Both the OxyArm™ and Capnoxygen mask provide clinically useful capnographic monitoring capability in volunteers

[L'OxyArm et le masque Capnoxygen permettent une surveillance capnographique chez des volontaires]

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Purpose: To compare the capnography monitoring performance of the new OxyArm™ (OA) with the Capnoxygen mask (CM), a conventional oxygen mask with a carbon dioxide sampling port.

Methods: Eleven healthy volunteer adult subjects underwent capnographic monitoring (in a non-randomized, un-blinded crossover study) at baseline and while receiving oxygen at seven different flow rates (0.5, 1.0, 2.0, 4.0, 6.0, 8.0, and 10 L·min⁻¹), applied first with the CM and then with the OA.

Results: Both the OA and CM produced acceptable capnographs with consistent waveforms. The measured end-tidal (ET) CO₂ was equivalent for the two devices at all seven oxygen flow rates. On average, the ET CO₂ measured with the OA was about 2 mmHg greater than that of the CM. Regression analysis showed an inverse relationship between oxygen therapy flow rate and measured ET CO₂ whereby the measured value of CO₂ decreased as the oxygen flow rate was increased ($P < 0.001$). Both the CM and OA produced consistent measurements of ET CO₂ as illustrated by their reliability coefficients, 0.95 and 0.86 respectively. The biggest source of variation in measured CO₂ for both devices was inter-subject differences, followed by variable oxygen flow rates.

Conclusions: This study suggests that the OA and CM can prove useful for respiratory monitoring and oxygen delivery in spontaneously breathing volunteers, and the OA could potentially be used as an alternative to the conventional methods of oxygen delivery and CO₂ sampling in patients.

Objectif: Comparer les capacités de surveillance capnographique du nouveau OxyArm (OA) à celles du masque Capnoxygen (MC), un masque à oxygène traditionnel comportant un port de prélèvement du gaz carbonique.

Méthode : Onze volontaires adultes en bonne santé ont été placés sous surveillance capnographique pendant une étude croisée, sans aveugle et non randomisée. Des mesures de base ont été prises, puis répétées pendant l'oxygénothérapie selon sept différents débits (0,5, 1,0, 2,0, 4,0, 6,0, 8,0 et 10 L·min⁻¹) administrée d'abord avec le MC, puis avec l'OA.

Résultats : Autant l'OA que le MC ont produit des capnographes acceptables et de forme cohérente. La valeur du CO₂ télé-expiratoire (ET "end-tidal") a été la même avec les deux appareils, pour les sept débits d'oxygène différents. En moyenne, les mesures du ET CO₂ de l'OA ont été plus élevées que celles du MC, de 2 mmHg environ. L'analyse de régression a montré une relation inverse entre le débit de l'oxygénothérapie et le ET CO₂ mesuré. La valeur du CO₂ a diminué à mesure que le débit d'oxygène a augmenté ($P < 0,001$). Le MC et l'OA ont tous deux produit des mesures cohérentes de ET CO₂ comme l'indiquent leurs coefficients de fiabilité, 0,95 et 0,86 respectivement. La plus importante source de variation des mesures de CO₂ a été, pour les deux appareils, les différences entre les sujets de l'étude, puis les différents débits d'oxygène.

Conclusion : L'étude montre que l'OA et le MC peuvent servir à la surveillance respiratoire et à l'oxygénothérapie chez des volontaires respirant spontanément. L'OA pourrait sans doute remplacer l'oxygénothérapie et le prélèvement de CO₂ traditionnels.

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THE measurement of end-tidal CO_2 (ETCO_2) in expired gases is one of the standard monitors used in the operating room for patients under general anesthesia.¹ In this setting ETCO_2 is useful as a confirmation of endotracheal intubation, an estimate of PaCO_2 for guiding ventilator settings, and as a monitor for malignant hyperthermia, bronchospasm and venous air embolism.² ETCO_2 monitoring also has practical applications in spontaneously breathing, non-intubated, patients. It can be used to detect airway obstruction or apnea, and also to identify the rate and pattern of respiration.³ For this purpose, divided nasal cannulae, specialized facemasks, and several make shift devices that utilize various combinations of angio-catheters and facemasks have been developed.³⁻⁵

