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Accuracy of a Novel Oxygen Mask Designed for Mainstream Capnometer in Non-intubated Pediatric Patients

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Abstract

Background: Capnography is useful for identifying postoperative apnea in non-intubated children. A Cap-ONE mask is a multi-functional face mask which can allow oxygen supply and simultaneous end-tidal CO_2 ($ETCO_2$) measurement in infant and pediatric as well as an adult patient. However, the accuracy of the $ETCO_2$ measured via Cap-ONE has not been well evaluated especially in infant and pediatric patient.

The aim of this study was to examine the correlation and level of agreement between $ETCO_2$ obtained via Cap-ONE mask and arterial blood gas partial pressure of CO_2 ($PaCO_2$) in postoperative non-intubated pediatric patients in the intensive care unit (ICU).

Methods: Postsurgical pediatric patients scheduled to admit to the ICU with invasive arterial pressure monitoring from April 2015 to March 2017 were enrolled. Patients with cardiac disease or facial abnormalities were excluded from the study. After arrival at the ICU, either small-sized (for 7-20 kg) or medium-sized (for 20-40 kg) Cap-ONE mask was installed on a patient face with oxygen supply at 5 L/min; then $ETCO_2$ measurement was started. Once stabilized, the sample of arterial blood gas was analyzed to measure $PaCO_2$. The relationship between $ETCO_2$ and $PaCO_2$ was examined by simple regression analysis. A Bland Altman plot was used to evaluate agreement between these two measurements.

Results: A total of 77 $ETCO_2$-$PaCO_2$ paired values were obtained from 29 patients. In 23 (79.3%) patients, dexmedetomidine was administrated for sedation. The mean ± SD for $ETCO_2$ and $PaCO_2$ was 39.0 ± 8.5 mmHg and 41.5 ± 6.5 mmHg respectively (small group; 35.2 ± 8.7 mmHg and 37.8 ± 5.3 mmHg, medium group; 41.8 ± 7.3 mmHg and 44.2 ± 5.8 mmHg). Correlation coefficient (R^2) was 0.554 ($P<0.01$) between $ETCO_2$ and $PaCO_2$ (small group; R^2=0.431, medium group; R^2=0.515). The mean bias ± SD between $ETCO_2$ and $PaCO_2$ was -2.38 ± 5.69 mmHg. The 95% level of agreement ranged from -13.54 to+8.78 mmHg (small group; -2.60 ± 6.55 mmHg, medium group; -2.40 ± 5.10 mmHg).

Conclusion: $ETCO_2$ obtained from Cap-ONE mask is correlated well with $PaCO_2$ in postoperative non-intubated pediatric patients (aged 7 months to 14 years). The present study demonstrated that the Cap-ONE mask can provide a continuous, non-invasive, relatively reliable respiratory measurement in non-intubated, lightly sedated pediatric patients.

Keywords: Capnography; $ETCO_2$; Oxygen mask; Cap-ONE

Introduction

Intraoperative and postoperative narcotics are the potential risk factor to cause postoperative respiratory depression and apnea. After emergence from anesthesia and extubating endotracheal tube, the assessment of oxygenation via pulse oximetry is generally employed in the initial phase of recovery. Pulse oximetry is a noninvasive and well established monitor for measuring oxygen saturation in the artery as well as heart rate. Under the oxygen supply, however, pulse oximetry alone may not detect all airway or other respiratory complications without delay [1].

Capnography provides a non-invasive estimate of arterial blood gas partial pressure of CO_2 ($PaCO_2$) and it has reported that there is a good linear correlation between End-tidal carbon dioxide ($ETCO_2$) and $PaCO_2$ in intubated infants [2]. In addition, it has been used for non-intubated patients to detect apnea or respiratory insufficiency [3-6] so that it can provide us with an early warning of postoperative respiratory depression before oxygen desaturation. Moreover, it has been shown that the combined use of pulse oximetry and capnography significantly improve patient safety in postoperative detection of respiratory depression and prevention of adverse events in avoidance of extra blood sampling, which may cause anemia, discomfort and pain [2,7].

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The measurement of $ETCO_2$ via capnography is monitored either side-stream or main-stream. For the side-stream, nasal cannulas are commonly used [8]; however, stable monitoring of $ETCO_2$ is challenging due to obstruction of the sampling tube by moisture, and inaccuracy of the CO_2 measurement when high oxygen flow rates are supplied. The use of a face mask with main-stream capnography has been reported to provide stable monitoring of $ETCO_2$ regardless of nose or mouth breathing while administering oxygen compared to a side-stream nasal cannula capnography system in children [9].

