Validation of a Transcutaneous CO₂ Monitor in Adult Patients with Chronic Respiratory Failure

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Key Words

Chronic respiratory failure · Home mechanical ventilation · Transcutaneous carbon dioxide

Abstract

Background: Home mechanical ventilation is usually started in hospital as arterial blood gas sampling is deemed necessary to monitor CO₂ and O₂ adequately during institution of ventilatory support. A non-invasive device to reliably measure CO₂ transcutaneously would alleviate the need for high care settings for measurement and open the possibility for home registration. **Objectives:** In this study we investigated whether the TOSCA[®] transcutaneous CO₂ (PtcCO₂) measurements, performed continuously during the night, reliably reflect arterial CO₂ (PaCO₂) measurements in adults with chronic respiratory failure. **Methods:** Paired measurements were taken in 15 patients hospitalised to evaluate their blood gas exchange. Outcomes were compared 30 min, 2, 4, 6 and 8 h after attaching the sensor to the earlobe. A maximum difference of 1.0 kPa and 95% limits of agreement (LOA) of 1 kPa between CO₂ pressure measurements, following the analysis by Bland and Altman, were determined as acceptable. **Results:** Mean PtcCO₂ was 0.4 kPa higher (LOA –0.48 to 1.27 kPa) than mean PaCO₂ after 30 min. These figures were 0.6 kPa higher (LOA –0.60 to 1.80 kPa) after 4 h, with a maximum

of 0.72 kPa (LOA 0.35 to 1.79 kPa) after 8 h. The corresponding values for changes in PtcCO₂ versus PaCO₂ were not significant (ANOVA). **Conclusions:** PtcCO₂ measurement, using TOSCA, is a valid method showing an acceptable agreement with PaCO₂ during 8 h of continuous measurement. Therefore, this device can be used to monitor CO₂ adequately during chronic ventilatory support.

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Introduction

Home mechanical ventilation (HMV) is an effective therapy which improves survival in patients with chronic respiratory failure due to neuromuscular disease and chest wall deformation [1, 2]. Recent guidelines describe when to start with HMV [3]. In general, a combination of symptoms such as fatigue, headache, dyspnoea and respiratory failure (arterial CO₂, PaCO₂, >6.0 kPa) suggests that ventilatory support is indicated. Usually HMV is started clinically as arterial blood gas sampling is necessary to confirm the diagnosis and monitor CO₂ and O₂ adequately during initiation of ventilatory support. Arterial cannulation is, however, an invasive and painful procedure with occasional complications including infection, vascular damage and thrombosis [4]. Especially

in this group of patients, severe deformities sometimes make the procedure technically challenging. In many hospitals patients have to be admitted to the intensive care unit (ICU) for logistical reasons, leading to higher costs and occupation of a scarce facility. Home monitoring in patients with non-invasive ventilation or long-term oxygen therapy is therefore an interesting alternative as was shown recently [5, 6]. The possibility to non-invasively and reliably monitor carbon dioxide in combination with oxygen saturation would lead to an enormous improvement of patient care and probably reduction of costs. In recent years, transcutaneous measurement of CO₂ has become available and several different devices have been tested. While Storre et al. [7] used the SenTec digital monitor, Janssens et al. [8] showed that transcutaneous carbon dioxide (PtcCO₂) can be measured with the Radiometer TCM-3 capnograph during 8 h and a sensor temperature of 43°C without recalibration. The TOSCA® monitor was used in both the acute setting of non-invasive ventilation for exacerbations of COPD [9] and during cardiopulmonary exercise testing [10]. Transcutaneous monitors have been evaluated in many settings like anaesthetised children [11], critically ill adults [12], during major surgery [13], in newborns [14] and in sleep studies [15]. However, until now no study has investigated whether the TOSCA PtcCO₂ monitor is a valid tool to monitor carbon dioxide gas exchange continuously without replacing the sensor during 8 h. In this study we investigated whether PtcCO₂ measurements, using the TOSCA PtcCO₂ monitor continuously during the night, adequately reflect arterial blood gas assessments in adults with chronic respiratory failure.

