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In vitro assessment of an ultrasonic flowmeter for use in ventilated infants

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In vitro *assessment of an ultrasonic flowmeter for use in ventilated infants. P. Scalfaro, J. Cotting, P.D. Sly. ©ERS Journals Ltd 2000.*

ABSTRACT: An ultrasonic flowmeter could be advantageous over a differential pressure pneumotachograph having a constant error in varying conditions. The *in vitro* accuracy of ultrasonic tidal volume (V_T) estimates for ventilated infants were evaluated.

Flow linearity and frequency response were tested, as was the influence of humidity and oxygen content on the accuracy of V_T estimates.

The linearity was within the 5% limits between -350 and 350 mL·sec^{-1} and was not affected by the presence of an endotracheal tube (ET). The frequency response was flat and unaffected by an ET up to 4.5 Hz. The V_T in the range 7–100 mL, in air showed a mean error of 0.1% (95% confidence interval (CI) -0.2–0.4%) with a maximum and minimum of 6.5 and -3.5% respectively. Humidity did not affect accuracy. After calibration in air, the maximal mean error for measurements in pure oxygen was 3.0% (95% CI 1.9–4.1%). Repeated measurements over 5.5 h had a mean error of 0.4% (95% CI -0.7–0.1%).

The *in vitro* evaluation of an ultrasonic flowmeter showed stable accuracy in mechanical ventilation conditions. Changing connection geometry and oxygen content did not increase the error to a clinically relevant degree. The flowmeter could therefore be a better alternative than the pneumotachograph for ventilated infants. *Eur Respir J 2000; 15: 566–569.*

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A number of types of flowmeter are available to measure airflow (V'). Optimal requirements for their use in infants include a small dead space (1–1.5 mL·kg^{-1}), a dynamic V' range of ± 200 mL·s^{-1}, allowing measurements of tidal volumes (V_T) of 6–10 mL·kg^{-1} with a maximal error of ±3%, and a flat frequency response up to 10 Hz [1]. Although the commonly used differential pressure pneumotachographs (PNTs) satisfy these requirements, they often need to be recalibrated or corrected when measurement conditions change, such as with increasing inspiratory oxygen fraction (F_{I,O_2}) [2], or when used with differently sized infant endotracheal tubes (ET) [3]. Considering the particular conditions in intensive care, the aim of this study was to evaluate a new ultrasonic flowmeter (UFM; Spiroson, Isler Biomedical Engineering, Dürnten, Switzerland).

Ultrasonic estimates are based on the principle that sound travelling through a medium is accelerated or slowed down by the movement of the medium itself. They are classified according to whether the operation is in the time or frequency domain, and whether the ultrasounds are continuous or pulsed [4]. A potential advantage of this type of flowmeter is an error range that does not change with different air/oxygen mixtures or with changing connection geometry. Reliable calibration during prolonged use would be a further valuable feature in intensive care. This study aimed to evaluate the *in vitro* accuracy of ultrasonic estimates of V_T under the conditions encountered during conventional mechanical ventilation of neonates and infants.

Methods

Ultrasonic flowmeter

The UFM was a miniaturized prototype of a device previously evaluated in adult humans and animals [5, 6]. The dead space with ventilator connectors was ~1 mL and the weight 75 g. V' was estimated by measuring the transit times of 80-kHz ultrasonic pulse trains (71–73 µs in air) over a given distance. V' decreased the transit time in an upstream (t_u) and increased the transit time in a downstream (t_d) direction. V' was calculated according to:

$$\left.\begin{aligned} t_u &= \frac{L}{c+u\cos\phi} \\ t_d &= \frac{L}{c+u\cos\phi} \end{aligned}\right\} \; u = \frac{L}{2\cos\phi} \times \frac{t_u - t_d}{t_u - t_d} \qquad (1)$$

$$V' = \pi^2 u, \qquad (2)$$

where c is the speed of sound, L is the length of the sound path, u is the mean V' on the sound transmission path, Φ is the angle between the flow channel and the sound path and πr^2 the channel cross sectional area. Given that c changes for different gases, solving the equations for u in Equation 1 minimizes the c-dependence since t_u-t_d reflects only V' [4]. Sound wave transmission with zero V' was calibrated automatically when turning on the control unit and not adjustable. The personal computer software (Wbreath version 1.24; Isler Biomedical Engineering) with a sampling frequency of 200 Hz allowed data

storage, offset, and inspiratory and expiratory gain adjustment. Real time V' was computed according to Equations 1 and 2. Inspiratory and expiratory V_T were integrated after data collection.