Although the oxygen mask with main-stream capnography would be beneficial to monitor respiration in children, it has not been fully evaluated the accuracy of mainstream mask capnography system in a postoperative non-intubated pediatric patient whom may be influenced by anesthetics and surgical stress in ICU.

We hypothesized that $ETCO_2$ measured via the oxygen mask with mainstream capnography system (Cap-ONE mask) would have the significant correlation and agreement with $PaCO_2$ in the postoperative pediatric patient.

The aim of this study was to examine the correlation and level of agreement between $ETCO_2$ obtained from mainstream capnography mask and $PaCO_2$ in non-intubated pediatric patients in ICU.

Patients and Methods

This study was approved by the institutional review board of our institute and registered to the University Hospital Medical Information Network- Clinical Trial Registry (UMIN-CTR) (unique trial number: UMIN000017616). All legal guardians of the children provided written informed consent to participate in this study. A consultant anesthesiologist trained in the use of the mainstream mask capnography system by a company technical consultant observed this research.

The Cap-ONE mask (YG-232T/YG-242T, Nihon Kohden Corporation, Tokyo, Japan) is an open-system face mask to deliver oxygen while measuring mainstream $ETCO_2$ (Figure 1). Its sensor is characterized by light-weight (4 grams) with small dead space, which can be easily adapted to pediatric patients. The feasibility of $ETCO_2$ measurement by Cap-ONE mask has been reported in a child manikin study [10]. The infant Cap-ONE mask, small group, is designed for body weights from 7-20 kg, and the pediatric Cap-ONE mask, medium group, is designed for body weights from 20-40 kg. Two sizes of Cap-ONE masks were evaluated. These equipments are FDA approved for use in children.

Postsurgical pediatric patients at Jikei University Hospital, less than 17 years old, scheduled to admit to the ICU with invasive arterial pressure monitoring from April 1, 2015 to March 31, 2017 were enrolled. Patients with cardiac disease, pulmonary disease, facial abnormalities, poor tissue perfusion, metabolic abnormalities, or noninvasive positive pressure ventilation were excluded.

Demographic information was collected for eligible participants. Children were classified into two groups according to their body weight (the small group as 7-20 kg; the medium group as 20-40 kg). The small group<20 kg wore the infant Cap-ONE mask, whereas the medium group>20 kg wore the pediatric Cap-ONE mask according to the manufacturer instructions. All patients were extubated in the operating room and transferred to ICU with a normal oxygen mask.

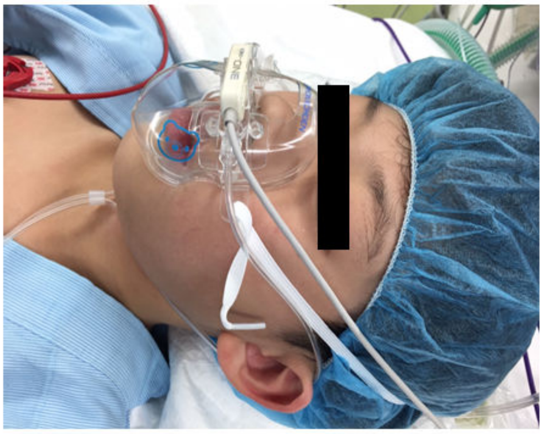

Figure 1: Cap-ONE mask (medium size) and mainstream CO_2 measuring probe on a patient face.

After arrival at the ICU, either the infant or the pediatric Cap-ONE mask was installed on a patient face with 5 L/min oxygen; then $ETCO_2$ measurement was started. Confirming the plateau of CO_2 waveform, peak $ETCO_2$ was recorded and stored for analysis and 1 mL of arterial blood was sampled in a heparinized tube and the sample was examined by blood gas analyzer (ABL 827 FLEX, Radiometer K.K., Tokyo, Japan). This machine was regularly serviced and quality-checked by the hospital laboratory diagnostics department as well as the local distributor. Additional data included the level of consciousness (Richmond Agitation-Sedation Scale: RASS), sedative agents and quantitative intraoperative opioids were collected. These values were retrieved from the database, Philips information management system, in ICU. If there were comments regarding the inappropriate installation of the mask, those values were excluded. We evaluated the correlation of $ETCO_2$ and $PaCO_2$ by linear regression analysis and assessed the agreement between these measurements bias [mean difference], precision [SD of the differences] and the 95% limits of agreement [2 × SD of the differences] by the Bland Altman plot technique. A bias ≤ 5 mmHg was considered acceptable bias and >5 mmHg an unacceptable bias [11]. Level of significance was set at $P<0.05$. Statistical analysis was performed by Prism 5.04 (Graph Pad).

