

A Randomized Multi-Arm Repeated-Measures Prospective Study of Several Modalities of Portable Oxygen Delivery During Assessment of Functional Exercise Capacity

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BACKGROUND: Ambulatory oxygen is an important component of long-term oxygen therapy. Pulse-dose technology conserves oxygen and thus increases the operation time of a portable oxygen system. **METHODS:** We tested 4 ambulatory oxygen systems (Helios, HomeFill, FreeStyle, and the compressed-oxygen cylinder system we regularly provide for long-term oxygen therapy at our Veterans Affairs hospital) with 39 subjects with stage-IV chronic obstructive pulmonary disease. Each subject performed one 6-min walk test with each oxygen system, and we measured blood oxygen saturation (via pulse oximetry [S_{pO_2}]), heart rate, and modified Borg dyspnea score, and surveyed the subjects' preferences about the oxygen systems. We also studied whether the 2 systems that provide gas with a lower oxygen concentration (from a home concentrator or portable concentrator) showed any evidence of not providing adequate oxygenation. **RESULTS:** With all 4 systems the mean pre-walk S_{pO_2} at the prescribed pulse-dose setting was 95–96%. The mean post-walk S_{pO_2} was 88–90% after each of the 4 walk tests. Between the 4 systems there were no statistically significant differences between the pre-walk-versus-post-walk S_{pO_2} ($P = .42$). With each system, the pre-walk-versus-post-walk S_{pO_2} difference was between –8% and –6%. **CONCLUSIONS:** Between these 4 ambulatory oxygen systems there were no significant differences in S_{pO_2} , walk time, or walk distance, and there was no evidence of inadequate oxygenation with the 2 systems that provide a lower oxygen concentration. *Key words:* long-term oxygen therapy, exercise, portable oxygen, chronic obstructive pulmonary disease, 6-minute walk test, liquid oxygen, portable concentrator. [Respir Care 2009;54(3):344–349. © 2009 Daedalus Enterprises]

Introduction

There are about 1.4 million individuals currently using long-term oxygen therapy (LTOT) in the United States, including approximately a million reported by the Centers for Medicare and Medicaid Services, and about 350,000 by Medicaid, Veterans Affairs, and private insurance.¹ LTOT is administered with one or a combination of 3 basic stationary delivery systems: compressed oxygen, liq-

uid oxygen, and/or oxygen concentrator. Each of the stationary oxygen systems has advantages and disadvantages regarding operation, function, and cost.

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The majority of LTOT users require oxygen during ambulation. Ambulatory oxygen is important not only in a practical sense for relief of dyspnea and promotion of more normal activities of daily living; it also increases exercise tolerance, reduces hospitalizations, and improves survival in individuals with chronic stable hypoxic chronic obstructive pulmonary disease (COPD).²

Pulse-dose technology, also referred to as demand oxygen delivery systems (DODS), is an important develop-

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ment in portable LTOT systems. Previous research studied differences between various DODS models.³⁻⁶ Bench testing by Bliss et al⁴ found that in some situations certain DODS deliver a higher effective oxygen concentration than does continuous-flow oxygen, although a 1996 study of 15 exercising subjects indicated that one model of DODS was inferior to continuous flow.⁷ Cuvelier et al suggested that the numbers used by DODS manufacturers are merely arbitrary settings to indicate higher or lower flow.⁸

Several models of portable LTOT system are available. The Sixth Oxygen Consensus Conference recommended that, "a portable or wearable device should be a size and weight that allow the patient to do activities of daily living suitable to his or her own lifestyle while maintaining proper oxygen saturation."⁹ The 2 most commonly used portable LTOT systems are compressed-oxygen cylinder and liquid-oxygen canister, both of which can incorporate DODS technology. The gas in these systems is an indirect product of air liquefaction. Suppliers must follow stringent production and transfilling procedures. Medical grade oxygen is at least 99.6% pure.

