HomeFill™ II Clinical Tri-fold Brochure

The purpose of this brochure is to highlight the clinical benefits of the HomeFill II system to medical professionals. This sales tool is specifically targeted to physicians, respiratory therapists, nurses and social workers—anyone involved in the ordering of oxygen or discharge planning process. This literature is intended to be used by the HME provider to support their HomeFill marketing efforts (Providers should stamp their contact information on the back of the brochure). This brochure highlights the key clinical principles and studies that support the benefits offered by HomeFill. These include: the significance of the retrospective NOTT study, the importance of ambulation for COPD patients, how HomeFill II provides ultimate mobility for patients, importance of using continuous flow oxygen at night, elements of 5th Consensus Oxygen Conference and how HomeFill II meets the criteria laid out by committee—size, weight, duration, and ease of use.

Key Elements:

- **Graph - Retrospective NOTT Study & the Importance of Mobility**
  - The original NOTT (Nocturnal Oxygen Therapy Trial) study was published in 1980 and conclusively demonstrated that COPD patients that used oxygen continuously lived longer than patients that only used oxygen at night.
  - The retrospective study reanalyzed the original NOTT data. This study concluded that in both the continuous and nocturnal oxygen groups, patients that ambulated lived longer than those that did not (green line). The results of this study are presented in the brochure graph.

- **HomeFill II Provides Ultimate Mobility**
  - Since HomeFill allows patients to fill their own cylinders, they have an unlimited supply of ambulatory oxygen (A standard patient setup includes 2 cylinders). Cylinders can be carried either over-the-shoulder or in a fanny-pack configuration. These configurations offer patients extended duration, hands-free portability. Also, by eliminating the need to wait at home for cylinder deliveries, HomeFill offers the patient a sense of independence and freedom, and allows them greater control of their life.

- **Continuous Flow Oxygen at Night**
  - Some liquid oxygen systems require the patient to connect their portable unit to the liquid reservoir when at home. Such a configuration results in the patient breathing through a conserving device even while sleeping. It is well known that breathing patterns change during sleep and the ability to trigger the conserving device can be limited. This is particularly critical in COPD patients that already suffer from reduced oxygen levels while sleeping. On the other hand, HomeFill allows patients to breath continuous flow oxygen at night directly from the concentrator.

- **5th Long-Term Oxygen Consensus Conference**
  - This conference of national clinical leaders established minimal acceptable criteria for portable oxygen systems. These criteria include; the ability of the portable device to be carried by the patient, the device must weigh less than 10 lbs. (the Ultimate Convenience Pack with an ML6 cylinder weighs only 4.3 lbs.), and must provide a minimum of 4 hours of flow at the equivalent of 2 liters per minute (the HomeFill II ML6 lasts 5.2 hours, and with an M9 it lasts 7.6 hours!).
Invacare® HomeFill™ II and Patient Convenience Pack

• Provides an unlimited ambulatory oxygen supply
• Patient breathes from a continuous flow oxygen concentrator at night
• Allows greater mobility than other traditional oxygen modalities
• Ideal for travel
• Fosters independence for ambulatory oxygen
• Patient Convenience Pack offers a continuous flow option at 2 lpm

Traditional Oxygen Modalities

• May limit the patient’s ambulatory oxygen supply
• May limit patient mobility
• Can be difficult to use
• May require the patient to breathe with a conserving device at night
• Foster dependence on provider for ambulatory oxygen

Patient Convenience Pack for Ambulatory Use

<table>
<thead>
<tr>
<th></th>
<th>ML6</th>
<th>ML9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capacity</td>
<td>170</td>
<td>255</td>
</tr>
<tr>
<td>Duration (hours)</td>
<td>5.2</td>
<td>7.9</td>
</tr>
<tr>
<td>Weight</td>
<td>4.3 lb.</td>
<td>6.0 lb.</td>
</tr>
</tbody>
</table>

*Based on 2 lpm flow @ 20 bpm
The 2nd through the 5th Consensus Conference on Home Oxygen Therapy(1-4) identified the need for portable oxygen therapy to enhance patient quality of life. Also, the NOTT study (see graph) demonstrates the effect that ambulation and portable oxygen has on longevity. The Invacare® Venture® HomeFill™ II system gives ambulatory oxygen patients control of their lives.

Patients control their own oxygen supply as they fill Invacare provided cylinders according to their needs and enjoy unprecedented freedom and independence. While at home, the patient rests or sleeps breathing continuous flow oxygen from the market-leading Invacare® Platinum™ 5 Concentrator. The lightweight Patient Convenience Pack allows patients to "get up and go" as often as they desire.

With HomeFill II, patients can fill Invacare provided M6/ML6 cylinders in about 1 hour and 20 minutes and enjoy greater than five hours of ambulatory time. (See table on reverse side.)

The Patient Convenience Pack uses advanced pneumatic conserving technology, requires no batteries or cumbersome connection lines and provides maximum ambulatory time.

Cylinders are connected to the HomeFill II with the OxyLock™ coupler which enables the patient to fill specially adapted Invacare provided cylinders easily and safely. To remove, the patient pushes down on the sleeve and lifts the cylinder from the HomeFill unit.

Survivorship vs Walking Level and Oxygen Therapy

In a re-analysis of the NOTT study5 by Petty/Bliss6 it was found that highly ambulatory patients on continuous oxygen therapy (COT*) had a 50% higher survival rate than low ambulatory patients on nocturnal oxygen therapy (NOT†).


6. Respir Care, 2000; 45(2): 204-211
* COT = oxygen intended to be used as close to 24 hours per day as possible
† NOT = Oxygen used for approximately 12 hours per day
(From Reference 6, with permission)
NOTT Study Revisited

Ambulatory Oxygen Therapy, Exercise, and Survival with Advanced Chronic Obstructive Pulmonary Disease (The Nocturnal Oxygen Therapy Trial Revisited)

Published in Respiratory Care, February 2000;45(2) Pages 204-213

This paper provided a reexamination of the original NOTT study, which established the scientific rational for long-term oxygen therapy. The first publication of the NOTT study identified that chronic lung disease patients that use oxygen for 12 hours a day or less are twice as likely to die as those that use oxygen continuously. This reexamination or “revisited” study further looks at the effect that ambulation has on survival and on hospitalization. The results can be summarized as follows:

- Ambulation, or exercise is an important contributor to survival. Patients that use oxygen continuously and regularly ambulate live longer and are hospitalized less frequently.

- The lowest survival level was for sedentary patients that only used oxygen for 12 hours a day. These patients also had the highest rate of hospitalization.

How does this relate to HomeFill™?

- More than anything, HomeFill is an ambulatory system.
- The small, portable, lightweight, long-duration oxygen supply promotes ambulation. Also, the Patient Convenience Pack allows patients to carry their oxygen hands-free, promoting more activity and freedom.
- Patients that are more active and use their oxygen continuously live higher quality, longer lives. This obviously benefits the patient, and there are benefits for the provider as well. Patients are more stable (less frequently hospitalized) and thus require fewer, less aggressive changes in their oxygen delivery needs.
- Patients that are more active live longer. This results in a positive shift of the Provider’s oxygen patient base. In other words, patients live longer and that means more months and years of revenue. Patients win with longer, higher quality lives and Providers win with more revenue and lower operating costs!
Ambulatory Oxygen Therapy, Exercise, and Survival with Advanced Chronic Obstructive Pulmonary Disease (The Nocturnal Oxygen Therapy Trial Revisited)

Thomas L. Petty MD FAARC and Peter L. Bliss BME

Introduction
Re-examination of the Nocturnal Oxygen Therapy Trial
Walking Information
Data Analysis
Results
Discussion
Summary

[Respir Care 2000;45(2):204–211] Key words: nocturnal oxygen therapy, long-term oxygen therapy, chronic obstructive pulmonary disease, oxygen transport, ambulation, tissue oxygenation, exercise.

Introduction

In the 1950s, Alvan Barach became a champion of ambulatory oxygen. He developed a small cylinder for compressed gas for ambulatory oxygen, illustrated in Figure 1. Figure 2 is a cartoon designed by Barach. This illustration encourages patients to get going and to walk as they pursue the adventures of life. At about the same time, Cotes reported on his observations in ambulatory oxygen. The increased exercise ability when the patient is breathing oxygen is probably due to a reduction toward the normal levels of ventilatory requirements for exercise, as a result of the relief of anoxia. It was Cotes's conclusion that "Portable oxygen should be regarded as an integral part of domiciliary oxygen therapy." At the time of that writing, he had been using oxygen successfully in 4 patients at home. Figure 3 shows how he transfilled a small high-pressure cylinder from a larger tank. Figure 4 shows two lightweight, high-pressure cylinders used by Cotes in his studies.

In the early Denver study, cited in the "Historical Highlights of Long-Term Oxygen Therapy," (Respir Care 2000; 45[1]:29–36) the most striking observation was a dramatic improvement in exercise tolerance during the oxygen administration month followed by the control month in two patients (Fig. 5). It could be argued, however, that this exponential improvement in exercise tolerance during the month those patients received oxygen was simply a continuation of the results of exercise training during the control month while breathing air. However, the slope of the improvement is much steeper in the oxygen month.

