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Influence of Leakage from Non-Invasive Positive Pressure Ventilation Mask on FiO_2 Value Delivered by Home Oxygen Therapy Concentrator: A Bench Study on Simulating Patients with Chronic Obstructive Pulmonary Disease

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Abstract

Introduction: During the application of non-invasive positive pressure ventilation (NPPV) therapy in home mechanical ventilation (HMV), leaks in the NPPV mask may occur owing to the position of the mask due to conditions such as skin disorders. **Methods**: To investigate whether such a leak affects FiO_2 supplied to the alveoli, we simulated a patient with chronic obstructive pulmonary disorder during NPPV in HMV. In addition, FiO_2 was measured in the portion assumed to be the mouth and lungs while setting the flow of the oxygen concentrator and leak amount based on a previous study. **Results**: FiO_2 supplied to the lungs increased statistically significantly upon increasing the amount of leak ($P < 0.001$). Moreover, values measured for the mouth were similar. However, our results were different from those of a previous study. **Conclusions**: We observed that FiO_2 supplied to alveoli can be reduced by a leak in the NPPV mask. Because our results differ from those previously reported, we believe that further studies should reassess the selection of respirators and oxygen concentrators.

Keywords

Mask, Oxygen, Ventilation, Positive-Pressure Ventilation, Chronic Obstructive Pulmonary Disorder

1. Introduction

In recent years, the application of noninvasive positive pressure ventilation (NPPV) therapy in home mechanical ventilation (HMV) has increased [1]. In particular, NPPV is useful for patients with chronic obstructive pulmonary disease (COPD) [2] [3], which is treated with long-term home oxygen therapy (HOT) [4]. NPPV therapy may confer therapeutic effects, such as a reduction in respiratory work, sustained improvement of arterial blood gas status, reduction in hospitalization frequency, and improved survival and quality of life [5]. In addition, in NPPV therapy, ventilation is performed using a mask without tracheal intubation; thus, NPPV therapy facilitates the ability to have conversations and eating, and has benefits such as a lower risk of infection. However, as a condition for obtaining a therapeutic effect, it is imperative to fit the mask to the patient.

In NPPV, in contrast to intermittent positive-pressure ventilation (IPPV), FiO_2 depends upon complex factors such as the amount of ventilation and leak that is associated with patients in addition to the devices [6]. A study reported that leaks in the mask may occur because of altered positioning of the mask resulting from a skin disorder or selection of an inappropriate mask on NPPV enforcement [7]. Leaks around the mask can compromise the effectiveness of NPPV, but NPPV ventilators can compensate for leaks [8]. However, when HOT device and NPPV therapy are used in combination, since the ventilator and HOT device are independent circuit configurations, it is difficult to compensate for the loss in oxygen concentration in the air taken in due to the leak (**Figure 1**). Therefore, in this study, we simulated lungs of COPD patients to determine the extent to which FiO_2 supplied to the alveoli can be affected by the reduction in oxygen concentration due to a leak in the mask.

2. Methods

2.1. Experimental Materials and Methods

We had to provide spontaneous respiration because we simulated COPD patients in this study. We used the following method, as described in a previous study [9]. First, the left lung of the TTL model lung (Training and Test Lung®, Michigan Instruments, Kentwood, MI, USA) was used to produce mandatory ventilation, and the right lung provided an inspiratory effort. Spontaneous respiration can be produced by attaching a lift bar between the left and right lungs. Mandatory ventilation of the left lung was performed using LTV-1000 (Pacific Medico, Tokyo, Japan). The ventilator was set in pressure-control continuous