Resistance, linearity and frequency response

Inspiratory and expiratory resistance (R) were measured across the UFM using a PNT (Series 3500; Hans Rudolph, Inc., Kansas City, KS, USA; linear range±35 L·min^{-1}) and two pressure transducers (Scireq, Inc., Montreal, Canada). The signals were fitted to $\Delta P=K_1V'+K_2V'^2$ ($r^2>0.99$), where ΔP is the pressure drop across the UFM, K_1 and K_2 are constants, V' the flow measured with the PNT and r^2 the coefficient of determination using Anadat software (RHT InfoDat, Montreal, Canada). R were calculated using K_1 and K_2 according to $R=K_1+K_2V'$. A steady V' (±500 mL·s^{-1}) of dry medical air (air conditioned with 21% oxygen for use in human patients) adjusted using a calibration rotameter (±5%; Fischer & Porter, Cumbria, CA, USA) was blown in the inspiratory or expiratory direction through the UFM connected with or without an ET (inside diameter 2.5 and 4.5 mm, SIMS Portex, Hythe, UK). Ten-second data epochs were collected. The frequency response was evaluated [7] using a closed loudspeaker which generated a complex 20–200-mL·s^{-1} V' with a frequency content of 1–10.5 Hz through the UFM. The pressure inside the loudspeaker was recorded using a piezoresistive transducer (Endevco, San Juan Capistrano, CA, USA; flat response up to 256 kHz). After Fourrier transformation, the magnitude and phase lag for each frequency component were normalized relative to the main frequency (2 Hz) and a Bode plot was constructed.

Evaluation under mechanical ventilation conditions

A 1-L plastic lung, filled with copper wire, was connected to a Bournes BP 200 infant ventilator (Bear Medical Systems, Riverside, CA, USA) which allowed air conditioning (continuous positive airway pressure (CPAP), humidity and F_{I,O_2}). F_{I,O_2} was monitored using a TED 16 (Teledyne Electronic Devices, Arlington, VA, USA; ±2% accuracy). V_T were applied manually using a syringe (Hans Rudolph, Inc.; 20–100 mL) or a small polyvinyl chloride syringe (7 and 12 mL). Measurements (n=135) were performed in air at different frequencies (0.5–2.0 Hz) and pressures (CPAP 0–20 cmH_2O). Ultrasonic V_T estimates were related to syringe V_T according to BLAND and ALTMAN [8]. Error (percentage), using frequency and pressure as the independent variables, was analysed graphically using interquartile boxplots. Multiple linear regression analysis was used to test for a linear relationship.

Effect of inspiratory oxygen fraction, humidity and prolonged use

After room air calibration the UFM was compared with the PNT for 20- and 40-mL syringe V_T with increasing F_{I,O_2}. Studying V_T variability (two-way analysis of variance) of ventilator breaths tested the effect of increasing humidity (0–90%). The nominal settings were: peak inspiratory pressure 30 cmH_2O, positive end-expiratory pressure 4 cmH_2O, ventilation frequency 60 breaths·min^{-1}, inspiratory:expiratory ratio 1, V' 10 L·min^{-1}, F_{I,O_2} 0.4 or 0.9. Temperature and humidity were measured using a hygrometer (Testo 615; Testo, Lenzkirch, Germany). In repeated measurements over 5.5 h (n=45), the ultrasonic V_T errors for syringe volumes of 20 and 40 mL were evaluated.

Analysis

Statistical analysis was performed using Minitab (Minitab Inc., State College, PA, USA). Errors were calculated using the means of five to 10 ultrasonic V_T measurements according to: $(V_T-V_S)/V_T$, where V_S was the syringe volume, and expressed as a percentage. Mean errors (and 95% confidence intervals (CIs)) were compared using nonparametric tests (significance level $p\leq0.05$). The integration of ultrasonic V' with Wbreath software was compared using Anadat integration.

