Are Oxygen-Conserving Devices Effective for Correcting Exercise Hypoxemia?

Sergi Martí MD, Virginia Pajares MD, Fátima Morante RN, Maria-Antònia Ramón PT, Jordi Lara, Jaume Ferrer MD, and Maria-Rosa Güell MD

BACKGROUND: Correction of exercise hypoxemia in advanced lung diseases is crucial and often challenging. However, oxygen-conserving devices have been introduced in the market with limited evidence of effectiveness. In the present study the efficacy of 2 oxygen-conserving devices, a pulse demand oxygen delivery (DOD) system and pendant reservoir cannula (PRC), were evaluated in subjects with COPD and interstitial lung disease (ILD). METHODS: A cross-sectional, crossover study included 28 COPD and 31 ILD subjects with oxygen desaturation on the 6-min walk test (average S_{pO_2} < 88%). Each subject underwent 3 walk tests with DOD, PRC, and continuous oxygen flow by standard nasal cannula (CFNC), in random order, taking average $S_{pO_2} \geq 90\%$ as the resaturation criterion. RESULTS: Exercise desaturation was corrected in 79%, 79%, and 86% of COPD subjects with CFNC, DOD, and PRC, respectively, and in 77%, 61%, and 81% of ILD subjects with CFNC, DOD, and PRC, respectively. When compared to CFNC, the oxygen-conserving devices showed similar efficacy, except a lower performance for the DOD in the ILD subjects ($P = .01$). CONCLUSIONS: Although these oxygen-conserving devices corrected exercise hypoxemia in most COPD and ILD subjects, correction was not achieved in about 20% of the severe COPD subjects, regardless of the device, and in nearly 40% of the ILD subjects with the DOD device. These findings underscore that individualized adjustment of oxygen flow is needed for optimal correction of exercise hypoxemia, especially with a DOD in an ILD patient. (Clinical Trials.gov NCT01086891). *Key words: COPD; conservers; exercise test; interstitial lung disease; oxygen inhalation therapy; technology assessment.* [Respir Care 2013;58(10):1606–1613. © 2013 Daedalus Enterprises]

Introduction

The use of supplemental oxygen during exercise reduces dyspnea and improves exercise performance in patients with hypoxemia due to COPD[1,2] or interstitial lung disease (ILD).[3,4] Traditional portable systems deliver continuous flow oxygen, most of which does not reach the alveoli. Consequently, a considerable amount of oxygen is wasted. Moreover, these systems are bulky, and the duration of oxygen delivery away from the stationary equipment is limited, thus reducing the patient's mobility and independence.

The development of oxygen-conserving devices has led to lighter-weight systems with longer duration of oxy-

Dr Martí, Ms Ramón, and Dr Ferrer are affiliated with the Pulmonology Department, Hospital Universitari Vall d'Hebron, and the Department of Medicine, Universitat Autònoma de Barcelona, Barcelona, Spain, and with the Centro de Investigación Biomédica en Red de Enfermedades Respiratorias, Instituto de Salud Carlos III, Madrid, Spain. Dr Pajares, Ms Morante, and Dr Güell are affiliated with the Pulmonology Department, Hospital Santa Creu i Sant Pau, Barcelona, Spain. Mr Lara is affiliated with the Laboratory of Biostatistics and Epidemiology, Universitat Autònoma de Barcelona, Barcelona, Spain.

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Correspondence: Sergi Martí MD, Pulmonology Department, Hospital Universitari Vall d'Hebron. Passeig Vall d'Hebron 119-129, 08035 Barcelona, Spain. E-mail: smarti@vhebron.net.

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gen delivery for outdoor mobility.[5] Currently available oxygen-conserving devices include pulse demand oxygen delivery (DOD) devices and reservoir cannulas. The newer DOD devices are integrated in portable liquid oxygen systems and deliver a pre-set bolus of oxygen only during early inspiration, triggered by the patient's inspiratory effort. Reservoir cannulas store oxygen during exhalation, making it available as a bolus at onset of the next inhalation. Despite these technical advantages, however, many oxygen-conserving devices have been placed on the market with limited published evidence regarding their efficacy.[6-8]

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The equivalency of oxygen-conserving devices to continuous flow oxygen for correcting hypoxemia has been evaluated in several studies. When the patient is at rest, the 2 types of systems have proven to be equivalent.[9-11] However, when oxygen requirements increase, specifically during exercise[10-16] and in patients with ILD,[17] oxygen-conserving devices do not seem to provide equivalent benefits.

