these patients, respiratory rates were fairly stable over the minute counted and are referred to as the stable population. Other patients exhibited a rapidly changing breathing rate over this minute as measured by respiR8 (4 readings at 15 second intervals) with greater than 4 breaths per minute variation over the 4 readings. These patients are referred to as the unstable population.

For first and second readings, the between-patient variability is lower in the stable population compared with the full analysis population. In the first reading, the within-patient variability is substantially lower in

Table 4. Full analysis population and patients with 2BPM difference comparison

	1st reading FAP	1st reading: patients whose R8 - manual count difference is ≤ 2BPM	1st reading: patients whose R8 - manual count difference is ≥ 2BPM	2nd reading FAP	2nd reading: patients whose R8 - manual count difference is ≤ 2BPM	2nd reading: patients whose R8 - manual count difference is ≥ 2BPM
Mean ± SD	13.5 ± 4.7	13.6 ± 3.80	13.1± 5.96	13.92 ± 4.17	13.5 ± 4.08	12 ± 4.27
Median	13.3	13.3	11.8	12.3	12.5	11.6
Min, max	0.0, 31.3	5.0, 26.0	31.3, 0	3.0, 26.8	5.5, 26.8	24.8, 3.0
Within-patient variability (SD)	18.8 (4.3)	13.3 (3.6)	31.5 (5.6)	15.7 (4)	15.5 (3.9)	14.6 (3.8)
Between-patient variability (SD)	8 (2.8)	4.5 (2.1)	16 (4)	6.9 (2.6)	4.6 (2.1)	14.5 (3.8)

Table 5. Comparison of respiR8 with capnography

	Capnography and respiR8: BPM	Manual count and respiR8: BPM	Capnography and manual count: BPM
Mean difference n=600	-0.19	0.017	0.216
Standard deviation	0.415	0.700	0.750

Source: Gandevia and McKenzie (2008)

the stable population mean (13.3 (SD=3.6) versus 18.8 (SD=4.3). This suggests that the greater variability in the difference between respiR8 and manual count is due in part to an increased within-patient variability during the first readings (*Table 4*).

RespiR8 counter questionnaire

The user assessment questionnaire demonstrated that 87% of users found respiR8 useful and 93% found it easy to use. All users found the digital display easy to read and 93% thought the audible alarm was valuable (*Figure 2*).

Adverse incidents and device events

A total of 69 patients (29.7%) reported adverse incidents (AIs), which were not related to the device being investigated. Two patients (0.9%) reported hypoventilation and nausea respectively and these incidents were considered possibly related to the respiR8 mask and were recorded as adverse device events (ADEs).

Hence, AIs were reported by 71 patients (30.6%). Of these, 1 patient (0.43%) reported bronchospasm (sudden constriction of the muscles in the walls of the bronchioles) which was categorized as severe.

Seventeen patients (7.3%) categorised the adverse incident they experienced as moderate and 53 patients (22.8%) categorized the adverse event they experienced as mild. The most common AIs reported were decreased respiratory rate in 21 patients (9.1%) and pain in 21 patients (9.1%).

There was one serious AI recorded, which was tachycardia. The patient experienced a persistent peri-operative tachycardia, which continued in the recovery room and the patient was admitted to hospital for observation. The tachycardia resolved by the time of discharge and was not considered to be related to the use of the respiR8. There were no deaths or other significant AIs recorded during this study.

Discussion

The primary objective of this study was to establish equivalence between the manual and digital methods of respiratory rate counting, defined as a difference within ±2 breaths per minute. The value of ± 2 breaths per minute for 95% of readings was derived from a study in healthy volunteers, where respiR8 was compared with capnography and the manual method of counting chest excursions. In this study, 95% of the differences between respiR8 and manual method lay within ± 2 breaths per minute (*Table 5*).

The results of this clinical study fell outside the predefined protocol limits of ±2 breaths per minute and were between +4 and -6 breaths per minute for the first readings and +3 and -4.5 for the second readings. This is different from results obtained in healthy volunteers.

The study identified a group of patients whose respiratory rates were erratic over the measurement period. These patients almost certainly contributed to the greater variability seen in post-operative patients compared with the variability seen in volunteers. The clinical significance of these unexpected results warrants further investigation.

Little has been published regarding the clinical significance of variable respiratory rates or fluctuations in the breath-to-breath interval (BBI), although it has been reported that patients with tachypnoea (greater than 25 breaths per minute) are more likely to have a worse outcome (Cretikos et al, 2008).

Erratic and irregular respiratory rates, particularly if the rate is over 20 breaths per minute, are considered to be 'of concern' (García-Suárez et al, 2010). Hence, the fact that the study failed to meet its primary endpoint, due to greater than expected variability in the BBI, may in fact, be due to the greater ability of the respiR8 to detect such variability compared to manual counting. Detection of this clinical variability in respiratory rates may be clinically relevant.

Since post-operative recovery patients are still under the influence of anaesthetics and opioid analgesics that depress respiratory rate and can induce episodic apnoea, respiratory variability is greatest immediately following surgery. In this study, patients' respiratory rates stabilized progressively over time and the differences between respiratory rates obtained by manual counts and the respiR8 counter became far less variable.

Therefore, the clinical relevance of not having met the primary objective is limited. Manual counting of chest movements over a period of time (15, 30 or 60 seconds) and calculating the respiratory rate from the count, averages out any changes in the BBI and reduces the ability to detect variability. The respiR8 is able to show variable breathing patterns as it occurs.

This study investigated the use of the respiR8 in the post-operative setting but its portability and ease of use facilitate its use in other areas. In endoscopy suites, sedation is administered by non-anaesthetic staff and monitoring of the respiratory rate is usually manual (American Association of Nurse Anesthetists, 2010). In this paper, 17% of patients experienced episodes of de-saturation. The minimum monitoring requirements recommended for patients under sedation is:

'Physiologic measurements including but not limited to blood pressure, respiratory rate, oxygen saturation, cardiac rate and rhythm, and level of

consciousness should be recorded at least every five minutes.' (Maurer, Walsh and Viazis, 2010)

Other authors have identified the need for respiratory monitoring of patients under sedation (Steichen et al, 2008). It would appear that the respiR8 would have a value in endoscopy suites or other sites were sedation is administered to patients and monitoring of the respiratory rate is recommended. The use of respiratory monitoring in acute care departments has also been advocated (Maurer et al, 2010).

Conclusion

This study has shown that the respiR8 has a good safety profile, is well-tolerated, easy to use and healthcare professionals found the audio and visual alarms useful. Moreover, the respiR8 counter gave greater insight into the degree of variability in postoperative recovery patients' respiratory rates that currently goes undetected using intermittent manual counts.

The biggest differences between respiR8 and manual counting occurred in the unstable population (difference equal to or greater than 4 breaths per minute). This may mean that clinically relevant information can be obtained by continuous respiratory rate monitoring that intermittent manual counting cannot provide.

Continuous monitoring of this critical vital sign will provide healthcare professionals with better trend information on which to base clinical decisions. BJHCA

Key Points

- Little has been published regarding the clinical significance of variable respiratory rates.
- This study shows that the respiR8 monitor is easy to use and safe.
- HCAs and APs can use this knowledge to help them discuss and decide which method of respiratory rate measurement to use.
- The biggest difference to be considered between respiR8 and manual counting is with the unstable population.
- Relevant information can be obtained by continous monitoring, which manual counting cannot provide.

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