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Oxygenation and Carbon Dioxide Rebreathing of a Well-fitting Non-rebreathing EcoLite™ Mask with a Reservoir: A Single-center Prospective Observational Study in Healthy Volunteers

YUSUKE MIYAZAKI[1] and JOJI KOTANI[2,*]

[1]*Department of Emergency Medicine and Intensive Care Medicine, Konan Medical Center, Kobe, Japan;*
[2]*Department of Disaster and Emergency Medicine, Kobe University Graduate School of Medicine, Kobe, Japan*
**Corresponding author*

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BACKGROUND: The fitting of oxygen mask affects the performance of it such as oxygenation or CO_2 elimination. The intersurgical EcoLite™ adult high-concentration oxygen mask (EcoLite with a reservoir, Intersurgical, UK) was developed to give well-fitting. The purpose of this study is to evaluate the performance of EcoLite with a reservoir compared to the conventional mask. METHODS: Ten healthy volunteers were included in this study. EcoLite with a reservoir and conventional mask were given to patients at different oxygen flow rates (5, 8, 10, 12, and 15 L/min). Fraction of inspiratory O_2 (F_IO_2) and partial pressure of inspiratory CO_2 (P_ICO_2) were measured by a sampling tube at the middle pharynx inserted via nose. RESULTS: The EcoLite with a reservoir had a significantly higher F_IO_2 than the control reservoir mask. However, the P_ICO_2 was significantly higher in the EcoLite with a reservoir than in the control reservoir mask, especially when the oxygen flow rate was low. CONCLUSION: The EcoLite with a reservoir provided improved oxygenation and a better fit than the conventional reservoir masks in healthy volunteers. However, the EcoLite with a reservoir might cause higher CO_2 rebreathing at low oxygen flow rates.

INTRODUCTION

In patients with respiratory failure, oxygenation using a mask is critical and essential as the first intervention. A reservoir mask is a system that achieves a high fraction of inspiratory O_2 (F_IO_2) with low oxygen flow. The F_IO_2 reaches up to 0.6 in a partial-rebreathing mask, and it increases with a non-rebreathing mask [1, 2]. However, the fitting of a conventional mask is limited, such that an ill-fitting mask will not maintain a high concentration.

To address the poor fit of conventional masks, the intersurgical EcoLite adult high-concentration oxygen mask (EcoLite with a reservoir, Intersurgical, UK) was developed. It is commonly used as a high-concentration oxygen mask for adult patients [4]. The mask consists of a soft elastomer, that comes into contact with the patient's face. It is designed to wrap around the chin to improve the fit, resulting in higher oxygenation compared to the conventional reservoir mask.

Although the application of the EcoLite with a reservoir increases the F_IO_2 concentration due to its tight fit, it causes carbon dioxide (CO_2) rebreathing and hypercarbia at low O_2 flow rates. Several guidelines state that the flow rate should be 10 L/min or higher for a non-rebreathing mask [2, 3, 5]. However, the risk of CO_2 rebreathing from the EcoLite with a reservoir in an area with a low O_2 flow rate remains unclear. This study aimed to evaluate the oxygenation and CO_2 rebreathing of the EcoLite with a reservoir compared with that of a conventional reservoir mask in healthy subjects.

MATERIALS AND METHODS

This study was approved by the Medical Ethics Committee of the Otsu Municipal Hospital and was conducted after obtaining informed consent. The study included healthy volunteers over 18 years old. Individuals with respiratory diseases, including pneumonia, asthma, and COPD, were excluded.

The EcoLite with a reservoir was given to patients, and a three-in-one oxygen mask (control reservoir mask, Japan Medicalnext, Japan) was given to patients as the control group. As a reference value, the oxygen mask

Phone: +81-78-382-6521 Fax: +81-78-341-5254 E-mail: kotanijo0412@gmail.com

three in one type was measured in the same way with one of the flap valves removed (Figure 1). This is because, the removal of the mask flap valve is recommended by Japanese guidelines [3] when the patient inhales strongly and the reservoir capacity is insufficient. A measurement was conducted to assess the impact of this practice.