The OxyArm™ (OA; Southmedic Inc., Barrie, Ontario, Canada) is a new minimal contact oxygen delivery device that was modeled after the headsets used for hands-free telecommunication devices. There are currently two versions of the device available, one for oxygen therapy alone and another that can be used for both oxygen therapy and capnographic measurement. The device consists of a headset that traverses across the top of the head, O_2 supply and CO_2 sampling (in the capnographic version) lines attached to an adjustable boom, and a diffuser consisting of a pin shaped like a mushroom with a hole in the centre in the original version and with a pin shaped like a funnel (or inverted cone) in the capnographic version.⁶ It was necessary to create a new diffuser in the capnographic version to prevent the delivered oxygen plume and surrounding ambient gases from contaminating the gas sampled at the CO_2 sampling port. The OA received FDA approval in February 2001 and has been available commercially since June 2001 (Southmedic Inc., Barrie, Ontario, Canada).

The Capnoxygen mask (CM) is an example of a modified oxygen mask that has a carbon dioxide sampling port for capnography. This device was approved by the FDA in September 1997 and has been available commercially since the spring of 1998 (Capnoxygen LLC, Lebanon, Tennessee).

The purpose of this study was to compare the capnography monitoring performance of the capnographic OA with that of the CM.

Methods

Eleven volunteer adult subjects (five female and six male) were recruited for the study after informed consent. All subjects were healthy, ASA physical status I or II. Each subject was monitored at baseline and while receiving oxygen therapy at seven different flow rates

(0.5, 1.0, 2.0, 4.0, 6.0, 8.0 and 10.0 $\text{L}\cdot\text{min}^{-1}$) applied with the CM first and then with the OA. Each monitoring period involved five repeated measurements of the ETCO_2 (% of exhaled gases) during rest by a single un-blinded investigator. Test subjects were not given any specific instructions regarding their breathing. Five readings, at one-minute intervals, were captured at each oxygen flow rate. The ETCO_2 measurements were made with a side-stream AS/3 Datex-Ohmeda monitor (Datex-Ohmeda, Helsinki, Finland), which sampled gases at 200 $\text{mL}\cdot\text{min}^{-1}$. Data was not collected for subject ten because of technical problems with the CO_2 sampling by the Datex-Ohmeda monitor at that time.

Analysis

To examine the differences between the measured values of ETCO_2 obtained by the two devices a paired sample t test was used. The mean $\text{ETCO}_2\%$ was calculated for each subject for both devices for each oxygen flow rate and this value was used to calculate the differences ($\text{OA } \text{ETCO}_2\% - \text{CM } \text{ETCO}_2\%$). The degree of agreement between the two measurements was further explored graphically by using the method of Bland and Altman, where the difference between the methods was plotted against their mean.⁷

It was observed that the measured ETCO_2 decreased as the rate of oxygen flow was increased. To investigate the relationship between ETCO_2 and oxygen flow rate a univariate regression analysis was done with ETCO_2 set as the dependent variable, oxygen flow rate set as the independent variable, and an interaction term defined by mask type and ETCO_2 . The resulting regression lines for the OA and CM were compared to assess if they had a common intercept and slope using a t test.

To examine the reliability of ETCO_2 measurement of the two devices the "variance components procedure" in the statistical software SPSS was employed

TABLE Reliability coefficient¹ for the Capnoxygen mask (CM) and OxyArm™ (OA)

Coefficient	Calculation ²	CM	OA
'Classic' reliability			
• Proportion of the total variance in measurements that was due to differences between subjects	$R = \frac{\sigma^2_S}{\sigma^2_S + \sigma^2_{\text{Error}}}$	0.95	0.86

1. Calculated from the variance components in end-tidal $\text{CO}_2\%$ ($\text{ETCO}_2\%$) derived from an ANOVA; 2. Where σ^2_S = variance in ETCO_2 due to differences between subjects (S); σ^2_{Error} = variance in ETCO_2 due to measurement error (E).

FIGURE 1 a) Original OxyArm™ with head band, boom, mushroom pin diffuser, and oxygen tubing; b) Capnographic OxyArm™ with head band, boom, funnel pin diffuser, oxygen tubing and carbon dioxide sampling tubing; c) Capnoxygen mask with headstrap, face mask, oxygen tubing and a carbon dioxide sampling port. The Capnographic OxyArm™ and Canoxygen mask were the devices compared in this study.

FIGURE 2 Example capnographs with ten consecutive waveforms obtained from (a) the Capnoxygen mask and (b) the Capnographic OxyArm™. Both examples were obtained from subject one while receiving oxygen at 1.0 L·min⁻¹.

