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A Novel Mainstream Capnometer System for Non-intubated Pediatric Patients Requiring Oxygen Administration

Fumihiko Takatori, Shinji Yamamori, Masayuki Inoue, Seiki Abe, and Katsuyuki Miyasaka

Abstract— **Capnometer has been widely used as a respiratory monitor. Stable carbon dioxide (CO_2) monitoring of non-intubated patient is especially problematic due to the frequent occurrence of tube obstruction and it could be even more difficult when oxygen is being administered. Oxygen is often administered by an oxygen mask or oxygen nasal cannula; however there are some problems with these methods. For oxygen masks, it is necessary to provide high-flow oxygen to prevent rebreathing of exhaled CO_2, and as for oxygen nasal cannula, it is incapable of increasing the oxygen concentration and patient may feel uncomfortable during oxygen administration because it could dry nasal mucous. To solve these problems, we developed a novel mainstream capnometer system, which provides stable monitoring of exhaled CO_2 while administering oxygen. This capnometer system has a mask with an opening large enough to facilitate the observation of patient's nose and mouth and the procedures such as daily oral care. Furthermore, the outer rim of the mask is designed to effectively retain oxygen flow without causing rebreathing.**

INTRODUCTION

CAPNOMETER is a very sensitive monitor for detecting apnea and malfunction in patients who need respiratory management [1]. Also, it has been used for non-intubated patients to decrease the number of respiratory accidents including respiratory depression in extubated or sedated patients [2].

There are two measurement methods for capnometer: mainstream method and sidestream method. The mainstream method uses a direct measurement from the patient exhaled CO_2. This method usually responds well to changes in exhaled CO_2 and rarely causes tube obstruction by water, but sensors used for this method are relatively large and heavy so it may not be applicable for non-intubated patients [3]. The sidestream method uses a sampling tube connected to a patient to perform the measurement. This method usually has smaller attachment part to patient but it may cause some time delay of measurement and could easily cause obstruction of sampling tube by water from aspirating gas.

cap-ONE® (Nihon Kohden, Tokyo, Japan) is a lightweight (4g) and small mainstream capnometer, which overcomes these problems [4] [5] [6] [7] [8].

Generally, oxygen is administered to non-intubated patients by an oxygen mask or oxygen nasal cannula but there are problems for both methods. The oxygen mask needs to provide high-flow oxygen of 5 L/min [9] [10] to prevent rebreathing of exhaled CO_2, while of the oxygen nasal cannula is incapable of increasing oxygen concentration [9] and patients may feel uncomfortable during oxygen administration as it could dry nasal mucous. To solve these problems some products are developing recently [11].

Performing a stable CO_2 monitoring for non-intubated patients could be difficult because patients may breathe through both nose and mouth. And it could be even more difficult when oxygen is being administered.

We developed a novel mainstream capnometer system to address above mentioned problems. This system is designed to provide stable monitoring of exhaled CO_2 while administering oxygen [12].

PROCEDURE FOR PAPER SUBMISSION

2.1. Materials

A) A novel mainstream capnometer system

This capnometer system consists of cap-ONE® and cap-ONE mask.

B) A mainstream capnometer, cap-ONE

The cap-ONE consists of a light unit and detector unit, and it measures density of infrared absorption (Fig. 1).

The light unit has a very small light source and an elliptical mirror. The light source is designed to be focused into one focal point of the elliptical mirror so that the reflected light is condensed efficiently in the detector unit.

The detector unit consists of three infrared filters, a half mirror and two detectors. CO_2 molecule absorbs the infrared light of 4.3μm. These filters are located in front of two detectors and a half mirror to shield unnecessary light and to convert the remaining light to signals. One of these two detectors is for decreasing the signals in the presence of CO_2, and the other is for maintaining constant signal level with or without CO_2. The cap-ONE calculates CO_2 density based on these two signal ratio.

Expired gas contains water vapor, which affects CO_2 measurement. Generally, measuring window needs a heater to prevent it from fogging, while the cap-ONE uses anti-fogging membrane to keep the windows clean. This membrane reduced the size of the sensor (8.3×13.7×37mm)

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F. Takatori. S. Yamamori, M. Inoue are with Nihon Kohden Corporation, 1-31-4 Nishiochiai, Shinjuku-ku,Tokyo, Japan.(Corresponding author to provide phone: +81-3-5996-8018; fax:+81-3-5996-8088; e-mail; Fumihiko_Takatori@mb2.nkc.co.jp)

