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A Pilot Study Comparing Two Oxygen Delivery Methods for Patients' Comfort and Administration of Oxygen

Gil Jun Lee[1,*], Sei Won Lee[2,*], Yeon-Mok Oh[2], Jae Seung Lee[2], Sang-Do Lee[2], Choongsoo S. Shin[3,#], and Tae Soo Lee[3]

[1]Gil Jun Lee, MS

- Contributions: Literature search, Data collection, Study design, Manuscript preparation
- E-mail: gjlee@sogang.ac.kr

[2]Sei Won Lee, MD, PhD

- Contributions: Literature search, Study design, Analysis of data, Manuscript preparation
- E-mail: seiwon@amc.seoul.kr

[2]Yeon-Mok Oh, MD, PhD

- Contributions: Study design, Analysis of data, Review of manuscript
- E-mail: ymoh55@amc.seoul.kr

[2]Jae Seung Lee, MD

- Contributions: Literature search, Study design, Review of manuscript
- E-mail: jsdoc1186@hanmail.net

[2]Sang-Do Lee, MD, PhD

- Contributions: Literature search, Study design, Review of manuscript
- E-mail: sdlee@amc.seoul.kr

[3,#]Choongsoo S. Shin, PhD: Corresponding Author

- Contributions: Study design, Manuscript preparation, Review of manuscript
- E-mail: cshin@sogang.ac.kr
- TEL: +82-2-705-8825, FAX: +82-2-712-0799

[3]Tae Soo Lee, PhD

- Contributions: Literature search, Manuscript preparation, Review of manuscript
- E-mail: tslee@sogang.ac.kr

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There is no commercial relationship which may lead to a conflict of interests in this study.

1. Graduate School of Sogang University

1 Shinsu-Dong, Mapo-Gu, Seoul, 121-742, Republic of Korea

2. Department of Pulmonary and Critical Care Medicine, Asan Medical Center, University of Ulsan College of Medicine

88, Olymipc-ro 43-gil, Songpa-gu, Seoul, 138-736, Republic of Korea

3. Department of Mechanical Engineering, Sogang University

1 Shinsu-Dong, Mapo-Gu, Seoul, 121-742, Republic of Korea

*These authors contributed equally to this study.

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Abstract

Background: The traditional oxygen delivery methods for oxygen therapy are continuous flow oxygen (CFO) and demand oxygen delivery (DOD); however, wastage of oxygen is considerable in CFO, while DOD is uncomfortable for patients. Synchronized DOD (SDOD), which was designed to overcome the drawbacks of both CFO and DOD, supplies oxygen according to the patient's breathing pattern and the desired oxygen-saving. This study was conducted to examine the overall performance of SDOD in terms of oxygen saturation (SpO_2), patients' comfort, and oxygen saving ratio (SR).

Methods: Study subjects were patients who required oxygen for chronic obstructive pulmonary disease (COPD) or pneumonia. Patients received oxygen through nasal prongs by CFO and SDOD for 30 minutes each. SpO_2 was measured every 10 minutes by pulse oximetry, and subjects recorded their level of comfort after 30 minutes. The flow rate of discharged oxygen was recorded to calculate SR.

Results: Ten patients (median age, 68 years; range, 56–86 years) were enrolled. The SpO_2 of patients during SDOD (97±2%) was similar to that during CFO (96±3%) with no statistically significant difference ($p=0.53$). Patients reported SDOD to be more comfortable than CFO. Comfort score of subjects treated with SDOD was 7.05±2.07 (0: very uncomfortable, 10: very comfortable); this was significantly higher ($p=0.02$) than the comfort score (5.20±1.83) of subjects treated with CFO. The inputted SRs set by clinicians were very similar to calculated SRs.

Conclusion: SDOD appears to be more suitable for oxygen therapy than CFO when considering SpO_2, patients' comfort, and SR.

Key words: oxygen therapy, synchronized demand oxygen delivery, continuous flow oxygen, SpO_2, discomfort, saving ratio

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Introduction

Oxygen therapy is an essential treatment for patients with hypoxemia. Almost any kind of acute severe respiratory disease, such as pneumonia, COPD, acute exacerbation of asthma, and pulmonary edema, can cause hypoxemia and necessitate oxygen supplementation. Oxygen supplementation has also been proved to be effective in treatment of chronic respiratory diseases. Long-term oxygen therapy (LTOT) can improve the survival of COPD patients with severe hypoxemia.[1-3] Ambulatory oxygen therapy also improves the exercise capacity of patients with interstitial lung diseases.[4,5] Because patients, who require such treatment, need it most of the time in their daily lives, the comfort of oxygen treatment is very important to the patients.