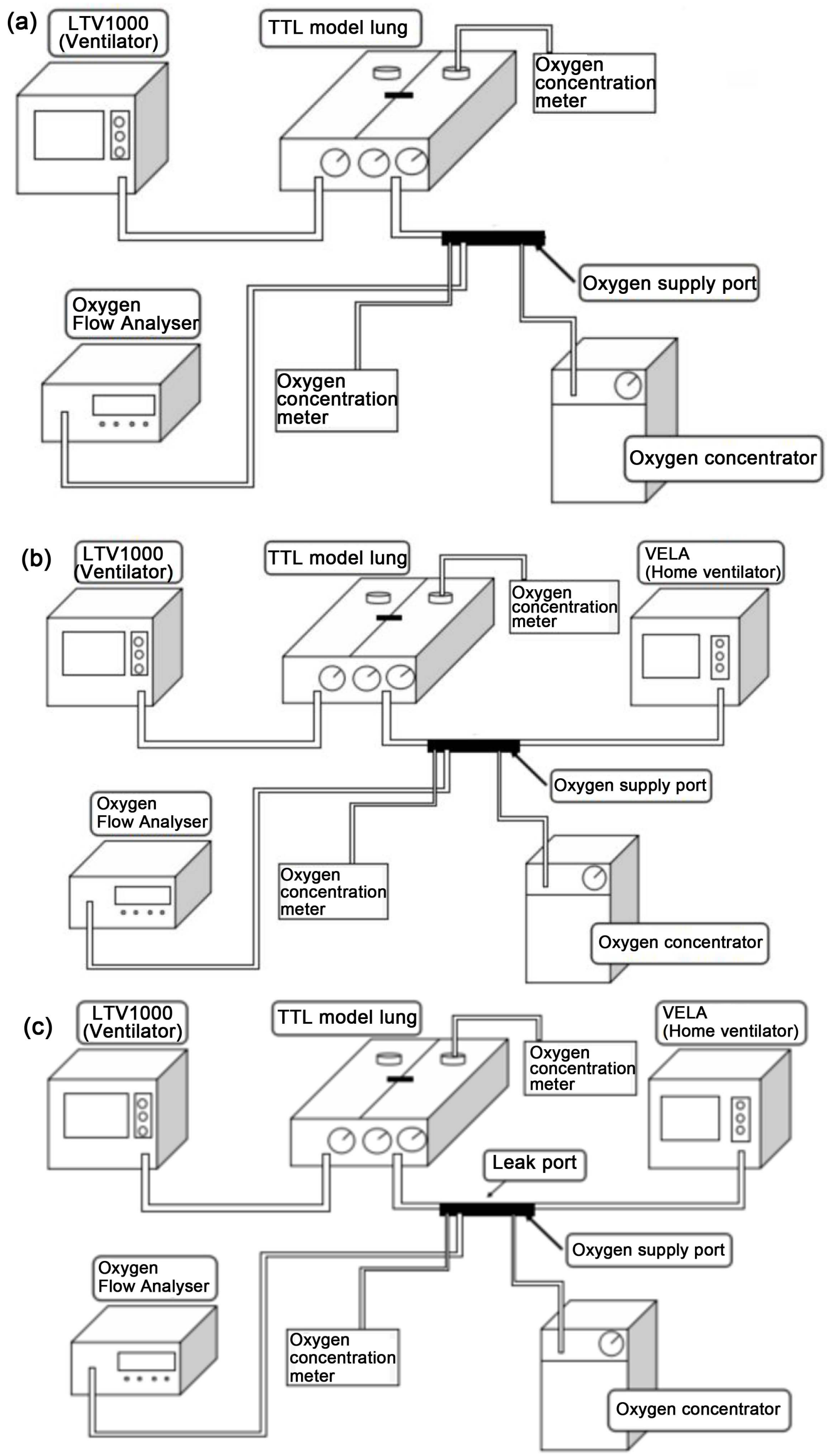

Figure 1. Circuit diagram. To simulate the NPPV mask, we developed an adapter with an O_2 supply port and a leak port attached between the inspiration side circuit of VELA and Y piece. Through this adapter, O_2 was supplied to the TTL model lungs and leaked. The left side of the figure of the TTL model lung represents the left lung, the right represents the right lung. Circuit diagrams show HOT only (a), using VELA without leakage (b), and spontaneous respiration with leakage (c).

