ORIGINAL ARTICLE

The PEP respiratory monitor: a validation study

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The search for a reliable and accurate respiratory rate monitor for use in non-intubated patients has proved to be a long and fruitless one. A new device fulfilling the criteria for such a monitor has recently been described. The pyroelectric polymer (PEP) device is safe, non-invasive, and cheap. In this study the PEP device, transthoracic impedance, and standard observer counting were all compared with the existing gold standard of capnography in 12 healthy adult volunteers. Using a standard statistical technique it was shown that the PEP device performed as well as a capnograph and was more accurate than the other currently available methods of monitoring respiratory rate.

Figure 1 The pyroelectric polymer that can be easily incorporated into an oxygen mask.

The respiratory rate is a component of many physiological scoring systems and guidelines in everyday use. It is fundamental in the assessment of traumatised, medically ill, or sedated patients. In particular, it is an essential component of the revised trauma score and is also used in protocols to assess the severity of acute asthma,¹ community acquired pneumonia,² and paediatric sedation.³ The respiratory rate has been shown to be a good indicator of respiratory infection at all ages^{4–6} but accurate measurement is considered an essential pre-requisite. Currently, the rate, although commonly recorded, is rarely truly measured.

Historically, measurement of the respiratory rate has been achieved by observer counting. In recent years though several rate devices have been developed. In intubated patients capnographic measurement is the standard method used. In awake patients, a number of methods exist but none have met the ideal criteria of being: safe, reliable, robust, and non-invasive. A pyroelectric polymer (PEP) transducer (fig 1) has previously been described for the measurement of respiratory rate awake patients.⁷ This device, when incorporated into a standard oxygen mask, seems to fulfil the requirements for a respiratory monitor in awake patients but there is no evidence that its performance is reliable and accurate in comparison with existing techniques. It was, therefore, decided to validate the PEP device against the gold standard of capnography together with two other methods of respiratory rate measurement in awake patients.

METHOD

The study was conducted on 12 healthy volunteers (both male and female ages 23 to 46). Four independent observers measured the respiratory rate of each volunteer simultaneously over 15 second periods using one of four methods: capnography, observational counting, the PEP device, and transthoracic impedance through standard chest electrodes. The values derived from the capnograph, PEP, and chest leads were displayed on screens remote both to other observers and the investigator who was manually counting the respiratory rate. As such, each observer was blinded to the other measurement methods and rates were measured concurrently. For the purposes of this study the capnograph sampling

tube was incorporated into a standard oxygen mask along with the PEP device. A reliable and accurate signal was achieved using this method and displayed on a laptop computer. Rates measured by transthoracic impedance and capnography were displayed using a Hewlett Packard Component Monitoring system. Interobserver error was eliminated by using the same observer on each occasion a patient was evaluated.

So that a range of respiratory rates could be measured an exercise bicycle was used to stimulate tachypnoea in the subjects. Measurements were made in three states: (1) at rest, (2) after one minute of exercise, (3) after five minutes of exercise. Rates were measured at 15 second intervals for one minute in each state. The respiratory rate was counted by the blinded observer for the full minute but was recorded at timings 15, 30, 45, and 60 seconds. The capnography, transthoracic impedance, and PEP measurements were recorded at each particular state at the timings 15, 30, 45, and 60 seconds. A total of twelve concurrent rate measurements were, therefore, obtained for each volunteer. Oxygen was delivered to each volunteer during the measurement series, the flow rate being randomised from 5–15 l/min using a standard randomisation chart.

Statistical analysis was performed using Bland and Altman's technique of assessing the agreement between different methods of measuring a physiological variable.⁸ Data analysis was performed using Minitab statistical software.

RESULTS

To assess the performance of a new method of respiratory rate measurement it is necessary to compare it with a "gold standard". For the purposes of this study capnography was deemed to represent the gold standard as it was the only measurement modality that directly monitored respiratory gas exchange. The respiratory rate measured by each of the other three methods was thus compared directly against capnography.

A correlation coefficient was calculated for each comparison and is shown in table 1.

Correlation does not imply agreement and a further stage of analysis is required to demonstrate agreement between the

Table 1 Correlation coefficients of each method compared with capnography

Measurement modality	Correlation coefficient
Transthoracic impedance	0.86
Observer counting	0.93
PEP	0.96

Table 2 Limits of agreement for each method against capnography

	Mean difference	Standard deviation	Limits of agreement (breaths per minute)
Transthoracic impedance	-0.81	2.56	-5.93 to 4.31
Observer counting	0.24	1.86	-3.49 to 3.96
PEP	0.04	1.39	-2.73 to 2.81

Figure 2 The limits of agreement between the PEP device and the capnograph. Range -2.73 to 2.81.

measurement methods used. As the true value of the respiratory rate was not known, the critical determining factor was whether that difference was clinically significant. The difference between the rates measured by the capnograph and the PEP device was plotted against the average respiratory rate measured by the two methods (fig 2). The range shown (-2.73 to 2.81) represents the levels of agreement of the two devices. The PEP device was found to be as accurate as the capnography in measuring the respiratory rate to within three breaths. The corresponding analyses for observer counting and transthoracic impedance revealed wider levels of agreement and therefore reduced accuracy when compared with the capnograph (table 2).