There are two common methods for oxygen therapy: continuous flow oxygen (CFO) and demand oxygen delivery (DOD), and both methods have their inherent shortcomings. CFO involves considerable wastage of oxygen because it supplies oxygen to patients during both inhalation and exhalation. CFO can restrict patients' activities because a large oxygen cylinder is required to compensate for the wasteful continuous delivery of oxygen. DOD is a relatively recent oxygen-conserving strategy that reduces wastage by delivering oxygen only during inhalation. Due to this, DOD may also reduce the volume of oxygen needed for portable oxygen delivery with the reduced number of oxygen cylinders. However, DOD can make patients uncomfortable because of the abrupt onset of oxygen supply at the beginning of inhalation.

Synchronized DOD (SDOD), a new oxygen delivery method, was developed and modified in our previous studies to overcome the drawbacks of both CFO and DOD.[6, 7] SDOD offers patients a greater level of comfort by delivering oxygen in a smooth sinusoidal pattern that is synchronized to their breathing; in addition the method permits oxygen conservation at

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different levels that can be set by physicians or patients.[6, 7] According to the study by Lee et. al. published in the March 2013 issue of Respiratory Care, the majority of subjects who had no respiratory disease were more comfortable with the sinusoidal curve of SDOD than with the pulsed pattern of DOD.[6] Nevertheless, the study on the comfort level of patients with respiratory diseases should be warranted because the comfort level of the patients might be different from that of subjects with no respiratory diseases.

The purpose of this study was to examine the overall performance of SDOD in terms of Saturation of peripheral oxygen (SpO_2), patients' comfort level, and oxygen saving ratio (SR). The following 3 hypotheses were tested (1) the SpO_2 levels of patients are not different under CFO and SDOD, (2) the comfort levels of patients are not different under CFO and SDOD, and (3) SDOD could reduce oxygen wastage.

Methods

Subjects

Subjects, who were admitted to the respiratory care center with SpO_2 less than 90% on room air and needed oxygen supplementation, were enrolled for this study. This was a pilot study for which we planned to enroll only 10 subjects. The study was reviewed and approved by the Institutional Review Board of Asan Medical Center (S2012-1904-0006). All subjects received a thorough explanation of the experimental procedures before signing informed consent forms.

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SDOD Device

SDOD was designed, delivered, and studied using a bench model previously described in other studies[6, 7]; thus, only a brief description is given here. SDOD, which uses a proportional valve to control oxygen flow rate, begins to supply oxygen just before inhalation in accordance with a sinusoidal discharge curve (Figure 1), unlike DOD which delivers oxygen abruptly only after sensing the onset of inhalation. SDOD monitored and recorded patient's breathing signals by using the pressure sensor. Based on the recorded breathing signal, SDOD determined the time to open the valve to supply oxygen smoothly before the inhalation. Thus, SDOD is expected to improve patient comfort during oxygen therapy. Moreover, SDOD has been designed to deliver oxygen by 4 delivery modes to conserve oxygen according to set saving ratios. [6, 7]

SDOD uses 4 oxygen delivery modes according to the inputted level of oxygen-saving (Figure 2).[6, 7] The first and second modes supply oxygen in a sigmoid pattern that peaks before inhalation. The third mode supplies oxygen before inhalation along a sigmoid curve that gives way to a pulsed pattern at the onset of inhalation. The fourth mode, which is similar to DOD, provides pulsed oxygen delivery at the beginning of inhalation. Therefore, SDOD can supply oxygen in different modes to achieve the desired saving ratio set by patients or clinicians.

The SDOD device was reduced in size (length: 330 mm, width: 230 mm, height: 150 mm, weight: 2.5 kg) and made portable for this study when compared to the previous bench model of the SDOD which consists of a mechanical respiratory simulator and the SDOD device. The device had previously been tested on the mechanical respiratory simulator, which mimics the human respiratory system, before being used on human subjects in the present study. Figure 3 shows the schematic of the SDOD device, which consisted of 3 components: a

RESPIRATORY CARE Paper in Press. Published on December 24, 2013 as DOI: 10.4187/respcare.02937

direct-acting miniature solenoid valve (RB2-0139; Numatics Inc., MI, USA) that supplies oxygen in a pulsed pattern; a miniature proportional valve (VSONIC-3S11-Q8; Parker, Cleveland, OH, USA) that delivers oxygen in a sinusoidal pattern; and the NI LabVIEW 2010 system design software (National Instruments, TX, USA) that controls the SDOD device.