Methods

The TOSCA PtcCO₂ monitor is a device which non-invasively assesses CO₂ levels in combination with standard pulse oximetry. The Institutional Review Board of our university approved this study. Informed consent was obtained from all participants prior to study inclusion. The PtcCO₂ monitor is attached to the patient's earlobe via a sensor and disposable clip. It warms the lobe to 42°C allowing arterialisatation of capillary blood and measures CO₂ using a Stow-Severinghaus-type electrode [16]. PtcCO₂ is measured by determining the pH of an electrolyte solution that is situated between the sensor and a Teflon membrane.

Validation of the TOSCA PtcCO₂ monitor was assessed by comparing PtcCO₂ by TOSCA with PaCO₂ in 15 consecutive patients. All patients were either using chronic ventilatory support or were expected to commence it in the near future. All patients were admitted to the ICU for invasive blood gas monitoring to evaluate their nocturnal gas exchange. Heparinised arterial blood gas samples were drawn from an arterial line every 2 h and anal-

ysed on the blood gas analyser ABL715 (Radiometer Medical ApS, Brønshøj, Denmark). Paired samples were taken from the radial artery and compared with transcutaneous monitor readings every 2 h. Thirty minutes after the sensor was attached, the first PtcCO₂ was determined, while at the same time the first arterial sample was taken. Subsequent paired measurements were taken at 2, 4, 6 and 8 h. Although the TOSCA device presents continuous readings, only the paired samples with the same interval as the arterial blood gas samples were used for the analysis.

Statistical Analysis

The method of Bland and Altman [17] was used to assess agreement between the arterial blood gas and transcutaneous variables. A maximum bias of 1.0 kPa (7.5 mm Hg) and 95% limits of agreement (LOA) of 1.0 kPa (7.5 mm Hg) between transcutaneous and arterial carbon dioxide pressure measurements were determined as acceptable. A maximum bias of <2 and 95% LOA of 4% were determined as clinically acceptable between arterial oxygen and transcutaneous saturation. To determine whether transcutaneous measurements differ significantly from the arterial values at the same time point we performed a Student's paired *t* test [10]. Analysis of variance for repeated measurements was used to determine changes from one time point to the next. Data analysis was performed with SPSS version 15 (SPSS Inc., Chicago, Ill., USA) and MedCalc for Windows, version 9.5.0.0 (MedCalc Software, Mariakerke, Belgium).

Results

Eight women and seven men with a mean (SD) age of 58 years [13] were enrolled in the study. The diagnosis was neuromuscular disease in 7 patients, chronic obstructive pulmonary disease in 5 patients and obstructive/central sleep apnoea syndrome in 3 patients. Thirteen patients received chronic ventilatory support and 2 were breathing spontaneously. A total of 75 paired measurements were taken 30 min, 2, 4, 6 and 8 h after attaching the sensor to the earlobe. Correlations are 0.96 after 30 min, 0.90 after 4 h and 0.91 after 8 h. To assess the measurement characteristics of the device, we calculated the bias and LOA as described by Bland and Altman (fig. 1). The mean PtcCO₂ was 0.4 kPa (3 mm Hg) higher than the mean PaCO₂ after 30 min. This difference increased slightly during the night to a maximum of 0.72 kPa (5.4 mm Hg) after 8 h. The LOA (bias $\pm$ 1.96 SD) ranged from -0.48 to 1.27 kPa (3.6 to 9.5 mm Hg) after 30 min, from -0.60 to 1.80 kPa (4.5 to 13.5 mm Hg) after 4 h and from -0.35 to 1.79 kPa (2.6 to 13.4 mm Hg) after 8 h. At all time points the paired difference was highly correlated (*p* < 0.004) with PaCO₂. The paired measurements, tested in 15 patients over 8 h, have mean values for PtcCO₂ - PaCO₂ after 30 min of 0.39 ± 0.44 kPa (2.9 ± 3.3 mm Hg), after 4 h of 0.59 ± 0.61 kPa (4.4 ± 0.61 mm Hg) and after 8 h

of 0.72 ± 0.54 kPa (5.4 ± 4.0 mm Hg) (repeated measures ANOVA, $p = 0.253$; fig. 2). The observed range of changes in PaCO_2 during repeated measurements was -0.7 kPa (5.25 mm Hg) to 1.3 kPa (9.75 mm Hg) and agreement among the changes in PtcCO_2 and PaCO_2 was close at 0.2 kPa (1.2 mm Hg) [LOA (bias ± 1.96 SD), 1.4 kPa (-10.5 mm Hg) and 1.85 kPa (13.7 mm Hg)], the difference was not significant.