Pierce and Miller showed reduced recovery time with oxygen-supported exercise, compared with oxygen breathing air. Liker et al were the first to conduct a controlled double-blind trial comparing portable liquid oxygen with liquid air. In their study all patients reported feeling better while carrying the portable device. Three of 9 patients showed a clear-cut increase in the distance walked while breathing oxygen, compared with air. This was a very difficult study to conduct, but it was important because it gave evidence that oxygen offered more than placebo value. Additional controlled exercise studies were conducted by Bradley et al and by Leggett and Fienley, among others. Bradley's group showed that walk endurance was significantly increased by oxygen, although the maximum work rate could not be equally improved.
The major purpose of this report on ambulatory oxygen is to offer a new analysis of the Nocturnal Oxygen Therapy Trial (NOTT) data in order to explore why continuous oxygen therapy (COT) was superior to nocturnal oxygen therapy (NOT). We aimed to determine if survival was related to the exercise capacities of the patients at the time of randomization to oxygen or if it was a function of the duration of oxygen administration.

Re-examination of the Nocturnal Oxygen Therapy Trial

In brief review, the NOTT study collected extensive data from a well-defined population of patients with advanced chronic obstructive pulmonary disease (COPD), who were randomly assigned to receive either NOT for approximately 12 hours per day from a stationary source or ambulatory oxygen (i.e., COT) that was intended to be used as close to 24 hours per day as possible. In the NOTT, extensive outcome data were obtained that can answer important questions about oxygen, exercise, survival, and hospitalization requirements in this well-defined population.

The details of the original NOTT study have been reported elsewhere. Patients with chronic stable hypoxemia with partial pressure of oxygen (P_{O_2}) of ≤ 55 mm Hg who had no significant co-morbidities and were willing to participate in an exercise-oriented rehabilitation program utilizing oxygen were randomized to receive either NOT from a stationary oxygen system or COT from an ambulatory system. The randomization process resulted in patients who were well-matched by age, gender, and indices of disease severity. After the NOTT report, the magnetic data tapes were placed in the public domain in hopes that further analyses would be made by other investigators. This goal was not achieved at first because of the complexities of the data methods originally used, which were state-of-the-art computer technology at the time of the study.

Recently, one of us (PLB), using newer software, was able to convert the original data into a personal computer format. The original NOTT data set was obtained from the National Heart, Lung, and Blood Institute in its original format and converted into an Access (Microsoft Corporation, Redmond, Washington) database. From this database, information was output to Excel (Microsoft Corporation, Redmond, Washington) for matching and analysis.

Fig. 1. The late Alvan Barach modeling a small high-pressure oxygen cylinder capable of being transfused from a large compressed gas L or K cylinder.

Fig. 2. Cartoon diagram by Dr Barach emphasizing the importance of walking with ambulatory oxygen.
Walking Information

In the NOTT, each candidate for the study was given a comprehensive pulmonary rehabilitation program, with exercise performed on a daily basis for 3 weeks prior to randomization to NOT or COT. Each patient was urged to walk as much as possible each day during the 3-week stabilization period, and each was given a pedometer to monitor the distance walked each day. This distance was recorded by a research nurse or technician. This 3-week

Table 1. Matching Data for Baseline Walking Comparison.\textsuperscript{a}

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Low Walk NOT</th>
<th>Low Walk COT</th>
<th>High Walk NOT</th>
<th>High Walk COT</th>
</tr>
</thead>
<tbody>
<tr>
<td>( n )</td>
<td>22</td>
<td>18</td>
<td>22</td>
<td>18</td>
</tr>
<tr>
<td>Age, median, years</td>
<td>67.6</td>
<td>66.5</td>
<td>67.6</td>
<td>66.5</td>
</tr>
<tr>
<td>( P_{aO_2} ), mm Hg</td>
<td>52.3</td>
<td>49.9</td>
<td>51.6</td>
<td>51.6</td>
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<tr>
<td>( P_{aCO_2} ), mm Hg</td>
<td>45.7</td>
<td>42.6</td>
<td>42.4</td>
<td>43.2</td>
</tr>
<tr>
<td>pH</td>
<td>7.40</td>
<td>7.40</td>
<td>7.42</td>
<td>7.40</td>
</tr>
<tr>
<td>Heart rate, min\textsuperscript{1}</td>
<td>92.6</td>
<td>95.2</td>
<td>85.9</td>
<td>95.8</td>
</tr>
<tr>
<td>Pulmonary artery mean pressure, mm Hg</td>
<td>31.6</td>
<td>29.1</td>
<td>26.9</td>
<td>30.1</td>
</tr>
<tr>
<td>Cardiac index, L/min\textsuperscript{2}</td>
<td>2.76</td>
<td>2.38</td>
<td>2.62</td>
<td>3.04</td>
</tr>
<tr>
<td>Pulmonary vascular resistance, dyne cm\textsuperscript{3}</td>
<td>381</td>
<td>363</td>
<td>383</td>
<td>379</td>
</tr>
<tr>
<td>FEV\textsubscript{1}, % of predicted pre-bronchodilator</td>
<td>25%</td>
<td>28%</td>
<td>25%</td>
<td>28%</td>
</tr>
<tr>
<td>FVC, % of predicted pre-bronchodilator</td>
<td>48%</td>
<td>51%</td>
<td>50%</td>
<td>49%</td>
</tr>
</tbody>
</table>

\textsuperscript{a}Cardiac and blood gas data taken at rest with supplemental oxygen. All values are mean values noted.

NOT = nocturnal oxygen therapy; COT = continuous oxygen therapy; FEV\textsubscript{1} = forced expiratory volume in the first second; FVC = forced vital capacity.

Fig. 4. Two small-high pressure cylinders used by JE Cotes. (From Reference 2.)

Fig. 5. Improvement in exercise tolerance in two patients trained at level walk. Note slow change during control month and marked rapid rise in tolerance during oxygen month. "H.S." and "W.M." are patients initials. Temporary decrease in H.S.'s exercise tolerance during the oxygen month was due to an episode of acute bronchitis. (From Reference 4.)
Ambulatory Oxygen Therapy, Exercise, and Survival with Advanced COPD

Data Analysis

The methods of Kaplan and Meier were used to produce the survival function, using the product-limit estimate model. Statistical significance was tested using the method described by Cox. Hospitalization data were analyzed by analysis of variance.

Results

Figure 7 presents the survival of patients with low and high exercise capability who received low (NOT) versus high (COT) oxygen. Differences in survival between the low walkers on low oxygen and high walkers on high oxygen is statistically significant (p = 0.01). The difference is also significant between low walkers on low oxygen and low walkers on high oxygen (p = 0.01).

Figure 8 presents the hospitalization data in terms of the number of admissions per year and the number of stays per admission for the 4 matched groups. Hospital utilization was less in the high oxygen group and least in the high oxygen group with "high" exercise capability (p = 0.05). Using analysis of variance, a statistically significant difference was found, with a shorter length of stay in the high walking subjects who received high oxygen (p = 0.02).

Discussion

The first long-term oxygen studies showed a reduction in pulmonary pressures and erythrocytosis in 6 patients in each of two studies with chronic stable hypoxemia associated with advanced COPD. Somewhat similar studies of continuous oxygen from a stationary source also showed improvement in pulmonary artery pressure, with shorter duration of oxygen therapy, including as low as 15 hours per day. These early observations formed the basis for both the British Medical Research Council and the NOTT randomized controlled clinical trials.

The British Medical Research Council study showed a survival benefit from oxygen given for approximately 15 hours per day, including during sleep, compared with air. The NOTT study, which used ambulatory COT for as many hours per day as possible (median 19.4 h, mean 17.8 h/d), compared with NOT from a stationary source (mean 11.8 h/d), showed a better survival with more continuous oxygen. Figure 9 shows a comparison of these survival curves.

Improved survival in the NOTT study was related to reversibility of pulmonary hypertension. Similar conclusions have been drawn by other investigators. It is difficult to understand, however, how a modest reduction in mean pulmonary artery pressure (only 3–5 mm Hg), which causes only a slight decrease in the afterload of the
right ventricle, could be the sole reason for the improved survival. In one study, improved survival was related to both a reduction in pulmonary pressure and an increase in maximum oxygen consumption. In some patients who had a reduction in pulmonary artery pressure, there was an increase of left ventricular ejection fraction, which may be a reflection of improved global cardiac function because of relief of hypoxemia.

Extensive exercise studies of right ventricular function during exercise in COPD have shown that an increase in exercise tolerance is related to an increase in right ventricular function and increased oxygen consumption. Increased exercise capacity in hypoxemic COPD often results from oxygen administration and is related to an improvement in right ventricular function. Increased right ventricular function and oxygen consumption may occur in spite of increases in pulmonary artery pressure and pulmonary vascular resistance. The elevated pulmonary pressure and resistance are most likely due to fixed vascular changes in the pulmonary vascular bed, which are not reversible, even with long-term oxygen therapy (LTOT). One study found a relationship between mixed venous oxygen tension and survival in patients who were candidates for LTOT. The 5-year survival was better in patients with the highest mixed venous \( P_{\text{vO}} \) and higher coefficient of oxygen extraction. This study suggested that measures designed to increase cardiac output would be appropriate to improve tissue oxygen delivery.