It has been suggested that oxygen supply should be increased in some patients treated with oxygen-conserving devices, to improve hypoxemia,[11,13,17] but there have been no studies evaluating in what cases adequate correction fails despite the increased supply.

The primary aim of this study was to assess the efficacy of 2 oxygen-conserving systems (a DOD device and pendant reservoir cannula [PRC]) versus continuous flow oxygen through a standard nasal cannula (CFNC) for correcting oxygen desaturation during exercise in patients with COPD or ILD. In contrast to previous studies, the oxygen delivery settings were individually adjusted with each subject, as needed, to correct hypoxemia. The secondary aim was to determine the subjects' preferences for each of the 3 types of devices tested.

QUICK LOOK

Current knowledge

Supplemental oxygen during exercise reduces dyspnea and improves exercise performance in patients with hypoxemia due to chronic lung disease. Pulse-dose oxygen systems conserve oxygen, but their ability to reverse exercise hypoxemia is suspect.

What this paper contributes to our knowledge

During the 6-min walk test, 20% percent of the subjects with severe COPD and oxygen desaturation failed to achieve re-saturation ($S_{pO_2} \geq 90\%$), even at the maximum flow provided by the pulse-dose system. With the pulse-dose system, failure to correct exercise desaturation occurred in about 40% of subjects with interstitial lung disease. Oxygen flow titration during exercise should be accomplished on a per patient basis, with the device being considered for use.

Methods

The study protocol was approved by the institutional review board of each participating center. The aim of the study was explained to each subject, and written informed consent was obtained from all subjects.

Subjects

The study population included consecutively enrolled patients with a diagnosis of COPD or ILD with exercise-related oxygen desaturation, seen between April 2008 and January 2010 in the Oxygen Therapy Control Units of 2 teaching hospitals: Hospital de la Santa Creu i Sant Pau, and Hospital Universitari Vall d'Hebron, Barcelona, Spain. In this study exercise desaturation was defined as average $S_{pO_2} < 88\%$ during the 6-min walk test (6MWT), in order to include patients with sustained exercise desaturation. The exclusion criteria were: active smoker, use of ambulatory oxygen therapy before the study, recent exacerbation (within 4 weeks), severe comorbidity, and locomotor abnormality preventing performance of the 6MWT.

Study Design

This was an open, cross-sectional, crossover study, carried out on 2 consecutive days.

Day 1. Pulmonary function testing was performed on day 1 (MasterLab, Erich Jaeger/CareFusion, San Diego, California). All tests were done according to the European Respiratory Society and American Thoracic Society guidelines.[18-20] Static lung volumes were measured using the plethysmography method, and diffusion capacity of the lung for carbon monoxide was measured using the single breath-hold method.[21] Baseline dyspnea was assessed with the modified Medical Research Council dyspnea scale.[22] At least 2 6MWT were performed: the first on room air, to confirm desaturation. After a 30-min rest, the second test was carried out with the subject on CFNC. The oxygen flow setting was decided by the pneumologist after the baseline (room air) test was evaluated. Resaturation was defined as maintenance of an average $S_{pO_2} \geq 90\%$ during the 6MWT. The oxygen setting was increased in a subsequent 6MWT if needed to achieve resaturation. The ap-

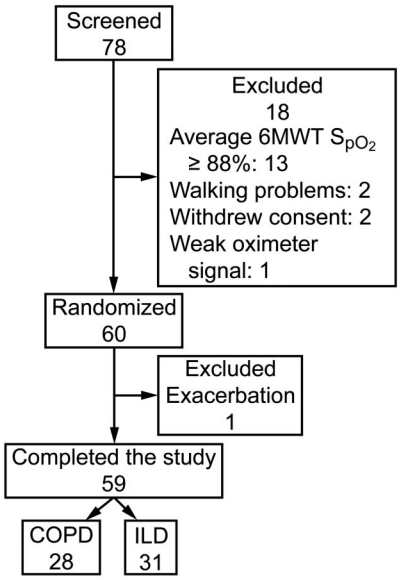

Fig. 1. Flow chart showing subject enrollment. 6MWT = 6-min walk test. ILD = interstitial lung disease.