One newer portable oxygen technology allows the patient to refill oxygen cylinders at home, from an oxygen concentrator. The cylinders required with this system incorporate a proprietary attaching coupler and a built-in DODS regulator. The oxygen percentage in the gas produced by a well-maintained home oxygen concentrator is in the range 85–96%.

Another recent technology is the portable concentrator. Designed to be small enough to be carried by the patient, a portable concentrator can be powered by standard household alternating current, direct current (available in most motor vehicles), or rechargeable battery. Portable concentrators can also use DODS technology and produce a variable oxygen percentage.

Physicians, patients, and home medical equipment providers have high hopes that the most recent enhancements in portable oxygen technology will lead to greater convenience, better patient adherence to therapy, and cost savings. Concerns have been voiced, however, that, even though the newer home and portable concentrator-based devices have logical technical designs, their clinical efficacy remains uncertain. There is particular concern that the lower oxygen concentration and lower bolus volume (ie, combining an 85–96% oxygen gas with a DODS) may cause hypoxia, especially during exercise.¹⁰

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Table 1. Subject Demographics (*n* = 39)

| | |
|---|------------|
| Age (mean ± SD y) | 68.1 ± 9.5 |
| Male (<i>n</i> , %) | 37 (95) |
| Female (<i>n</i> , %) | 2 (5) |
| White (<i>n</i> , %) | 36 (92) |
| African American (<i>n</i> , %) | 3 (8) |
| Prescribed home oxygen flow (<i>n</i> , %) | |
| 1 L/min | 4 (10) |
| 2 L/min | 21 (54) |
| 3 L/min | 14 (36) |

We tested 4 DODS models with subjects with stable hypoxic COPD before, during, and after functional exercise testing in a clinical setting. We hypothesized that the subjects would have similar blood oxygen saturation (measured via pulse oximetry [S_{pO_2}]) values with the 4 systems.

Methods

Thirty-nine veterans, previously diagnosed with COPD, were enrolled (Table 1). All the subjects were recruited from the out-patient pulmonary clinic at the Harry S Truman Memorial Veterans' Hospital in Columbia, Missouri. Each subject was screened and met the criteria for category-IV (very severe) COPD, as described by the Global Initiative for Chronic Obstructive Lung Disease.¹¹ All the subjects denied having had a COPD exacerbation during the 6 weeks immediately preceding the study, and all had dyspnea and resting $S_{pO_2} < 90\%$ while breathing room air. All the subjects had an LTOT prescription from his or her physician, and had been issued the ambulatory oxygen system we regularly issue at our Veterans Affairs hospital, which includes a compressed oxygen cylinder, DODS system (CR50, Puritan Bennett), cannula, and shoulder carrying bag. Individuals whose physical limitations prohibited walking were excluded, as were individuals with cardiac ailments that caused hypertension and/or unstable angina.

Prior to each subject's test session, baseline data were obtained while the subject was at rest and using his or her prescribed oxygen flow. Under our LTOT protocol the subject uses a pulse-dose setting that is numerically equivalent to a continuous-flow oxygen prescription. We recorded health information, heart rate, blood pressure, S_{pO_2} (OxiMax N-560, Nellcor Puritan Bennett, Pleasanton, California), and Borg dyspnea score modified for breathlessness.¹² The subjects were not tested on continuous-flow oxygen; only pulse-dose flow was used.

Each test session began with a 5-min room-air "wash-out" period with the subject at rest, and vital signs were again recorded.

With each subject the first 6-min walk test was according to American Thoracic Society guidelines, with the

subject carrying (via shoulder strap) the ambulatory oxygen system we regularly issue at our Veterans Affairs hospital, set at his or her prescribed pulse-dose setting, and the pulse oximeter.¹² That prescribed pulse-dose setting was used during all the 6-min walk tests.

The subject then conducted 3 more 6-min walk tests, with 3 other LTOT systems: a liquid-oxygen system (Helios, Nellcor-Puritan Bennett, Pleasanton, California), a compressed-oxygen cylinder system that is filled from a home concentrator (HomeFill, Invacare, Elyria, Ohio), and a portable battery-powered concentrator (FreeStyle, Air-Sep, Buffalo, New York). The LTOT systems were tested in random order to eliminate potential bias caused by fatigue.