The performance of the PEP device was not affected by varying flow rates of oxygen through the mask. Indeed flow rates as high as 15 litres per minute had no effect on accuracy of respiratory rate measurement.

DISCUSSION

This pilot study validated the PEP as an accurate measure of the respiratory rate. It was compared with the current gold standard for respiratory rate measurement the capnograph and was found to have limits of agreement of less than three breaths.

In current clinical practice though, routine recording of the respiratory rate has frequently been noted as being error prone and inconsistent.⁵⁻⁹ As such, there have been calls for its abandonment altogether because of a high level of inaccuracy.¹⁰

Furthermore, although capnography has become established as the gold standard for the measurement of respiratory rate in intubated patients, in awake patients no method has proved to be ideal.

The reliance on observer counting has now given way to a variety of more sophisticated methods. In recent years, ECG monitors have been modified to incorporate respiratory rate measurement using changes in transthoracic impedance. This method is, however, extremely sensitive to patient movements and has a slow response time, therefore, making accurate recording impossible in any non-sedated patient.

Capnography was considered the most accurate method of measuring respiratory rate for the purposes of this study because of its extensive role in intubated patients and recent research reporting its use in awake patients.^{11,12} In these studies the capnography proved extremely reliable in the measurement of end tidal carbon dioxide.

It is widely agreed that the standard statistical method for the comparison of a new and established measurement technique is that described by Bland and Altman.⁸ Previously, comparisons were based on the product moment correlation coefficient. However, a high degree of correlation does not imply agreement between the two methods. Using the Bland and Altman technique in this comparison demonstrates that the PEP device, when compared with the capnograph, has limits of agreement of less than three breaths—a clinically insignificant amount except at very low respiratory rates. This implies that the two measurement methods may be used interchangeably. The traditional methods of observer counting and transthoracic impedance are not as accurate as the PEP device.

The PEP device incorporates a strip of pyroelectric polymer, which is self exciting responding to external temperature and pressure changes. Incorporating such a device into a standard oxygen mask exposes it to the changes of temperature associated with respiratory gas exchange without the confounding influence of patient movement. The use of pyroelectric polymers within oxygen masks was first described by Kulkarni in 1990.¹³ Since then, further development has resulted in the production of a measurement device that has proved to be robust, cheap, and non-invasive. Although in this pilot study the rate measured by the PEP was displayed on a laptop computer, it is anticipated that its incorporation into a standard Hewlett Packard display monitor via a transducer would be straightforward. By validating the accuracy and reliability of the PEP device, further clinical trials may well establish it as a standard for the measurement of the respiratory rate in both awake and sedated patients.

It is appreciated that there are limitations in the interpretation of this study. Our study group comprised of a small group of healthy adult volunteers. In addition, although we simulated clinical conditions by exercising the subjects and by randomly varying the rates of oxygen flow, these attempts were entirely artificial and cannot accurately reproduce true physiological states. In particular, it is recognised that our volunteers' tidal volume would have been increased by exercise whereas ill patients generally have a significantly reduced tidal volume. Notwithstanding this, exercise is the best physiological non-pathological way of increasing the respiratory rate for testing purposes. Finally, the respiratory rates achieved in the study did not extend beyond the range of 8 to 28 and therefore further work would need to be undertaken to ensure the accuracy of the PEP device beyond this range. It is also unclear as to the performance of the PEP device in children, the sick, and the elderly population where low tidal volumes may affect the accuracy of the device. Further clinical trials are presently underway to investigate these issues.

Despite these limitations the results of this study suggest that the PEP device fulfils the role of an ideal respiratory rate monitor for awake and sedated patients as it is cheap and non-invasive. However, expanded clinical trials should thus be

conducted to develop the monitor further, particularly with the patients encountered in emergency medicine. Such trials would confirm its applicability and quantify its accuracy and validity in the compromised patients who present to emergency departments.

Contributors

DD and CM initiated the research and adapted the pyro-electric polymer as a device for counting the respiratory rate. CB and JW initiated the study, formulated the protocol, collected the data, and analysed them. In addition CB and JW wrote the research paper. The contents of this were discussed with and revised by CM who is the guarantor for the paper.

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