Results

Resistance, linearity and frequency response

Mean±SD inspiratory and expiratory R were 1.07±0.01 and 1.10±0.02 kPa·L^{-1}·s at V' 100 mL·s^{-1}. At V' of 200 mL·s^{-1} R were 1.21±0.01 and 1.28±0.03 kPa·L^{-1}·s respectively. The steady V' accuracy was within ±5% for a V' of ±350 mL·s^{-1} and not affected by the ET. From ±350–500 mL·s^{-1}, although within ±5%, there was a decreased

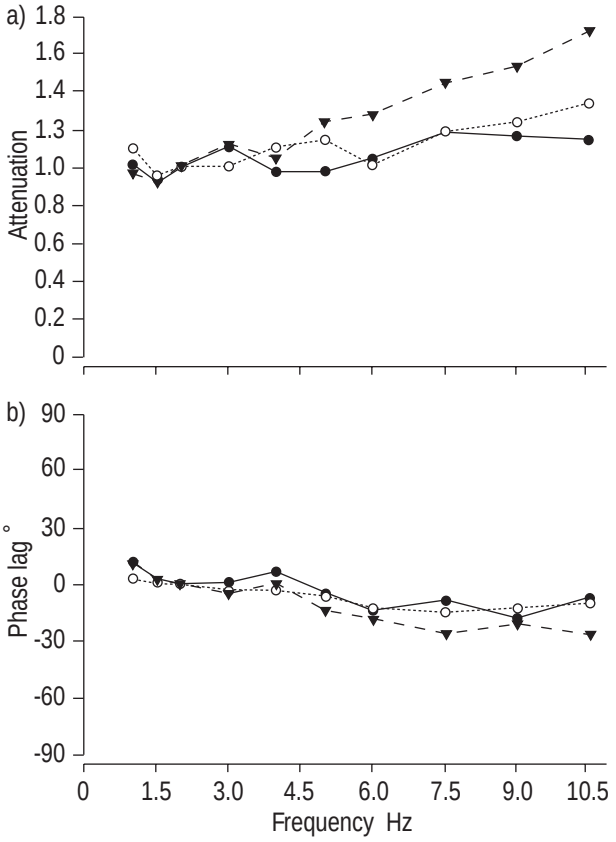

Fig. 1. – Bode plot of the frequency response of the infant ultrasonic flowmeter prototype: a) ultrasonic flow estimate attenuation; b) ultrasonic flow estimate phase lag. (●: without an endotracheal tube (ET); ■: with a 2.5-mm ET; ▼: with a 4.5-mm ET. A loudspeaker generated an airflow with a frequency of 1–10.5 Hz. Ultrasonic measurements are compared against a piezoresistive pressure transducer. Each flow component is expressed relative to the signal's main frequency (2 Hz).

signal-to-noise ratio, as manifested by a larger SD. The frequency response is shown in figure 1. The response was flat up to 4.5 Hz and not influenced by an ET. At 5–10 Hz, a distortion, which was accentuated with a bigger ET, was apparent both for attenuation and phase lag.

Effect of tidal volume, ventilation frequency and pressure

Peak V' ranged 35–550 mL·s^{-1} at a V_T of 7–100 mL. The agreement between ultrasonic V_T estimates and syringe volumes is shown in figure 2. The mean difference (V_T - syringe volume) was 0.1 mL (95% CI -1.4–1.6 mL). There was no increase or change in distribution with r^2=0.01 either increasing frequency or pressure (p=0.30 and p=0.54, respectively).

Effect of inspiratory oxygen fraction, humidity and prolonged use

Figure 3 shows the errors with increasing F_{I,O_2} for the UFM and PNT, both calibrated in air. The range was -1.9–3.5% for the UFM and -0.9–12.6% for the PNT. The mean ultrasonic V_T estimate with increasing humidity was 33.3±1.0 mL. Ultrasonic V_T estimate variability was not increased by humidity (p=0.26): V_T was 32.6±0.5 mL at a mean humidity of 10%, 33.7±0.5 mL at 60% and 33.9±1.4 mL at 90%. V_T was significant lower with a higher F_{I,O_2}: 32.6±0.4 mL at an F_{I,O_2} of 0.9 *versus* 33.9±1.0 mL at an F_{I,O_2} of 0.4 (p=0.01).