A saving ratio is defined as the ratio of prescribed flow over supply flow. CFO does not save oxygen because it supplies oxygen continuously at the same flow rate as prescribed by the clinician. In other words, the saving ratio of CFO is equal to 1. On the other hand, a saving ratio as high as 3.4 is seen in DOD, which was designed primarily to conserve oxygen.[8] DOD is therefore widely used for treating COPD patients because the cost of oxygen is an important factor in the choice of treatment method.

The average supply rate was calculated by integrating the actual flow of oxygen over the period of each experiment; the prescribed flow rate was then divided by the calculated average supply rate to derive the actual saving ratio. The actual saving ratio was compared with the input saving ratio, which is the saving ratio inputted to the SDOD algorithm by patients, clinicians, or manufacturers.

Study Design

CFO and SDOD were tested on all 10 subjects in a randomized order. The study consisted of the following 3 steps: (1) Oxygen was administered to subjects via nasal prongs for 30 min by either CFO or SDOD; (2) SpO_2 was measured every 10 min using a Fairy-A2 pulse oximetry (ShenZhen HeXin ZONDAN Medical Equipment Co. Ltd., Guangdong, China); and (3) Subjects were asked to score the degree of their discomfort on a scale from 0 (very

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uncomfortable) to 10 (very comfortable) after 30 min using visual analogue scale (VAS) shown in Figure 4. The subjects were asked to be seated or reclined with no physical activity during the oxygen treatment. Oxygen delivery was interrupted for 10 minutes between CFO and SDOD when subjects were switched over from one to the other, to allow SpO_2 to drop to pre-treatment levels. The SDOD device supplied oxygen by the first or second mode using sigmoid time-dependent oxygen profiles in this study. The actual flow rate of discharged oxygen was recorded to calculate the actual saving ratio.[7] Oxygen flow, when subjects were put on CFO, was set at the rate prescribed for individual subjects.

Statistical Analysis

SpO_2 and the comfort level of subjects were compared between the 2 treatment methods by Wilcoxon signed ranks test. All statistical analyses were performed using SPSS® Version 18.0 for Windows (SPSS Inc.; Chicago, IL, USA). A p value of < 0.05 was considered statistically significant.

Results

Ten subjects were enrolled in the study. There were 9 men and 1 woman, with a median age of 68 years, ranging from 56 to 86 years. All patients were examined after clinical stabilization with regular breathing and $SpO2 \geq 90\%$ by low oxygen delivery via nasal prong on bed. The demographic data of all subjects is summarized in Table 1.

The SpO_2 of each subject after 30 min of treatment by each oxygen delivery method is summarized in Figure 5. The mean SpO_2, as measured by pulse oximetry after 30 min of oxygen treatment by SDOD, was 97 ± 2 %. When compared to that the value of SpO_2 under CFO, There was no difference of SpO_2 between two methods ($p = 0.53$).

Subjects found SDOD to be more comfortable than CFO. The comfort score of subjects after 30 min of oxygen treatment by SDOD was 7.05 ± 2.07; this was significantly higher ($p = 0.02$) than the comfort score of 5.20 ± 1.83 after CFO treatment (Figure 5).

The actual saving ratios achieved by SDOD, as calculated from the recorded flow of oxygen, were very similar to the saving ratios inputted by clinicians (Figure 6). This indicates that SDOD can be adjusted to achieve set levels of oxygen-saving preferred by users. The mean actual saving ratio was 1.90; this means that a supply flow rate of approximately 1 L/min, delivered by the SDOD method, should be enough to treat a patient who has been prescribed oxygen at the rate of 1.9 L/min.

Discussion

The present study investigated the performance of the SDOD device, which was driven by a PC and LabVIEW, in patients with respiratory disease by conducting a bedside bench study. The SpO_2 of subjects on SDOD was compared with that of the same subjects on CFO, to assess the efficacy of SDOD in patients of COPD or pneumonia. Our results show that 30 min of oxygen treatment by SDOD method could raise SpO_2 to a desirable level. Furthermore, mean SpO_2 in subjects on SDOD was statistically similar to that in subjects on CFO. These results indicate that the SDOD device does indeed provide patients with an adequate supply of oxygen, and thus could replace CFO as the preferred method of oxygen therapy.

