Assessing Need for Long-Term Oxygen Therapy: A Comparison of Conventional Evaluation and Measures of Ambulatory Oximetry Monitoring

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BACKGROUND: Appropriate identification of hypoxic patients with chronic obstructive pulmonary disease (COPD) is important because of the demonstrated survival benefit of long-term oxygen therapy (LTOT) and its associated cost. Resting oxygen saturation (measured via pulse oximetry [S_{pO_2}]) and lowest exercise S_{pO_2} (during a 6-min walk test) is the standard method of determining LTOT requirements, but that method does not measure the patient's oxygenation during sleep or activities of daily living. We hypothesized that values obtained via the standard method would correlate poorly with values obtained via ambulatory oximetry monitoring. METHODS: We conducted a prospective, cohort study in an out-patient pulmonary clinic in a tertiary care referral center, with 20 stable COPD patients who were being evaluated for LTOT with conventional evaluation versus 16–24 hours of ambulatory oximetry. RESULTS: The resting S_{pO_2} did not correlate well with mean ambulatory S_{pO_2} ($r = 0.64$) or the percent of monitored time spent with $S_{pO_2} < 88\%$ ($r = 0.49$). The lowest exercise S_{pO_2} also did not predict mean ambulatory S_{pO_2} ($r = 0.39$) or the percent of monitored time spent with $S_{pO_2} < 88\%$ ($r = 0.32$). Conventional evaluation overestimated LTOT requirements with 16 of the 20 patients developing an $S_{pO_2} < 88\%$, most of them with exercise only (ie, most had normal resting S_{pO_2}). With ambulatory monitoring, however, only 3 of the 16 patients spent > 10% of the monitored time with S_{pO_2} < 88%. CONCLUSION: There was a poor relationship between the conventional oxygenation assessment method and continuous ambulatory oximetry during LTOT screening with COPD patients. *Key words: long-term oxygen therapy, lung disease, chronic obstructive pulmonary disease, COPD, oxygen, ambulatory oximetry, monitoring.* [Respir Care 2003;48(2):115–119]

Introduction

Long-term oxygen therapy (LTOT) and smoking cessation are the only treatments that have been shown to improve survival among hypoxemic patients with chronic obstructive pulmonary disease (COPD).[1,2] Under the current Medicare guidelines, LTOT is prescribed to COPD patients based on a single measurement of oxygenation at rest or during exercise. Patients qualify for LTOT with either P_{aO_2} of $\leq$ 55 mm Hg or a pulse oximetry ([S_{pO_2}]) value of $\leq$ 88%.[3] The qualifying values are higher ($P_{aO_2} < 59$ mm Hg or $S_{pO_2} < 89\%$) in the setting of hypoxic end-organ damage. Currently, approximately 800,000 patients receive LTOT in the United States, at a total yearly cost estimated to be $1.8 billion.[4] Accordingly, the proper identification of patients who would benefit from LTOT is an important public health issue. Continuous ambulatory oximetry is now available, and although further investigation is required to determine the optimal criteria for evaluating and interpreting the results, it may allow for better identification of those who would benefit from LTOT.

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The purpose of this study was to assess the relationship between the conventional method of LTOT assessment and a continuous ambulatory oximetry method. The measures we chose to represent conventional evaluation included the resting S_{pO_2} (ie, a single, isolated S_{pO_2} reading after the patient had been at rest for 5 min) and the lowest S_{pO_2} recorded during a 6-min walk test.

The measures we chose to represent the data from continuous ambulatory oximetry included the mean S_{pO_2} from the 16–24-hour ambulatory oximetry monitoring period (mean ambulatory S_{pO_2}) and the percent of time that the patient's S_{pO_2} was below 88% during the monitoring period (percent of time with $S_{pO_2} < 88\%$). There are no published criteria for prescribing LTOT based on continuous ambulatory pulse oximetry. During this study we chose to define a positive requirement for LTOT as either a mean ambulatory S_{pO_2} of $< 88\%$ or $> 10\%$ of time with $S_{pO_2} < 88\%$

We hypothesized that there would not be a close correlation between the resting S_{pO_2} and either the mean ambulatory S_{pO_2} or the percent of time with $S_{pO_2} < 88\%$. We further hypothesized that there would be a poor correlation between the lowest S_{pO_2} during a 6-min walk test and either the mean ambulatory S_{pO_2} or the percent of time with $S_{pO_2} < 88\%$.

