

ORIGINAL RESEARCH

Delivered Oxygen Concentrations of Two Nonrebreather Reservoir Masks

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Abstract

Background: High-concentration nonbreathing reservoir masks are frequently used for patients with hypoxemia but vary in shape, affecting mask fit. Mask fit affects the ability to inhale gas from the reservoir bag during inspiration and therefore makes it difficult to ensure a reliable concentration of oxygen delivered consistently to the patient. The EcoLite reservoir mask (EcoLite, Intersurgical, United Kingdom) reports a more consistent oxygen concentration delivery based on mask fit when compared with other products.

Methods: A bench study was conducted comparing the consistency of high oxygen concentration delivery via a conventional reservoir mask (Inspiron, Japan Medicalnext, Japan) and EcoLite. The study was performed using an electronic breathing simulator and a mannequin to simulate spontaneous breathing. Each mask was applied to the mannequin per the product instructions. An oxygen analyzer was placed in the simulated left bronchus, and oxygen was delivered through each mask at increasing flow. The delivered oxygen concentration was recorded for each procedure and measured 3 times.

Results: The EcoLite exhibited higher delivered oxygen concentrations at each oxygen flow and the simulator's inspiratory flow. The cumulative mean oxygen concentration across set parameters was 64% (SD ± 13) for the EcoLite and 50% (SD ± 10) for the Inspiron, with a significant difference ($P < .008$). Oxygen flow impact on delivered oxygen concentration revealed a difference between the EcoLite and Inspiron of P value $> .05$.

Conclusions: EcoLite provided an oxygen concentration consistently higher than that of the conventional product observed. This may be attributed to mask fit, valve assembly, and reservoir bag function. These results may impact clinical decisions in product choice and applications. Further studies are needed to assess the clinical impact of this product.

Keywords: nonbreathing mask, low-flow oxygen therapy, oxygen concentration

Introduction

Nonbreathing reservoir masks (NRMs) are used in patients with hypoxemia and have been used in respiratory management for severely hypoxic patients.¹⁻⁵ The NRM provides supplemental oxygen at high concentrations because of its design, which incorporates a one-way valve on each side of the mask that closes during inhalation and opens upon exhalation, and a one-way

valve between the mask and reservoir bag openings during inhalation and closing upon exhalation. This valve ensures a higher oxygen concentration on inspiration if the source flow to the device is adequate to meet the patient's inspiratory requirements.

A reservoir mask system utilizes an oxygen flow range of between 6 and 15 L/min to deliver an oxygen concentration of between 45% and 95%.⁶ However, to ensure

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This study was presented at the Open Forum of the American Association for RESPIRATORY CARE (AARC) Congress 2024 in Orlando, FL, United States.

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these concentrations, the reservoir mask must be used properly to maximize its function. In addition to the inspiratory flow requirements of the patient, the actual oxygen concentration delivered is also dependent upon the fit of the interface. Because reservoir masks vary in shape across manufacturers, the oxygen concentration delivered by these products has been reported to be variable as a result of issues related to mask fitness.⁷ The variability of oxygen delivery as a result of fit may impact the management of hypoxemic patients.⁸ When using a conventional NRM (Inspiron, Japan Medicalnext, Japan) with inadequate improvements in a patient's S_{pO_2} , upon switching to an EcoLite reservoir mask (EcoLite, Intersurgical, United Kingdom), we saw an acceptable recovery. For this reason, we decided to perform a study to identify the nature of this observed difference.

EcoLite has been reported to provide higher and more stable oxygen concentration delivery than commonly used nonrebreather masks.⁹ This difference may be related to the mask fit, which is unique in composition and design materials.⁹ The purpose of this study is to compare the difference in oxygen concentration provided by the EcoLite and Inspiron.