mandatory ventilation (PCV-CMV) mode, spontaneous respiration was set at 12 times, inspiratory pressure was set at 15 cmH_2O, and inspiratory time was set at 1 sec. In the right lung, spontaneous respiration was enabled using VELA (Care Fusion 207, Palm Springs, CA, USA) to simulate respiration in patients with COPD. VELA was set in the NPPV-pressure support ventilation (PS) mode. PS was set at 10 cmH_2O, positive end-expiratory pressure (PEEP) was set at 5 cmH_2O, and the flow trigger was set at 2 L/min. Airway resistance in the left lung of the TTL model lung was set at 20 cmH_2O to produce spontaneous respiration, and compliance was set at 0.05 L/cmH_2O. Airway resistance in the right lung of the TTL model lung was set at 50 cmH_2O to simulate lungs of patients with COPD, and compliance was set at 0.04 L/cmH_2O. To simulate the leaks from NPPV mask, we developed an adapter with an O_2 supply port and a leak port, and attached it between the inspiration side circuit of VELA and the Y piece. Through this adapter, O_2 was supplied to the right lung of the TTL model lungs and leaked (**Figure 1**).

2.2. Method of FiO_2 Measurement Simulating No Air Leak Using HOT Device and VELA

For HOT, an oxygen concentrator (O_2 Green SHIZUNE IT-5 L, TERUMO, Japan) was used. Six flow rates of O_2 (0.5, 1, 2, 3, 4, 5 L/min) in the TTL model lung were used. The oxygen concentration meter was placed at two locations: the right lung of the TTL model lung, which simulated a COPD patient, and the connection port of the circuit (simulated patient mouth), used to measure FiO_2 after 5 minutes. In order to obtain a stable O_2 value, O_2 was passed through the O_2 supply port for 5 minutes. The O_2 measurement was repeated ten times for each flow setting. For the FiO_2 measurement of the simulated patient's mouth, the combined Y portion was measured using an oxygen concentration meter. Furthermore, after performing the measurements for 5 minutes, in order to eliminate the accumulated O_2, FiO_2 in the left lung of the TTL model lung was released into room air until the O_2 concentration reached 21%, and then O_2 supply was initiated.

2.3. FiO_2 Measurement Method Simulating Air Leak Using HOT Device and VELA

In order to simulate NPPV by VELA, oxygen was supplied from the oxygen concentrator to the lungs of the TTL model lung and at the same time a ventilator was attached. In addition, oxygen at concentrations ranging from 0.5 to 5 L/min was released from the adapter. From the summed-up value of the ventilation volume per minute from the respirator and the oxygen volume per minute in the oxygen concentrator, leaked at 5 L/min, the leak amount was precisely measured using the flow analyzer (PF-300, Ver. 3.1, imt Medical, Switzerland). From there, FiO_2 was measured for 5 minutes in the TTL model lung part and Y piece part. Measurements were repeated 10 times for each setting.

2.4. Statistical Analysis

The FiO_2 measurements using HOT device and VELA simulating each state were compared between three groups of leaks: 0 L/min, 5 L/min, and 10 L/min. For comparison between groups and all variables, multiple comparisons were performed by the Tukey HSD method. Statistical analyses were performed with statistical software "R" (Version 3.5.0, The R Foundation for Statistical Computing, Vienna, Austria), and $P < 0.01$ was considered statistically significant.

3. Results

When supplying O_2 to the lungs using the oxygen concentrator alone, FiO_2 > 90% was obtained at an O_2 flow rate of 4 - 5 L/min. At an O_2 flow rate of less than 4 L/min, FiO_2 was 88.9% at 3 L/min, 82.3% at 2 L/min, 60.8% at 1 L/min, and 35.9% at 0.5 L/min. When the O_2 flow rate was set at less than 3 L/min, FiO_2 was markedly decreased. Furthermore, when NPPV therapy was used in combination, FiO_2 decreased to 28% to 41% at an O_2 flow rate of 2 to 5 L/min. The largest reduction in FiO_2 using NPPV therapy combined with HOT device was 55.5% at 3 L/min O_2 flow rate (**Figure 2**).