The mean PaO_2 at baseline was 9.4 kPa (70.5 mm Hg), after 4 h 9.9 kPa (74.3 mm Hg) and after 8 h 10.0 kPa (75 mm Hg). Figure 3 shows the agreement between the arterial and transcutaneous oxygen saturation. Arterial oxygen saturation was between 74 and 99% , while the transcutaneous oxygen saturation was between 76 and 99% . There was only a mean difference (bias) of maximal 0.2% at all time points.

The attachment of the sensor to the earlobe was good, none of the patients showed skin problems due to the sensor or the resulting temperature of 42°C .

Discussion

This study shows that PtcCO_2 measurement by the TOSCA has a clinically acceptable agreement with PaCO_2 during 8 h of unsupervised continuous measurement. Earlier studies have also assessed the TOSCA system in different settings, but none have done this in a non-supervised continual measurement, while asleep, as in our study [3, 7–15, 18]. All referred studies performed mea-

Fig. 1. Mean (x-axis) versus difference (y-axis) of transcutaneous and arterial carbon dioxide tension according to Bland and Altman [17] in 15 subjects, 30 min (a), 4 h (b) and 8 h (c) after attaching the sensor to the earlobe.

Fig. 2. Mean values of $\text{PtcCO}_2 - \text{PaCO}_2$ and SD, in 15 patients. Drift in PtcCO_2 over 8 h is not significant (ANOVA).

measurements with a reported mean difference (bias) between PaCO_2 and PtcCO_2 ranging from 0.4 to 1.0 kPa (3 to 7.5 mm Hg). The observed range of changes in PaCO_2 during repeated measurements in our study was -0.7 kPa (5.25 mm Hg) to 1.3 kPa (9.75 mm Hg) and agreement among the changes in PtcCO_2 and PaCO_2 was close at 0.2 kPa (1.2 mm Hg). The difference in CO_2 measurements between transcutaneous and arterial values are small and are not likely to influence the decisions in adjusting the ventilator settings. Measuring the SpO_2 with the TOSCA sensor revealed a clinically acceptable bias between SaO_2 and SpO_2 of 0.2% difference at all time points. We believe that measuring gas exchange continuously in patients with chronic ventilatory support provides more information about the changes over night than single arterial measurements during admission on the ICU [19]. Nevertheless, the transcutaneous assessment has some limitations: it lacks information on bicarbonate, pH and arterial oxygen, it is expensive, it needs disposable items for measurements and, finally, it is rather fragile. However, the advantage of not being admitted to the ICU provides a more realistic view of the clinical condition over night. This study suggests that measurement in a high care setting, such as an ICU, might no longer be necessary in many patients, thus saving costs. Currently, we are testing the TOSCA monitor for registration at home during the initiation phase of HMV, thereby alleviating even more the need for hospitalisation and reducing costs. All personnel, whether inside or outside the hospital, require training before working with the TOSCA transcutaneous monitor.

In summary, we showed that the TOSCA transcutaneous monitor can be used to replace the arterial sampling with clinically acceptable accuracy in adults with chronic respiratory failure using ventilatory support. Measuring oxygen saturation and carbon dioxide continuously provides more information about changes during the night than single arterial measurements. The sensor was well tolerated in patients during the 8-hour observation period and was not associated with a significant drift of the PtcCO_2 signal.

Fig. 3. Bias and LOA of arterial and transcutaneous oxygen saturation according to Bland and Altman [17] in 15 subjects, 30 min (a), 4 h (b) and 8 h (c) after attaching the sensor to the earlobe.

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