Methods

An electronic breathing simulator (HR1101; Series 1101 Breathing Simulator, Hans Rudolph) and a mannequin (Laerdal airway management trainer, Laerdal Medical) were used to simulate spontaneous breathing. An oxygen analyzer (Multigas/Flow unit DF-220R, Nihon Kohden) was attached to the simulated left bronchus, and the simulated right bronchus was completely obstructed (Fig. 1). The oxygen analyzer was calibrated before measurement began. After that, it was automatically calibrated every 2 h. The simulated bronchus was selected over the simulated trachea to isolate the measurement of oxygen concentration closer to the alveoli. The simulated left bronchus was chosen, as it was easier to connect to the mannequin. The oxygen flow meter is capable of supplying oxygen at a maximum flow of 15 L/min at 50 psi via an in-wall pipe system, and we used oxygen at a flow between the minimum 6 L/min and maximum 14 L/min, based on the reservoir mask specifications. Oxygen levels at the simulated left bronchus were measured through a sampling tube and displayed on a biological monitor (bedside monitor BSM-6000 series, Nihon Kohden) (Fig. 1). The sampling port flow was 200 mL/min and was not considered high enough to impact analysis accuracy. The reservoir bag for each mask was measured by using water. Each mask was placed on the face of the mannequin according to the product instructions, with prefilled reservoir bags.

Simulated spontaneous breath settings included: resistance 5 cm $H_2O/L/s$, compliance 80 mL/cm H_2O , rate

QUICK LOOK

Current knowledge

In oxygen therapy, it is known that the patient's ventilation status, oxygen flow, and mask fitting affect the concentration of inhaled oxygen. The reservoir mask system achieves oxygen concentrations of 45–95% using an oxygen flow range of 6–15 L/min. However, these concentrations vary depending on the patient's inspiratory flow and the inflow of air affected by the fit of the interface.

What this paper adds to our knowledge

Using mannequins with the same facial shape and under the same breathing conditions, we investigated the difference in oxygen concentration using 2 types of reservoir masks, and we were able to confirm that the EcoLite provided a higher delivered oxygen concentration. The EcoLite has a better-fitting mask than the Inspiron and has the potential to maintain a more effective concentration of delivered oxygen.

20 breaths/min, and inspiratory flow varied by changing the amplitude setting on the artificial lung throughout each trial. The resistance and compliance were set to normal ranges. The I:E ratio was set at 1:1.5, and the respiratory rate was 20 times/min, so the inspiratory time was 1.2 seconds each. An Inspiron and the EcoLite were used in this comparison (Fig. 2). We visually checked the mask fitting and confirmed the difference in the gaps (Fig. 2). We also checked the state of contraction of the reservoir bag. Oxygen was then delivered at 6, 8, 10, 12, and 14 L/min for each mask. The peak inspiratory flow of the HR1101 was set at 20, 30, 40, 50, 60, 70, 80, 90, and 100 L/min for each oxygen flow. Oxygen concentrations at the simulated left bronchial tube were recorded 3 times for each procedure. One minute was allowed for sampling stabilization for each observed measurement. There was a total of 270 tests (2 samples \times 3 tests per sample \times 5 oxygen flow settings \times 9 inspiratory flow settings = 270 tests total). The mean oxygen concentration across the 3 measurements was obtained, and the results of each condition were compared.

Statistical analysis

All analyses were performed using SPSS. To test for normal distribution of the variables, Kolmogorov–Smirnov tests of normality were completed. Descriptive statistics were examined and reported for continuous data as means and SD for all normally distributed variables. For variables that were not normally distributed, continuous data were reported as median and interquartile range. Since some of the data were not normally distributed, the Wilcoxon signed-rank test was used to determine if there was a

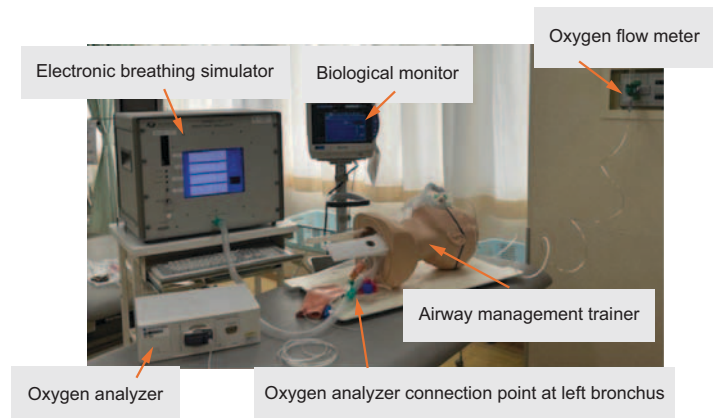


Fig. 1. Experimental setting.

statistically significant difference between the types of devices at a set flow. All statistical tests were 2-tailed and based on a 0.05 significance level.