propriate oxygen setting to achieve resaturation was established with no more than 3 walk tests. The 6MWT was carried out in a 30-meter-long hall and monitored by a trained nurse, who always used the same expressions of encouragement.[23] The subjects walked at a rhythm similar to that used in their daily activities, while pulling along an oxygen cylinder in a small, light, wheeled cart, and were instructed to breathe through their nose during the test. We recorded heart rate and S_{pO_2} (Pulsox 300i, Konica/Minolta, Osaka, Japan).

Day 2. On the second day the subjects performed at least 3 6MWTs, with a 30-min rest between each test, using CFNC, a DOD system (Spirit 300, Caire Medical, Ball Ground, Georgia), and a PRC (Oxymizer Pendant, Chad Therapeutics, Chatsworth, California). The CFNC and PRC were connected to a portable cylinder weighing 3.63 kg with continuous flow liquid oxygen (Stroller, Caire Medical, Ball Ground, Georgia). The DOD system was integrated with a lighter cylinder (1.95 kg) with pulse delivery of 15 mL per setting (that is, setting 1 = 15 mL, setting 2 = 30 mL, et cetera). With each subject the 3 devices were tested in random order, assigned using a computer-generated sequence. Oxygen delivery was established as follows. With CFNC the oxygen flow was set according to the adjustment performed on day 1. With the DOD the setting was the manufacturer's equivalent to the required CFNC flow. With the PRC the initial flow was 1 L/min less than the required CFNC flow. With any of the devices, if an average $S_{pO_2} \geq 90\%$ was not maintained, the 6MWT was repeated with a higher oxygen setting, up to the maximum possible with the system (6 L/min with continuous flow, and setting 5 with the DOD), attempting to correct desaturation. The appropriate oxygen setting to achieve the resaturation criterion was established with no more than 3 walk tests for each device.

Table 1. Subject Characteristics

	COPD (n = 28)	ILD (n = 31)
Age, y	66.3 ± 8.6	68.7 ± 9.9
Male/female, no.	23/5	19/12
BMI, kg/m^2	26.4 ± 2.8	27.2 ± 4.9
FEV_1, L	0.93 ± 0.36	1.62 ± 0.45
FEV_1, % predicted	31.0 ± 10.5	65.5 ± 15.8
FVC, L	2.52 ± 0.95	1.89 ± 0.56
FVC, % predicted	59.4 ± 17.2	56.6 ± 14.8
FEV_1/FVC	0.39 ± 0.12	0.86 ± 0.10
TLC, % predicted	126.0 ± 24.8	60.1 ± 14.6
RV, % predicted	219.0 ± 71.5	59.2 ± 23.1
D_{LCO}, % predicted	29.6 ± 10.1	32.3 ± 11.4
P_{aO_2}, mm Hg	60.2 ± 6.6	65.3 ± 10.0
P_{aCO_2}, mm Hg	42.7 ± 6.1	39.9 ± 4.7
$P_{(A\text{-}a)O_2}$, mm Hg	37.6 ± 8.3	35.8 ± 9.7
MRC dyspnea score ≥ 2, no. (%)	24 (85.7)	28 (90.3)
Previous LTOT (not portable), no. (%)	14 (50.0)	9 (29.0)

The values are mean ± SD unless otherwise indicated.
ILD = interstitial lung disease
BMI = body mass index
TLC = total lung capacity
RV = residual volume
D_{LCO} = diffusion capacity of the lung for carbon monoxide
$P_{(A\text{-}a)O_2}$ = alveolar-arterial oxygen difference
MRC = Medical Research Council
LTOT = long-term oxygen therapy

Measurements

The main outcome variable was the percentage of subjects in whom desaturation on exercise was ultimately corrected (average $S_{pO_2} \geq 90\%$) in the 6MWT with each device. Heart rate, breathing frequency, and dyspnea score (measured with a modified Borg visual analog scale ranging from 0 to 10[24]) were recorded before and after each 6MWT. If more than one 6MWT was needed with any device, the last measurements were recorded. After the 6MWTs we asked the subjects if they had a preference for any of the 3 devices.