After each 6-min walk test, vital signs were measured. Between each 6-min walk test, the subject rested for a minimum of 15 min or until he or she felt ready to proceed. The subject was then placed on the next randomized LTOT system and remained at rest for an additional 5 min. The vital signs were again measured before that 6-min walk test.

If at any time the subject reported shortness of breath, fatigue, or experienced a desaturation ($S_{pO_2} < 80\%$) during exertion, the 6-min walk test was discontinued. Oximetry data were downloaded to a computer after each test, with the oximeter manufacturer's software (Score, Nellcor Puritan Bennett, Pleasanton, California). The oxygen saturation outcomes were the difference between the pre-walk and post-walk S_{pO_2} values and the total time (in seconds) during a 6--min walk test that S_{pO_2} was $< 88\%$.

Each subject completed testing in one 4-hour session and was not required to return for further testing. Measurements obtained included S_{pO_2} , walk time, and walk distance. After each 6-min walk test, the subject responded to a survey designed by the research sponsor (Fig. 1), which was read to the subject. After all four 6-min walk tests were completed the subject responded to another survey (Fig. 2).

The study had a randomized block design in which each subject was the blocking factor. We used Friedman's test for the randomized block design to compare LTOT systems with respect to each of the study outcomes.¹³

Results

Table 2 shows the pre-walk S_{pO_2} values. The mean pre-walk S_{pO_2} was 95% (range 88–100%) with all the LTOT systems. Table 3 shows the post-walk S_{pO_2} values. Table 4 shows the differences between the pre-walk and post-walk values. The mean pre-walk-versus-post-walk difference range was $6 \pm 4\%$ to $7 \pm 5\%$. The minimum S_{pO_2} values show instances of impressive declines, but the overall group differences in S_{pO_2} decline were not statistically significant ($P = .42$).

| | | | | | | | | | | | | | |
|---|----------------|----|---|---|---|---|---|---|---|---|---|----------|----------|
| 1. The equipment was easy to use while walking | Strongly Agree | 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | Disagree | Strongly |
| 2. The equipment was responsive to my breathing | Strongly Agree | 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | Disagree | Strongly |
| 3. I liked the weight of the equipment | Strongly Agree | 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | Disagree | Strongly |
| 4. I liked the size of the equipment | Strongly Agree | 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | Disagree | Strongly |
| 5. The equipment had a nice appearance | Strongly Agree | 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | Disagree | Strongly |
| 6. Overall the equipment was very comfortable | Strongly Agree | 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | Disagree | Strongly |

Fig. 1. Questionnaire used after each 6-min walk test.

Forty-four percent of the subjects were unable to complete an entire 6-min walk test, and mean walk time was 4.7 min. Neither LTOT system effect nor sequence significantly affected test completion, which eliminates fatigue as a factor in inability to complete the 6-min walk test. The subjects who were unable to complete a 6-min walk test while using one LTOT system were also unable to complete a 6-min walk test with any of the other 3 systems.

The compressed-oxygen cylinder system we regularly issue at our Veterans Affairs hospital had the least favorable survey responses (Fig. 3). The other 3 systems were similar in receiving more favorable survey scores. The final survey also indicated that very few subjects (3%) preferred the oxygen cylinder system we regularly issue (Fig. 4). Overall, the majority of the subjects favored the Helios liquid-oxygen system.

Discussion

This study's primary objective was to determine S_{pO_2} differences during exertion with 4 ambulatory LTOT systems. We believe our subjects, from both a disease and prescription viewpoint, give a good representation of typical ambulatory oxygen users. We found no statistically significant S_{pO_2} differences between the 4 LTOT systems ($P = .42$). This finding is consistent with a similar study by Furhman et al, who tested 4 DODS models and a continuous-flow oxygen system with 9 subjects performing

Please answer these questions after you have finished breathing on ALL of the oxygen units.
 1 = compressed oxygen cylinder, 2 = Helios, 3 = FreeStyle, and 4 = HomeFill

1. Overall, which oxygen equipment did you feel the best breathing on?
 1 2 3 4

2. Overall, which oxygen equipment was easiest to use while walking?
 1 2 3 4

3. If you were given a choice, which oxygen equipment would you like to have to use at home?
 1 2 3 4

Fig. 2. Final questionnaire, used after all 4 walk tests were completed.