Ultrasonic V_T estimates were stable over 5.5 h. The mean error was -0.3% (95% CI -0.7%–0.1%). The mean error of inspiratory V_T was 4.1% (95% CI 2.9–5.3%), the maximum 14.9% and the minimum -2.3%. The mean error of expiratory V_T was -4.7% (95% CI -6.4–-3.0%) the maximum 1.8% and the minimum -20.7%. When the inspiratory/expiratory gains and baseline were corrected prior to measurement, the mean V_T error was 0.1% (95% CI -0.2–0.4%) with a range of -3.5–6.6%. The mean error of inspiratory V_T was 0.8% (95% CI 0.3–1.3%) with a range of 10.3–-8.5%. The mean error of expiratory V_T was -0.5% (95% CI -0.2–-0.8%) with a range of 8.0–-7.0%. When the ultrasonic V' was integrated using Anadat, the mean V_T estimates had an error of 0.8% (95% CI 0.6–1%) with a range of -2.4–4.1%.

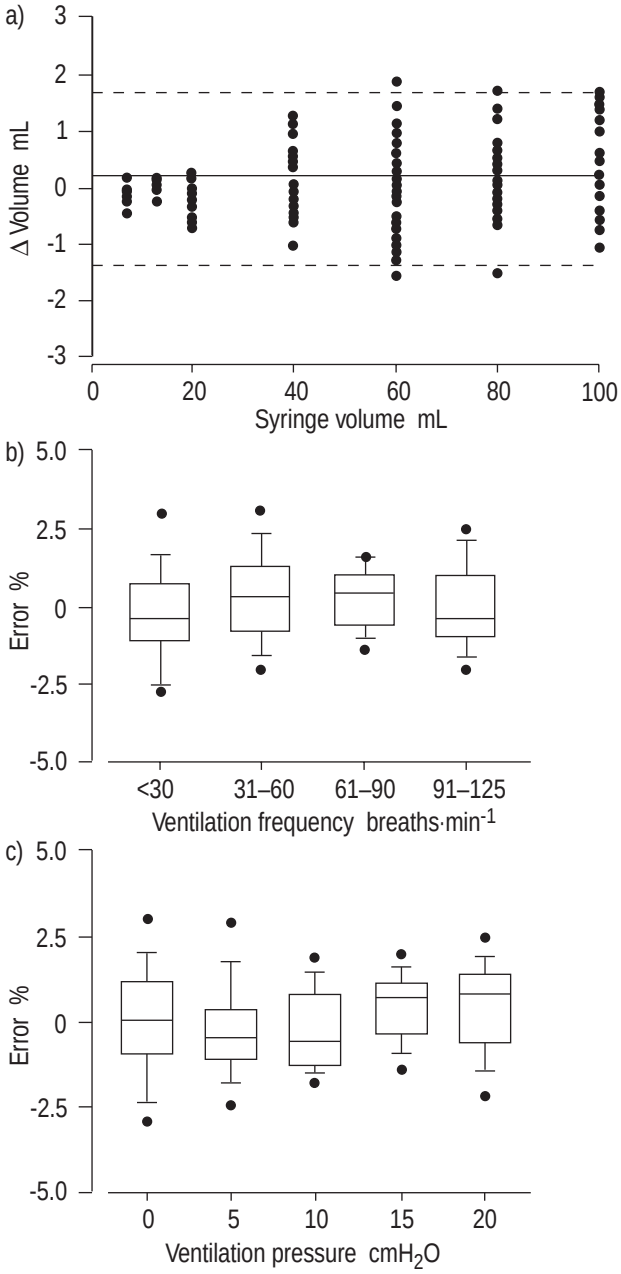

Fig. 2. – Ultrasonic tidal volume (V_T) estimate errors with increasing volume, frequencies and pressure. a) Bland-Altman plot of the difference between ultrasonic V_T estimates and syringe volume (volume; ——) *versus* syringe volume. The mean volume was 0.1 mL. (.... : 95% confidence interval (CI) (-1.4–1.6 mL)). b) Boxplot of ultrasonic V_T estimate errors against ventilation frequency. c) Boxplot of ultrasonic V_T estimate errors against ventilation pressure. The Boxplots show means and interquartile ranges; vertical bars represent 95% CIs (●: outlier).