In other studies, patients who exhibited little or no ability to increase their cardiac output and systemic oxygen transport did not have increased exercise capacity. These observations led to the conceptualization of the "right ventricular hypothesis." The right ventricular hypothesis is based on the concept that limitation of right ventricular function limits systemic tissue oxygen transport. Before oxygen is given, ventricular function and oxygen transport may be limited by poor oxygenation of the myocardium. After oxygen is administered, right ventricular function can still be limited by structural damage of the right ventricle or by elevated right ventricular afterload from fixed pulmonary vascular changes. In any event, failure to improve right ventricular systolic function may limit tissue oxygen transport. By improving oxygen to the right ventricular myocardiun, and by reducing right ventricular afterload, right ventricular function may improve. This, in turn, results in improved global cardiac function, increased tissue oxygen transport, and increased tissue energy production.

It is likely that tissue metabolic phenomena are responsible for improved survival. In the British Medical Research Council study, in men who received oxygen versus
men who did not receive oxygen, improved survival did not become apparent until after 500 days. In the NOTT study, improved survival did not become statistically significant until 18 months (see Fig. 9). These data suggest that the survival benefit from oxygen was a function of restorative metabolic changes in multiple organs, which occurred over months of LTOT.

The restorative value of oxygen in brain function has been previously reported. Figure 10 shows an improvement in performance IQ, which was similar in both NOT
and COT. However, in COT there was further improvement over the subsequent 6 months. Similarly, Figure 11 shows improvement in brain age quotient, with improvement in both NOT and COT after 6 months, but further improvement after 12 months with COT. An improvement in brain function could reasonably be expected to require increased energy production. Such an increase in energy production would require increased systemic oxygen delivery. This has been demonstrated in patients who can increase their exercise tolerance with supplemental oxygen. We believe that increased exercise tolerance and improved survival are a result of increased systemic oxygen delivery during oxygen administration.

A restoration of arterial blood oxygenation while breathing air has been reported following several months of LTOT. This improvement in oxygen transfer across the lungs is believed to be due to improved ventilation-perfusion matching as a result of improved oxygenation, which is known to reduce pulmonary arteriolar constriction and bronchospasm. The long-term impact of LTOT on heart, brain, lung, and skeletal muscle function may also be due to a sustained increase in tissue oxygen transport and improved energy production of multiple organ systems.

A weakness of our study is that it is a retrospective analysis of a limited number of patients. But the NOTT study involved extremely well-characterized patients with exercise physiology and hospitalization outcomes. The present study suggests that improved tissue oxygen transport occurs in patients with relatively better exercise capacity who also receive more continuous ambulatory oxygen. Patients with lower levels of exercise capacity had better survival with oxygen delivered for longer periods of time.

This study suggests that new clinical trials are needed to compare outcomes from ambulatory oxygen for as many hours per day as possible, compared with stationary oxygen for an equivalent length of time. Such studies could answer the critical question about survival in relation to an ambulatory or stationary oxygen delivery source, and address the possibility of reducing hospitalizations with continuous ambulatory LTOT.

Summary

The NOTT study showed improved survival in COT patients who received LTOT for longer periods (mean 17.7 h/d, median 19.4 h/d) from an ambulatory oxygen system, compared with the survival of NOT patients who received oxygen for a mean of 11.8 h/d from a stationary system. The differences in survival could have been due to the method or the duration of oxygen therapy, or both. An increase in cardiac output and increased oxygenation of the arterial blood (oxygen content) results in increased tissue oxygen transport. In addition, COT was associated with better survival and reduced hospitalizations, compared with NOT patients who were unable to increase their walking level.

REFERENCES

Discussion

Kacmarek: I just wanted to ask you to comment on the restorative effects that you were discussing. You indicated that if a patient is on oxygen therapy because he or she is hypoxic at rest, and he or she recovers from that a year or two down the road so that resting $P_O_2$ is in the 60s, you would continue oxygen therapy. How about a patient who is discharged (after an acute exacerbation) with a $P_O_2$ that necessitates oxygen therapy, but after a month or two they've recovered? Is that a patient who should have oxygen discontinued?

Petty: That's a very good question, and we addressed it during the oxygen consensus conferences. Certainly, with that unstable patient who has just come out of an exacerbation (often a pneumonia or just an exacerbation of COPD), we want them to go on home oxygen so they can get out of the hospital fast. We're not going to commit him or her to life-long oxygen, though, because he or she may not be a candidate in terms of being in a stable, steady state. I'm only recommending continued oxygen for patients who have a long-term, demonstrable need after a good stabilization period and then improved their ventilation-perfusion matching but don't change their overall basic spirometry. Those are the ones who shouldn't be taken off oxygen. And, Walter, you might want to elaborate on that because this was your concept.

References


**Objective:** To compare the effect of Homefill™ oxygen (93±3%) and standard oxygen (99.6%) on the ability of COPD patients to exercise.

**Study Method:** The form of exercise was walking, and the measurement was how far the patient could walk with each type of oxygen. This study had three separate segments, with the patient breathing a different type of oxygen with each segment. The oxygen types were room air, standard oxygen and Homefill oxygen – no conserving device was used. In each segment, the patients were asked to walk as far as possible in 6 minutes. After each minute and at the end of the 6 minutes, the patient’s oxygen saturation, heart rate and sense of shortness of breath were measured. Ten patients were studied.

**Results:**
- There was no difference in oxygen saturation, heart rate or shortness of breath between standard oxygen and Homefill oxygen. However, there was a difference between both standard oxygen and Homefill oxygen when they were compared to room air, with room air consistently resulting in lower blood oxygen levels.
- Patients were able to walk farther when breathing standard oxygen or Homefill oxygen as compared to when they were breathing room air. There was no difference in how far the patients walked when breathing standard oxygen or Homefill oxygen.
- **The authors conclude that “...in spite of a slightly lower oxygen concentration, our study showed that Homefill oxygen improved blood oxygen saturation as well as standard oxygen”**.
Refillable Oxygen Cylinders May Be an Alternative for Ambulatory Oxygen Therapy in COPD*

Antoine Cuvelier, MD; Jean-François Nuir, MD, FCCP; Nadia Chakroun, MD; Jérôme Aboab, MD; Gabriella Onea, MD; and Daniel Benhamou, MD

Study objectives: To compare, in clinical conditions, the efficacy of refillable oxygen cylinders (O₂-HFs) in improving oxygenation and exercise capacity of patients with COPD during a 6-min walking test.

Design: Prospective randomized study with a cross-over design.

Setting: A university teaching hospital.

Patients: Ten patients with COPD, in a stable state and previously treated with long-term domiciliary oxygen therapy. Baseline characteristics were as follows: age, 65 ± 7 years; PaO₂ on room air, 55.4 ± 6.3 mm Hg; PaCO₂ on room air, 46.2 ± 7.4 mm Hg; FEV₁/vital capacity, 47 ± 7%; and FEV₁, 30 ± 7% of predicted value (mean ± SD).

Design: All patients performed three successive 6-min walking tests, the first test in room air and the other tests in a randomized order with either a conventional oxygen cylinder (O₂-C) or an O₂-HF.

Measurements and results: The fraction of inspired oxygen (FIO₂) delivered by O₂-HFs was significantly lower than the FIO₂ delivered by O₂-Cs (94.2 ± 2.6% vs 98.8 ± 4.9%, p = 0.02). Mean O₂-HF and O₂-C weights before the walking tests were similar (3,510 ± 251 g and 3,770 ± 142 g, respectively; p = 0.09). Mean transcutaneous oxygen saturation was similarly improved with both oxygen delivery systems. Mean distances with O₂-C (373.5 ± 81 m) and O₂-HF (375 ± 97 m) were not different but significantly improved, as compared with room air (334.5 ± 90 m; p = 0.03 and 0.02, respectively). Dyspnea sensations were similar for the three tests.

Conclusion: O₂-HFs are as efficient as O₂-Cs for performing short-term exercises. Because of a lower cost, pressurizing units may be worthwhile for improving ambulatory oxygen therapy and pulmonary rehabilitation programs.

Key words: COPD; exercise; oxygen inhalation therapy; rehabilitation

Abbreviations: FIO₂ = fraction of inspired oxygen; O₂-C = conventional oxygen cylinder; O₂-HF = refillable oxygen cylinder; SaO₂ = arterial oxygen saturation; VC = vital capacity

At the beginning of the 1980s, long-term oxygen therapy was shown to significantly improve long-term survival of hypoxemic patients with COPD.¹² The duration of oxygen therapy during both daytime and nighttime is a key factor in improving survival among patients with COPD and chronic respiratory failure. It is generally accepted that compliance to treatment should be at least 15 h/d,¹³–⁵ and two prospective studies⁴,⁵ demonstrated the importance of ambulatory oxygen devices for improving this compliance in COPD patients. Pépin and Barjhoux⁴ showed that ambulatory oxygen supplies may lead to a threefold increase of probability to perform oxygen therapy for > 15 h/d. Vergeret and Brambilla⁵ demonstrated that oxygen use during the day was significantly higher if an ambulatory device was provided to the patient.