Results

The mannequin mask fitting was observed as different between the EcoLite and Inspiron (Fig. 2). The bag capacity of each reservoir mask was 1,200 mL for the EcoLite and 1,000 mL for the Inspiron. EcoLite exhibited higher delivered oxygen concentrations at each oxygen flow and simulated inspiratory flow. Oxygen flow impact on oxygen concentration revealed a difference of 15–27% at an oxygen flow of 6 to 14 L/min, with a significant difference of $P < .05$ (Table 1, Fig. 3). For both masks, the delivered oxygen concentrations lowered as the simulated inspiratory flow increased (Fig. 4). Simulated inspiratory flow impact on oxygen concentration revealed a difference of 26% at an inspiratory flow of 20 L/min and decreased to 12% at an inspiratory flow of 100 L/min, both measures favoring the efficiency of the EcoLite when compared to the Inspiron (Fig. 4). The cumulative mean oxygen concentration across set parameters was 64% ($SD \pm 13$) for the EcoLite and 50% ($SD \pm 10$) for the Inspiron, with a significant difference ($P < .008$) between the 2 products. As the simulated inspiratory flow increased, the volume also increased. At 20 L/min for each device, the volume was around 280 mL, and at 100 L/min, the volume was around 1,400 mL. It was visually observed that the increase in simulated inspiratory flow and volume enhanced the contraction of the reservoir bag, and the EcoLite had better contraction of the reservoir bag. We found a statistically significant difference ($P < .05$) when comparing oxygen concentration differences between each mask at set flows (Table 1).

Discussion

In this study, we used mannequins to create the same breathing conditions and investigated the oxygen concentration supplied by Inspiron and EcoLite. EcoLite

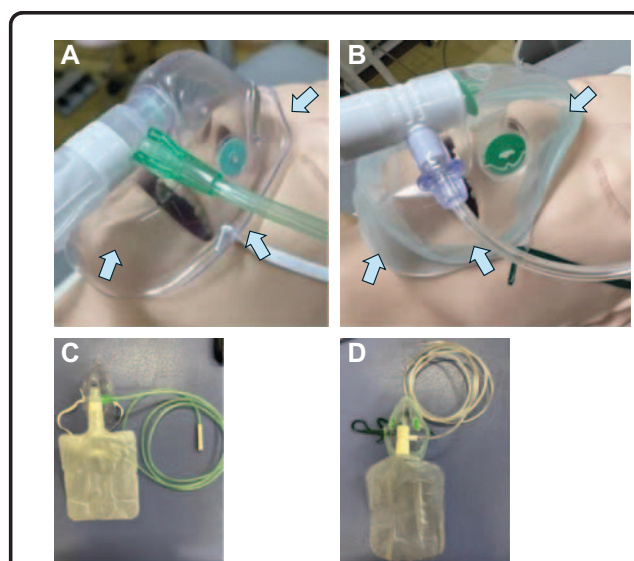


Fig. 2. Two of nonregreasing reservoir mask; Inspiron and EcoLite. The arrow indicates the area where the gap between the mask and the face was visually confirmed. We used each according to its respective instruction manual, but we could clearly see a gap in the Inspiron. (A) Fitting condition of Inspiron. There is a gap. (B) Fitting condition of EcoLite. There is almost no gap. (C) Full view of Inspiron. (D) Full view of EcoLite. The major difference between the two products was the mask shape; no other obvious differences were observed.

Table 1. Delivered oxygen concentrations each mask

	Oxygen flow (L/min)	Sample size	Oxygen concentration (%) min-max	Oxygen concentration (%) median (IQR)	P value
EcoLite	6	27	41-76	59 (52-63)	<.01
Inspiron	6	27	32-49	39 (36-44)	
EcoLite	8	27	46-86	66 (54-72)	<.01
Inspiron	8	27	36-59	45 (40-53)	
EcoLite	10	27	52-90	71 (54-74)	<.01
Inspiron	10	27	40-67	51 (44-59)	
EcoLite	12	27	53-96	76 (54-75)	<.01
Inspiron	12	27	40-70	52 (45-61)	
EcoLite	14	27	53-96	75 (56-79)	.005
Inspiron	14	27	42-81	60 (48-67)	

IQR, interquartile range.

was able to deliver a higher oxygen concentration than Inspiron.