Methods

The institutional review board at Saint Thomas Hospital approved the protocol for the study, and all patients gave informed consent. Study participants were consecutive, stable out-patients with COPD undergoing LTOT evaluation. Initially patients underwent spirometry and conventional LTOT evaluation with resting S_{pO_2} and S_{pO_2} measured during a standard 6-min walk test (with the lowest S_{pO_2} recorded). This was followed by continuous ambulatory pulse oximetry on room air for 16–24 hours while the patient was at home performing his or her activities of daily living, including sleep. We used the OxyHolter (OxyHolter, Nashville, Tennessee) monitor during both evaluations, to minimize sampling error.

The OxyHolter monitor is a commercially available device, approved by the Food and Drug Administration, similar in concept to the cardiac Holter monitor. The OxyHolter measures $14.6 \times 7.6 \times 3.8$ cm and weighs about 450 g. The device uses a pulse oximetry finger probe and electrocardiograph chest leads to record S_{pO_2} and heart rate every 15 seconds. The OxyHolter has a liquid crystal display, which we removed so as to blind the patient to his or her performance, minimizing bias from the Hawthorne effect.[5]

Once the monitoring was completed, we analyzed the data with commercially available software (NorthEast, Boston, Massachusetts) that graphs the S_{pO_2} and electrocardiograph data. We reviewed the tracings and removed any obvious artifacts before further data analysis. The software then generated a report of the mean, maximum, and minimum S_{pO_2} and the percent of time that S_{pO_2} was below 90%, 89%, 88%, 87%, and 86%. This report provided the results discussed below.

All data are expressed as mean ± standard deviation. The relationship between the conventional measurements for determining the need for LTOT, and those obtained with continuous ambulatory oximetry were compared using linear regression.

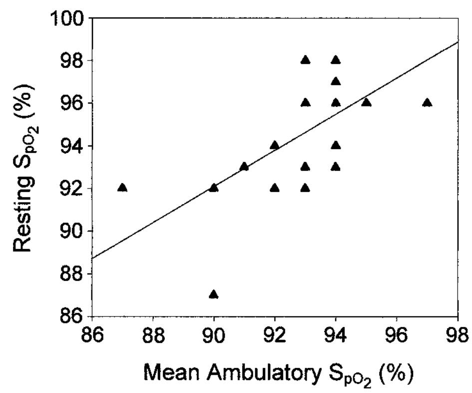

Fig. 1. Resting S_{pO_2} (oxygen saturation measured via pulse oximetry) versus mean ambulatory S_{pO_2}.

Results

We studied 20 COPD patients (11 men and 9 women) who were undergoing evaluation for LTOT. Their mean age was 66.5 ± 7.3 years. Their mean forced expiratory volume in the first second (FEV_1) was 1.16 ± 0.7 L. Their mean forced vital capacity (FVC) was 2.07 ± 0.77 L. On room air, their mean resting S_{pO_2} was 94.9 ± 2.8%, and the mean lowest S_{pO_2} during the 6-min walk test was 83.4 ± 7.0%. The mean duration of ambulatory oximetry was 21 ± 2.5 hours. On room air, the mean ambulatory S_{pO_2} was 93.0 ± 2.5%, and the mean percent of time with $S_{pO_2} < 88\%$ was 7.0 ± 13.4%.