When leakage was 5 or 10 L/min and O_2 flow rate was 3 to 5 L/min, FiO_2

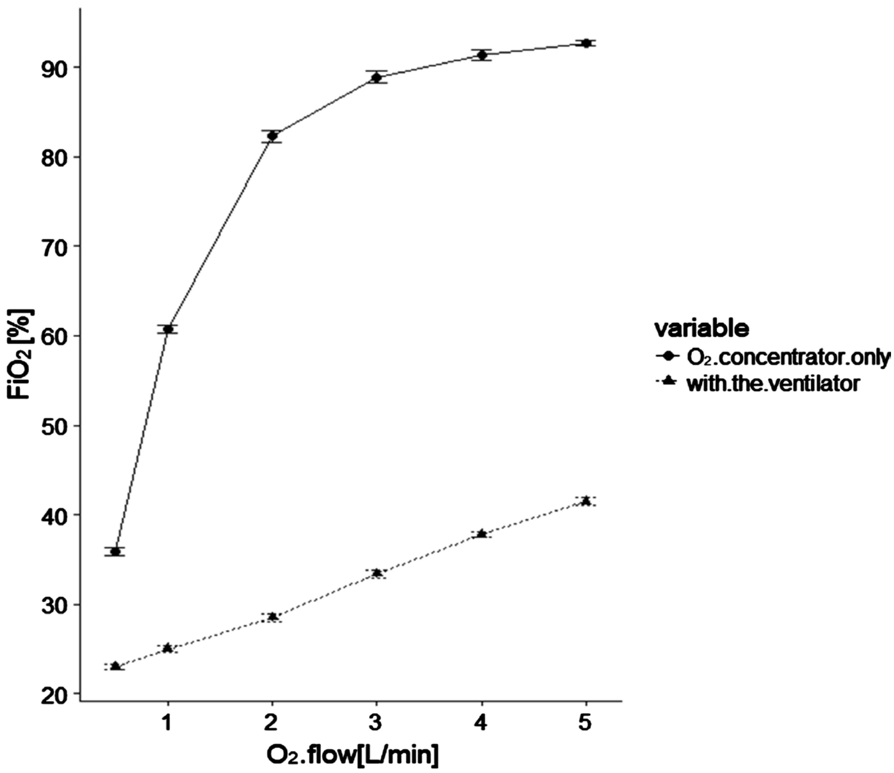

Figure 2. Variation in FiO_2 with O_2 flow. Using the oxygen concentrator alone, more than 90% of FiO_2 was obtained at an O_2 flow rate of 4 - 5 L/min. At O_2 flow rates of less than 4 L/min, FiO_2 was 88.9% at 3 L/min O_2, 82.3% at 2 L/min O_2, 60.8% at 1 L/min O_2, and 35.9% at 0.5 L/min O_2. When the O_2 flow was less than 3 L/min, FiO_2 markedly decreased. When using a ventilator, the highest reduction in FiO_2 was 55.5% at an O_2 flow rate of 3 L/min.

decreased by approximately 3% in all cases. Thus, when the leakage increased from 0 to 10 L/min, the maximum FiO_2 reduction was approximately 6% (Table 1, Figure 3).

However, FiO_2 decreased by 2.8% at 1 L/min O_2 flow and 1.4% at 0.5 L/min O_2 flow when the leakage was increased from 0 to 10 L/min. At low rates of O_2 flow, FiO_2 was minimally affected by the leakage (Table 1, Figure 3).

These results revealed a marked difference between each leak amount, and

Table 1. Estimation of FiO_2 in lungs imitating an NPPV mask leak.

Leak [0 L/min]		Leak [5 L/min]		Leak [10 L/min]	
O_2 fLow [L/min]	FiO_2 [%/min]	O_2 fLow [L/min]	FiO_2 [%/min]	O_2 fLow [L/min]	FiO_2 [%/min]
0.5	23.0	0.5	22.2	0.5	21.6
1	25.0	1	23.6	1	22.2
2	28.5	2	26.3	2	23.9
3	33.4	3	31.0	3	27.7
4	37.8	4	35.2	4	31.5
5	41.5	5	39.1	5	35.2