A low-flow oxygen delivery system is defined as a system that delivers oxygen at a flow lower than the patient's actual inspiratory flow. Therefore, a low-flow system cannot accurately deliver a specific, constant oxygen concentration.¹⁰⁻¹⁶ The NRM is a simple oxygen delivery device that can deliver high concentrations of oxygen, even among low-flow oxygen delivery systems. Milross et al¹⁷ investigated the oxygen delivery of the Hudson OxyOne face mask and found that F_{IO_2} changed in a predictable way depending on ventilation and oxygen flow when the mask was fitted tightly. Yorozu et al used one type of NRM and created 3 mask-fitting patterns (loose, moderate, tight) and investigated the differences in inhaled oxygen concentration in each, finding that the looser the mask fit, the more air was inhaled and the lower the inhaled oxygen concentration.¹⁸

Based on these research results, it is known that the factors that affect high oxygen supply are mask fit, ventilation conditions, and oxygen flow. In our study, we investigated the oxygen concentration delivered by fitting 2 reservoir masks from different manufacturers to a mannequin model according to the product instructions and then conducting ventilation and oxygen flow under the same conditions. As the same mannequin was used, the facial shapes were the same, and even though the 2 types of reservoir masks were fitted in the same way, the fact that the EcoLite was able to deliver a higher oxygen concentration suggests that the EcoLite may have had better mask adhesion. This is thought to be because the design of the EcoLite incorporates an internal flange along the edge of the mask, which may have affected the entrainment of ambient air (Fig. 2). During the EcoLite test, the volume of air exchanged was slightly higher than during the Inspiron test, and there was a significant difference between the 2 products. This is thought to be because the volume is indirectly determined by a certain value of resistance, compliance, and respiratory rate (I:E ratio). When the mask does not fit well, the volume should normally decrease the oxygen concentration. However, the results of this study show that the oxygen concentration was higher with EcoLite. This may be evidence that the EcoLite has a better fit than the Inspiron.

The bag capacity of each reservoir mask was 1,200 mL for the EcoLite and 1,000 mL for the Inspiron. When the inspiratory flow setting of the simulator was 80 L/min or more, the volume was 1,100 mL or more, and the one-way valve installed in the mask of the EcoLite functioned,

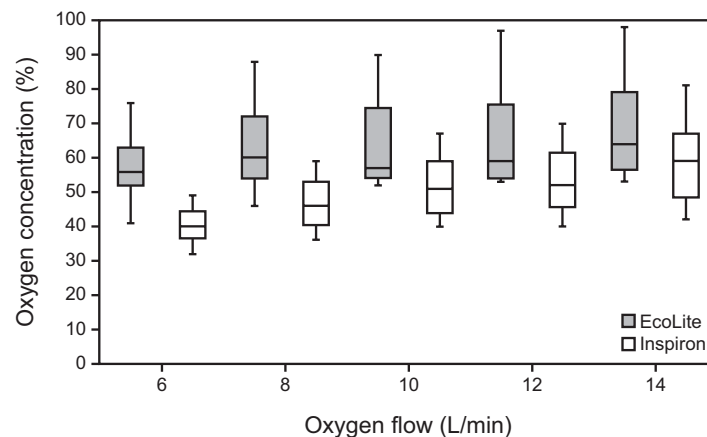


Fig. 3. Delivered oxygen concentration: a difference between each mask at 6–14 L/min oxygen flow. The box shows the interquartile range (IQR) from the first quartile (Q1) to the third quartile (Q3), and the central line represents the median (Q2). The “whiskers” extending from both ends of the box indicate the range from the minimum to the maximum value, excluding outliers. When oxygen flow was increased from 6 L/min in 2 L/min increments and oxygen concentration was measured, the EcoLite delivered 15–27% higher oxygen supply.