[SPSS Graduate Pack (Statistical Software) – Version 10.0. SPSS Inc. of Chicago, Illinois. 1999]. For the procedure, $\text{ETCO}_2\%$ was set as the dependent variable, and measurement number (numbered 1–5 for each oxygen flow rate), subject number and oxygen flow were set as random factors. A reliability coefficient was constructed from the resulting variance components as an estimate of the repeatability of the two methods of ETCO_2 measurements.⁸ The ‘classic’ reliability was calculated by the proportion of the variance that was due to differences between subjects.

For the paired sample *t* test that was used to compare the mean differences in ETCO_2 between the two devices a Bonferroni adjustment (P value = 0.05/number of tests) was made for significance testing; for the remaining tests significant differences were assumed with P values ≤ 0.05 .

Results

The subjects included in the analysis included five females and five males with a mean age of 39 yr. Photographs of the devices used in the study are shown

FIGURE 3 Mean end-tidal $\text{CO}_2\%$ ($\text{ETCO}_2\%$) difference (OxyArm™ $\text{CO}_2\%$ minus Capnography mask%) with 95% confidence intervals. The mean $\text{ETCO}_2\%$ was calculated for each subject for each device at every oxygen flow rate and this value was used to calculate the mean differences. The $\text{ETCO}_2\%$ obtained with each device was compared at each oxygen flow rate using a paired sample *t* test. For all comparisons the *P* values were not significant.

in Figure 1 and examples of the capnographs produced by the devices are shown in Figure 2. Capnography worked well throughout the study period for both devices, producing consistent waveforms.

The analyses of the overall differences in ETCO_2 at each oxygen therapy flow rate are shown in Figure 3. The mean difference in $\text{ETCO}_2\%$ (OA minus CM) was greater than zero at all oxygen flow rates and there was a trend for this difference to increase with increasing oxygen flow rates. A paired sample *t* test showed no significant differences in $\text{ETCO}_2\%$ between the two devices at all oxygen flow rates. Figure 4 displays a plot of the mean differences in $\text{ETCO}_2\%$ (OA minus CM) against the average $\text{ETCO}_2\%$ obtained by the two devices. The mean difference in $\text{ETCO}_2\%$ between the two devices was 0.24 with a 95% confidence interval of -0.81 to 1.29, illustrating that the OA measurements were on average greater than the CM measurements. The difference translates to approximately a 2-mmHg difference in pCO_2 at sea level.

The regression analysis revealed that there was a significant inverse linear relationship between ETCO_2 and oxygen therapy flow rate ($P < 0.001$). The comparison between the two regression equations showed no significant difference in the intercept (projected

FIGURE 4 Difference against the mean for end-tidal $\text{CO}_2\%$ ($\text{ETCO}_2\%$) data. Mean values for $\text{ETCO}_2\%$ were calculated for each subject at each oxygen flow rate and these values were used to calculate the difference. The average $\text{ETCO}_2\%$ was calculated using all repeated measurements for both devices (ten measurements at each oxygen flow rate).

baseline ETCO_2), but the slope of the CM regression line was significantly greater than that of the OA line (Figure 5). The greater slope for the CM is a reflection of a stronger influence of oxygen flow rate on ETCO_2 measurements.

The sources of variance in ETCO_2 measurements were explored with an ANOVA. For both the CM and the OA the main source of variance in ETCO_2 measurements was the subjects, indicating that most of the variability in measurements was due to systematic differences between subjects. The second largest source of measurement variance was oxygen flow rate, and repeated measurements at a given oxygen flow rate did not contribute significantly to the variance. The reliability coefficient for ETCO_2 measurement for both the OA and CM is shown in the Table. The classical reliability coefficient, which describes the proportion of the total variance in measurements that was due to differences between subjects, was greater than 0.85 for both devices. Generally, a reliability coefficient of 0.85 is considered acceptable for repeatability in a measurement.⁸

An a priori sample size calculation was not done, but a post hoc power calculation showed that the sample size was sufficient to detect a difference in

FIGURE 5 Regression analysis results of ETCO₂ and oxygen flow rate. The regression line equations show the estimates for the intercepts and slopes with the 95% confidence interval. The asterisks (*) denote a significant difference between the groups.

ETCO₂% of less than one with 80% power. Hence this study had the power to detect approximately a 2-mmHg difference in pCO₂ at sea level. This small difference in ETCO₂ is less than what would be considered a minimal clinically important difference.