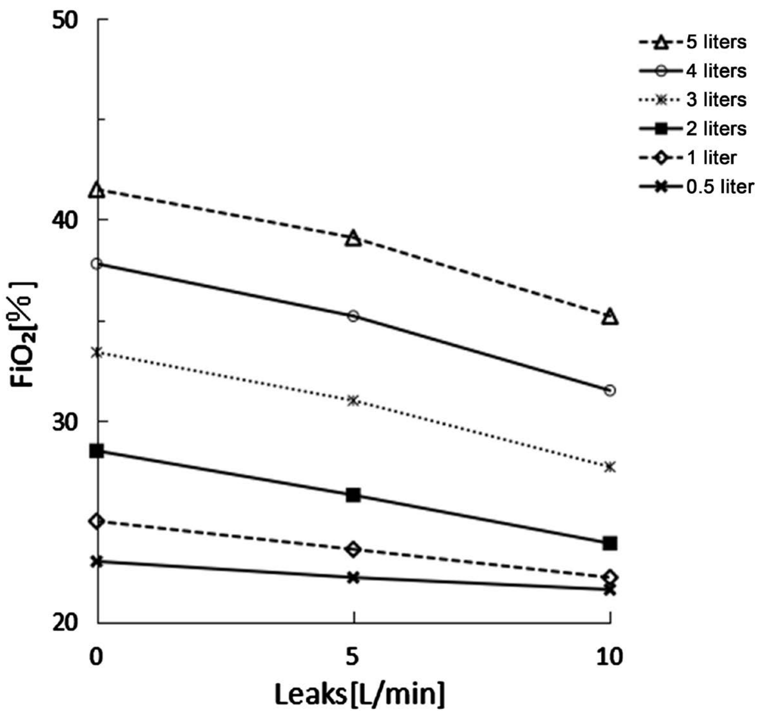

Figure 3. Comparison of FiO_2 with changes in leakage and O_2 flow. When comparing 5 and 10 L/min rates of leakage with 3 and 5 L/min O_2 flows, we observed that FiO_2 decreased by approximately 3% in both leakage cases. Thus, when the leakage increased from 0 to 10 L/min, a maximum reduction of approximately 6% of FiO_2 occurred. However, FiO_2 decreased by 2.8% at 1 L/min O_2 flow and 1.4% at 0.5 L/min O_2 flow when the leakage increased from 0 to 10 L/min. At low rates of O_2 flow, FiO_2 was not markedly affected by leakage.

indeed, there was a significant difference in FiO_2 ($P < 0.001$) (**Table 1**, **Figure 3**).

4. Discussion

This study differs from previous study by Goutorbe *et al.* (2013) in two respects. First, HOT device has not been used in the previous study, but in this study, HOT device was used to measure lung oxygen concentration. Second, in the previous study, an oxygen cylinder was connected to the ventilator, but in this study, oxygen concentration was measured by connecting the HOT device to the respiratory circuit instead of the ventilator. Here, it is worthwhile to note that in Japan, oxygen therapy at home is performed using NPPV therapy and HOT device in combination, and the HOT device is connected to a ventilator circuit.

Three noteworthy points were confirmed in this study. First, the FiO_2 value when using NPPV therapy and HOT device was clearly lower than the FiO_2 value using only HOT device. The difference was the maximum when the O_2 flow rate was 3 L/min. Second, upon setting the O_2 flow rate at less than 1 L/min, the FiO_2 value markedly decreased. Third, the FiO_2 value decreased as the leak amount increased. This phenomenon has not been observed in the previous study.

Regarding the first observation, at an O_2 flow rate of 5 L/min and using only HOT device, the FiO_2 was 93%, and a difference of approximately 51% was observed compared to the measurement obtained using a mechanical ventilator with HOT device. A maximum difference of about 55% was observed at a flow rate of 3 L/min. When O_2 was delivered in combination with a ventilator in a previous study, FiO_2 was approximately 39% in the absence of leakage and at an O_2 flow rate of 4 L/min. In the present study, the FiO_2 was approximately 38%, which is not a substantial difference. However, it is important to note that a maximum reduction in FiO_2 of 55.5% is observed when using HOT device with a mechanical ventilator, with an O_2 flow rate of 3 L/min or more, as compared to the FiO_2 obtained when HOT device is used alone.