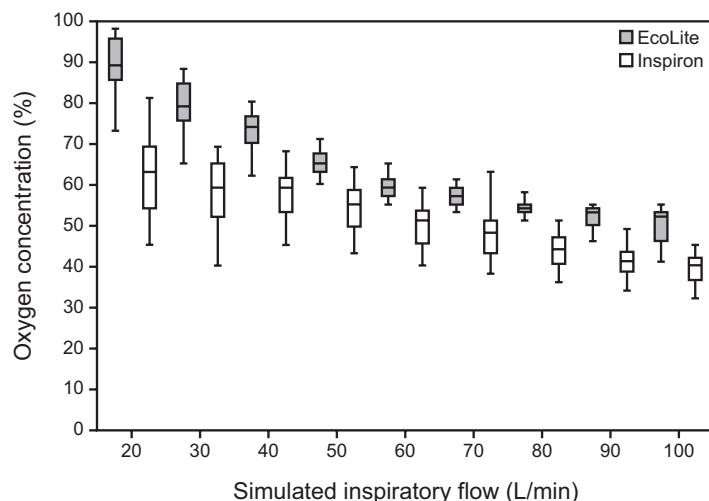


Fig. 4. Delivered oxygen concentration between each mask at different simulator flow. We set the flow on the simulator from 20 L/min to 100 L/min, which is considered to occur in respiratory failure, and confirmed the extent of oxygen delivery achievable with oxygen administration using both products. The EcoLite product provided higher oxygen concentrations at all flow settings simulator settings; resistance 5 cm H₂O/L/s, compliance 80 mL/cm H₂O, rate 20 breaths/min.

causing the reservoir bag to contract by more than two-thirds. This suggests that the mask fit was good. On the other hand, in the Inspiron, the one-way valve showed almost no movement under the same conditions, and the reservoir bag only contracted slightly. If the mask fit was good in Inspiron, the bag should have contracted under the same conditions. However, the fact that the bag did not contract shows that the gas in the bag was not being inhaled effectively, and as a result, the oxygen concentration delivered was thought to have become lower. It is thought that the mask fit may have affected the functional operation of the one-way valve, allowing air entrainment. If the fit of both masks is good and the reservoir bag contracts, the measured oxygen concentration may have been affected by the size of the reservoir bag. However, the contraction of the reservoir bag was different under the same conditions, so the mask fit and air entrainment were affected by the difference.

Because they are unable to provide precise oxygen concentrations in situations where high concentrations of oxygen are required, clinicians often choose advanced high-flow systems.^{5,19–21} These include venturi systems, high-flow nasal cannulas, and noninvasive ventilators. These systems require advanced technical expertise for setup and maintenance, and they also have high oxygen consumption and costs. The benefits of these high-flow devices have been confirmed in the literature on specific diseases, but they do not suggest an obvious inferiority of NRM in acute hypoxic states.^{22,23} NRMs are used as devices to support rapid response in acute situations

where hypoxia is detected or suspected and as oxygen supply devices during preintubation or sedation during procedures.^{24,25} We believe that the results of this study will be useful in making more effective use of this oxygen delivery device, which can be easily used by medical staff and provides high concentrations of oxygen.

Limitations

This bench study utilized a mannequin, which resulted in a set and specific fitting of each mask applied per manufacturer's recommendations in a static environment; respiratory rate, breathing pattern, anatomical shape of the upper respiratory tract, material of the mannequin, condition of the patient's skin, and facial shape. Measurements of mask fit based on manufacturer recommendations were beyond the scope of this investigation. The extent of leakage has not been investigated regarding mask fit. This model may not be the optimal model to universally identify the effect of mask fit. Future work may employ 3D printing models to represent a wider variety of facial shapes. There was no air flash between each measurement, so there is a possibility that this had an effect. If the adhesiveness of the 2 products is the same, the difference in the size of the reservoir bag is thought to affect the delivered oxygen concentration. It would be necessary to investigate whether the size of the reservoir bag affects the movement of the one-way valve. Also, the effects of carbon dioxide in exhaled air, humidity, and patient activity were untested. The lower flows used are

not typically seen in the clinical arena and were used for testing purposes only.

Conclusion

To the best of our knowledge, this is the first observational study using a simulation model to determine a difference in oxygen concentration supplied by Inspiron and EcoLite when the simulator's inspiratory and oxygen flow are varied. This study found that delivered oxygen levels significantly differed between the 2 products. Whether using the EcoLite or Inspiron, adequate management of mask fitting is fundamental in care. It was suggested that in oxygen therapy provided by NRM, mask fit is of significant clinical importance. Clinical application of this information may impact oxygen device selection and patient compliance. More research is warranted.

Acknowledgment

In this research, Dr. Lanny Inabnit provided invaluable assistance with statistical interpretation and the creation of graphs and other visualizations, making a significant contribution to this work. The authors express their heartfelt gratitude.

Author Disclosure Statement

No competing financial interests exist.

Funding Information

No funding was received for this article.

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