Table 2. Pre-Walk S_{pO_2} Values

| Oxygen System* | Pre-Walk S_{pO_2} (%) | | | |
|----------------|-------------------------|--------|---------|---------|
| | Mean \pm SD | Median | Minimum | Maximum |
| Cylinder | 95 \pm 3 | 96 | 88 | 99 |
| FreeStyle | 95 \pm 2 | 96 | 90 | 99 |
| HomeFill | 95 \pm 2 | 96 | 90 | 100 |
| Helios | 96 \pm 2 | 96 | 90 | 100 |

* Each system was used by 39 subjects.
 S_{pO_2} = arterial oxygen saturation measured via pulse oximetry

Table 3. Post-Walk S_{pO_2} Values

| Oxygen System* | Post-Walk S_{pO_2} (%) | | | |
|----------------|--------------------------|--------|---------|---------|
| | Mean \pm SD | Median | Minimum | Maximum |
| Cylinder | 89 \pm 5 | 89 | 76 | 99 |
| FreeStyle | 88 \pm 6 | 88 | 70 | 98 |
| HomeFill | 88 \pm 6 | 89 | 71 | 98 |
| Helios | 89 \pm 6 | 90 | 70 | 97 |

* Each system was used by 39 subjects.
 S_{pO_2} = arterial oxygen saturation measured via pulse oximetry

6-min walk tests.⁶ Furhman et al found no significant S_{pO_2} differences between the DODS and the continuous-flow oxygen systems, but some DODS models performed better than others.

All 4 DODS we tested provided clinically desirable pre-walk (resting) S_{pO_2} (mean > 95%). The average 6–7% pre-walk-versus-post-walk difference is certainly noteworthy. Such a substantial S_{pO_2} drop reflects an ongoing concern, best stated by Casaburi,¹⁴ that “we are remarkably casual in clinical practice about how we assign supplemental oxygen dose.” We agree with Casaburi and others, and strongly recommend individualized titration and appropriate prescribing of ambulatory oxygen.^{4,5,9,14,15}

Table 4. Difference Between Pre-Walk and Post-Walk S_{pO_2} Values

| Oxygen System* | Pre-Walk Versus Post-Walk S_{pO_2} Difference (%) | | | |
|----------------|---|--------|---------|---------|
| | Mean \pm SD | Median | Minimum | Maximum |
| Cylinder | -6 \pm 4 | -6 | -15 | 2 |
| FreeStyle | -7 \pm 5 | -5 | -22 | 1 |
| HomeFill | -7 \pm 5 | -7 | -21 | 1 |
| Helios | -6 \pm 5 | -5 | -21 | 1 |

* Each system was used by 39 subjects.
 S_{pO_2} = arterial oxygen saturation measured via pulse oximetry

Our secondary objective was to determine if the combination of a DODS low-flow oxygen bolus and the lower oxygen concentration with the FreeStyle and HomeFill systems provided inadequate oxygen. Clinical testing of a DODS with lower-concentration oxygen has not been reported. Gallegos and Shigeoka suggested that that combination could cause hypoxemia, even with increased flow,¹⁰ but we found no evidence of under-treatment with the FreeStyle or HomeFill. However, long-term research on under-treatment should be pursued, especially as the concentrator ages or if the preventive-maintenance schedule is not followed.