Results

A total of 77 $ETCO_2$-$PaCO_2$ paired values were obtained from 29 patients, 13 children in a small group using the infant Cap-ONE mask and 16 in the medium group using the pediatric Cap-ONE mask. Each patient provides a mean of 2.7 pairs (range, 1-5 pairs). All patients had uneventful anesthetics and entered the ICU without respiratory complication and returned to the medical ward on the next day. No patients in either group experienced respiratory complications including hypoxia and apnea. Due to the comment of refusal to wear the oxygen mask or wailing at ICU, 7 pairs of data were excluded

Patient characteristics were shown in Table 1 and surgical procedure in Table 2. Age ranged from 3 months to 14 years with a median age of 9 years. The median age (range) for the small and medium group was 23.5 (3-82) months and 12(6-14) years respectively. The median (range) for weight was 30 (6.7-61)kg, the small group; 11.2 (6.7-11.5)kg, medium group; 40.5 (22.2-61)kg.

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	Small size (n=13)	Medium size (n=16)	Total (n=29)
Age, median (range), months	23.5 (3-82)	148 (78-206)	119 (3-206)
Weight, median (range), kg	11.2 (6.7-11.5)	40.5 (22.2-61)	30 (6.7-61)
Number of Samples per patient, mean (range)	2.8 (1-5)	2.6 (1-5)	2.7 (1-5)
RASS, mean ± SD			-3.8 ± 3.7
Intraoperative fentanyl, mean ± SD, ug/kg	18.0 ± 9.1	5.9 ± 6.0	11.1 ± 9.4
Use of dexmedetomidine (%)	8 (66.7)	15 (88.2)	23 (79.3)

Table 1: Characteristics of Study patients (n=29) and Sample (n=77).

	Small (n=13)	Medium (n=16)
Brain surgery	3	4
Cranioplasty	3	0
Lung surgery	1	0
Partial nephrectomy	1	0
Pectus excavatum repair (Nuss procedure)	0	12
Spinal tumor surgery	5	0

Table 2: Surgical procedure.

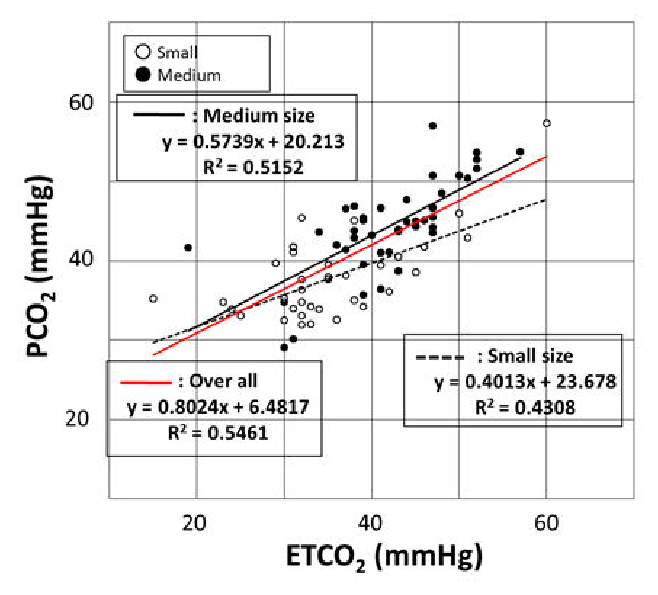

Figure 2: Liner correlation between $ETCO_2$ and $PaCO_2$..

The mean ± SD for $ETCO_2$ and $PaCO_2$ was 39.0 ± 8.5 mmHg and 41.4 ± 6.5 mmHg respectively (small group; 35.2 ± 8.7 mmHg and 37.8 ± 5.3 mmHg, medium group; 41.8 ± 7.3 mmHg and 44.2 ± 5.8 mmHg).

Figure 2 shows the linear correlation between $ETCO_2$ and $PaCO_2$. The two values were highly correlated in both sizes (Overall; R_2=0.554, small group; R_2=0.431, medium group; R_2=0.515). There was no statistically significant difference between the two regression lines of two sizes.