There was no close relationship between the resting S_{pO_2} and the mean ambulatory S_{pO_2} (Fig. 1). The correlation coefficient was only 0.64, and the resting S_{pO_2} both overestimated and underestimated the mean ambulatory S_{pO_2}. For example, one patient had a resting S_{pO_2} of 92% but a mean ambulatory S_{pO_2} of 87%. Another patient had a resting S_{pO_2} of 87% but a mean ambulatory S_{pO_2} of 90%. In general, however, the resting S_{pO_2} was higher than the mean ambulatory S_{pO_2}. This is not completely unexpected, as mean ambulatory S_{pO_2} includes data obtained during sleep, during which time S_{pO_2} was lower in a number of our patients.

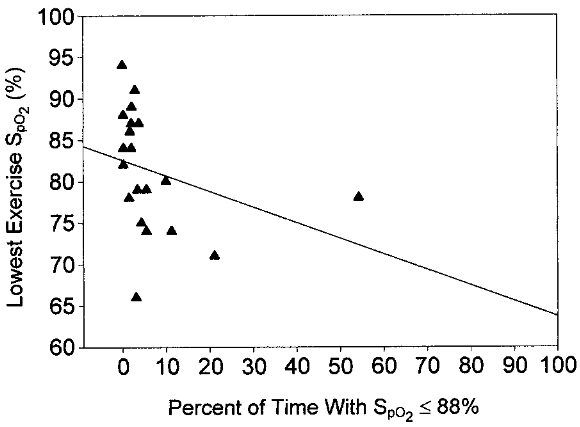

Fig. 2. Lowest exercise S_{pO_2} (oxygen saturation measured via pulse oximetry) versus percent of time with $S_{pO_2} \leq 88\%$.

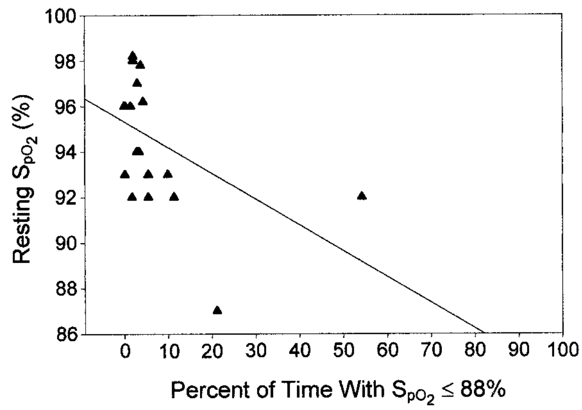

Fig. 4. Resting S_{pO_2} (oxygen saturation measured via pulse oximetry) versus percent of time with $S_{pO_2} \leq 88\%$.

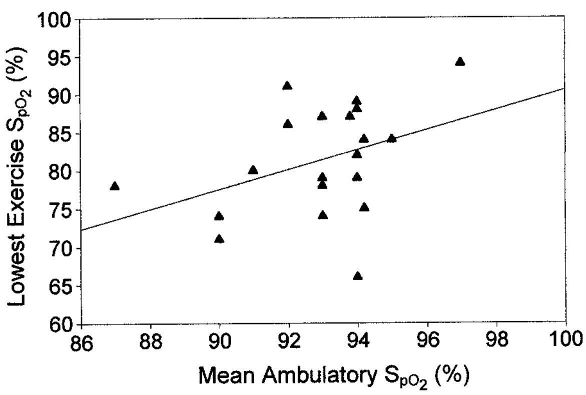

Fig. 3. Lowest exercise S_{pO_2} (oxygen saturation measured via pulse oximetry) versus mean ambulatory S_{pO_2}.

There was also a poor correlation between the resting S_{pO_2} and the percent of time with $S_{pO_2} < 88\%$ ($r = 0.49$, Fig. 2). For example, one patient had a resting S_{pO_2} of 92% but spent more than 50% of his monitored time with $S_{pO_2} < 88\%$. Overall, 3 patients spent > 10% of their monitored time with $S_{pO_2} < 88\%$.