To maintain mobility and quality of life, oxygen therapy has to be simple to use and carry. Because concentrators are not portable, ambulatory oxygen therapy is performed with gaseous cylinders or the more expensive liquid oxygen devices. Pressurizing units that are able to fill up oxygen cylinders from concentrators have been recently developed. Thus, refill cylinders could therefore represent a new alternative for improving overall oxygen therapy.
while reducing costs of production and delivery. To the best of our knowledge, no prior similar studies were dedicated to this equipment. This study was designed to compare, in real clinical conditions, the efficacy of refilled oxygen cylinders (O2-HFs) in improving oxygenation and exercise capacity of patients with COPD during a 6-min walking test.

**Materials and Methods**

**Patients**

Patients with COPD defined according to American Thoracic Society criteria were prospectively included in the study. All patients had to be in a stable state, already treated at home with long-term oxygen therapy, and able to perform walking tests. The study was performed in the ambulatory division of our department, which is devoted to ambulatory follow-up of patients with chronic respiratory insufficiency. Inclusion criteria were PaO2 at rest and on room air ≤ 60 mm Hg, FEV1 of < 55% of predicted value, FEV1/Vital capacity (VC) of < 65%, previously documented oxygen desaturation at rest (arterial oxygen saturation [SaO2] < 90% on room air) and a stable clinical state for at least 3 months prior to inclusion. Patients with PaO2 > 60 mm Hg in room air but with a previous demonstration of significant desaturation during exercise were also included in the study. All patients gave informed consent to participate in the study, after they received information on the objectives and interest of the study. The protocol was approved by our local university ethical committee.

**Materials**

The pressurizing unit that was used is a domiciliary oxygen supply equipped with a compressor that fills up an oxygen cylinder from a standard oxygen concentrator (HomeFill system; Invacare; Elyria, OH). The compressor fills up portable D-sized cylinders (O2-HF) with oxygen-enriched air under a 140-bar pressure; in comparison, commercial oxygen cylinders (O2-Cs) are filled under a 200-bar pressure. The O2-HF is linked to the compressor with a dedicated valve, and a manometer controls the filling of the cylinder. The fraction of inspired oxygen (FiO2) delivered by the compressor was permanently controlled by an oxygen-concentration sensor (SensO2; Invacare). The compressor automatically stops when the cylinder is filled up or if the oxygen concentration is < 85%. At rest, the patient can use the concentrator simultaneously with the working compressor, but the flow to the patient will always remain priority as compared with the flow to the compressor. Filling time of a D-sized O2-HF is approximately 2 h, although longer if the patient is using the concentrator simultaneously. O2-HF autonomy is about 140 min, with an average flow of 2 L/min.

**Study Design**

A prospective randomized study with cross-over design, double dummy, and single blind was performed. Each patient performed a reference 6-min walking test carrying a new O2-C with nasal prongs but breathing room air (the cylinder was voluntarily switched off during this first 6-min walking test). If significant desaturation was observed, the patient was then randomized into the study and performed two successive 6-min walking tests while inhaling oxygen with either an O2-HF or an O2-C. All three tests were separated by 60-min rest periods. In order to have similar conditions for the three walking tests, we used the same model of D-sized oxygen cylinders (Air Liquide Santé; Taema, France). All cylinders had an identical appearance.

All 6-min walking tests were performed under supervision of a trained respiratory therapist in a 10-m corridor, in the second half of the morning. Just before each test, the O2-HFs were completely filled up by the medical team. Walking tests with the O2-C and the O2-HF were performed with a same oxygen flow of 2 L/min. When 6-min walking tests in room air were not tolerated, they were then carried out on 1 L/min of oxygen and the following tests performed with 3 L/min of oxygen. Transcutaneous SaO2 and cardiac frequency were recorded each minute during all the tests with a portable oximeter (Nonin 8500; Nonin; Plymouth, MN) and secondly recorded on a printer. Oxygen concentrations were measured at the beginning of each walking test with an oxygen sensor (Oxy 2100; CFPO; Paris, France). Cylinder weights were also measured at the beginning of each walking test with a 0.1-kg sensibility scale. Dyspnea at rest and after exercise was measured with a Borg scale. Twelve patients agreed to participate in the study. Two patients were excluded because a severe dyspnea obliged them to stop one of the three walking tests before the end. Data from 10 patients were available for analysis.

**Statistical Analysis**

Statistical data were obtained with software (GB-Stat 6.5; Dynamic Microsystems; Silver Spring, MD). Paired data were analyzed by the Wilcoxon rank test, and nonpaired data were analyzed by the Mann-Whitney test. Each test was considered as significant if p values were ≤ 0.05. Equivalence of the two oxygen delivery devices was defined by a SaO2 difference of < 1.5%. The sample size was calculated with software (nQuery; Statistical Solutions; Saugus, MA). For an equivalence hypothesis, 23 patients are needed for a study power or 80% and an α significance level at 0.05. Because of a cross-over design and a mean correlation of 0.5, the final required number of patients was 10.

**Results**

Ten patients with COPD (9 men and 1 woman; mean age, 65 ± 7 years) were included in the study. Mean FEV1 was 0.84 ± 0.14 L (30 ± 7% of predicted value), FEV1/VC was 47 ± 7%, total lung capacity was 5.89 ± 1.64 L (98 ± 27% of predicted value), and residual volume was 3.86 ± 1.32 L (144 ± 73% of predicted value). Room air arterial blood gases in a stable state showed a PaO2 of 55.4 ± 6.3 mm Hg and a PaCO2 of 46.2 ± 7.4 mm Hg. All individual data are reported in Table 1. All patients were previously treated with long-term oxygen therapy (between 1.5 L/min and 3 L/min), and three patients were also treated with noninvasive mechanical ventilation at home (patients 2, 5, and 8). Three patients had basal PaO2 > 60 mm Hg in room air but were previously documented as having significant desaturation when walking and were treated by long-term oxygen therapy.

At the beginning of the study, FiO2 measured
from O2-HFs was significantly lower than with O2-Cs (94.24 ± 2.56% vs 98.85 ± 4.89%, respectively; p = 0.025). The mean O2-HF weight before walking tests was 3,510 ± 251 g, and the mean O2-C weight was 3,770 ± 142 g. This difference was not significant (p = 0.09).

Individual data are reported in Figure 1. Transcutaneous SaO2 with either O2-C or O2-HF was better than in room air. Both walking tests under oxygen were performed with a 2 L/min flow except for patient 8, who performed O2-C and O2-HF walking tests with a 3 L/min flow because of severe dyspnea on room air. Mean SaO2 values with O2-C and O2-HF were very similar throughout the walking tests (Table 2). With the exception of one value at 6 min, there was a significant improvement of SaO2 at each minute of the tests with oxygen (O2-C or O2-HF) as compared with room air.

No significant individual cardiac intolerance (bradycardia or tachycardia) was observed. Mean cardiac frequencies were very similar under each condition (Fig 2). A slight increase of mean cardiac frequencies was due to the reflex tachycardia during the tests.

Mean walking distance in room air was 334.5 ± 90 m. This distance was significantly increased when performed with either O2-C (373.5 ± 81 m, p = 0.03) or O2-HF (375 ± 97 m, p = 0.02). No statistical difference was found between distances performed under oxygen either with O2-C or O2-HF (Fig 3).