Statistical Analysis

Sample size was calculated with a chi-square test to compare 2 expected proportions for independent data. The expected proportions of successful response (average $S_{pO_2} \geq 90\%$ during the 6MWT) were 60% and 50% for DOD in COPD and ILD, respectively, and 90% and 85% for PRC. Thus, 30 subjects in each pulmonary disease

Table 2. Cardiopulmonary Measurements at Rest Before, During, amd After the Baseline Room Air 6-Min Walk Test

	COPD (n = 28)	ILD (n = 31)
At rest before 6MWT		
S_{pO_2}, %	91.0 ± 2.8	92.1 ± 2.9
Breathing frequency, breaths/min	20.7 ± 4.0	28.3 ± 6.0
Heart rate, beats/min	86.4 ± 10.4	85.3 ± 11.6
Borg dyspnea score	1.1 ± 1.3	1.3 ± 1.5
During 6MWT		
Average S_{pO_2}, %	81.5 ± 6	80.4 ± 6.7
Time with $S_{pO_2} < 90\%$, %	92.3 ± 7.7	80.4 ± 6.7
Immediately after 6MWT		
S_{pO_2}, %	78.1 ± 8.6	76.2 ± 7.3
Breathing frequency, breaths/min	24.8 ± 4.8	36.5 ± 7.1
Heart rate, beats/min	103.2 ± 15.5	105.1 ± 20.0
Borg dyspnea score	4.7 ± 2.2	5.4 ± 3.0
6-min walk distance, m	325.3 ± 79.1	344.6 ± 76.3

The values are mean ± SD unless otherwise indicated.
ILD = interstitial lung disease
6MWT = 6-min walk test

group would suffice to observe significant differences between the devices, assuming a 2-sided type 1 error of 5% and a statistical power of 80%.

Baseline data are described as absolute frequency and percentage for qualitative variables, and mean and standard deviation for quantitative variables. Inferential analyses were performed with a general linear model for quantitative variables or a generalized estimated equation for qualitative variables, to assess intra-subject variability, including device, sequence of use, and period as fixed factors, and subject effect nested in sequence as random effect.

Device preference was analyzed using the Prescott test,[25] which includes the non-preferences, bearing in mind the order in which the devices were tested by the subject. Two-sided significance tests were used throughout, and a P value $< .05$ was considered significant. Statistical analyses were performed with statistics software (SAS 9.1.3, SAS Institute, Cary, North Carolina).

Results

Subject enrollment is shown in Figure 1. Of the 60 subjects randomized, 59 completed the study: 28 with COPD and 31 with ILD. The ILD diagnoses were: 14 idiopathic pulmonary fibrosis, 7 nonspecific interstitial pneumonia, 7 hypersensitivity pneumonitis, 1 cryptogenic organizing pneumonia, 2 unclassifiable interstitial pneumonia. Carbon monoxide diffusion in both groups was around 30% of predicted (Table 1), indicating severely impaired respiratory function. The baseline (without oxygen) 6MWT results showed marked desaturation on exer-

Table 3. Cardiopulmonary Measurements in the COPD Subjects at Rest Before, During, and After the 6-Min Walk Test With 3 Oxygen Delivery Systems (n = 28)

	CFNC	DOD	P DOD vs CFNC	PRC	P PRC vs CFNC
At rest before 6MWT					
S_{pO_2}, %	95.9 ± 0.2	95.6 ± 0.2	.12	96.1 ± 0.2	.60
Breathing frequency, breaths/min	19.3 ± 0.5	19.0 ± 0.5	.67	19.3 ± 0.5	.95
Heart rate, beats/min	82.0 ± 1.1	80.5 ± 1.1	.33	80.0 ± 1.1	.18
Borg dyspnea score	0.6 ± 0.1	0.6 ± 0.1	.56	0.5 ± 0.1	.61
During 6MWT					
Average S_{pO_2}, %	90.4 ± 0.3	91.1 ± 0.3	.07	91.6 ± 0.3	.004
Average $S_{pO_2} \geq 90\%$, no. (%)*	22 (79)	22 (79)	.49	24 (86)	.15
Time with $S_{pO_2} < 90\%$, %	34.1 ± 3.5	25.1 ± 3.5	.07	19.8 ± 3.5	.005
Immediately after 6MWT					
S_{pO_2}, %	89.4 ± 0.3	89.4 ± 0.3	.99	90.8 ± 0.3	.003
Breathing frequency, breaths/min	23.3 ± 0.5	24.2 ± 0.5	.25	22.8 ± 0.5	.52
Heart rate, beats/min	99.9 ± 1.5	98.5 ± 1.5	.49	95.3 ± 1.5	.03
Borg dyspnea score	3.4 ± 0.2	3.0 ± 0.2	.16	3.6 ± 0.2	.60
6-min walk distance, m	352.2 ± 2.2	347.9 ± 2.1	.16	346.5 ± 2.1	.07