Discussion

Comparing the OA device to the CM showed that the OA could measure ETCO₂ as well as the CM over a range of oxygen flow rates. On average, the ETCO₂ measured with the OA was about 2 mmHg greater than that of the CM. Although there was an inverse relationship between the measured ETCO₂ and oxygen flow rate for both devices, this effect is more pronounced with the CM. Presumably the cause of this inverse relationship between measured ETCO₂ and delivered oxygen is increased contamination of expired respiratory gases at the sampling port with increasing oxygen flow rates. The main source of variability in ETCO₂ for both devices was inter-subject differences, followed by variable oxygen flow rates.

No attempt was made in this study to test the validity of the measured ETCO₂ values. That is, how they compared to arterial pCO₂ values. Given the main purpose of measuring ETCO₂ in conscious, spontaneously breathing, un-intubated patients is to monitor for respiratory depression and apnea, it is not neces-

sary to know the precise value of the arterial pCO₂ in this setting. Avoiding arterial blood gas analysis made the study much less invasive for the volunteer subjects.

This study was a non-randomized, un-blinded crossover trial. Blinding was considered unnecessary because of the objective nature of reading a digital display of ETCO₂ values. Some crossover trials randomize subjects to the order in which they receive the alternative treatments; randomization was also considered unnecessary for this trial. The purpose of the randomization is to control for any potential period effect or treatment-by-period interaction.⁹ A period effect can happen when the patient's condition changes over the time frame of the trial, getting better or worse. Since this study used healthy subjects one would not expect their clinical/physiological status to change over the short duration of the study period, making a period effect unlikely. A treatment-by-period interaction can occur when there is a residual carryover effect from the first treatment that affects the outcome of the second treatment. The only intervention in this study was oxygen therapy and this would not be expected to affect the ETCO₂ values in healthy subjects, making a residual carryover effect unlikely.

The OA is an alternative to the conventional oxygen mask and nasal cannula. Besides delivering oxygen, it can also be used in a variety of healthcare settings where it is necessary to monitor for respiratory depression and apnea. The most obvious applications would be to monitor sedated patients in the emergency room, operating theatre and postanesthetic care unit. Apnea monitoring would also be useful in the intensive care unit for newly extubated patients. The OA has the potential (although unproven) advantages of being more comfortable than nasal cannula or oxygen masks and it may not hinder verbal communication and eating like the oxygen mask does.

At this point further studies are necessary to assess the clinical utility of the capnographic capabilities of the OA, the relative comfort of the OA in comparison with nasal cannulae and the oxygen mask and its acceptance amongst patients in a clinical setting.

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References

- 1 *Canadian Anesthesiologists' Society*. Guidelines to the practice of anesthesia. Revised edition 2000. Can J Anesth 1999; (Suppl) 46: 9.
- 2 Moon R, Camporesi E. Respiratory monitoring. In: Miller RD (Ed.). Anesthesiology, fourth edition, vol-

- ume 1. New York: Churchill Livingstone Inc.; 1994: 1253–91.
- 3 *Egleston CV, Aslam HB, Lambert MA.* Capnography for monitoring non-intubated spontaneously breathing patients in an emergency room setting. *J Accid Emerg Med* 1997; 14: 222–4.
 - 4 *Loughnan TE, Monagle J, Copland JM, Ranjan P, Chen MF.* A comparison of carbon dioxide monitoring and oxygenation between facemask and divided nasal cannula. *Anaesth Intensive Care* 2000; 28: 151–4.
 - 5 *Cheng KI, Tang CS, Tsai EM, Wu CH, Lee JN.* Correlation of arterial and end-tidal carbon dioxide in spontaneously breathing patients during ambulatory gynecologic laparoscopy. *J Formos Med Assoc* 1999; 98: 814–9.
 - 6 *Ling E, McDonald L, Dinesen TR, DuVall D.* The OxyArm™— a new minimal contact oxygen delivery system for mouth or nose breathing. *Can J Anesth* 2002; 49: 297–301.
 - 7 *Bland JM, Altman DG.* Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986; I: 307–10.
 - 8 *Streiner DL, Norman GR.* Health Measurement Scales. A Practical Guide to Their Development and Use. Second Edition. New York: Oxford University Press; 1995.
 - 9 *Hills M, Armitage P.* The two-period cross-over clinical trial. *Br J Pharmac* 1979; 8: 7–20.

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