All of our subjects completed testing within 4 hours. After a 15-min rest period, the subject was placed on the next LTOT system for a 5-min stabilization period prior to beginning the next 6-min walk test. In a 2005 study, Langenhof and Fichter reported using arterial blood gas values and pulse oximetry to compare the efficacy of DODS to continuous-flow oxygen systems in 13 at-rest subjects with COPD.⁵ Oxygenation was adequate with all the tested systems at rest, but they did not test during exercise. They found, however, that reaching the optimal P_{aO_2} and S_{pO_2} was slower with the DODS. The P_{aO_2} and S_{pO_2} values continued to rise during the 15–30 min of DODS use, so Langenhof and Fichter recommend that DODS titration trials last at least 15 min. That recommendation has po-

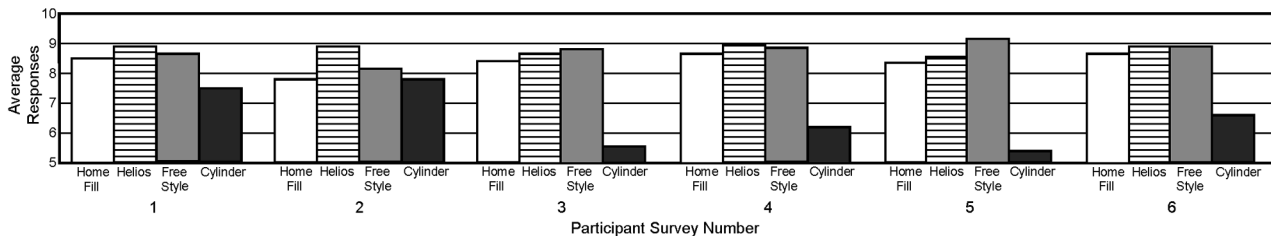


Fig. 3. Responses to questionnaire used after each 6-min walk test.

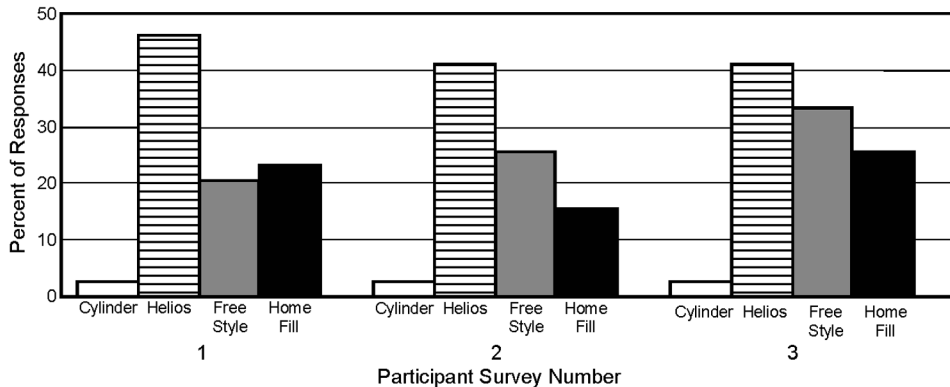


Fig. 4. Responses to final questionnaire.

tential implications for future research and home oxygen providers.

Our subjects' nearly unanimously (37 of the 39 subjects) preferred the Helios, FreeStyle, and HomeFill systems to the cylinder system we regularly issue. It may be valuable to research whether patient preference influences adherence to therapy, use in daily activity, or quality of life.

Limitations

The short stabilization period we used could be considered a weakness in our protocol design. Because of its weight and size, the oximeter we used was less than ideal for use in a 6-min walk test. This study was not designed to compare the 4 LTOT systems to continuous-flow or other DODS. The 4 LTOT systems we studied are in common use, and are well-advertised in the home-care industry, but other portable LTOT devices are commercially available and may give different 6-min-walk-test and S_{pO_2} results. We encourage further research of that possibility.

The development of portable LTOT technology is dynamic and difficult to accommodate in research. Our study was a short-term, clinician-guided study in a clinical setting and may not accurately reflect the home environment. We recommend a long-term study in the home environment to determine the effect of improved adherence to LTOT on activities of daily living and quality of life.

Further research on the stabilization period for DODS titration and functional use would also be helpful.