There was also no close correlation between the lowest S_{pO_2} during the 6-min walk test and the mean ambulatory S_{pO_2} ($r = 0.39$, Fig. 3). Several patients with very low S_{pO_2} (< 80%) during 6-min walk test had mean ambulatory S_{pO_2} > 92%.

There was also a poor correlation between the lowest S_{pO_2} during 6-min walk test and the percent of time with $S_{pO_2} < 88\%$ ($r = 0.32$, Fig. 4). In fact, the patient with the most severe desaturation during 6-min walk test had S_{pO_2} below 88% for only 3% of the ambulatory monitored time.

We found that 16 of the 20 patients would have qualified for LTOT based on conventional evaluation, mostly based on low S_{pO_2} during the 6-min walk test. In comparison, only 3 patients qualified for LTOT based on our criteria for continuous ambulatory oximetry, all 3 having spent > 10% of their monitored time with an $S_{pO_2} < 88\%$.

Discussion

We hypothesized that the conventional methods of evaluation would not reflect the patient's overall oxygenation status because they fail to capture the minute-to-minute variation of S_{pO_2} and the variations during routine activities of daily living. The present study shows that the results of conventional methods of determining need for LTOT do not correlate with the results from a continuous ambulatory oximetry method. This observation suggests limitations in the current method of oxygen prescription.

Hypoxemia ($P_{aO_2} < 55$ mm Hg) results in several physiologic changes, including increased ventilatory drive, tachycardia, pulmonary vasoconstriction, and erythrocytosis, all of which may have short-term benefits (improving blood oxygenation and delivery to tissues) but adverse long-term consequences.[6] In 1981 the Medical Research Council Working Party[2] demonstrated that patients with chronic resting hypoxemia given 15 hours of continuous daily oxygen had better survival than controls given no oxygen therapy. The Nocturnal Oxygen Therapy Trial[1] then showed that the benefits of oxygen therapy were proportional to the number of hours of therapy. Patients who were randomized to receive continuous oxygen therapy (average of 18 h) had a 50% lower mortality than the group that received only nocturnal oxygen therapy (average of 12 h).

It has therefore become widely accepted that identifying and correcting hypoxemia in COPD patients has important therapeutic implications that can affect long-term mortality. The current criteria[3] for determining need for LTOT are $P_{aO_2} \leq 55$ mm Hg or $S_{pO_2} \leq 88\%$ at rest, with exertion, or during sleep. Higher values (P_{aO_2} 55–59 mm Hg or $S_{pO_2} \leq 90\%$) are acceptable in the setting of hypoxic end-organ damage such as right heart failure, neuropsychiatric impairment, or erythrocytosis. It should be noted, however, that there are currently no randomized controlled trials that demonstrate benefit from LTOT with patients who have exertional desaturation but do not have resting hypoxemia.

Conventional evaluation for LTOT involves a resting S_{pO_2} or P_{aO_2} and the lowest S_{pO_2} during some form of exertion, to identify patients who suffer substantial desaturation during activities of daily living. The difficulty is that it has never been shown that those measures are predictive of the patient's oxygenation status during those daily activities. In fact, only a few investigators have evaluated the temporal trends in oxygenation in COPD patients during activities of daily living.

Decker et al,[7] in 1989, first showed that ambulatory monitoring of oxygen saturation was feasible and accurate, compared to CO-oximetry data. Ambulatory oximetry has since been used by various investigators to demonstrate the variability of S_{pO_2} during sleep and activities of daily living in COPD patients without resting hypoxia.

Soguel Schenkel et al[8] used continuous oximetry monitoring to study 30 stable COPD patients who did not have resting hypoxia. They found that mean S_{pO_2} was significantly lower at night than during the day but that the lowest recorded S_{pO_2} occurred during daytime activities.

Morrison et al[9] studied 20 COPD patients receiving LTOT, using 24 hours of continuous oximetry, and found that the 11 patients who did not have resting hypoxia ($S_{pO_2} > 90\%$) spent an average of 22% of the 24-hour study period with $S_{pO_2} < 90\%$, demonstrating that some patients with normal resting S_{pO_2} spend a substantial amount of time hypoxemic.