Values are least-squares means ± standard error of the mean for continuous variables unless otherwise indicated.
* Correction of desaturation was defined as average $S_{pO_2} \geq 90\%$.
CFNC = continuous flow with standard nasal cannula
DOD = demand oxygen delivery oxygen device
PRC = pendant reservoir cannula
6MWT = 6-min walk test

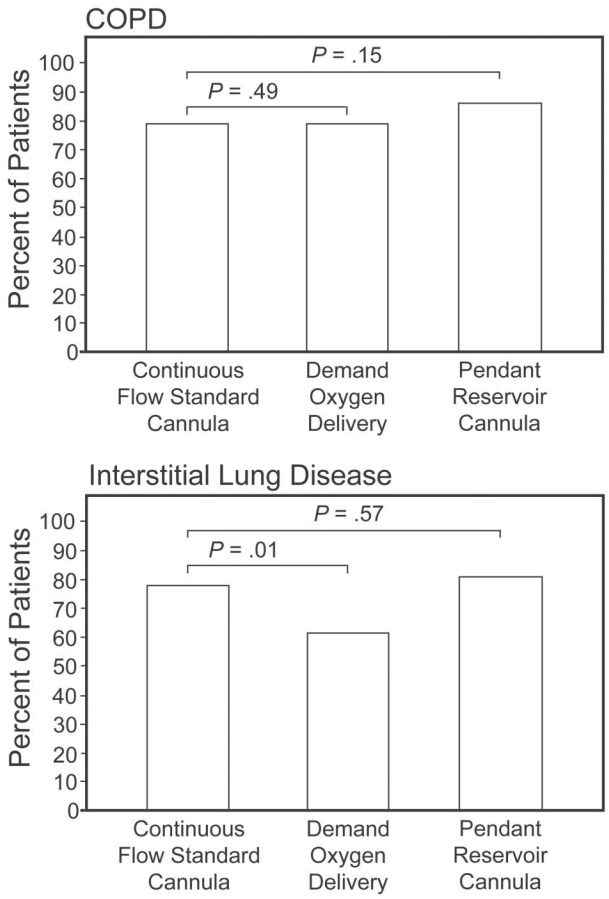

Fig. 2. Correction of exercise oxygen desaturation (6-min walk test average S_{pO_2} ≥90%) with the 3 oxygen supplementation systems tested, in subjects with COPD and subjects with interstitial lung disease.

cise: average S_{pO_2} was 81% in the COPD subjects and 80% in the ILD subjects (Table 2).

COPD Subjects

On oxygen supplementation by CFNC, desaturation during exercise was corrected in 79% of the COPD subjects (Table 3 and Fig. 2). In the remaining 21%, desaturation correction was not achieved even at the highest flow available on the device. When the oxygen-conserving devices were used, correction was achieved in 79% of subjects with the DOD and 86% with the PRC. The final adjusted median (and IQR) oxygen settings in the 28 COPD subjects were 4 (3–5.5) for CFNC, 4 (3–5) for DOD, and 3 (2–4) for PRC. The number of subjects in whom desaturation was corrected, the dyspnea scores, and the walk distances were similar with the 3 systems tested (see Table 3). Although 75% of the COPD subjects preferred the DOD system and only 11% preferred CFNC or PRC, the difference was not statistically significant (*P* for preference 0.43); 1 COPD subject (3%) did not prefer one system over any other.

