Abstract

EVALUATION OF A NEW PULSED-DOSE DEVICE IN PATIENTS WITH CHRONIC LUNG DISEASES AT REST AND WITH EXERCISE

Trina Limberg, BS,RRT, Andrew Ries, M.D., M.P.H., Roseann Myers, BS, RN, Lela Prewitt. University of California San Diego Medical Center, San Diego CA

Background: Oxygen therapy is an important treatment and has been shown to improve survival in hypoxemic COPD patients. Due to potential cost savings and portability benefits, demand oxygen systems have increased in use. Previous studies have demonstrated mixed results of conservation systems during exercise and with activities of daily living. We sought to evaluate use of an O₂XPRESS pneumatic device by comparing it to continuous flow during exercise in pulmonary rehabilitation program graduates.

Method: Twenty-one O₂ dependent patients (18 COPD, 3 Restricted lung disease) with documented hypoxemia on room air (SaO₂ <88% or PaO₂ 55mmHg) were studied. All were receiving long term oxygen therapy. During the one visit testing, patients were provided with either a continuous flow nasal cannula or the Salter Labs demand oxygen conserving device (DOCD) . Vital signs and oxygen saturations were assessed at rest and during exercise. While seated, subjects received sequential flow rates of 1, 2, 3 and 4 LPM of supplemental oxygen, once with continuous flow and once with the DOCD device for 5 minute periods. Oximetry was recorded during the final 15 seconds of each five minute interval. Then subjects were tested while walking on the treadmill based on workload prescriptions determined during the previously completed pulmonary rehabilitation program. At UCSD, exercise training targets are set to approximate maximum symptom-limited levels reached during an initial incremental exercise test. In obstructive patients, supplemental oxygen was delivered sequentially, at 4, 3, 2, and 1 liters per minute during treadmill exercise for 3 minutes each. Following each change in flow rate subjects were required to rest for 10 minutes. Restrictive patients received higher flow rates, sequentially, at 6, 4, 2 and 1 LPM. Ratings of perceived breathlessness and muscle fatigue were also obtained via the Borg scale at the end of exercise. Assessments were terminated if oxygen saturations fell below 85%. COPD patients were analyzed in a group while the restrictive patients were studied individually. Repeated measures analysis of variance was used to compare oxygen saturation with the two methods of continuous flow via nasal cannula and the Salter Labs DOCD cannula and device. Separate analysis was performed for rest and exercise with paired-t tests.

Results: For COPD patients, results showed there was no significant difference in SaO₂ at comparable flow rates between the two devices, although with exercise SaO₂ was significantly (p< 0.05) higher at the lowest flow rate with the DOCD device (mean SaO₂ 91.5% versus 90.2%). SaO₂ was higher for the DOCD in 10 patients (range 1-5%), higher for the nasal cannula in 4 (range 1-2%), and equal in 3 subjects. One subject did not exercise on 1 lpm due to a low SaO₂. Overall, there was no significant difference in ratings of muscle fatigue or breathlessness. Individual results for restrictive patients showed that at rest, the DOCD appeared to produce higher SaO₂ in one of three patients. During exercise there did not appear to be any consistent difference between continuous flow and use of the Salter Labs DOCD.

Conclusions: This pilot study demonstrated that the Salter Labs DOCD was comparable to continuous flow by nasal cannula at rest and during exercise in patients with chronic lung disease. It is important to note treadmill speeds in some patients were as high as 2.8 mph. Previous studies appear to have been conducted at much lower workloads. Since respiratory rates increase with higher workloads it is imperative that patients using conservation devices be assessed with exertion.

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EVALUATION OF A NEW DEMAND OXYGEN CONSERVATION DEVICE IN PATIENTS WITH CHRONIC LUNG DISEASES AT REST AND WITH EXERCISE

Trina M. Limberg, B.S., R.R.T., FAARC\textsuperscript{1}, Andrew L. Ries, M.D., M.P.H.\textsuperscript{1,2}, Roseann Myers, R.N., J.D.\textsuperscript{1}

\textsuperscript{1}University of California, San Diego, Division of Pulmonary and Critical Care Medicine.
\textsuperscript{2}University of California, San Diego, Department of Family and Preventive Medicine.

This research was sponsored by Salter Labs.