S. Abe is Anesthesia and Intensive Care Unit, Nagano Children's Hospital, Nagano, Japan

K. Miyasaka is St.Luke's College of Nursing, Tokyo, Japan

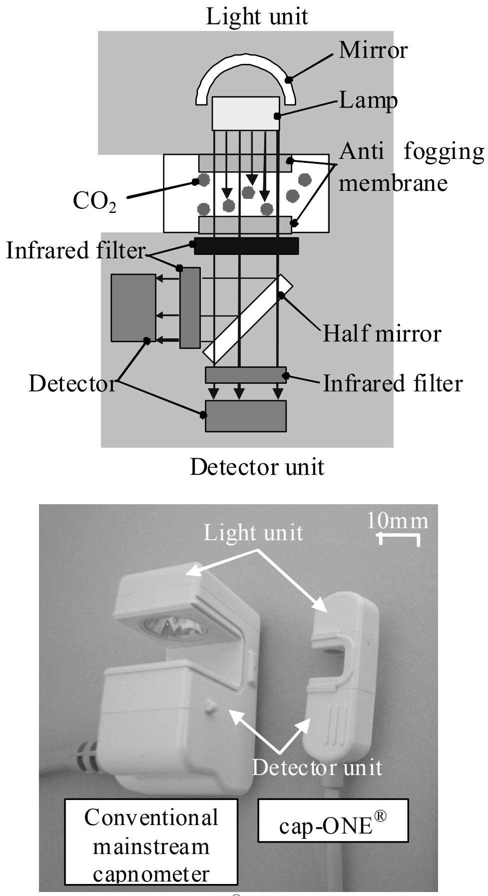


Fig. 1. The structure of cap-ONE®

and achieved considerable energy saving.

C) cap-ONE mask

The cap-ONE mask consists of an inside cup, measuring port, outside mask and oxygen tubing (Fig. 2).

Expired gas from either the nose and/or mouth is guided to the measuring port through the inside cup. This measuring port is designed to hold cap-ONE and its measuring window has an anti-fogging membrane. The outside mask has a large opening, which prevents re-breathing and facilitates the observation of patient's nose and mouth to promote daily medical procedures such as oral suctioning.

Oxygen flow is provided from the oxygen tube located on the right and left side of the mask. The flow is diffused by a diffuser plate so that it does not interfere with the accurate measurement. Additionally, this method is more comfortable for patients compared to the direct oxygen supply to nasal mucous. The outside mask has a wide opening but the concave structure prevents the oxygen concentration from decreasing without causing re-breathing.

2.2. Numerical analysis

We used finite element method (FEM) for numerical analysis to validate the design of the system. The FEM can solve the behavior of the complicated object being divided in the limited domain by the approximate numerical value solution. Navier-Stokes equation for the incompressible Newton fluid was used as a dominant equation for this fluid flow model and the results were derived by connecting each difference equation for mass, a momentum, a nonlinear individual difference for the law of the conservation of