ILD Subjects

Correction of desaturation was achieved in 77% of the ILD subjects with CFNC, 61% with the DOD, and 81% with the PRC (Table 4 and Fig. 2). Thus, nearly 40% of the ILD subjects using the DOD system did not attain correction even with the highest setting, and performance was poorer than that with CFNC ($P = .01$). The adjusted median (and IQR) oxygen settings in the 31 ILD subjects were 5 (3–6) for CFNC, 5 (3–5) for DOD, and 4 (2–5) for PRC. Despite the poorer S_{pO_2} correction with the DOD system, no differences were found between the 2 oxygen-conserving devices and CFNC in dyspnea score or walk distance (see Table 4). CFNC was the system of choice in 35% of the ILD subjects, 35% chose DOD, and only 6% preferred PRC. Five ILD subjects (24%) did not prefer one system over any other ($P = .33$).

Discussion

Although the oxygen-conserving devices were effective in correcting exercise hypoxemia in most of the COPD and ILD subjects, there remained a considerable percentage of subjects in whom correction was not achieved. The lack of correction was more pronounced in the ILD subjects with the DOD, even though the oxygen flow was increased to the maximum.

Variation in the response to DOD devices according to the subjects' underlying disease has not been previously reported. Palwai et al[15] assessed the performance of 4 DOD systems, both in technical terms, in a bench study, and clinically, in 13 COPD subjects. Although all the devices tested were activated during nose and mouth breathing, there was poor synchronization between triggering and inspiration, and major discrepancies were found between the predicted and actual amounts of oxygen delivered. Palwai et al found that performance was device-dependent rather than subject-dependent. It may be hypothesized that different respiratory patterns between COPD subjects and ILD subjects could be implicated in our results. The mean breathing frequency recorded at completion of exercise was 23 breaths/min in the COPD subjects and 32 breaths/min in the ILD subjects, and this difference could have had an impact on our results, mainly because of 2 factors. First, the efficacy of oxygen delivery systems in terms of F_{IO_2} is inversely related to the breathing frequency.[7] Second, the higher breathing frequency in ILD subjects may place a stress on the mechanical performance of these devices, which are reported to have some technical limitations.[15] Although the DOD system we chose for the present study has good trigger sensi-

Table 4. Cardiopulmonary Measurements in the ILD Subjects, at Rest Before, During, and After the 6-Min Walk Test With 3 Oxygen Delivery Systems ($n = 31$)

	CFNC	DOD	*P* DOD vs CFNC	PRC	*P* PRC vs CFNC
At rest before 6MWT					
S_{pO_2}, %	97.2 ± 0.3	96.2 ± 0.3	.009	97.4 ± 0.3	.78
Breathing frequency, breaths/min	26.8 ± 1.1	26.8 ± 1.1	> .99	29.0 ± 1.1	.16
Heart rate, beats/min	78.9 ± 1.1	79.9 ± 1.1	.51	80.6 ± 1.1	.29
Borg dyspnea score	0.4 ± 0.1	0.6 ± 0.1	.24	0.7 ± 0.1	.03
During 6MWT					
Average S_{pO_2}, %	90.9 ± 0.3	89.4 ± 0.3	.001	91.8 ± 0.3	.07
Average $S_{pO_2} \geq 90\%$, no. (%)*	24 (77)	19 (61)	.01	25 (81)	.57
Time with $S_{pO_2} < 90\%$, %	40.0 ± 3.5	46.0 ± 3.5	.24	28.5 ± 3.5	.02
Immediately after 6MWT					
S_{pO_2}, %	88.3 ± 0.4	86.6 ± 0.4	.005	89.9 ± 0.4	.01
Breathing frequency, breaths/min	32.6 ± 0.7	31.4 ± 0.7	.24	33.1 ± 0.7	.59
Heart rate, beats/min	106.1 ± 1.3	105.6 ± 1.3	.80	101.8 ± 1.3	.03
Borg dyspnea score	4.1 ± 0.1	3.9 ± 0.1	.55	3.8 ± 0.1	.25
6-min walk distance, m	348.0 ± 3.0	347.9 ± 3.0	.97	346.7 ± 3.0	.75