To measure the F_IO_2 and partial pressure of inspiratory CO_2 (P_ICO_2), a sampling tube (FUKUDA COLIN, Japan) was inserted into the middle pharynx through the nose and connected to the BP-608 Evolution (FUKUDA COLIN, Japan). F_IO_2 and P_ICO_2 were monitored during oxygen administration at different flow rates (5, 8, 10, 12, and 15 L/min). After 5 min of incubation at each O_2 flow rate, the average value of five consecutive breaths was recorded. The presence of adverse events (e.g., headache, nausea, respiratory distress) and derangements in vital signs during hypoxic and hypercarbic states were monitored.

All statistical analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R 2.13.0 (R Foundation for Statistical Computing, Vienna, Austria) [6]. Group differences with each oxygen flow rate were assessed using repeated-measures analysis of variance. Measurements were compared using mean ± standard deviation (SD). P values < 0.05 were considered statistically significant.

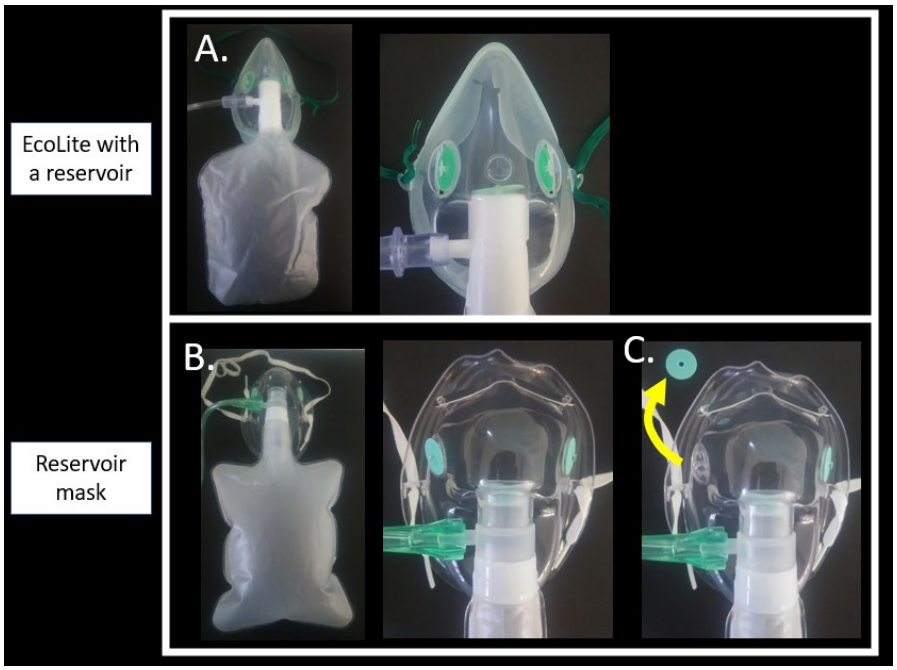

Figure 1. Non-rebreathing masks with a reservoir
A. The EcoLite mask with a reservoir
B. Reservoir mask three in one type
C. One flap valve on the mask removed from the body

RESULTS

This study included five males and five females with an average age of 29.3 years, average height of 163.8 cm, and average body weight of 56.2 kg. All participants were non-smokers with no medical history of respiratory disease (Table I).

Table I. Cohort characteristics: mean ± SD

Age (years)	29.3 ± 4.7
Male (n)	5
Female (n)	5
Height (cm)	163.8 ± 10.0
Body Weight (kg)	56.2 ± 10.3
Body Mass Index (kg/m^2)	20.8 ± 2.0

For each mask, the F_IO_2 increased and the P_ICO_2 decreased as the oxygen flow rate increased. The EcoLite with a reservoir had a significantly higher F_IO_2 than the control reservoir mask ($p < 0.05$) (Table II, Figure 2). However, the P_ICO_2 was significantly higher in the EcoLite with a reservoir than in the control reservoir mask ($p < 0.05$), especially when the oxygen flow rate was low. In addition, the three-in-one oxygen mask with one

removed flap valve was not significantly different compared to the mask with two flap valves. During the examination, there were no adverse events or changes in vital signs suggesting hypoxia and hypercarbia in both mask groups.