Discussion

It has recently been stressed that as bedside monitoring systems become available their accuracy should be evaluated under the conditions in which they are to be used [3]. Measurement conditions may particularly affect the accuracy of flowmeters used for ventilated infants [9]. In the present study, the UFM had a V_T error of ±3% in the range 7–100 mL under differing conditions. Steady V' was within ±5% and not affected by the presence of an ET. During mechanical ventilation, changes in ventilation frequency, pressure, humidity or F_{I,O_2} did not alter the error. Although a statistically significant increase in the error was observed with increasing F_{I,O_2}, it was still within ±3% and therefore without clinical relevance. These performance characteristics are encouraging. The autocalibration of the UFM is potentially a useful feature for persons not familiar with accurate PNT calibration.

A major drawback with the UFM was the considerable difference between inspiratory and expiratory V_T estimates. To overcome this problem, the manufacturer recommends modifying the inspiratory and expiratory gains. However, in the present study, this procedure did not decrease the differences. One possible explanation for this finding is a

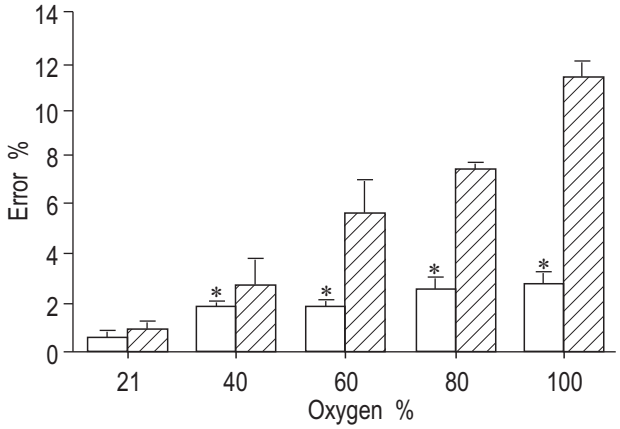

Fig. 3. – Tidal volume estimate errors measured using an ultrasonic flowmeter (□) and a differential pressure pneumotachograph (▨) in different air/oxygen mixtures. Both flowmeters were calibrated with room air. Errors (mean±SD) were calculated against delivered syringe volumes. *: $p<0.05$ *versus* pneumotachograph.

small leak in the flow head, as inspiratory V_T was overestimated and expiratory V_T underestimated. Alternatively, the algorithm the software Wbreath, supplied with the device, used to correct baseline drift may have been inaccurate. It was not possible to evaluate this possibility as the authors did not have access to the algorithm. The mean V_T estimates were accurate when the V' signal was exported and integrated using different software. Finally, the difference between inspiratory and expiratory V_T estimates might be due to a poor signal-to-noise ratio. As originally stated, tu and t_d should theoretically be equal when V' is zero [6]. However this is physically unrealizable as it is impossible to build a perfectly precise and symmetrical device. A poor signal-to-noise ratio would result in less precision in determining when flow was zero, an important part of accurately separating the inspiratory and expiratory phases of respiration. This problem could also affect the frequency response. The V' components at >4.5 Hz were considerably smaller than at lower frequencies and might therefore have been detected less accurately. This is illustrated by the observation that V' at >4.5 Hz was smallest when using a 4.5-mm ET, the situation in which the worst frequency response was seen. However V_T estimates in conditions encountered in ventilated infants were not affected in a relevant way by this deterioration in frequency response.

The small dead space of the prototype is appropriate for premature neonates of >1 kg. However, the relatively high resistance may cause a problem, leading to an increased respiratory work if used with spontaneously breathing older infants. Further study and proper *in vivo* assessment is necessary to evaluate the device for use with spontaneously breathing subjects.

In summary, this ultrasonic flowmeter had an adequate *in vitro* accuracy for infant tidal volume estimates without compulsory recalibration under differing measurement conditions. The integration of the flow signal for separate inspiratory and expiratory tidal volume estimates using the software supplied (Wbreath) did however increase the error considerably.

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