Regarding the second observation, in addition to the performance of the adsorptive oxygen concentrator, the maximum ventilation volume of the TTL model lung is thought to be related to the performance. Because the maximum ventilation volume of the TTL model lung used in this study was 2 L, when the O_2 flow was set to less than 1 L/min, the lungs were not sufficiently filled with oxygen, as measured at 5 minutes. Therefore, it is thought that FiO_2 was markedly reduced at O_2 flow of less than 1 L/min. When we set the O_2 flow at 1 L/min and measured FiO_2 for 30 minutes twice, then similar values were obtained compared with measurements recorded for 5 minutes. Thus, we found that the FiO_2 concentration was difficult to increase in the simulated lung at an O_2 flow rate of less than 1 L/min. In the guidelines for respiratory therapy, it remains unclear how much FiO_2 decreases when a mechanical ventilator is added to an oxygen concentrator.

As regards the third observation, this difference is thought to be due to the difference in the mode of oxygen supply. In the previous study, an oxygen cylinder was used, and O_2 was mixed directly from a ventilator and sent to the simulated lung. Therefore, FiO_2 increased despite the rate of leakage increasing from 5 to 10 L/min, at O_2 flow rates of 1, 2, and 4 L/min. This is considered to be a problem when the leak amount is adjusted. Although an effect of the leak on FiO_2 has been reported previously by Miyoshi *et al.* (2005), the reduction in FiO_2 when using HOT device has not yet been clarified. Furthermore, in the study by Goutorbe *et al.* (2013), the increase in FiO_2 with an increase in the leak amount could not be confirmed. By contrast, in this study, we mainly considered home care in Japan, so we used HOT device to supply O_2 to the middle of the inspiratory side circuit of VELA. In this research method, it is considered that the cause of O_2 decrease that cannot be compensated by the leakage from the HOT device occurs due to the difference in the method of mixing air and O_2. Therefore, it was found that when the O_2 flow rate was 3 L/min or more, FiO_2 decreased by about 6% as the leakage increased at this flow rate (**Table 1**).

O_2 is supplied through a piping in the clinical setting. In our study, O_2 was supplied from HOT device because there is no oxygen piping facility at home. In a previous study, O_2 was supplied on the same principle as piping from a ventilator [9]. This is an indicator when using respiratory equipment in the hospital. We believe that this research provides very useful and important knowledge for home medical applications.

In our study, important findings on the use of HOT device in combination with a ventilator have been reported, but there are some limitations to this study. First, we simulated COPD patients using TTL model lungs, but we have not studied this phenomenon in humans. Therefore, inter-individual differences such as gender and physical differences were not reflected in the reduction of FiO_2. We expect to obtain more robust results in future by conducting the same experiments on humans and increasing the sample size.

Second, errors in FiO_2 measurement may occur due to the performance of the ventilator. Currently, there are many types of ventilators used at home care, and the performance of the equipment varies from manufacturer to manufacturer. Future research is warranted to identify the correct FiO_2 value by performing a number of validation experiments using various types of ventilators. Third, even for the same ventilator, it is necessary to compare the difference between FiO_2 supplied from oxygen piping and FiO_2 supplied from HOT device. In the previous study, the measurement was based on the former method, so the result showed that FiO_2 increased at a leakage rate of 10 L/min compared to a leakage rate of 5 L/min. In this study, different findings were obtained using the latter method. This may have been caused by different oxygen supply methods. We believe that this discrepancy can be resolved by performing more comparative experiments. Our current research provides scientific evidence to obtain multiple measurements of FiO_2 reduction caused by leaks when using HOT device in the future.

5. Conclusion

In this study, we observed that FiO_2 decreases because of a leak in the NPPV mask. Moreover, we measured the FiO_2 for each oxygen flow rate supplied from the oxygen concentrator and the reduction in FiO_2 with the use of a mechanical ventilator. However, our results differ from those of a previous study; therefore, we believe that further studies should be conducted using the same method of oxygen supply as that used in the previous study. To elucidate these differences, it will be important to reconsider the selection of respirators and oxygen concentrators.

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