Table II. Oxygen concentration and P_ICO_2 values (mean ± SD) in each mask for varying flow rate

Mean ± SD		EcoLite with a reservoir		Reservoir mask		Reservoir mask (one valve open)	
		O_2 (%)	P_ICo_2 (mmHg)	O_2 (%)	P_ICo_2 (mmHg)	O_2 (%)	P_ICo_2 (mmHg)
Flow rate (L/min)	5	57.8 ± 8.0	3.14 ± 1.32	49.6 ± 4.6	1.87 ± 0.76	49.4 ± 4.6	1.95 ± 0.94
	8	67.0 ± 8.8	2.5 ± 1.16	55.5 ± 5.7	1.15 ± 0.70	55.2 ± 6.1	1.74 ± 0.85
	10	75.9 ± 9.9	2.08 ± 1.04	60.6 ± 6.3	0.90 ± 0.48	59.6 ± 5.6	1.34 ± 0.60
	12	83.8 ± 8.2	1.76 ± 1.07	64.4 ± 5.4	0.98 ± 0.67	62.3 ± 5.5	1.08 ± 0.55
	15	91.3 ± 5.6	1.20 ± 0.73	68.4 ± 5.5	0.70 ± 0.47	65.6 ± 5.1	0.92 ± 0.50

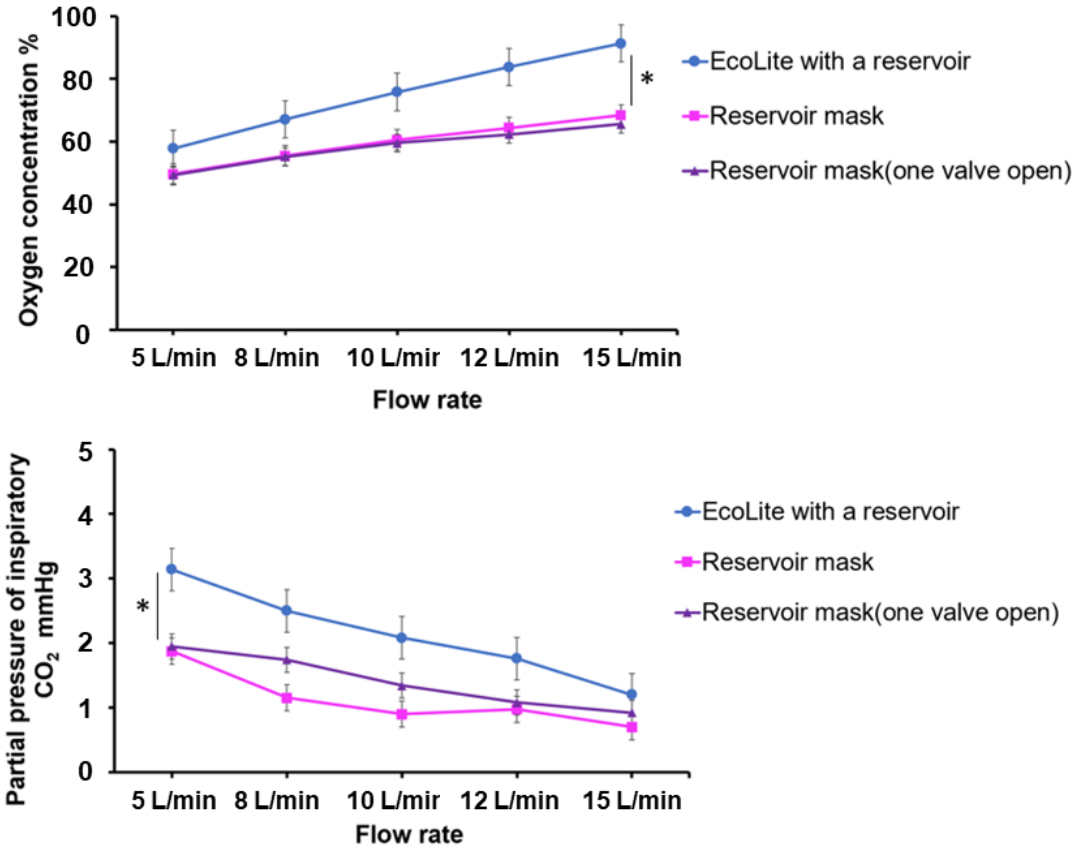

Figure 2. Changes in Oxygen concentration and P_ICO_2 versus oxygen flow rate with three different oxygen supply systems *p < 0.05 compared with the reservoir mask.