Almost all subjects found SDOD to be more comfortable than CFO after 30 min of treatment, and the difference was statistically significant (Figure 4). The level of comfort can

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be an important determinant in choosing the method of oxygen delivery, and SDOD appears to be more suitable than CFO based on the results of this study, especially for COPD patients, most of whom require long-term treatment.

The cost of oxygen has become a significant issue in view of the widespread application of LTOT, and SDOD assumes importance in this scenario by providing the additional benefit of oxygen conservation. The average saving ratio of SDOD was approximately 2 in our study. The saving ratio of SDOD is lower than that of DOD devices that focus entirely on conserving oxygen. However, SDOD offers the simultaneous advantages of oxygen conservation and a high level of comfort during treatment.

SDOD allows smaller oxygen carriers to be used because it consumes less oxygen than CFO. The resultant decrease in the size of the oxygen cylinder can greatly improve patients' mobility. Thus, SDOD not only makes oxygen treatment more cost-effective according to less wasted oxygen, but also enhances the ability of patients to participate in physical activities because the size of the oxygen cylinder could be reduced by SDOD.

The reason that oxygen was supplied to the subject using the first or second mode of SDOD is to remove the effect of DOD's pulsed patterns. The third or fourth mode of SDOD is very similar to the current DOD devices because these modes supply oxygen using pulsed patterns at the onset of the inhalation. Since the purpose of this study was to compare the SpO_2 level and comfort of the subjects under the treatment of SDOD and CFO, we tested only the first or second mode of SDOD which supplied oxygen without the pulsed pattern. In addition, the difference between the first and second mode of SDOD is whether oxygen is supplied during exhalation or not. As shown in Figure 2, in the first mode, oxygen is supplied with a base oxygen flow lower than the prescribed flow, and then oxygen flow smoothly increases to the prescribed flow before inhalation. In the second mode, oxygen flow rises from zero to the

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prescribed flow according to the smooth oxygen discharge curve. Therefore, the SR of second mode is higher than that of the first mode. Because the first and second mode of SDOD supply oxygen according to the very similar oxygen discharge pattern, it seems that the patients feeling of comfort under the two modes does not vary.

The size of the SDOD device can be reduced as much as that of the current DOD device attached to the oxygen cylinder. The SDOD device used in this study is still a prototype driven and controlled by a laptop with the NI LabVIEW. Because the SDOD algorithm can be programmable into a micro processor, the SDOD device can be driven by the programmed micro processor without the laptop. The SDOD prototype was powered by AC, however, the power source is able to be replaced with a battery like the current DOD devices. Thus, the expected size of the SDOD device targeted to a marketplace will be more compact and much lighter than that of the current prototype.

The SDOD device might be used for LTOT by simply plugging it to the oxygen cylinder. Due to this, the cost of oxygen can be saved in hospitals by reduced oxygen wastage of SDOD. Moreover, oxygen can be supplied to the patients more comfortably at their home or the other places, if the SDOD is portable and commercialized in the future.

One limitation of the current study is the small number of subjects (ten patients) with various clinical conditions involved and only part of them were receiving LTOT before admission; further studies with more subjects with specific condition and disease are, therefore, needed to prove the effectiveness of SDOD more objectively. However, despite the small number of subjects in our study, SDOD showed statistically significant advantages over CFO in terms of patient comfort, while maintaining SpO_2 at similar levels.

Another limitation of this study is that SpO2 was measured only by pulse oximetry without

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measuring arterial oxygen saturation (SaO_2) or arterial oxygen pressure (PO_2). There is controversy over the adequacy of pulse oximetry for evaluating patients under LTOT[9-11]. Yelderman et al.[12] and Mendelson et al.[13] have shown that pulse oximetry measures oxygen saturation accurately in healthy subjects. Pulse oximetry has also been shown to measure oxygen saturation accurately in critically ill patients.[14]

Our study is also limited by the relatively short-term use of SDOD for just 30 min, since the comfort level of patients treated with SDOD for hours or days may be quite different. It is thus necessary to conduct longer-duration studies to compare SDOD and CFO. In addition, the subjects were asked to sit or recline during the test. Under the activities of daily living, the breathing patterns of the subjects can be changed when compared to the normal breathing patterns. Because of this, another experiment under the subjects' physical activities should be warranted to examine the performance of SDOD more thoroughly. Furthermore, during the sleep, demand valves do not work occasionally due to the breathing pattern and triggering sensitivity of the oxygen conserving devices.[15] Thus, adequacy and safety of the proportional valve used in this study should be carefully assessed.