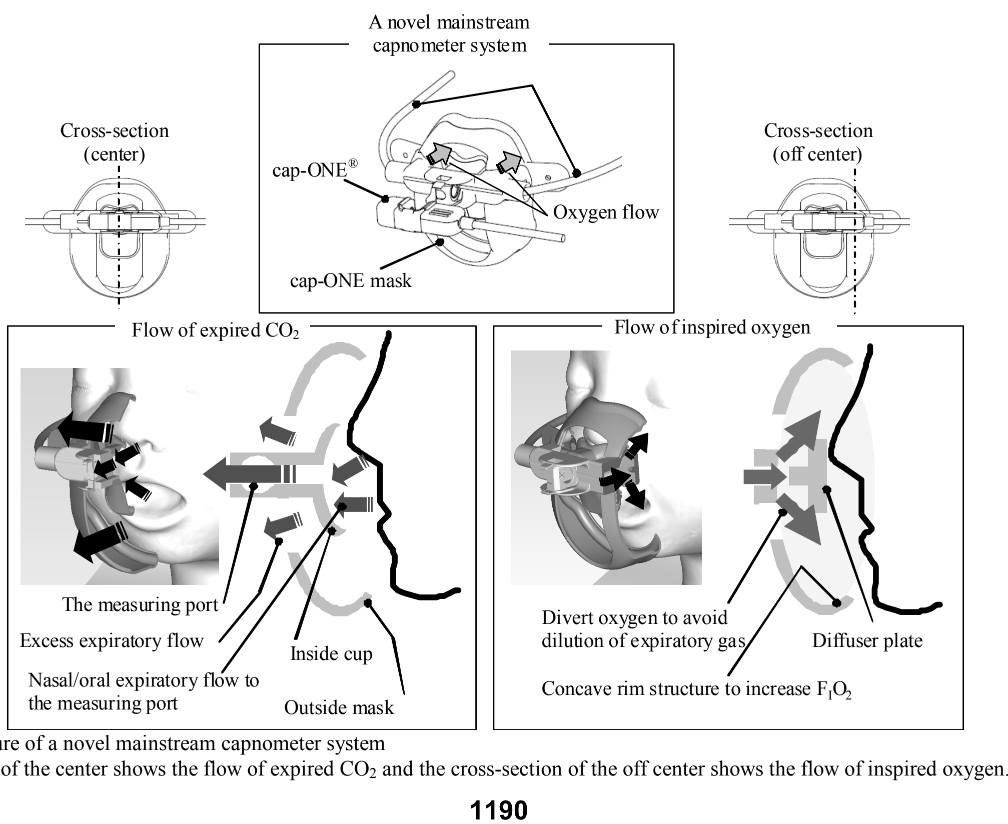


Fig. 2. The structure of a novel mainstream capnometer system
The cross-section of the center shows the flow of expired CO_2 and the cross-section of the off center shows the flow of inspired oxygen.

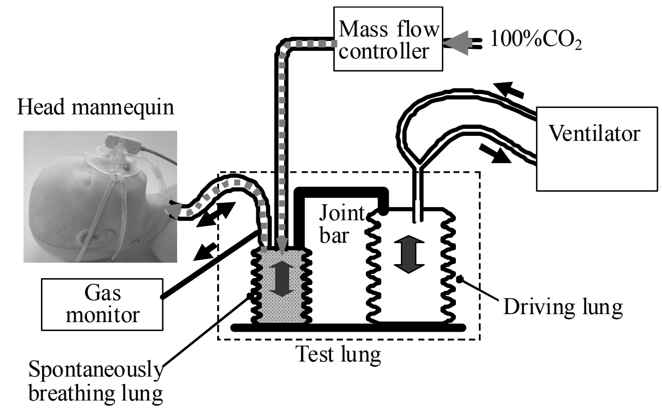


Fig. 3. Spontaneously breathing model

energy.

NX-IDEAS 6 (ISID, Tokyo, Japan) was used as a numerical analysis tool.

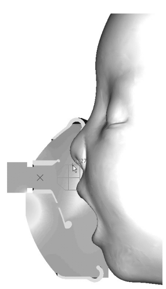
For the analysis, respiration of one year old infant was simulated with oxygen flow of 6 L/min. The cap-ONE mask was compared to a standard facemask.

2.3. Evaluation of the capnometer system using a spontaneously breathing model

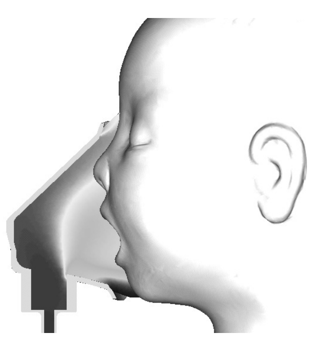
We used a spontaneously breathing model to evaluate the capnometer system. This model includes Adult/Infant Training/Test Lung, model 1601 (Michigan Instruments, MI, USA), a ventilator, Evita 2 (Dräger, Lübeck, German), a head mannequin, Infant Airway Management Trainer (Laerdal Medical Japan, Tokyo, Japan) and a mass flow controller, SEC-B40/B50 (HORIBA STEC, Kyoto, Japan) (Fig. 3). The test lung consists of two lungs. One is for driving and the other is for spontaneously breathing. Both lungs are connected by a joint bar. The driving lung is connected to the ventilator and the spontaneously breathing lung is connected to the head mannequin. The spontaneously breathing lung can supply CO_2 gas which is regulated by a mass flow controller and an expired CO_2 concentration is kept at 38 mmHg during the evaluation. The concentration was monitored by a respiratory gas monitor, NORMOCAP200 (DATEX, Helsinki, Finland) and the capnometer system was compared with a standard facemask, Pedimask OX-130 (Atom Medical, Tokyo, Japan).

The evaluation used a one year old infant model with tidal volume of 78 ml; respiration rate of 38; IE ratio of 1:1.5; and residual lung volume of 70 ml.

The variability of oxygen concentration (F_IO_2) was monitored by moving a mask ±10, 20 mm for vertical/horizontal direction.



(a) Capnometer system
Oxygen is blowed over the whole face.



(b) Standard facemask
Oxygen escapes along nasal crest and oxygen distribution is not uniform.

Fig. 4. Results of numerical analysis

RESULT

3.1. Numerical analysis

The oxygen concentration delivered by the capnometer system was constant (Fig. 4 (a)).

On the other hand the oxygen concentration delivered by the standard facemask was not constant. This result shows that the concentration varies depending on the fit of the mask (Fig. 4 (b)).