DISCUSSION

The study revealed that the EcoLite with a reservoir achieved a higher F_IO_2 concentration than the conventional reservoir mask among healthy volunteers due to its superior fit. A non-rebreathing mask with a reservoir bag achieved a high F_IO_2 despite the low oxygen supply flow rate. However, the fit of the mask is crucial, and the F_IO_2 decreases because of the increased air entrainment, when the flap valve is removed or loose [7].

Despite some trends, there was no significant difference in F_IO_2 and P_ICO_2 by number of the flap valves (one removed or not) on the conventional reservoir mask in this study. This is likely because, this study conducted on

healthy volunteers and there was no shortage of reservoir capacity due to strongly inhalation, so the number of flap valves was unlikely to have affected the measured values.

The EcoLite with a reservoir had an improved fit on the face due to the thermoplastic elastomer, which decreases the gap between the mask and face. Additionally, the mandibular fit was based on two patterns ("on chin position" and "under chin position"). Thus, the fit is maintained in various face sizes. The improved fit of the EcoLite resulted in a higher F_IO_2 compared to the conventional non-fitting mask.

However, the EcoLite with a reservoir caused higher CO_2 rebreathing compared to the reservoir mask at low oxygen flow rates. The EcoLite without a reservoir mask provided increased O_2 concentrations and lower $EtCO_2$ levels at lower oxygen rates, compared to the conventional masks within the 0–15 L/min O_2 range [8]. Sano et al. reported that the perioperative $EtCO_2$ levels were significantly higher with the EcoLite without a reservoir mask than with a control mask. Meanwhile, there were no significant differences in the $PaCO_2$ values among patients undergoing elective surgery [9]. However, these two reports are different from our study. First, only EcoLite without a reservoir was used. Second, they were and/or different cohorts. Therefore, this was the first study to evaluate the oxygenation and CO_2 reburning of the EcoLite with a reservoir bag.

The reservoir mask system has a high risk of rebreathing of exhaled air at lower O_2 flow due to the decreased air entrainment around the mask, despite the gap between the mask and the face. To avoid this, a non-rebreathing mask with a reservoir bag has flap valves to facilitate exhalation on both sides of the mask. The EcoLite also has the same safety system. Moreover, the valve is bidirectional and can be opened during inhalation if the flow rate is insufficient. We speculate that the situation in which the improved fitting reduces air entrainment from around the mask, although the safety valve, may explain our result that P_ICO_2 in EcoLite with a reservoir was higher than that in a reservoir mask. According to a study reporting the harmful effects on the body of exposure to low concentrations of CO_2, CO_2 concentrations ranging from 500 to 5000 ppm can lead to changes such as increased heart rate, elevated blood pressure, as well as symptoms like headaches, fatigue and difficulty concentration [10]. This CO_2 concentration of 500 to 5000 ppm corresponds to 0.38 to 3.8 mmHg assuming an atomospheric pressure of 760 mmHg. NIOSH (National Institute for Occupational Safety and Health) also recommends that the limit for CO_2 exposure is 3% for 15 minutes and 0.5% for 8 hours. These CO_2 concentrations of 3% and 0.5% correspond to respectively 22.8 and 3.8 mmHg in P_ICO_2 [11]. In this study, at low flow rate (5 L/min), the value of P_ICO_2 is 3.14 ± 1.32 mmHg for EcoLite with a reservoir, which is significantly higher than that of a conventional reservoir mask. Although this value of P_ICO_2 is lower than the NIOSH warning value, there is concern about the harmful effects of prolonged exposure and the possibility of an increase in the value due to changes in breathing conditions. Considering the absence of specific adverse events in this study, the results suggest that the risk of CO_2 rebreathing should always be considered, especially when using low oxygen flow rates. Healthcare workers including physicians were reported to have inadequate knowledge of oxygen therapy, especially reservoir bags [12], and we hope that the results of this study will be helpful to healthcare workers who provide oxygen therapy.

This study has some limitations. First, it was based on a small sample size and data from healthy volunteers. Second, F_IO_2 and P_ICO_2 were monitored; however, PaO_2, $PaCO_2$, and arterial blood pH were not. Further studies are needed to determine the appropriate O_2 flow to avoid CO_2 accumulation and hypercarbia in critically ill patients, especially those with respiratory failure.

CONCLUSION

The EcoLite with a reservoir provided improved oxygenation and a better fit than the conventional reservoir masks in healthy volunteers. However, the EcoLite with a reservoir might cause higher CO_2 rebreathing at low oxygen flow rates.

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