Conclusions

In conclusion, we conducted the present study to document the effectiveness of oxygen therapy by SDOD in comparison with CFO. Our results show that the difference of SpO_2 between CFO and SDOD was not statistically significant; in other words, SDOD could elevate SpO_2 to desirable levels just as well as CFO did. However, subjects found SDOD to be more comfortable than CFO. Thus, SDOD has the potential to replace CFO, especially in the care of patients who need LTOT, by offering a greater level of comfort with the additional benefit of conserving oxygen, while providing equivalent SpO_2 levels. However, further studies need to be conducted on a larger number of subjects treated with long-term SDOD, to validate the results of the present study, which was done with just 10 subjects given oxygen treatment for only 30 min.

Acknowledgement

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Figure Legends

Figure 1. Time-dependent oxygen discharge profile of synchronized demand oxygen delivery (SDOD). SDOD supplies oxygen in a sigmoidal pattern starting before inhalation, by synchronizing flow with the patient's breathing pattern.

Figure 2. Four oxygen delivery modes of SDOD. First and second modes: the oxygen discharge profile rises to the prescribed flow rate along a sigmoid curve before inhalation. Third mode: oxygen supply pattern changes over from a sigmoid curve to a pulsed pattern at the onset of inhalation. Fourth mode: pulsed oxygen delivery is used at the beginning of inhalation, the same way as in DOD.

Figure 3. Schematic of a synchronized demand oxygen delivery (SDOD) device used in the study. Patients' breathing patterns were recorded and then predicted by the PC that implemented the SDOD algorithm. SDOD supplied oxygen in sigmoid and pulsed patterns by controlling 2 valves according to the patients' breathing pattern and the inputted saving ratio.

RESPIRATORY CARE Paper in Press. Published on December 24, 2013 as DOI: 10.4187/respcare.02937

Figure 4. Visual analogue scale (VAS) for patients' comfort. Subjects scored their comfort level from 0 (very uncomfortable) to 10 (very comfortable) after 30 min of treatment with either CFO or SDOD via VAS.

Figure 5. Oxygen saturation (SpO_2) and comfort levels of patients on synchronized demand oxygen delivery (SDOD) and continuous flow oxygen (CFO). Study participants scored their comfort level on a scale of 0 to 10 (0: very uncomfortable; 10: very comfortable) after 30 min of treatment with either CFO or SDOD.

Figure 6. Inputted saving ratio and actual saving ratio during 30 min of oxygen treatment with synchronized demand oxygen delivery (SDOD). The saving ratio is defined as the ratio of the prescribed flow rate over the rate of actual supply rate integrated over the breathing cycle (saving ratio = prescribed flow rate/supply flow rate); the higher the saving ratio, the more the oxygen conserved. The saving ratio of CFO is equal to 1 because CFO supplies oxygen continuously at the prescribed flow rate.

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Table1. Patient Demographics

Patient No.	Gender	Age	Main causes of hypoxemia	FEV_1. L (% of predicted value)	FVC, L (% of predicted value)	FEV_1/FVC	LTOT usage before admission*	Prescription Flow (L/min)
1	Male	66	Pneumonia	3.11 (99%)	3.57 (85%)	0.87	NO	3
2	Female	69	Pneumonia	2.08 (97%)	2.60 (88%)	0.80	NO	3
3	Male	70	Pneumonia	-		-	NO	1
4	Male	75	Pneumonia	2.07 (71%)	2.85 (63%)	0.73	NO	2
5	Male	59	Pneumonia	0.95 (30%)	0.97 (24%)	0.98	NO	3
6	Male	85	ILD	-		-	NO	1
7	Male	67	Pneumonia	0.91(28%)	1.77 (40%)	0.51	YES	1
8	Male	66	COPD	0.83(37%)	1.90 (60%)	0.44	YES	2
9	Male	56	Pneumonia	-		-	NO	2
10	Male	86	COPD	0.87 (32%)	2.02 (45%)	0.43	YES	1

FEV_1: forced expiratory volume in 1 second, FVC: forced vital capacity, LTOT: long-term oxygen therapy, ILD: interstitial lung disease, COPD: chronic obstructive pulmonary disease