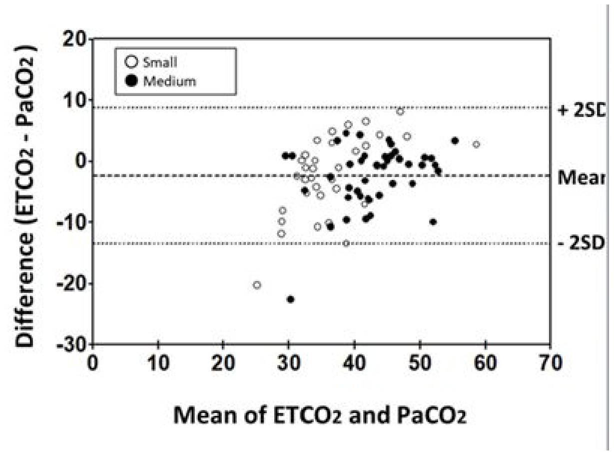

Figure 3: Bland Altman Plots of the differences between $ETCO_2$ and $PaCO_2$.

Figure 3 presents the Bland-Altman plots of the differences between $ETCO_2$ and $PaCO_2$. The mean bias ± SD between $ETCO_2$ and $PaCO_2$ values was -2.38 ± 5.69 mmHg (small group; -2.60 ± 6.55 mmHg, medium group; -2.40 ± 5.10 mmHg). The 95% limits of agreement between $ETCO_2$ and $PaCO_2$ ranged from -13.54 to +8.78 mmHg. $EtCO_2$ was within ± 5 mmHg of $PaCO_2$ in 54 of the 77 values. The Bland Altman plot did not show any systemic or proportional biases.

In 23 (79.3%) patients, dexmedetomidine was administrated for sedation. They showed the mean ± SD for RASS was (-3.8) ± 3.7. As for intraoperative use of opioids, amount of fentanyl which was only administrated intraoperatively was 11.1 ± 9.4 ug/kg (mean ± SD). There was no additional opioid administered in ICU.

Discussion and Conclusion

Postoperative pediatric patients may involve serious risks including hypoventilation, apnea, airway obstruction and cardiopulmonary dysfunction. For safer patient management in ICU, it is essential to closely observe patients after extubation. We report on the clinical evaluation of mainstream $ETCO_2$ monitoring, focusing on a pediatric population which would derive the greatest benefit from continuous, noninvasive CO_2 assessment. Although arterial blood gas analysis remains the most accurate method of ascertaining blood CO_2 tensions, alternative methods are desirable because these patients have limited blood volumes. The need to quickly assess and respond to changes in CO_2 pressures has become more critical with the increased recognition that both low and high $PaCO_2$ for even brief periods of time are associated with long term morbidity in these patients. Furthermore, inadequate spontaneous breathing could lead to hypocapnia and hypercapnia if not recognized.

This study revealed that $ETCO_2$ obtained from Cap-ONE mask is correlated well with $PaCO_2$ in non-intubated pediatric patients (aged 7 months to 14 years). In this study, mainstream mask capnography system monitoring in both the small group and medium group produced similar decision coefficients (R^2=0.431 and 0.515, respectively). The bias we report (-2.38 ± 5.69 mmHg) was well less than 5 mm Hg, which is considered acceptable bias [11]. The correlation and agreement of $ETCO_2$ and $PaCO_2$ were well in both groups. Several investigators reported similar results for good correlation with $PaCO_2$ and mainstream $ETCO_2$ in the pediatric population [2,11]. Henry J et al. reported that mainstream $ETCO_2$ monitoring in the intubated neonatal in the ICU produced better decision coefficients (R^2=0.693) [11]. However, both of these studies measured $ETCO_2$ in intubated population. Our study results regarding $ETCO_2$ obtained from the mask, which differs from reported results for that obtained from intubation, should be interpreted as the usefulness of $ETCO_2$ monitoring in non-intubated pediatric patients. Although the bias of $ETCO_2$ was relatively small in our study, the 95% limits of agreement were relatively large (-13.54 to +8.78 mmHg) in our study as well as in the other studies. Thus, $ETCO_2$ should not replace $PaCO_2$ measurements but rather serve as a complementary tool for trending and for real-time continuous assessment of the CO_2 levels.

The consistent negative bias of the $ETCO_2$ value in this study is within the range reported in previous studies of mainstream capnometry in neonates [12]. The lower value for the end-tidal measurement may be attributable to gas mixing intra-mask. CO_2 measurements from gas sampled distally to the mask more closely match the arterial value [13]. If the goal of ventilation monitoring is to avoid hypocapnia or hypercapnia, rather than achieving a specific level or range of $PaCO_2$, then continuous noninvasive monitoring by capnometry may be relevant to clinical treatment.