At basal conditions, the Borg scale showed a mean

---

**Table 1—Clinical Characteristics of the Patients in the Study**

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Age, yr</th>
<th>FEV1, L (%)</th>
<th>VC, L (%)</th>
<th>FEV1/VC, %</th>
<th>TLC, L (%)</th>
<th>RV, L (%)</th>
<th>PaO2, mm Hg</th>
<th>PaCO2, mm Hg</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>64</td>
<td>0.76 (24)</td>
<td>1.92 (49)</td>
<td>40</td>
<td>7.14 (116)</td>
<td>5.22 (22)</td>
<td>46.6</td>
<td>46.3</td>
</tr>
<tr>
<td>2</td>
<td>67</td>
<td>0.9 (43)</td>
<td>1.80 (69)</td>
<td>50</td>
<td>4.71 (96)</td>
<td>3.69 (164)</td>
<td>53.3</td>
<td>42.8</td>
</tr>
<tr>
<td>3</td>
<td>76</td>
<td>0.7 (28)</td>
<td>1.50 (44)</td>
<td>47</td>
<td>6.94 (112)</td>
<td>3.75 (122)</td>
<td>60.1</td>
<td>38.3</td>
</tr>
<tr>
<td>4</td>
<td>69</td>
<td>0.87 (35)</td>
<td>1.72 (55)</td>
<td>51</td>
<td>6.19 (116)</td>
<td>4.47 (206)</td>
<td>47.3</td>
<td>56.1</td>
</tr>
<tr>
<td>5</td>
<td>59</td>
<td>0.94 (32)</td>
<td>2.22 (61)</td>
<td>42</td>
<td>8.46 (138)</td>
<td>6.24 (253)</td>
<td>55.6</td>
<td>55.3</td>
</tr>
<tr>
<td>6</td>
<td>57</td>
<td>0.64 (20)</td>
<td>1.20 (30)</td>
<td>53</td>
<td>3.95 (61)</td>
<td>2.46 (111)</td>
<td>60.8</td>
<td>46.1</td>
</tr>
<tr>
<td>7</td>
<td>59</td>
<td>1.13 (34)</td>
<td>3.44 (78)</td>
<td>33</td>
<td>7.64 (123)</td>
<td>4.20 (179)</td>
<td>66.1</td>
<td>42.2</td>
</tr>
<tr>
<td>8</td>
<td>60</td>
<td>0.74 (26)</td>
<td>1.54 (41)</td>
<td>48</td>
<td>5.24 (86)</td>
<td>3.70 (164)</td>
<td>57.1</td>
<td>36.4</td>
</tr>
<tr>
<td>9</td>
<td>61</td>
<td>0.76 (25)</td>
<td>2.04 (51)</td>
<td>52</td>
<td>3.60 (57.5)</td>
<td>1.56 (71.8)</td>
<td>57.8</td>
<td>42.4</td>
</tr>
<tr>
<td>10</td>
<td>78</td>
<td>0.91 (35)</td>
<td>1.66 (48)</td>
<td>55</td>
<td>4.98 (76)</td>
<td>3.32 (122)</td>
<td>48.8</td>
<td>53.6</td>
</tr>
<tr>
<td>Mean</td>
<td>65</td>
<td>0.84 (30)</td>
<td>1.90 (53)</td>
<td>47</td>
<td>5.89 (98)</td>
<td>3.86 (144)</td>
<td>55.4</td>
<td>46.2</td>
</tr>
<tr>
<td>SD</td>
<td>7.36</td>
<td>0.14 (7)</td>
<td>0.61 (14)</td>
<td>7</td>
<td>1.64 (27)</td>
<td>1.32 (73)</td>
<td>6.3</td>
<td>7.4</td>
</tr>
</tbody>
</table>

* TLC = total lung capacity; RV = residual volume.
† Helium residual volume assessment; otherwise, plethysmographic assessment.

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**Figure 1.** Individual values of transcutaneous SaO2 (%) during exercise. RA = room air.
dyspnea score of 3.3 ± 1.5. This value did not significantly change after the walking tests; mean dyspnea scores after walking tests in room air were not different from walking tests with either O₂-C or O₂-HF (Fig 4).

**Discussion**

**Our Results**

The purpose of our study was to evaluate the pressurizing unit in a realistic situation, like an exercise test. We show that O₂-Cs and O₂-HFs may provide a similar level of oxygenation on a short-term basis during a 6-min walking test. Although our data were obtained from a population of patients with COPD with different degrees of pulmonary impairment, individual SaO₂ curves displayed identical trends for the three walking tests. These original data show that SaO₂ improvements are equivalent with both oxygen supplies and, therefore, demonstrate a similar performance between O₂-HFs and O₂-Cs. Noteworthy, these results were obtained in spite of a lower filling gas pressure (140 bars) and a slightly lower FIO₂ (94.24 ± 2.56%) in O₂-HFs as compared to O₂-Cs (200 bars and 98.85 ± 4.89%, respectively). It is not sure that such a difference may be of clinical relevance, at least on a short-term basis. In fact, the actual average FIO₂ received by the patients does not differ significantly when considering the entraining room air via the Venturi effect. As previously described in most studies from the literature,7,8 we found an increase of mean distances performed under oxygen as compared with room air, and this improvement was similar with either oxygen device. Moreover, our patients had variable dyspnea improvements with oxygen but without any difference between both oxygen supplies. We suggest that performances (mean distances, dyspnea score) achieved through the walking tests are similar with both oxygen devices, mainly because both type of cylinders have similar weights. Overall, pressurizing units allow easy use of effective oxygen cylinders, at least on a short-term basis.

**Technical Advantage of Pressurizing Units**

As a source of ambulatory oxygen, O₂-HFs may be an alternative to portable O₂-Cs and liquid oxygen devices. Few clinical studies have compared the

---

**Table 2—Mean SaO₂ During Walking Tests (n = 10)**

<table>
<thead>
<tr>
<th>Time</th>
<th>Room Air</th>
<th>O₂-C</th>
<th>O₂-HF</th>
<th>p Value† Room Air vs O₂-C</th>
<th>p Value† Room Air vs O₂-HF</th>
<th>p Value† O₂-C vs O₂-HF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SaO₂ (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>84.8 ± 4.05</td>
<td>90.6 ± 3.81</td>
<td>90.5 ± 2.92</td>
<td>0.0051</td>
<td>0.0051</td>
<td>0.9594</td>
</tr>
<tr>
<td>1 min</td>
<td>81.8 ± 3.94</td>
<td>86.8 ± 3.58</td>
<td>86.7 ± 2.67</td>
<td>0.0051</td>
<td>0.0125</td>
<td>0.9326</td>
</tr>
<tr>
<td>2 min</td>
<td>80.9 ± 5.24</td>
<td>85.4 ± 3.75</td>
<td>85.3 ± 4.27</td>
<td>0.0077</td>
<td>0.0166</td>
<td>0.9442</td>
</tr>
<tr>
<td>3 min</td>
<td>79.8 ± 5.60</td>
<td>85.0 ± 3.89</td>
<td>86.4 ± 4.24</td>
<td>0.0166</td>
<td>0.0051</td>
<td>0.2135</td>
</tr>
<tr>
<td>4 min</td>
<td>79.5 ± 5.25</td>
<td>85.6 ± 4.65</td>
<td>86.9 ± 4.41</td>
<td>0.0051</td>
<td>0.0051</td>
<td>0.03</td>
</tr>
<tr>
<td>5 min</td>
<td>81.6 ± 5.54</td>
<td>85.4 ± 4.62</td>
<td>85.9 ± 4.51</td>
<td>0.0093</td>
<td>0.0051</td>
<td>0.398</td>
</tr>
<tr>
<td>6 min</td>
<td>79.7 ± 5.93</td>
<td>86.0 ± 4.67</td>
<td>86.3 ± 5.56</td>
<td>0.077</td>
<td>0.0051</td>
<td>0.4838</td>
</tr>
</tbody>
</table>

*Data are presented as mean ± SD. Data are provided for each minute of the tests.
†Statistical analysis performed with Wilcoxon rank test.

---

**Figure 2. Mean cardiac frequencies during walking tests performed (n = 10).** See Figure 1 legend for expansion of abbreviation.
relative advantages of gaseous and liquid oxygen for portable use in patients with COPD. Comparing both devices in a prospective controlled study, Vergeret and Brambilla did not find any difference in total ambulatory oxygen use, and observed that compliance to long-term oxygen therapy was improved whatever the ambulatory system used. Other authors highlighted a slight preference for a liquid oxygen system because the oxygen lasted longer, filling was easier, and the canister was easier to carry. However, substitution of gaseous oxygen by liquid oxygen therapy for all hypoxemic COPD patients is not medically justified, and is not largely available in most countries for economic reasons.

Used with either liquid or gaseous sources, oxygen-conserving devices may provide significant savings and enhance patient autonomy, during either exercise or sleep. O2-HFs may be of significant help in order to enable exercise in hypoxemic patients. Supplemental oxygen in patients with COPD with exercise-induced hypoxemia has been shown to be associated with improvement of exercise tolerance and dyspnea.

At home or during rehabilitation, oxygen may be delivered for the relief of short episodes of dyspnea either before, during, or after exercise. Such practices have been shown to be beneficial for symptomatic relief of dyspnea. O2-HFs may be a good compromise at home, since ambulatory patients will be able to manage their physical autonomy without the constraints of oxygen home delivery and with overall decreasing costs. On a long-term basis, savings on home delivery expenses should ameliorate the initial high costs of the pressurizing units. Similarly, O2-HFs should be important to respiratory care departments in order to lower the costs of exercise testing and walking tests.

**Conclusion**

In conclusion, when used in clinical conditions and in spite of a slightly lower $F_{IO_2}$ delivered, our study showed that O2-HFs improve $SaO_2$ as well as O2-Cs,

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**Figure 3.** Mean distances during walking tests. Statistical analysis was performed using the Wilcoxon rank test.

**Figure 4.** Quantification of dyspnea sensations during exercise.
at least on a short-term basis. This new technology may facilitate exercise testing and enhance the feasibility of pulmonary rehabilitation programs.

ACKNOWLEDGMENT: The authors thank Richard Medeiros for his advice in editing the manuscript, and Patricia Etienne, Annie Daras, Aline Clavera, and Marie-France Hellot for technical assistance.

REFERENCES

**Objective:** To determine the effectiveness of Homefill™ oxygen on an active, oxygen-dependant COPD patient.

**Study Method:** This was a case study of one patient that normally used a Puritan-Bennett® 590 concentrator and a CR-50 conserving device and M6 cylinders. For this study the patient agreed to wear a continuously recording pulse oximeter for 6 days and to keep a log of her daily activities. For the first 3 days she continued to use her standard portable oxygen system, and for the next 3 days she used oxygen via Homefill portable system, which included an M6 cylinder, Venture® IDD20EX conserving device and carrying bag. At the end of the six days the oximeter and activity log results were compared.