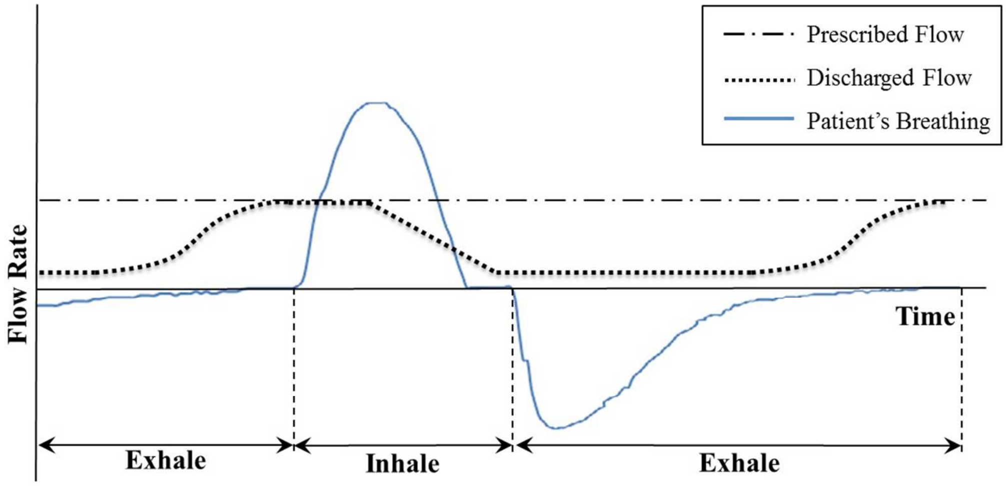

Figure 1. Time-dependent oxygen discharge profile of synchronized demand oxygen delivery (SDOD). SDOD supplies oxygen in a sigmoidal pattern starting before inhalation, by synchronizing flow with the patient's breathing pattern.
306x150mm (96 x 96 DPI)

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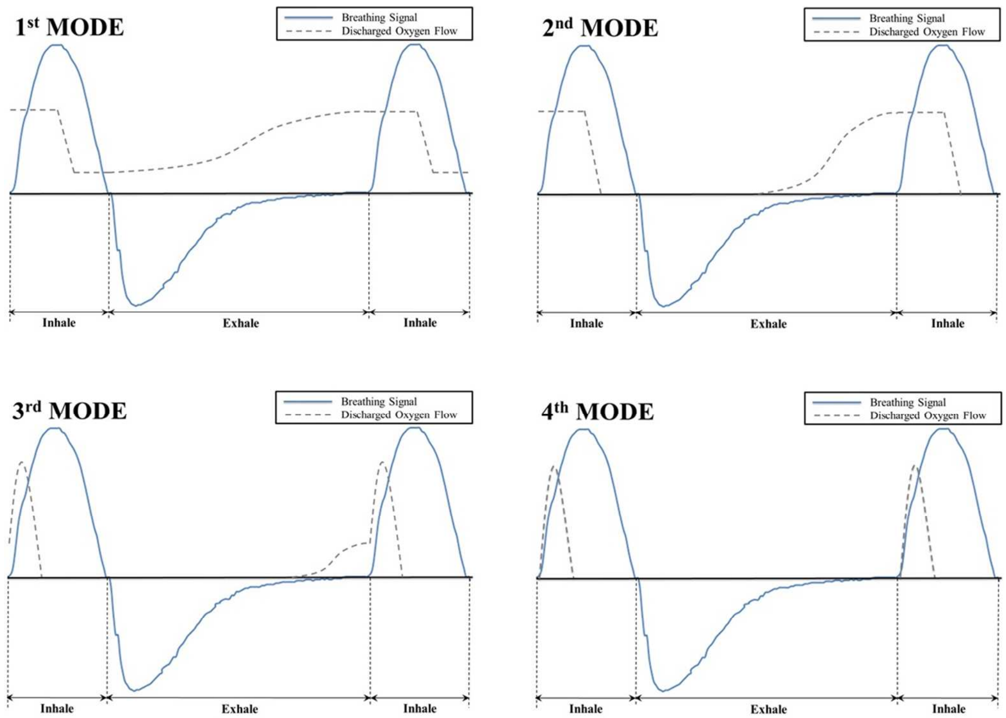

