Nocturnal Oxygenation Using a Pulsed-Dose Oxygen-Conserving Device Compared to Continuous Flow

Robert L Chatburn RRT-NPS FAARC, Joseph S Lewarski RRT FAARC, and Robert W McCoy RRT FAARC

BACKGROUND: The pulsed-dose oxygen-conserving device (PDOCD) has gained wide acceptance as a tool to reduce the cost and inconvenience of portable oxygen delivery. Despite the widespread use of PDOCDs in awake and ambulating patients, few studies report their use during sleep. This study was designed to compare heart rate and oxygen saturation (measured via pulse oximetry [S_{pO_2}]) of sleeping patients using one brand of PDOCD versus continuous-flow oxygen. METHODS: We studied 10 home-oxygen patients who were using various continuous-flow oxygen systems and prescriptions. Baseline asleep and awake S_{pO_2} and heart rate were recorded while the patients used their existing home-oxygen systems (liquid oxygen or oxygen concentrator with nasal cannula) and continuous-flow oxygen prescription. Patients were then switched to a nasal cannula connected to a PDOCD. The PDOCD setting was adjusted to produce an S_{pO_2} equal to the patient's awake baseline on continuous-flow. This setting was then used while the patient subsequently slept. Mean values for S_{pO_2} and heart rate and hours of sleep were calculated by the software in the oximeter. Mean values for S_{pO_2} and heart rate were compared with the paired Student's *t* test. RESULTS: There was a statistically significant but clinically unimportant S_{pO_2} difference between the patients who used continuous-flow oxygen and those who used the PDOCD (95.7% vs 93.2%, respectively, $p = 0.043$). There was no difference in heart rate (77.3 beats/min vs 77.9 beats/min, $p = 0.70$). The sample size was adequate to detect a difference in heart rate of 5 beats/min at a power of 80%. For the subset of patients whose PDOCD triggering sensitivity was set on *sensitive* (vs the *default* lower sensitivity) there was a statistically significant but clinically unimportant S_{pO_2} difference (continuous-flow 95.6% vs PDOCD 93.2%, $p = 0.044$). All other comparisons showed no differences, but the samples sizes were too small to make any firm conclusions. One patient experienced an 11% S_{pO_2} drop with the PDOCD because of an inadequate triggering sensitivity setting. CONCLUSIONS: The PDOCD model we studied was able to deliver oxygen therapy (via nasal cannula) comparable to continuous-flow in 9 of 10 patients. The resting daytime S_{pO_2} on continuous-flow appears to be an appropriate target for setting the PDOCD to ensure adequate oxygenation, even

Robert L Chatburn RRT-NPS FAARC is affiliated with the Respiratory Care Department, University Hospitals of Cleveland, Cleveland, Ohio, and with the Department of Pediatrics, Case Western Reserve University, Cleveland, Ohio. At the time of this study, Robert L Chatburn RRT-NPS FAARC had no affiliation or financial relationship with Inogen Incorporated, Goleta, California. He is now a volunteer member of Inogen's scientific advisory board; he receives no financial compensation from Inogen and has no financial relationship with Inogen.

Joseph S Lewarski RRT FAARC is affiliated with Inogen Incorporated, Goleta, California. At the time of this study, Joseph S Lewarski RRT was serving as a member of Inogen's advisory board. He was not directly involved with patient study or data collection, but he received stock options in Inogen. In November 2004 he became an employee of Inogen.

Robert W McCoy RRT FAARC is affiliated with Valley Inspired Products, Apple Valley, Minnesota. At the time of this study, Robert McCoy RRT FAARC was an independent contractor consultant for Inogen. In January 2005 that consulting agreement ended, and since then he has had no financial relationship with Inogen.

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Correspondence: Robert L Chatburn RRT-NPS FAARC, Respiratory Care Department, University Hospitals of Cleveland, 11100 Euclid Avenue, Cleveland OH 44106. E-mail: robert.chatburn@uhhs.com.

during sleep, with the PDOCD we tested. We conclude that the PDOCD we tested is able to maintain adequate S_{pO_2} during sleep in selected patients. Because of differences in design, triggering-signal sensitivity, and oxygen-pulse volume, these results cannot be generalized to all patients or all oxygen-conserving devices. Further research is needed to determine the general performance of PDOCDs on larger populations of oxygen-dependent patients and patients with sleep-disordered breathing. *Key words: oxygen, pulsed-dose, conserving device, COPD, long-term oxygen therapy, oxygen inhalation therapy/methods*. [Respir Care 2006;51(3):252–256. © 2006 Daedalus Enterprises]

Introduction

Pulsed-dose oxygen-conserving devices (PDOCDs) have become a clinical benchmark for nearly all compressed and liquid portable oxygen systems, and their use is considered a standard of practice with stable home-oxygen patients. Although PDOCD use is common in awake and ambulating patients, there is some hesitancy among many clinicians and providers regarding the use of PDOCDs at night. Despite published data suggesting that PDOCDs perform just as effectively during sleep,[1–3] there are some concerns regarding PDOCD triggering sensitivity and response to varying nocturnal breathing patterns. The objective of this study was to compare the heart rate and saturation of sleeping, oxygen-dependent patients using one PDOCD model, versus continuous-flow oxygen.