**Results:**
- The authors concluded that there was no difference in activity levels. When using the Homefill (93±3% oxygen) portable system with a conserver, the patient was able to maintain the same level of activity, both in and out of the home, as compared to using a standard oxygen (99.6% oxygen) system with a conserver.
- Although there were desaturation events with both systems, there was no appreciable difference between systems.
- The authors concluded: “In this single patient study, the data showed no adverse effects of using the Homefill II system while performing activities of daily living”.
Evaluation of the
Venture HomeFill II Oxygen System
During Activities of Daily Living

Robert McCoy BS RRT, Peter Bliss BME
December 2001
Evaluation of the Venture HomeFill II Oxygen System During Activities of Daily Living

Robert McCoy BS RRT, Peter Bliss BME

December 2001

Introduction

The use of Long Term Oxygen Therapy (LTOT) in the home has been increasing over the past several years due to an increase in the number of COPD patients requiring oxygen and the understanding of the value of early diagnosis and treatment. With this increase in the number of patients receiving oxygen therapy, there is an increase in the overall costs associated with LTOT. CMS (Medicare), being the largest payer for LTOT, has been evaluating and attempting to control this increase in costs with a decrease in payment. As reimbursement decreases, Home Medical Equipment (HME) suppliers are faced with the challenge of providing home oxygen therapy appropriately and cost effectively.

One of the new options for controlling costs associated with LTOT are oxygen-conserving devices (OCDs). OCDs used with packaged gases such as liquid oxygen (LOX) and compressed gases can reduce the number of systems required for service or can reduce the cost associated with refilling these systems as often as is necessary with continuous flow.

Another option that has become available to the market is a system that allows gas from an oxygen concentrator to fill a high-pressure cylinder. The Venture HomeFill II (Invacare Corp, Elyria OH) was recently introduced at a national trade show. The system includes a concentrator that is equipped to supply oxygen to a compressor unit. The compressor unit fills the cylinders from the concentrator’s supply of oxygen. The specially designed cylinders connect to an OCD to extend the operating time of the small cylinders.

The purpose of this investigation was to determine if a cylinder filled from a concentrator with approximately 93% * oxygen, coupled to an OCD could maintain the same level of oxygenation as a cylinder using 99.6% USP oxygen with a patient performing activities of daily living.

* Oxygen output specification for the Homefill II is 93 \pm 3%
Case Summary

Patient Selection

A patient was selected that was active and using 4-6 M6 (180 liter) oxygen cylinders a week. This 68-year-old white female had been on 2-lpm oxygen for over four years. She had a history of smoking for over 30 years. The patient was interviewed to determine her interest in participating in the investigation, her activity level, and her ability to work with the equipment and to maintain a diary of activity. The patient was capable and agreeable to the study.

The study would monitor the patient on her existing oxygen system for 72 hours, then switch to the HomeFill II system for the next 72 hours. An oximeter would be worn for the entire period of the study and downloaded after each segment of the evaluation. A diary would be used by the patient to record daily activity and any unique episodes that might have an impact on oxygenation.

Method

The patient's existing oxygen system was a Puritan Bennett 590 concentrator, a Puritan Bennett CR-50 OCD and M6 cylinders (Puritan Bennett is a division of TYCO, Pleasanton CA). The evaluation unit was a Venture HomeFill II concentrator and compressor unit, the Venture DODD conserving unit and HomeFill II M6 cylinders (Invacare, Elyria OH). Oxygen saturation was monitored with the PalmSat 2500 (Nonin, Plymouth MN) and analyzed with nVision software (Nonin). A patient activity log was created to record significant activity on an hourly basis during waking hours.

Results

Activity Log

The patient activity log indicated that there was no limit or change to activity with either system. The patient had a daily routine that was similar with both systems that included household chores and outside trips. One episode of desaturation was recorded in the activity log, on the existing system, when the patient returned from a shopping trip and became short of breath entering the house. The Sp0\textsubscript{2} dropped to 85\% and the heart rate was 107.

More activity related to the HomeFill II system was recorded due to the closer observance of a different system. Details related to the connection of the portable cylinders to the compressor were noted and the connecting of the supply tubing to the OCD. There was one episode of desaturation on the HomeFill II system related to walking approx. 40 feet inside the house. The Sp02 dropped to 87\% and the heart rate to 104. The OCD alarmed once when the tubing disconnected from the cylinder to the OCD. The patient appreciated this alarm since the NPB CR-50 does not have a disconnect alarm.
**Oximeter Summary**

The patient was very compliant with the use of the oximeter. Total hours recorded on the baseline test of the existing system was 71 hours. Hours recorded for the HomeFill II system was 72 hours.

The oximeter data indicated that there were fewer number of desaturation events with the baseline test, yet the total time in desaturation events was the same on either system. The average duration of an event was similar between both tests. Average pulse rate and lowest pulse rates were the similar between both tests.

**Oximeter Data**

<table>
<thead>
<tr>
<th>Events</th>
<th>Current System</th>
<th>Evaluation System</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PB 580 &amp; CR 50</td>
<td>HomeFill II</td>
</tr>
<tr>
<td></td>
<td><strong>SP0₂</strong></td>
<td><strong>Pulse</strong></td>
</tr>
<tr>
<td>Total events</td>
<td>55</td>
<td>24</td>
</tr>
<tr>
<td>Time in Events (min)</td>
<td>43</td>
<td>14</td>
</tr>
<tr>
<td>Avg. Events Dur. (sec)</td>
<td>47</td>
<td>35</td>
</tr>
<tr>
<td>% Artifact</td>
<td>6</td>
<td>6</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Measure</th>
<th>Current System</th>
<th>Evaluation System</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PB 580 &amp; CR 50</td>
<td>HomeFill II</td>
</tr>
<tr>
<td>Base O₂ (%)</td>
<td>97.4</td>
<td>98.1</td>
</tr>
<tr>
<td>Time (min) &lt; 88%</td>
<td>67.9</td>
<td>28.6</td>
</tr>
<tr>
<td>Events &lt; 88%</td>
<td>20</td>
<td>11</td>
</tr>
<tr>
<td>Min. O₂ (%)</td>
<td>59</td>
<td>60</td>
</tr>
<tr>
<td>Avg. Pulse rate (bpm)</td>
<td>78.9</td>
<td>76.3</td>
</tr>
<tr>
<td>Low Pulse rate (bpm)</td>
<td>24</td>
<td>24</td>
</tr>
</tbody>
</table>

**Analysis Parameters**

Desaturation Event: Drop in SpO₂ by at least 6% for a minimum duration of 8 seconds.
Pulse Event: Change in rate by at least 6 bpm for a minimum duration of 8 seconds.
Discussion

New technology is entering the home care market due to reimbursement changes and the development of innovative solutions to delivering therapy. Understanding the principles of operation of these new devices is necessary and the clinical implications understood before a clinician can appreciate the impact a device might have on a patient. Oxygen conserving devices are a recent addition to the LTOT market and research has documented the variability of individual products.\(^1\)

Oxygen concentrators have been clinically accepted and oxygen levels of 85% or greater are therapeutically equivalent to 100% oxygen according the findings of the first Consensus Conference on Home Oxygen Therapy.\(^2\) The compounding of lower oxygen concentration, OCD use and an active patient could be a concern. This study was intended to determine if desaturation would occur with an active patient using the new HomeFill II system. The findings indicate that the patient did not have any adverse effects while using the new system.

This evaluation was conducted on one patient during a 3-day period. Numerous variables could have been monitored that might effect oxygenation and the findings, including activity level, activity time, cylinders used, etc. This study was intended to provide initial information on the subject of concern regarding the compounding of several variables related to patient oxygenation. There was no indication that the patient had any additional desaturation using the HomeFill II system compared to the system already being used.

Conclusion

In this single patient study, the data showed no adverse effects of using the HomeFill II system while performing activities of daily living. More studies, including a larger group of patients, are recommended to determine the value and applications of the HomeFill II oxygen system.

References

1. McCoy R. Oxygen Conserving Techniques and Devices. Respir Care. 2000;45:95-103
Recommendations for Portable Oxygen Systems

Recommendations of the Fifth Oxygen Consensus Conference
Published in Respiratory Care, August 2000, Pages 940-944

The purpose of this conference was to continue to build on the recommendations established in the previous 4 consensus conferences. The sixth recommendation from this conference established standards for portable oxygen systems. Those standards are as follows:

- Ambulatory oxygen is the **standard of care** for patients who are able to be active both inside and outside the home.

- Ambulatory oxygen equipment must **be able to be carried** by most patients on their person during activities of daily living.

- Ambulatory LTOT equipment must weigh less than 10 pounds.

- Ambulatory oxygen equipment must provide at least the equivalent of **2 L/min of continuous flow** oxygen for 4 hours or more.

How does this relate to HomeFill™?