Corresponding Author/Reprint Requests: Trina M. Limberg, B.S., R.C.P., R.R.T.
UCSD Medical Center - #8377
200 West Arbor Drive
San Diego, CA 92103-8377
619.543.7411
Fax:619.543.7345
tlimberg@ucsd.edu

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Abstract

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Trina Limberg, BS, RRT, Andrew Ries, MD., M.P.H., Roseann Myers, RN, J.D. University of California San Diego Medical Center, San Diego CA

Background: Oxygen therapy is an important treatment and has been shown to improve survival in hypoxemic COPD patients. Demand oxygen systems have increased in use due to potential cost savings and portability. Previous studies have demonstrated mixed results of conservation systems during exercise and with activities of daily living. We evaluated a pneumatic demand oxygen conserver (PDOC) device (O2XPRESS, Salter Labs) at rest and during exercise in pulmonary rehabilitation graduates.

Method: We studied 21 patients (18 COPD, 3 Restricted) with documented hypoxemia (room air SaO2 <88% or PaO2<55mmHg). All were receiving long term oxygen therapy. Subjects were tested at rest and while walking on the treadmill at symptom-limited walk levels used during training in pulmonary rehabilitation. In COPD patients, supplemental O2 was delivered sequentially, at 4, 3, 2, and 1 LPM at rest and during treadmill exercise for 3 minutes each. Subjects rested for 10 minutes between changes in flow rates. Restricted patients received higher flow rates, sequentially, at 6, 4, 2 and 1 LPM. Ratings of perceived breathlessness and muscle fatigue were obtained at the end of exercise. Tests were terminated if SaO2 fell below 85%. Patients were tested twice in one session with the PDOC and with continuous flow; the order of testing for the two modes was determined randomly.

Results: For COPD patients, there was no significant difference in SaO2 at comparable flow rates between the two devices, although with exercise SaO2 was significantly (p< 0.05) higher at the lowest flow rate with the PDOC (mean SaO2 91.5% versus 90.2%). SaO2 was higher for the PDOC in 10 patients (range 1-5%), higher for the nasal cannula in 4 (range 1-2%), and equal in 3. Overall, there were no significant differences in ratings of breathlessness or muscle fatigue. The PDOC appeared to produce a higher SaO2 at rest in one restricted patient. During exercise there were no consistent differences between continuous flow and the PDOC.

Conclusions: This pilot study demonstrated that the Salter Labs PDOC was comparable to continuous flow O2 at rest and during exercise in patients with chronic lung disease. Treadmill speeds in some patients were as high as 2.8 mph. It is important that conservation devices be evaluated both at rest and at walking levels that approximate the patient’s usual activities.
Introduction

Chronic obstructive pulmonary disease (COPD) is a major cause of death and disability. COPD is the fourth leading cause of death in the United States and is recognized in approximately 10 to 15% of adults over the age of 55 years.\textsuperscript{1,2} It affects at least 15 million people in the United States with an annual medical care cost of $6.6 billion. Roughly one third of the cost or $2.3 billion dollars is spent on supplemental long-term oxygen therapy (LTOT).\textsuperscript{3} Oxygen therapy is an important treatment that has been shown to improve survival in hypoxemic patients with COPD.\textsuperscript{4,5}

Oxygen conservation devices were developed to improve the efficiency of oxygen delivery and have been available since the early 1980’s.\textsuperscript{6} In recent years, changes in oxygen reimbursement policies have spurred demand and wide-spread distribution of oxygen conservation devices. In response to market forces of lower and fixed reimbursement rates, durable medical equipment companies have been motivated to use more efficient methods for delivering oxygen and servicing patients who require LTOT. Respiratory equipment manufacturers have responded to this increased need for cost containment by developing several new and different oxygen conservation devices.

Pulmonary patients have benefited from advances in product development in greater freedom from home systems and use of lighter weight portable oxygen units. Most published studies show adequate support of oxygenation with demand or pulsed devices during resting conditions when respiratory rates are often lower and milder hypoxemia is likely to occur.\textsuperscript{7,8,9}

Adequately treating hypoxemia, improving patient adherence, and reducing the cost of LTOT are primary goals. Continuous oxygen flow with a standard nasal cannula has been
shown to support oxygenation at rest and with exercise in patients with COPD, but the costs of continuous therapy are high and the delivery method is inefficient.\textsuperscript{7,8,9,10} This is particularly true for patients with obstructive lung disease who spend the majority of their respiratory cycle in expiration when continuous flow gas is wasted. With continuous flow systems, patients who require higher flow rates (i.e. above 2 L/min) are often limited by less freedom time away from home reservoir systems or by the weight and cumbersome nature of larger compressed gas cylinders.