3.2. Evaluation of the capnometer system using a spontaneously breathing model

With the capnometer system administering high-flow oxygen of 5 L/min, good and consistent capnograms were derived in both nasal and oral breathing high-flow oxygen (Fig. 5). To assess the impact of high-flow oxygen on the measurement of end tidal CO_2 (E_TCO_2), we compared E_TCO_2 measurements with different oxygen flow. The E_TCO_2 when administering oxygen flow of 2 L/min was 34 - 38 mmHg, while when administering oxygen flow of 5 L/min it was 31-35 mmHg. This shows that there is an impact of high flow oxygen on E_TCO_2.

The oxygen concentration (F_IO_2) delivered by the capnometer system was higher than that by the standard facemask (Fig. 6).

The inspired CO_2 (F_ICO_2) without administering oxygen flow of the capnometer system was smaller than the standard facemask (9 mmHg vs. 22 mmHg) (Fig. 7).

DISCUSSION

Capnometers are very sensitive respiratory monitors, and they are not used as widely as pulse oximeters, especially on non-intubated children.

There are some disadvantages for both mainstream and sidestream capnometers. The sensors of mainstream capnometer is usually larger and heavier, while as for the sidestream capnometer, there is some time delay and tubes

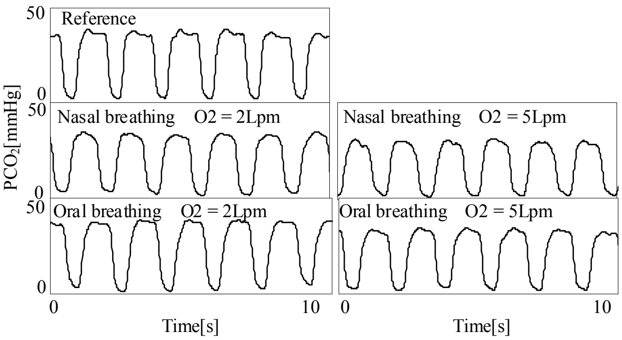
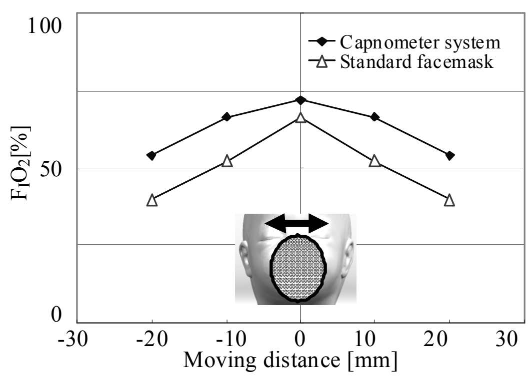
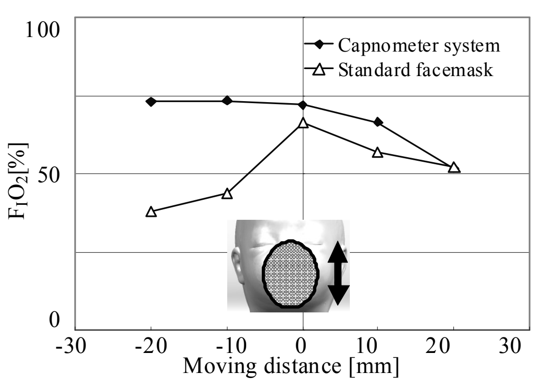


Fig. 5. Comparison of capnograms with a nasal / oral breathing when administering different oxygen flow about a capnometer system



(a) Horizontal mask movement



(b) Vertical mask movement

Fig. 6. Comparison of F_IO_2 with a capnometer system and a standard facemask

could easily get obstructed. The capnometer system was developed to address these problems.

Further evaluation is needed to establish the effectiveness of the system for a wider field of application; however we believe that the system will contribute to improving the quality and safety of sedated pediatric patients.

Conclusion

We developed a novel mainstream capnometer system which provides stable CO_2 monitoring with administering oxygen. We evaluated the performance of this system and concluded as follows:

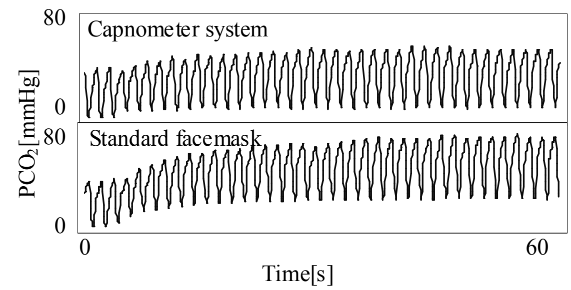


Fig. 7. Comparison of F_ICO_2 with a capnometer system and a standard facemask

1) The capnometer system provided good and consistent capnograms both in nasal and oral breathing even when high-flow oxygen was administered.
2) The oxygen concentration delivered by the system was high and stable.
3) The degree of rebreathing of exhaled CO_2 was small.

This study shows that this system may improve the safety, especially of non-intubated patients.

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