Figure 2. Four oxygen delivery modes of SDOD. First and second modes: the oxygen discharge profile rises to the prescribed flow rate along a sigmoid curve before inhalation. Third mode: oxygen supply pattern changes over from a sigmoid curve to a pulsed pattern at the onset of inhalation. Fourth mode: pulsed oxygen delivery is used at the beginning of inhalation, the same way as in DOD.
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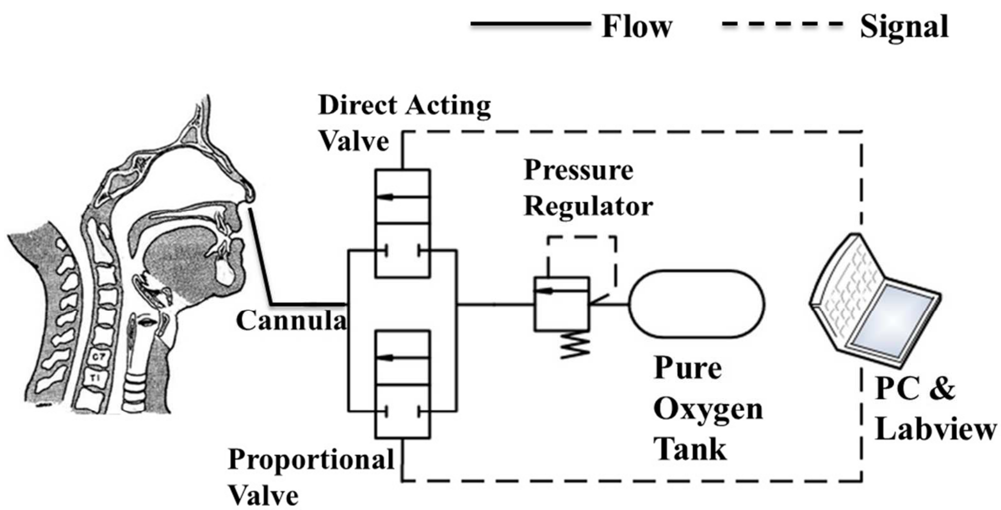

Figure 3. Schematic of a synchronized demand oxygen delivery (SDOD) device used in the study. Patients' breathing patterns were recorded and then predicted by the PC that implemented the SDOD algorithm. SDOD supplied oxygen in sigmoid and pulsed patterns by controlling 2 valves according to the patients' breathing pattern and the inputted saving ratio.
277x139mm (96 x 96 DPI)

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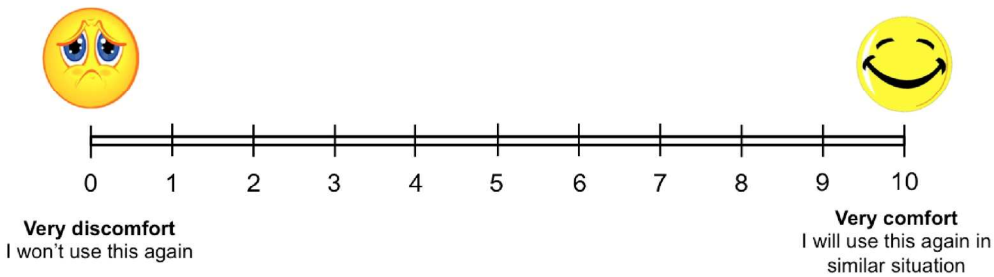

Figure 4. Visual analogue scale (VAS) for patients' comfort. Subjects scored their comfort level from 0 (very uncomfortable) to 10 (very comfortable) after 30 min of treatment with either CFO or SDOD via VAS.
395x112mm (144 x 144 DPI)

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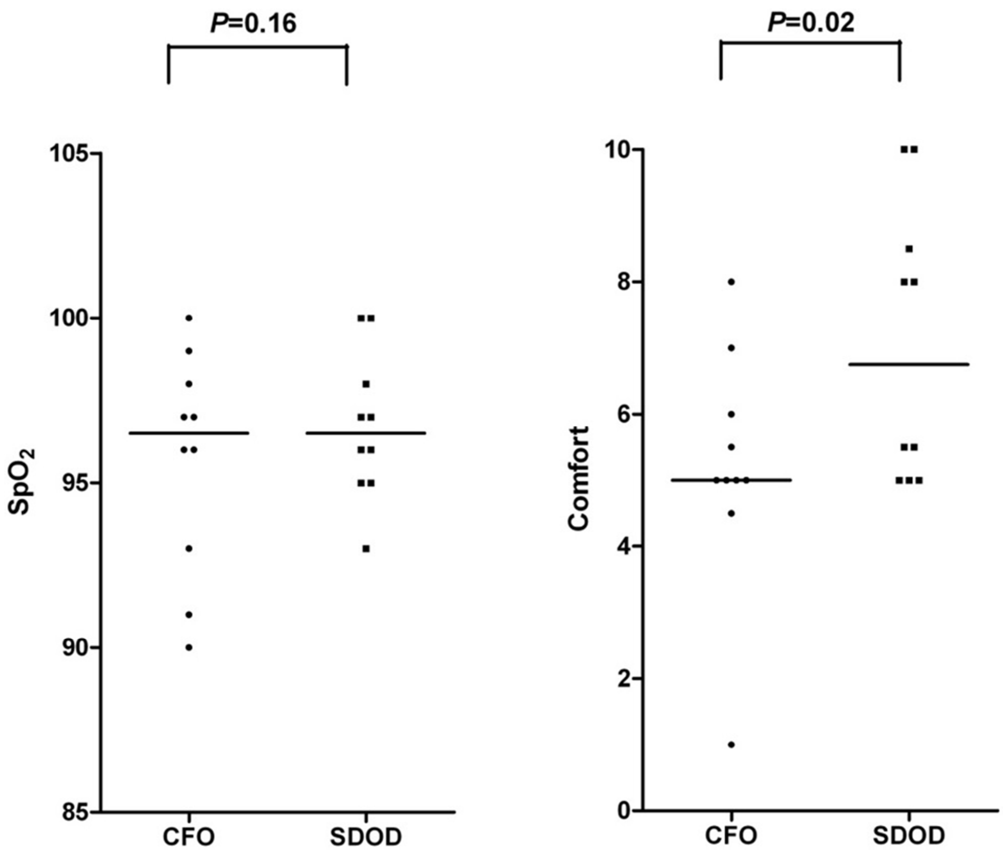