- More than anything, HomeFill IS an ambulatory system and ambulatory oxygen is now the standard of care.

- The Patient Convenience Pack allows almost all ambulatory patients to be able to carry their own oxygen, either in the over-the-shoulder fashion, or as a fanny-pack.

- Weighing in at only 4.3 pounds, the Patient Convenience Pack is less than 50% of the maximum weight for a portable system.

- By incorporating the Precision Medical Easypulse® oxygen conserver, the HomeFill II Patient Convenience Pack provides 5.2 hours of oxygen at 2 L/min when using a ML6 cylinder. When a M9 cylinder is used, the time is further extended to 7.6 hours!

- E-tanks in a pull cart **DO NOT** meet the accepted criteria for portable oxygen systems!
Recommendations of the Fifth Oxygen Consensus Conference

Thomas L Petty MD and Richard Casaburi PhD MD for the Writing and Organizing Committees

(1) To reconsider and expand on the scientific basis of home long-term oxygen therapy (LTOT),

(2) To address present challenges in prescribing LTOT and limitations in access to LTOT because of reimbursement restrictions,

(3) To determine how LTOT education among physicians, manufacturers, suppliers, and payers can be improved so that evolving LTOT knowledge and technology can be widely and cost-effectively disseminated, and

(4) To discuss new challenges for LTOT research and technology development for the new millennium.

There were 54 invited attendees (see Appendix), representing physicians, other health care professionals, manufacturers, suppliers, and patients. The conference used the Delbecq Nominal Group Interactive Process1 to develop specific recommendations. The first day of the conference featured a series of presentations that summarized the current science and practice of oxygen therapy. During the second conference day, participants divided into working groups (each group having approximately balanced representation from physicians, other health professionals, manufacturers, suppliers, and patient groups). Each group analyzed a current area of controversy in oxygen therapy and formulated recommendations. In a subsequent meeting of all conference attendees, each subgroup's recommendations were debated and consensus was achieved. These recommendations amplify and supplement the recommendations of the four previous Oxygen Consensus Conferences2-5 and offer new LTOT guidelines.

LTOT is the established standard of care for patients with chronic obstructive pulmonary disease (COPD) and chronic stable hypoxemia. Ambulatory oxygen equipment is preferred for patients who are capable of participating in ambulatory activities of daily living. Recently, the United States Health Care Financing Administration (HCFA) implemented a 30% reduction in LTOT reimbursement, with Congressional approval. The reimbursement reduction decision was based primarily on an analysis of LTOT reimbursement in Department of Veterans Affairs (VA) hospitals, which has been less than reimbursement outside VA hospitals. Some VA hospitals' costs are lower because of arbitrary limits on the kinds of systems provided, regardless of patient need. Most VA hospitals simply provide an oxygen concentrator and a small number of wheeled high-pressure oxygen tanks (usually E-cylinders). Ambulation is restricted when the patient must pull a wheeled cart. Some VA hospital contracts for LTOT are "a la carte" and therefore do not include charges for regulators, tubing, cannulae, etc. The reimbursement reduction is causing some suppliers to restrict the use of ambulatory oxygen systems in the private sector, even though they are medically necessary and prescribed by physicians.

**Statements and Recommendations**

1. LTOT must be viewed as a high-technology service that includes provision of a prescription of oxygen as well as a wide range of patient and equipment-focused services. It should be viewed as a compendium of services, including assessment of the patient's oxygen needs, provision of the oxygen prescription, patient education, monitoring therapeutic benefits, evaluating patient compliance, communicating with prescribing physicians, and providing and maintaining necessary equipment.
2. Minimum service standards should be established with respect to supply of LTOT services by home care providers, such as respiratory care professionals, on a 24-hour-a-day basis.

Recent emphasis on health care cost containment has promoted earlier hospital discharges and caused patients to be discharged at higher acuity levels. This increases the need for supportive management of chronically ill patients in the outpatient setting. In particular, in many patients hypoxemia has not stabilized at the time of hospital discharge, which has increased the frequency of need for home LTOT. Therefore:

3. Patients who are discharged from hospitals following an exacerbation of respiratory disease requiring oxygen therapy should be retested (recertified) 90 days after discharge, either by arterial blood gas analysis or oxygen saturation measurement. Repeat oxygenation measurements are necessary (1) to evaluate the course of the disease, (2) to determine adjustments to the oxygen prescription (ie, change oxygen flow rates), and (3) to discontinue LTOT if it is no longer necessary. If an ongoing need for LTOT is determined at the 90-day retesting, then additional arterial blood gas or saturation measurements are unnecessary.

Patient compliance is essential to the efficacy of LTOT. Compliance can be improved by initial and ongoing patient education, and by ensuring patient access to appropriate LTOT services, systems, and choices that best meet their medical needs. Health care professionals should monitor and promote patient compliance with LTOT prescriptions.

4. A more active approach to the education of patients, caregivers, and medical professionals is recommended. An LTOT Education Consensus Conference should be organized to assess, improve, innovate, and standardize LTOT education. The mission of this conference should include dissemination of the findings of the current literature, definition of new educational tools, and exploration of more effective ways to assure patient compliance.

5. Additional lobbying and education programs are needed to increase LTOT awareness on a national level. Involved groups should include the National Home Oxygen Patients Association, the American College of Chest Physicians, the American Thoracic Society, the American Association for Respiratory Care, the American Association of Cardiovascular and Pulmonary Rehabilitation, the National Association for Medical Direction of Respiratory Care, the Pulmonary Education and Research Foundation, the Department of Veterans Affairs, the HCFA, oxygen providers, and LTOT equipment manufacturers. These organizations should be encouraged to form a coalition to promote, improve, and increase education and awareness among patients, medical professionals, and others involved with LTOT and related services.

6. Ambulatory oxygen is the standard of care for patients who are able to be active both inside and outside the home, beyond the limits of a stationary system. Ambulatory oxygen equipment must be able to be carried by most patients on their person during activities of daily living. Ambulatory LTOT equipment must weigh less than 10 pounds and provide at least the equivalent of 2 L/min of continuous flow oxygen for 4 hours or more. Appropriate systems should be selected by the prescribing physician for the specific needs of the individual patient.

7. Technology development should focus on devices that are more compatible with patients' life styles, such as lighter ambulatory oxygen systems.

8. The Fifth Oxygen Consensus Conference participants agree that the United States Government Accounting Office report on the impacts on access to LTOT resulting from the recent
Congressionally-mandated reimbursement restrictions is inadequate because it did not measure access to LTOT prior to the payment cuts, thereby making it very difficult to assess the impact of the cuts. The report failed to define "access," and it did not use a random sample of the Medicare LTOT population. Therefore, more thorough, better-designed, and more accurate studies concerning LTOT access should be conducted.

9. To assure patients' rights and informed choices of LTOT delivery systems that meet medical needs, an accepted definition of "access" should be developed by clinicians. This definition should address issues such as accessibility of medical care, pulmonary rehabilitation, as well as selection and service of oxygen equipment and related supplies. Once the definition is established, it should be presented and promoted to the HCFA and other third-party payers.

10. Support of patients requiring oxygen therapy during travel should be readily available. In particular, patients have a right to medically necessary oxygen during air travel. The airline industry should develop and promote industry guidelines regarding provision of and pricing of supplementary oxygen during air travel. Those guidelines should include provision that the oxygen equipment provided aboard airplanes delivers metered and adjustable oxygen flow sufficient to meet the patient's oxygen prescription.

11. Upon initial setup and periodically thereafter, all oxygen therapy devices, particularly oxygen-conserving devices, should be titrated to the proper flow rate at rest, exercise, and sleep, to achieve maximum benefit for patients.

12. Professional respiratory therapy organizations should create clinical practice guidelines for the evaluation and monitoring of LTOT. This should include both short-term and long-term plans.

13. An LTOT patient bill of rights should be developed to assure minimum standards of care to be used by all patients and health care providers. Supporting documents should include education checklists, defined patient responsibilities, and a statement of the role of the respiratory care practitioner in the care of LTOT patients.

14. A system of patient advocacy should be developed to represent LTOT users and providers. The system should include a mechanism to resolve complaints and concerns, which could improve patient compliance and satisfaction. HCFA needs to understand the importance of patient advocacy.

15. The full and actual costs of LTOT, including the cost of electrical power to operate home LTOT equipment, should be recognized.

16. Additional research is needed to determine the medical efficacy and cost-effectiveness of various LTOT technologies and strategies. Among the highest research priorities, a study is needed to compare outcomes of LTOT delivered via stationary systems with LTOT delivered via ambulatory systems. Total costs, survival, quality of life, and utilization of hospitalization and nursing home services should be compared, and the study should be in the form of a randomized prospective controlled clinical trial similar to the Nocturnal Oxygen Therapy Trial Group7 and British Medical Research Council8 studies of oxygen therapy. Research is also needed on other indications for oxygen therapy, including exercise-related hypoxemia and sleep-related hypoxemia in patients with daytime normoxia.