Methods

Patients with a primary diagnosis of emphysema or pulmonary fibrosis and with a history of prolonged oxygen use were recruited from the Minneapolis American Lung Association and volunteered to participate in the study. All the subjects were in the greater Minneapolis, Minnesota, area.

Patient Screening

Each patient either (1) had undergone a sleep-apnea study within the previous year or (2) underwent a nighttime sleep-apnea study, under the direction of Valley Inspired Products company (Apple Valley, Minnesota). The sleep-apnea studies were performed to rule out obstructive sleep apnea and to provide baseline blood oxygen saturation (measured via pulse oximetry [S_{pO_2}]) and heart-rate data, both awake and asleep. For the awake measurements, patients were monitored continuously for 20–30 min while seated and resting. The sleep studies were conducted in the patients' homes, using their existing oxygen system (liquid oxygen or oxygen concentrator, with nasal cannula) and continuous-flow oxygen prescription. Valley Inspired Products provided an explanation of the study objectives and the study protocol to each patient and his or her physician, and obtained a signed patient consent form and a signed physician consent form for each patient included in the study. An apnea-hypopnea index (the total number of apneas and hypopneas per hour of sleep, calculated according to American Academy of Sleep Medicine standards) was recorded for each patient, by the software programmed into the sleep screening device (Third Shift, Valley Inspired Products, Apple Valley, Minnesota).

Study Design

Between 24 hours and 7 days after the initial sleep screening, patients entered the PDOCD study and acted as their own controls. None of the patients had any change in their clinical condition during the period between the sleep screening and the PDOCD study. Each patient was switched from their continuous-flow system to the PDOCD (Inogen One, Inogen, Goleta, California) with nasal cannula (model 1600, Salter Labs, Arvin, California) for one night. The PDOCD setting was adjusted to produce an S_{pO_2} equal to the patient's S_{pO_2} on continuous-flow while awake, and this PDOCD setting was used while the patient slept.

The Inogen One PDOCD has 2 triggering sensitivity options: *default*, which triggers at 0.23 cm H_2O below atmospheric pressure, and *sensitive*, which triggers at 0.12 cm H_2O below atmospheric pressure. Seven patients were tested with the PDOCD on the sensitive setting, and 3 patients were randomly selected to be tested on the default setting. In this study the minimum acceptable sleep duration was 5 hours. Oximetry data were downloaded within 24 hours of the sleep period. Mean values for S_{pO_2}, heart rate, and hours of sleep were calculated by the software in the oximeter (Palmsat 2500 or WristOx 3100, Nonin Medical, Plymouth, Minnesota).

Statistical Analysis

Mean values for sleep hours, S_{pO_2}, and heart rate were compared with Student's paired *t* test using statistical software (SigmaStat 3.0 for Windows, Aspire Software International, Leesburg, Virginia). Differences associated with p values ≤ 0.05 were considered significant. A power analysis was performed for nonsignificant results (using the Power and Precision software package, Biostat, Englewood, New Jersey). The power calculations were based on

Table 1. Patient Demographics

Patient	Age	Sex	Diagnosis	AHI	Years on Oxygen
1	73	M	Emphysema	1.0	3
2	65	F	Emphysema	2.6	6
3	58	M	Pulmonary fibrosis	0.8	3
4	73	M	Emphysema	9.0	3
5	77	M	Emphysema	4.4	0.4
6	71	F	Emphysema	5.0	6
7	74	F	Emphysema	5.0	2.5
8	76	F	Emphysema	3.8	7
9	72	F	Emphysema	NA	1.5
10	64	F	Emphysema	1.6	5

AHI = apnea-hypopnea index (total number of apneas and hypopneas per hour of sleep)
NA = data not available

the ability to detect a heart-rate difference of 5 beats/min and an S_{pO_2} difference of 4%.

Results

Ten patients were enrolled in the study (Table 1). Study data are displayed in Table 2. The mean continuous-flow setting was 2 L/min (range 0.75–3), and the mean PDOCD setting was 3 (range 1–5). PDOCD settings incorporate a combination of variables, including oxygen bolus size per setting, sensitivity, speed of response, bolus flow, and waveform.[4] Therefore, it was not expected that the continuous-flow setting would consistently match the PDOCD setting, although this did occur in 20% of the patients.