Previous studies have demonstrated mixed results of conservation systems when they are evaluated with exercise in pulmonary patients. Hagarty and colleagues compared standard nasal (continuous flow) and reservoir cannula to a demand flow device at rest and during exercise in COPD patients.\textsuperscript{10} The patients were also evaluated with typical daily care activities, such as dressing and undressing. The results showed that the pulsed dose device was unable to adequately maintain oxygen saturation during these daily activities.\textsuperscript{10} Braun and colleagues compared continuous flow with five oxygen conservation delivery systems at rest and during twelve-minute walk exercise tests.\textsuperscript{8} Their results indicated that systems delivering a bolus in early inspiration or systems that increased oxygen delivery as the respiratory rate increased, tended to perform better under exercise conditions than systems that delivered oxygen during a fixed portion of inspiration. The authors concluded that oxygen-conserving devices varied in their ability to maintain SpO\textsubscript{2} during exercise and that patients should be assessed on their particular home delivery systems. This is a common practice within established pulmonary rehabilitation programs, but is not standard practice for many patients on LTOT who do not undergo pulmonary rehabilitation evaluation and treatment. We have encountered many obstructive and some restrictive lung disease patients with inadequate oxygen prescriptions,
particularly with exercise and activities. In most of these patients, assessment for oxygen therapy was performed with continuous flow oxygen only. In our pulmonary rehabilitation program, we typically evaluate oxygen therapy requirements using the patients’ actual home systems during supervised exercise sessions. We have also observed that oxygen saturations of greater than 90% could not be maintained during exercise in many patients using some demand systems.

The purpose of this study was to evaluate a new pneumatic demand oxygen conservation device - the O₂Xpress Pneumatic Demand Oxygen Conserver (PDOC) designed and produced by Salter Labs of Arvin, California - in stable patients on LTOT during standardized conditions at rest and with exercise.

Methods

Twenty-one oxygen dependent patients with stable chronic lung disease were recruited and agreed to participate in the study. All were graduates or current participants in a comprehensive pulmonary rehabilitation program and signed consent forms approved by our Institutional Review Board. Eighteen patients had obstructive lung disease and three had restrictive lung disease. The most recent pulmonary function tests were reviewed to classify patients. The subjects had documented hypoxemia on room air (SpO₂ <88% or PaO₂ <55 mmHg) at rest and/or with exertion and all were receiving LTOT.

The study evaluation was conducted in one visit. During tests, supplemental oxygen was provided with either a continuous flow nasal cannula or the Salter PDOC device. Blood pressure, heart rate and respiratory rate were measured following a ten-minute rest period. Patients were then transferred from their own portable oxygen systems to an E-size compressed
gas cylinder. Patients were continuously monitored with a finger probe using a Quartz Q400 pulse oximeter and Masimo Set technology.

All subjects were assessed both at rest and during exercise. First, subjects were seated quietly while receiving, sequentially, flow rates of 1, 2, 3, and 4 liters per minute of supplemental oxygen, each for a five-minute period. Oximetry was recorded during the final 15 seconds of each five-minute period. Each subject repeated the rest assessments twice - once with the nasal cannula and once with the Salter PDOC device. The order in which the devices were tested was assigned randomly.

After completing the rest assessments, subjects were tested on each device while walking on a treadmill. The workload or treadmill speed was set based on the walking exercise prescription which was determined during the previous treatment course of pulmonary rehabilitation. Rehabilitation exercise prescriptions were set to approximate the maximum, symptom-limited levels reached during an initial maximal, incremental treadmill exercise test (or the level of the anaerobic threshold, if reached). For these subjects, treadmill speeds for testing ranged from 0.8 to 2.8 mph. In the patients with obstructive lung disease, the supplemental oxygen was administered, sequentially, at flow rates of 4, 3, 2, and 1 liters per minute during treadmill exercise for 3 minutes each. Patients with restrictive lung disease received higher flow rates, sequentially, at 6, 4, 2, and 1 liters per minute for 3 minutes each. Following each change in oxygen flow rate, subjects were required to rest quietly for 10 minutes before beginning the next 3 minute exercise period. Oximetry was recorded during the final 15 seconds at each level of oxygen therapy. Subjects also rated symptoms of perceived breathlessness and fatigue using a modified Borg Scale immediately following oximetry recordings for each exercise period. The assessments were terminated if the patient’s oxygen saturation fell below 85%.
Results