Values are least-squares means ± standard error of the mean for continuous variables unless otherwise indicated.
* Correction of desaturation was defined as average $S_{pO_2} \geq 90\%$.
ILD = interstitial lung disease
CFNC = continuous flow with standard nasal cannula
DOD = demand oxygen delivery oxygen device
PRC = pendant reservoir cannula
6MWT = 6-min walk test

tivity (0.14 cm H_2O), an important factor related to its efficacy,[12] and is able to deliver F_{IO_2} of nearly 0.40 at 15 breaths/min and 35% at 30 breaths/min at the maximum output (setting 5),[7] we cannot exclude that limitations may manifest in clinical practice in highly demanding conditions, particularly in ILD patients.

We analyzed 31 subjects with ILD, and the efficacies of CFNC and PRC were similar, with correction of S_{pO_2} in around 80% of the ILD subjects, whereas with DOD only 61% of the ILD subjects achieved correction. Previous studies have evaluated oxygen-conserving device performance in ILD,[17,26,27] but the small number of subjects (< 10) in those studies makes it difficult to extract universally applicable conclusions. In contrast to our findings, studies assessing various DOD systems[26,27] have reported performance equivalent to the continuous flow types. However, those devices were tested at a low level of exercise, so their efficacy was not examined under technical or physiological stress. Therefore, our results provide a new view of these devices and indicate some difficulty in correcting S_{pO_2} in some ILD patients with a DOD system.

The DOD system was the device of choice in 75% of the COPD subjects. In contrast, the PRC system was preferred by only 2 ILD subjects (6%), even though it had the greatest efficacy in correcting their desaturation (see Fig. 2). This finding seems to indicate that patients prioritize esthetics and comfort (eg, cannula size and weight of the device) over other factors. Acceptance of PRC was assessed in a previous study in 17 subjects with COPD and 4 with restrictive lung disease.[28] Following 1 month of home use, 9 of the 21 subjects had abandoned the PRC, citing bulkiness and discomfort as the factors leading to poor adherence. Therefore, despite the good results with the PRC in our subjects, poor acceptance of PRC might limit its application.

Our study has some limitations that should be considered when interpreting the results. The first is our selection of the 6MWT to evaluate exercise hypoxemia. The 6MWT evaluates the global and integrated responses of the pulmonary, cardiovascular, and muscular systems, and is easily performed, well tolerated, reproducible, and a good reflection of the activities of daily living.[23,29] In the context of long-term oxygen therapy there are no uniform criteria for evaluating and adjusting oxygen flow on exercise, but the 6MWT is the most commonly used test, and the oxygen flow required to maintain $S_{pO_2} \geq 90\%$ is a commonly used threshold.[30] Therefore, this value was used in the present study to establish adequate S_{pO_2} when walking with oxygen supplementation.

Second, the study was performed in the oxygen therapy units of 2 reference hospitals, in which the subjects are more likely to have severe disease, and S_{pO_2} correction is more likely to fail than in settings where less severe cases

are treated. Nonetheless, the findings should alert clinicians evaluating these patients for oxygen therapy that the more severe cases (eg, low carbon monoxide diffusion, high lung hyperinflation, marked desaturation on exercise, high-flow oxygen requirements) may not achieve resaturation with the device chosen.

Third, our assessment was carried out at a single time point, using a 6MWT, so our results do not necessarily reflect the acceptance and effectiveness of this treatment in patients' daily lives.[31] Longer-term studies are needed to determine the impact on quality of life of the various oxygen-conserving devices.

Fourth, we tested only one of the multiple valve systems on the market, and our findings cannot be generalized to other available DOD devices. However, our results support the notion that these systems may have limitations in certain groups of patients, as has been previously reported.[15]

Conclusions

Around 20% of the severe COPD subjects with oxygen desaturation did not achieve resaturation during the 6MWT, even when oxygen flow was increased to the maximum with 3 portable oxygen systems. Moreover, failure to correct desaturation occurred in 40% of the ILD subjects when exercising with the pulse DOD device. These findings underscore the need to individually adjust oxygen flow during exercise for each patient with the device being considered for use. Furthermore, in the light of these findings, it would be advisable to carry out studies evaluating the benefits of new portable oxygen delivery systems that can provide greater flow.

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