The patients slept an average of 1 hour more when using the PDOCD than during the baseline sleep screening test ($p = 0.013$). There was a statistically significant but clinically unimportant difference in S_{pO_2} between continuous-flow and PDOCD (95.7% vs 93.2%, $p = 0.043$). There was no difference in heart rate (77.3 beats/min vs 77.9 beats/min, $p = 0.70$). The sample size was adequate to detect a heart-rate difference of 5 beats/min at a power of 80%.

For the subset of patients whose PDOCD was set on sensitive, there was a statistically significant but clinically unimportant difference in S_{pO_2} (continuous-flow 95.6% vs PDOCD 93.2%, $p = 0.044$). All other comparisons showed no differences, but the samples sizes were too small to make any firm conclusions (Table 3).

One patient in the default (lower) sensitivity group experienced a clinically important lower S_{pO_2} with the PDOCD than with continuous-flow (86% vs 97%), and the the oxygen concentrator data log suggested that he frequently failed to trigger the PDOCD throughout the sleep period.

Discussion

PDOCDs minimize consumption of gas from portable oxygen sources. Advancements and improvements in PDOCD performance and reliability have stimulated the acceptance of many new oxygen technologies, including portable (< 10 lbs) oxygen concentrators.

The PDOCD generally works by detecting the patient's inspiratory effort and triggering the delivery of a small bolus of oxygen at the beginning of inspiration. The oxygen then remains off until the next inspiration is detected.

Table 2. Study Results

Patient	Continuous-Flow (L/min)	PDOCD Sensitivity Setting	PDOCD Setting	Hours of Sleep		Mean S_{pO_2} (%)			Mean Heart Rate (beats/min)		
				Continuous-Flow	PDOCD	Continuous-Flow	PDOCD	Difference	Continuous-Flow	PDOCD	Difference
1	0.75	Sensitive	1	7.4	9.2	94.0	93.2	−0.8	75	73.4	−1.6
2	2	Sensitive	3	7.1	6.6	96.0	95.8	−0.2	89.6	89.8	0.2
3	2	Default	5	8.1	9.0	90.1	90.3	0.2	74.1	82.7	8.6
4	3	Sensitive	3	9.5	9.0	97.5	96.1	−1.4	79.7	69.6	−10.1
5	2	Sensitive	2	7.2	8.6	96.9	94.6	−2.3	64.3	63.9	−0.4
6	2	Sensitive	3	7.2	9.6	96.5	97.2	0.7	64.3	69.6	5.3
7	2	Sensitive	3	6.6	6.6	97.2	93.3	−3.9	69.3	69.6	0.3
8	2	Default	2.5	7.2	9.0	96.9	86.3	−10.6	79.9	84.3	4.4
9	2	Sensitive	3.5	5.1	7.2	96.5	94.0	−2.5	80	80.5	0.5
10	2.5	Default	3	5.6	6.5	95.0	91.6	−3.4	97	96.0	−1.0
			Mean	7.1	8.1	95.7	93.2	−2.4	77.3	77.9	0.6
			SD	1.2	1.2	2.2	3.2	−3.3	10.4	10.3	5.0

PDOCD = pulsed-dose oxygen-conserving device
SD = Standard deviation

Table 3. Results of Statistical Tests

Test	Condition	S_{pO_2}				Heart Rate			
		Continuous-Flow (%)	PDOCD (%)	p	Power (%)	Continuous-Flow (%)	PDOCD (%)	p	Power (%)
1	All patients	95.7	93.2	0.043	N/A	77.3	77.9	0.703	80
2	Set on sensitive	96.4	94.9	0.044	N/A	74.6	73.8	0.652	68
3	Set on default	94.7	89.4	0.284	12	83.7	87.7	0.287	18

Effect Size for Power Analysis

$$\text{effect size} = \frac{\text{desired detectable difference}}{\text{standard deviation of differences}}$$

All patients: effect size (heart rate) = 5/4.99 = 1.0

Set on sensitive: effect size (heart rate) = 5/4.63 = 1.1

Set on default: effect size (S_{pO_2}) = 4/5.50 = 0.7

effect size (heart rate) = 5/4.81 = 1.0

PDOCD = pulsed-dose oxygen-conserving device

At a 2-L/min setting on a typical PDOCD, the bolus is generally between 15 mL and 36 mL. A variation on this design is to deliver the bolus on selected breaths, depending on the oxygen prescription (eg, a pulsed dose on every fourth breath would equate to 1 L/min of continuous flow).[5]