Figure 5. Oxygen saturation (SpO2) and comfort levels of patients on synchronized demand oxygen delivery (SDOD) and continuous flow oxygen (CFO). Study participants scored their comfort level on a scale of 0 to 10 (0: very uncomfortable; 10: very comfortable) after 30 min of treatment with either CFO or SDOD.
262x223mm (96 x 96 DPI)

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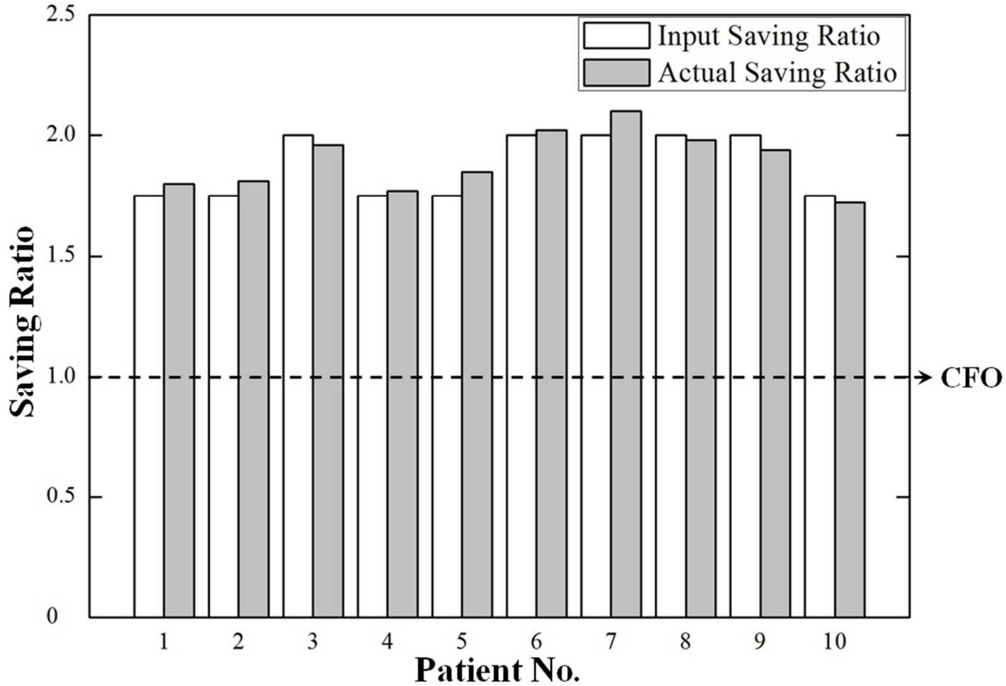

Figure 6. Inputted saving ratio and actual saving ratio during 30 min of oxygen treatment with synchronized demand oxygen delivery (SDOD). The saving ratio is defined as the ratio of the prescribed flow rate over the rate of actual supply rate integrated over the breathing cycle (saving ratio = prescribed flow rate/supply flow rate); the higher the saving ratio, the more the oxygen conserved. The saving ratio of CFO is equal to 1 because CFO supplies oxygen continuously at the prescribed flow rate.
276x188mm (96 x 96 DPI)