Summary

It should be recognized that the advent of LTOT created a new health care system that is based on powerful scientific data. Oxygen therapy studies such as those by the Nocturnal Oxygen Therapy Trial Group and the British Medical Research Council study clearly demonstrated that LTOT improves...
both the length and quality of life of hypoxemic COPD patients. Keeping patients at home and out of the hospital or nursing home has both psychosocial and economic benefits. Efforts should be towards enhancing, not limiting, the availability of LTOT.

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Therapeutic Equivalence of Oxygen from a Concentrator with Other Sources of Oxygen used in the Home

Conference Report – Problems in Prescribing and Supplying Oxygen for Medicare Patients (1st Oxygen Consensus Conference)

The purpose of this 1986 conference was to ensure that the guidelines that Medicare was establishing for oxygen therapy were consistent with accepted medical practice. The attendees of the conference were the leading authorities on long-term-oxygen-therapy and their recommendations became the standards for reimbursement and clinical practice as it exists today.

- One of the most important standards (Recommendation 5) addresses therapeutic equivalence of oxygen from various systems. This recommendation states “….oxygen levels of 85% or greater are therapeutically equivalent to 100% oxygen”. In other words, oxygen from a concentrator = oxygen from a cylinder = liquid oxygen.


This concept of therapeutic equivalence is also supported in the American Association for Respiratory Care’s Clinical Practice Guidelines for Oxygen Therapy in the Home and Extended Care Facility (Respir Care 1992;37:918-922). [http://www.rcjournal.com/online_resources/cpgs/othefcpg.html](http://www.rcjournal.com/online_resources/cpgs/othefcpg.html)

How does this relate to HomeFill™?

- The Food and Drug Administration has cleared the Invacare HomeFill system for sale and has rated HomeFill Oxygen at 93±3%. In other words, the lowest oxygen concentration present in a HomeFill cylinder has been rated at 90%.
- To ensure that requirement is met, all Homefill systems are fitted with an oxygen sensor that continuously samples the oxygen from the concentrator before it is compressed into the cylinder. This analyzer system governs the HomeFill II compressor and prevents cylinder filling if the concentration falls below 90%.
- Thus, all oxygen manufactured by the Invacare HomeFill II system exceeds all established standards for purity and therapeutic equivalence.
Problems in Prescribing and Supplying Oxygen for Medicare Patients

(Summary of a Conference on Home Oxygen Therapy held in Denver, February 28 and March 1, 1986).

Introduction

The benefit of long-term home oxygen for selected patients with advanced COPD and hypoxemia is now established. Life is prolonged in proportion to the number of hours per day that oxygen is used. Brain function and ability to ambulate and thus carry out activities of daily living are also better with the continuous use of home oxygen. Similar benefits can be attained in patients with other hypoxemic disease states such as in cystic fibrosis and interstitial lung disease.

New technologies offer options in oxygen delivery systems. Paralleling both the knowledge and technological advances of the past decade are new requirements in oxygen prescribing as essential prerequisites for third party reimbursement. Social and economic forces are demanding improved methods of oxygen administration and its conservation. Proposals to control or limit the amount of oxygen used or possibly the method by which it can be administered are under consideration. The field is in transition. Accordingly, experts with established credentials and experience in oxygen studies were convened in Denver, Colorado to consider these issues in the context of the totality of comprehensive care of the patient with chronic respiratory insufficiency.

Inconsistencies in interpretation among third party payers and so-called "cost containment" initiatives have already resulted in coverage and reimbursement policies that may place patients with a need for home oxygen therapy at a significant medical risk, and is not consistent with optimum patient care. Before such initiatives are implemented, we believe it important that competent medical input be received by those charged with third party reimbursement.

This report summarizes the essence of the discussions of the special conference developed and conducted by the Webb-Waring Lung Institute in Denver on February 28 and March 1, 1986. Succinct answers to major questions and considerations in the broad field of home oxygen therapy are stated in this report.

Comments on Oxygen Prescribing Guidelines

The group was in general agreement with HCFA's prescribing requirements as set forth in the Federal Register. However, it was felt that a few clarifications are in order, and several recommendations were offered:

(A.) Regulation 14a, Column 3, Page 13748 which states, "The patient has not been appropriately treated for hypoxemia," represents a misstatement of medical intent and practice and is inappropriate.

RECOMMENDATION 1: There is no substitute for oxygen therapy. It is appropriate that each patient should receive optimum therapy before long-term home oxygen therapy is ordered. This term "optimum therapy" will depend on the overall condition of the patient as viewed by the prescribing physician. Furthermore, "optimum therapy" will remain a part of the patient's total treatment even while receiving oxygen therapy.

(B.) In general, except for oxygen therapy given primarily for hypoxemia during sleep and exercise, arterial blood gas measurements, rather than oxygen saturation measurements made with an ear or pulse oximeter, should be used for the initiation of long-term oxygen therapy. An arterial oxygen tension (PaO2) of 55 (mm Hg) whenever cited) or less has been used as a selection criterion for long-term home oxygen therapy for chronic stable patients. A PaO2 of 55 corresponds to an oxygen saturation of 88% under normal circumstances. If a patient's oxygen saturation is less than 85% as stated in the present regulations, it is virtually certain that the PaO2 is also less than 55. Conversely, under some clinical circumstances, which can occur in patients with chronic lung diseases, a PaO2 of 55 may be associated with an oxygen saturation of greater than 88%.

(C.) It is important to emphasize the exercise occasioned by ambulation for all daily activities, both in and out of the home, is a major component of the standard care and rehabilitative patients with advanced chronic lung disease. To clarify, the term "exercise" is not intended to limit a patient's activity to a specific activity. It is intended to allow for ambulation in and out of the home.

RECOMMENDATION 2: In patients with an arterial PaO2 of 55 at rest, it is deemed medically necessary that a portable oxygen delivery system be provided to facilitate ambulation in addition to a stationary oxygen delivery system. Similarly, in patients who develop hypoxemia (PaO2 only during exertion, a portable system should be approved for ambulation.

RECOMMENDATION 3: The requirement to demonstrate "clinical improvement" in the patient's condition, as evidence of an increase in the patient's ability to perform various activities or exercise should be removed. That exert induced hypoxemia occurs is sufficient evidence of the need for oxygen therapy during exercise. Data from carefully conducted clinical trials clearly document the long-term benefits of oxygen therapy in hypoxemic chronic lung disease patients.

(D.) Many of the current Medicare reimbursement policies and guidelines are based on the premise that "only" oxygen is necessary. Current carrier initiatives which equate reimbursement for delivery systems with one another, or which equate oxygen utilization with reimbursement, fail to recognize that different systems have different capabilities and require different support services. It is stressed that the clinical condition which induces hypoxemia vary greatly among patients. All of these factors impact the appropriateness of the system prescribed for the individual patients. Tient factors which substantially influence the selection of an oxygen delivery system, include but are not limited to the following: general strength...
dexterity, ability to ambulate, alertness and comprehension, compliance, the mechanism and degree of hypoxemia and accessibility to the oxygen supplier.

RECOMMENDATION 4: It should be recognized that the cost of various systems and accompanying support services may vary considerably. The physician's considered judgment regarding the type of system to be provided is based on physical, psychological, social, and regional factors as well as cost. Therefore, cost considerations should not be used to overrule the medical necessity of a particular method of providing oxygen.

RECOMMENDATION 5: Where ambulation in and outside of the home is judged to be part of the therapeutic regimen, a portable system will be necessary. When oxygen concentrators are provided as the sole means of oxygen delivery, a supplemental oxygen system is medically necessary because of unpredictable power failures or electrical malfunctions. The current regulations require that the physician indicate the concentration of oxygen to be used. If the delivery system provides greater than 85% oxygen at the liter flow prescribed, then the requirement for a statement of the concentration is unnecessary. For purposes of these regulations, oxygen levels of 85% or greater are therapeutically equivalent to 100% oxygen.

RECOMMENDATION 6: Consideration should be given to developing a standardized prescription form for use by suppliers and carriers. Such a form would facilitate compliance by physicians in providing the data required by the regulations.

RECOMMENDATION 7: HCFA should urge carriers to obtain consultants who are expert in the nuances of oxygen therapy to advise them on unusual prescriptions for home oxygen therapy, as set forth in regulations 4 and 5, Page 13746, Federal Register. In addition, HCFA itself should solicit the comments of experts in the field as part of the policymaking process.

RECOMMENDATION 8: It is not possible to offer a recommendation at present concerning the clinical use of oxygen conserving devices. Long-term studies are sorely needed.

RECOMMENDATION 9: An educational effort needs to be mounted to better educate the profession in the principles and practice of home and ambulatory oxygen therapy. The appropriate professional bodies should be contacted to begin planning such an effort.

RECOMMENDATION 10: A small workshop of 20-30 persons should be convened to explore areas of concern between suppliers and carriers, with representatives of HCFA and the medical profession serving as resource personnel. The emphasis in this workshop should be on making recommendations for resolving differences and establishing open lines of communication between carriers and suppliers. Ideally, this workshop should be convened under the auspices of the Department of Health and Human Services, with cosponsorship by professional organizations such as the American Thoracic Society, the American Association for Respiratory Care and other interested organizations.