Conclusions

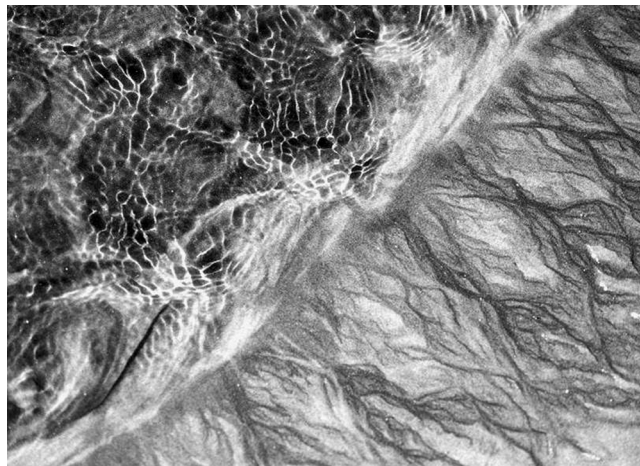
Between the 4 LTOT systems there were no significant differences in S_{pO_2} , walk time, or walk distance, and there was no evidence of inadequate oxygenation with the 2 systems that provide a lower oxygen concentration.

REFERENCES

- Centers for Medicare and Medicaid Services. Medicare program, home health prospective payment system rate update for calendar year 2007 and deficit reduction act of 2005. Changes to Medicare payment for oxygen equipment and capped rental durable medical equipment; final rule. 42 CFR: 414, 484, CMS-1304-FJ, RIN 0928-AN76.
- Petty TL, Bliss PL. Ambulatory oxygen therapy, exercise and survival with advanced chronic obstructive pulmonary disease: the Nocturnal Oxygen Therapy Trial revisited. *Respir Care* 2000;45(2):204-213.
- Shigeoka JW. Demand valves for oxygen therapy: your mileage may vary. (editorial). *Respir Care* 2004;49(2):156-157.
- Bliss PL, McCoy RW, Adams AB. Characteristics of demand oxygen delivery systems: maximum output and setting recommendations. *Respir Care* 2004;49(2):160-165.
- Langenhof S, Fichter J. Comparison of two demand oxygen delivery devices for administration of oxygen in COPD. *Chest* 2005;128(4):2082-2087.

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6. Fuhrman C, Chouaid C, Herigault R, Housset B, Adnot S. Comparison of four demand oxygen delivery systems at rest and during exercise for chronic obstructive lung disease. *Respir Med* 2004; 98(3):938-944.
7. Roberts CM, Bell J, Wedzicha JA. Comparison of the efficacy of a demand oxygen delivery system with continuous low flow oxygen in subjects with stable COPD and severe oxygen desaturation on walking. *Thorax* 1996;51(8):831-834.
8. Cuvelier A, Nuir JF, Chakroun N, Aboab J, Onea G, Benhamou D. Refillable oxygen cylinders may be an alternative for ambulatory oxygen therapy in COPD. *Chest* 2002;122(2):451-456.
9. Doherty DE, Petty TL. Recommendations of the sixth oxygen consensus conference. *Respir Care* 2006;51(5):519-521.
10. Gallegos LC, Shigeoka JW. Novel oxygen-concentrator-based equipment: Take a test drive first! (editorial). *Respir Care* 2006;51(1):25-28.
11. Global Initiative for Chronic Obstructive Lung Disease. Pocket guide to COPD diagnosis, management and prevention. 2006.
12. American Thoracic Society. Guidelines for the 6-minute walk test. *Am J Respir Crit Care Med* 2002;166(1):111-117.
13. Daniel WW. Applied nonparametric statistics. 2nd ed. Boston: PWS-Kent; 1990.
14. Casaburi R. Assessing the dose of supplemental oxygen: let us compare methodologies (editorial). *Respir Care* 2005;50(5):594-595.
15. Cutaia M. Ambulatory monitoring of oxygen saturation in chronic lung disease: optimizing long-term oxygen therapy (abstract). *Clin Pulm Med* 2002;9(6):297-305.



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