Sliwinski et al[10] studied 34 COPD patients receiving LTOT, using 24 hours of continuous oximetry, and found that, despite a mean resting S_{pO_2} of 94 ± 1.8%, the subjects spent an average of 29 ± 26% of the monitored time with $S_{pO_2} < 90\%$.

Pilling and Cutaia[11] showed that oxygen prescriptions based on the current methods of evaluation resulted in patients spending a substantial amount of time with oxygen saturation below 90%. In that study 20 of 27 patients spent > 10% of their oximetry-monitored time in the hypoxic range ($S_{pO_2} < 90\%$) and 9 of 27 patients spent > 25% of their oximetry-monitored time hypoxic, suggesting that the conventional method of LTOT evaluation largely underestimates the patient's need for oxygen therapy.

Though the desaturations noted in the aforementioned studies are of unknown clinical importance, Fletcher et al[12] observed that patients with daytime $P_{aO_2} > 60$ mm Hg and nocturnal desaturation had a markedly higher mortality (11 of 39 patients died during the 3-year study) than controls (0 of 11 patients died during the 3-year study). However, that study failed to show that nocturnal oxygen changed that mortality rate over the 3-year period.

It has also been demonstrated, with pulmonary artery catheter measurements, that withdrawing oxygen from COPD patients on LTOT results in worsening pulmonary hemodynamics, cardiac function, and gas exchange.[13] Specifically, significant changes in pulmonary vascular resistance developed within only 2.5 hours of removal of supplemental oxygen. Other studies have demonstrated that similar changes in pulmonary vascular resistance and pulmonary artery pressure occur with exercise in patients with severe COPD, along with substantial increases in pulmonary capillary wedge pressure.[14] These studies may explain why LTOT's survival benefit is proportional to the number of hours of therapy, as even short periods of hypoxia can result in detrimental hemodynamic changes. However, it should be noted that with patients who do not have resting hypoxia it has not been demonstrated that correcting these small periods of hypoxia results in any survival benefit.

In summary, the latter studies demonstrate that ambulatory oximetry monitoring can uncover hypoxia that occurs during activities of daily living and that is not revealed by conventional LTOT evaluation. These findings are similar to our data, which also demonstrate that ambulatory oximetry can identify patients who, by conventional evaluation, appear to need LTOT but who in fact spend very little time in the hypoxic range and therefore are unlikely to need LTOT.

The most notable limitation of our study is that we used only oximetry measurements, without measurement of arterial oxygen saturation. There has been some controversy as to whether pulse oximetry is adequate for screening and evaluating patients for LTOT,[15–17] but multiple investigators have shown that pulse oximetry accurately measures oxygen saturation in both healthy[18,19] and critically ill patients.[20] On the other hand, there have been conflicting data concerning the reliability of pulse oximetry measurements during exercise,[21–23] which may have some bearing on the usefulness of continuous oximetry during activities of daily living. The new generation of ambulatory oximeters are small, lightweight, and capable of providing detailed analysis of a patient's mean S_{pO_2} and percent of time with $S_{pO_2} < 86\%$, $< 88\%$, $< 90\%$, and $> 95\%$, making clinical evaluation and decision-making easier and faster than in previous studies. The cost to operate the monitor is minimal (uses 2 AA batteries for a 24-h monitoring period), and our patients had no difficulty with the monitors during the study period.

Conclusions

The present study supports the hypothesis that there is a poor relationship between the results of conventional LTOT assessment methods and results from continuous ambulatory oximetry. Ambulatory oximetry coupled with computer analysis is feasible, inexpensive, and applicable to the clinical setting. Additional studies are needed to determine if the prescription of oxygen based on continuous ambulatory oximetry can result in a higher percent of time in the desired saturation range of S_{pO_2} 88–92%.

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