Lung condition was reported to affect the accuracy of capnometry in several studies. The more severe the ventilation-perfusion mismatch, the higher the difference between $ETCO_2$ and $PaCO_2$ [14]. Experimental data from an animal study have shown that sedation, which contains α_2-agonists, impaired pulmonary gas exchange for the mismatch between ventilation and perfusion in the lungs [15]. In our study, 23 (79.3%) pediatric patients were sedated with dexmedetomidine and opioids which were administrated intraoperatively might be remaining in all participants. The mean bias was -2.38 mmHg, which was larger than the result of the previous study receiving mechanical ventilation (-1.1 mmHg) [2]. The difference between monitoring from mask and intubation might result in this misleading. It is unknown that with the use of sedative agents the ventilation-perfusion problems thought to cause the increased variability.

We used the novel method of the mainstream capnography mask system, which was used previously only in several studies. We initially used this device for pediatric patients in ICU, which allowed continuous measurement of $ETCO_2$ via mask. This mask is composed of airway adaptor with an anti-fogging membrane. Droplets of water cause uneven reflection of light which leads to inaccurate CO_2 measurement. Traditional CO_2 sensors eliminate the droplets with a window heater. The anti-fogging membrane of the Cap-ONE mask forms a smooth layer of water which allows accurate CO_2 measurement with no heater. This reduces power consumption and sensor weight, which weighs only 4g. This weigh allows this devise on the mask for children. Additionally, Cap-ONE mask has a wide opening in front to let oral and nasal exhaled gas out of the mask. This design prevents exhaled gas from remaining in the mask even when oxygen flow is low. Also, well dispersed oxygen is supplied from the sides of Cap-ONE mask, so oxygen concentration inside the mask remains consistent and stable.

Although there is no debate that noninvasive CO_2 assessment is important, there is a debate regarding the preferred method. Murat Pekdemir et al concluded that mainstream $ETCO_2$ values were lower than the $PaCO_2$ values [16]. Some report has shown that a mainstream mask system performed with precision than sidestream nasal cannula monitoring regardless of mouth breathing [9]. Because pediatric patients are likely to breathe via mouth, mask system should be applied to those patients. With sidestream system, stable monitoring of CO_2 is challenging due to obstruction of the sampling tube from moisture and inaccuracy of the CO_2 measurement when high oxygen flow rates are used. The mainstream capnography mask system might be thought to be an ideal device for pediatric patients.

Some limitations of this study should be discussed. First, pediatric patients with no sedation often dislike wearing oxygen masks when breathing spontaneously. When $ETCO_2$ is low (<26 mmHg), mask position should be adjusted to record more accurate value. These data might affect these sampling of the pair of the $ETCO_2$ and $PaCO_2$. Those data should be regarded as not accurate because of other similar research [2,11]. Second, because data regarding the waveforms were not recorded and analyzed in our study, it is not possible to know whether adding some form of wave analysis to the $ETCO_2$ values. Thus, some of the differences between capnography and $PaCO_2$ could be attributed to failure to obtain a proper alveolar gas sample when a plateau of the capnogram was not fully achieved. Third, we did not correlate the value of $ETCO_2$-$PaCO_2$ with mean arterial pressure (mAP) or volume status which may affect the production of carbon dioxide. However the correlation was not significant between them ($ETCO_2$-$PaCO_2$ vs. mAP; P=0.18, $ETCO_2$-$PaCO_2$ vs. intravenous fluid balance; P=0.11 by spearman correlation).

Although our study is the first to use the mainstream capnography mask system in pediatric patients in ICU, more studies are needed to show the usefulness of this method in those patients. Though our study confirms Cap-ONE mask can accurately measure expiratory carbon dioxide concentration at the same flow rate of oxygen, future study is needed to examine the correlation at different flow of oxygen.

The novel method of measuring $ETCO_2$ via Cap-ONE mask was found to have good correlation and agreement with $PaCO_2$ and remained reliable in lightly sedated pediatric patients. The method is not invasive and thus is safe to be used even in infants. $ETCO_2$ does not replace $PaCO_2$ but may be useful for trending and for the real-time continuous screening of abnormal $PaCO_2$ levels. Because noninvasive CO_2 monitoring is important for the outcome of non-intubated pediatric patients and the currently available methods are limited, the medical team should consider the use of this mainstream capnography mask system for assessing $ETCO_2$ in ICU. The present study demonstrated that the Cap-ONE mask can provide a continuous, non-invasive, relatively reliable respiratory measurement in non-intubated, lightly sedated pediatric patients.

Acknowledgments

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