Like other PDOCDs, the Inogen One uses pressure sensing to identify the onset of inspiration and trigger delivery of a bolus of oxygen in the first 100 ms of the breath. Unlike other PDOCDs, the Inogen One has a microprocessor that monitors the respiratory rate and adjusts the bolus volume to maintain a consistent minute volume of oxygen. For example, at the 2 setting, the device delivers a fixed volume of 300 mL of oxygen per minute. At 10 breaths/min, each bolus is 30 mL. At 20 breaths/min each bolus is 15 mL. If a patient takes a long pause (ie, apnea), the next bolus is adjusted up. This oxygen dosing method might partially explain the results of the present study. A common concern regarding PDOCD use during sleep is the effect of slower respiratory rate and smaller tidal volume (hypoventilation) on oxygenation. In response to a decreasing respiratory rate, the Inogen One increases the bolus size per breath, which increases the fraction of inspired oxygen (F_{IO_2}) per breath. If the tidal volume decreases, the effect of increasing F_{IO_2} would be even greater. This effect on breath-by-breath F_{IO_2} might tend to offset any decrease in oxygen delivery due to breaths that failed to trigger the PDOCD. We speculate that this approach to oxygen delivery, in conjunction with effective trigger sensitivity, may prove more effective than the conventional PDOCD design in maintaining adequate and consistent S_{pO_2} during sleep.

As a consequence of PDOCDs being pressure-triggered, there is a legitimate concern on the part of caregivers that PDOCDs might fail with patients who have sleep-disordered breathing. For this reason we restricted our study to patients who had no substantial sleep apnea. All the patients in our study had an apnea-hypopnea index below 10. This is a limitation of the study, and the results cannot be generalized to all patients who require nocturnal oxygen. The apnea-hypopnea index has become the standard by which to define and quantify the severity of obstructive sleep apnea-hypopnea syndrome. An apnea-hypopnea index greater than 15 events per hour indicates possible presence of the syndrome. Generally, as the apnea-hypopnea index increases, the severity of apnea increases.[6]

Bower et al[2] compared continuous-flow to demand pulse-dosed oxygen during all patient activities, including sleep. They concluded that demand oxygen systems produced arterial oxygenation equivalent to continuous-flow during all activities.

In a large (n = 100), unblinded, cross-over study that compared continuous-flow oxygen to pulse-dosed oxygen in hospitalized patients, Kerby et al[1] concluded that the PDOCD and continuous-flow systems they tested produce similar S_{pO_2} in hypoxemic patients over the course of day and night.

More recently, Cuvelier et al,[3] using polysomnography, compared the efficacy of continuous-flow and pulse-dosed oxygen in sleeping, hypoxemic patients. The PDOCD (as compared to continuous-flow) did not induce any significant alteration in physiologic variables in the majority of patients with moderate-to-severe chronic obstructive pulmonary disease who required supplemental oxygen.

The results of the present study agree with these previous studies. The Inogen One provided the same clinical benefit as a continuous-flow nasal cannula in 90% of a small sample of patients. Regarding the one study subject in the default (lower) triggering sensitivity group who experienced a clinically important lower S_{pO_2} with the PDOCD (86% vs 97%), it is important to note than no device adjustments, titrations, or retesting were performed during the single-night study. In actual clinical practice this could

be remedied by increasing the sensitivity and the oxygen setting during sleep.

We used the awake baseline S_{pO_2} as the target for setting the during-sleep oxygen delivery. One might expect the asleep oxygen requirement to be more than the awake requirement to maintain the same S_{pO_2}, yet our results showed equivalent S_{pO_2}. Also, 7 of the 10 patients slept longer with the PDOCD than during the initial sleep screening. These findings lead us to be even more confident in our conclusions.

Conclusions

With the Inogen One PDOCD, 9 of 10 patients maintained nocturnal S_{pO_2} and heart rate that were clinically equivalent to their continuous-flow baseline values. One patient failed to trigger the PDOCD appropriately and therefore experienced an 11% lower S_{pO_2} with the PDOCD, whereas all the other patients maintained S_{pO_2} within 4% of their continuous-flow baseline while using the PDOCD. None of the patients had a history of substantial apnea-hypopnea. The resting daytime S_{pO_2} on continuous-flow appears to be an appropriate target for setting the PDOCD to ensure adequate oxygenation, even during sleep, with the Inogen One. With the Inogen One we recommend the sensitive setting during sleep.

We conclude that the Inogen One is able to maintain adequate S_{pO_2} during sleep in selected patients. Because of differences in design, triggering-signal sensitivity, and pulse volume, these results cannot be generalized to all patients or all PDOCDs. Further research is needed to determine the general performance of PDOCDs in larger populations of oxygen-dependent patients and patients with sleep-disordered breathing.

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