Results for the patients with COPD are presented in Figures 1 and 2 for the rest and exercise conditions, respectively. Overall, there was no significant difference in SpO\textsubscript{2} at comparable flow rates between the two devices, although with exercise SpO\textsubscript{2} was significantly (p<0.05) higher at the lowest flow rate (1 liter per minute) with the Salter PDOC device (mean SpO\textsubscript{2} 91.5% versus 90.2%). During this latter condition, of the 17 subjects tested, SpO\textsubscript{2} was higher for the Salter PDOC device in 10 (range 1-5%), higher for the nasal cannula in 4 (range 1-2%), and equal in 3. One subject did not exercise on 1 liter per minute because SpO\textsubscript{2} was too low at 2 liters per minute. Overall, there was no difference in ratings of perceived breathlessness or muscle fatigue during exercise at comparable oxygen flow rates between the two devices, although perceived breathlessness was significantly lower at the highest oxygen flow rate with the nasal cannula. Results for the three individual patients with restrictive lung disease are presented in Figures 3 and 4 under rest and exercise conditions, respectively. At rest, the Salter PDOC device appeared to produce higher SpO\textsubscript{2} in one of the three patients at the lower flow rates. During exercise, there did not appear to be any consistent differences.

Discussion

The results of this pilot study demonstrate that the new Salter O\textsubscript{2}Xpress PDOC oxygen delivery device was comparable to continuous flow by nasal cannula at rest and during exercise in patients with chronic lung disease. There is a suggestion that the PDOC produced higher SpO\textsubscript{2} during exercise at the lowest flow rate (1 liter per minute) in patients with COPD. The device was well tolerated by these patients, although the symptom ratings of perceived breathlessness were significantly higher with the PDOC at the highest flow rate tested (4 liters per minute).
It should be emphasized that these patients were tested at treadmill workloads used during a previously completed pulmonary rehabilitation program that approximated their maximal, symptom-limited levels. This is an exercise level that is appropriate for activities of daily living for many of these patients. The O₂Xpress is a pneumatic device that delivers a large bolus of oxygen early on during the first-third of inspiration. The product is internally designed to be sensitive and responsive to the patient’s breathing pattern. Although we did not evaluate cost savings benefits, the manufacturer reports the same 2:1 or 3:1 ratio as the other devices in this same classification based on the patient’s respiratory disease and breathing pattern. The O₂Xpress is easy for patients to use and adjust flow rates. In our experience, some devices are difficult for patients to adjust when higher settings are required for exertion than at rest. When demand devices are difficult to use, many patients will remain on a resting or lower flow setting despite instructions. The easier the device is to use, the more likely patients are to adhere to recommendations. Although this is a pilot study, it is important to note that exercise measures were obtained at speeds higher than many other studies have reported.
References


Figure Legends

Figure 1.
Comparison of oxygen saturation in patients with obstructive lung disease using Salter Labs PDOC versus nasal cannula at rest. Mean ± 95% confidence. n=18.

Figure 2.
Comparison of oxygen saturation using Salter Labs PDOC versus nasal cannula during treadmill exercise in patients with obstructive lung disease. Mean ±95% confidence. n=18.

Figure 3.
Three patients with restrictive lung disease at rest using the Salter Labs PDOC versus nasal cannula.

Figure 4.
Three patients with restrictive lung disease during treadmill exercise using the Salter Labs PDOC versus nasal cannula.
Figure 1.

Comparison of oxygen saturation in patients with obstructive lung disease using Salter Labs PDOC versus nasal cannula at rest. Mean ± 95% confidence. n=18.
Figure 2.

Comparison of oxygen saturation using Salter Labs PDOC versus nasal cannula during treadmill exercise in patients with obstructive lung disease. Mean ± 95% confidence. n=18.
Figure 3.

Three patients with restrictive lung disease at rest using the Salter Labs PDOC versus nasal cannula.
Figure 4.

Three patients with restrictive lung disease during treadmill exercise using the Salter Labs PDOC versus nasal cannula.

*PDOC flow-equivalent based on manufacturer's settings.