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A Comparative Study of Three Portable Oxygen Concentrators during a 6-Minute Walk Test in Patients with Chronic Lung Disease

Carole J. LeBlanc, RRT (corresponding author)

The Ottawa Hospital Rehabilitation Centre

1201-505 Smyth Road

Ottawa, Ontario K1H 8M2

cleblanc@ottawahospital.on.ca

Lyne G. Lavallée, BSc, BSc(PT)

The Ottawa Hospital Rehabilitation Centre

University of Ottawa

llavallee@ottawahospital.on.ca

Judy A. King, PhD, PT

Assistant Professor, Faculty of Health Sciences, University of Ottawa

The Ottawa Hospital

jking@uottawa.ca

Rebecca E. Taylor-Sussex, BSc(Hons)

Ottawa Hospital Research Institute

rtaylorsussex@ohri.ca

Andrew Woolnough, MSc

Ottawa Hospital Research Institute

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andrew.woolnough@gmail.com

Douglas A. McKim, MD

Medical Director, Respiratory Services, CANVent Program

The Ottawa Hospital Rehabilitation Centre and

The Ottawa Hospital Sleep Centre

Associate Professor, Faculty of Medicine, University of Ottawa

dmckim@ottawahospital.on.ca

This study was conducted at The Ottawa Hospital Rehabilitation Centre, Ottawa, Canada.

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Conflicts of Interest:

The POCs were donated by the respective manufacturers for the purpose of the study. The manufacturers had no role in the design and conduct of this study. The authors report that no potential conflicts of interest exist with any of the manufacturers or distributors of products discussed in this article.

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Abbreviations

6MWT: 6-minute walk test

ANOVA: Analysis of variance

ATS: American Thoracic Society

CLD: Chronic lung disease

COPD: Chronic Obstructive Pulmonary Disease

FEV_1: Forced expiratory volume in 1 second

FVC: Force vital capacity

FiO_2: Fraction of inspired oxygen

LTOT: Long term oxygen therapy

PF: Pulmonary Fibrosis

POC: Portable Oxygen Concentrators

POS: Portable Oxygen System

SpO_2: Saturation of Oxygen as measured by pulse oximetry

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Abstract

Background – The purpose of this study was to compare the ability of 3 portable oxygen concentrators (POCs) to maintain $SpO_2 \geq 90\%$ during exercise in patients with chronic lung disease (CLD). **Methods –**Twenty-one participants with CLD (18 COPD, 3 PF) and documented room air exertional $SpO_2 \leq 85\%$ performed four, 6-minute walk tests (6MWTs): a control walk using the participant's current oxygen system and prescribed exertional flow rate and 1 walk with each of the 3 POCs at maximum pulse dose setting. **Results –** There was a significant interaction between POC type and time point for SpO_2 measurements with higher saturations pre- and post- walk when participants used the Eclipse 3 when compared to the other POCs (all $p<0.01$). Participants were also able to walk further and maintain a mean $SpO_2 \geq 90\%$ while using the Eclipse 3 (both $p<0.01$), the device with the largest bolus size. Participants indicated that they preferred the EverGo's physical characteristics but that the Eclipse 3 responded best to their breathing. The iGo was rated less favourably than the other 2 POCs. **Conclusions –** The Eclipse 3, with the largest bolus size of the POCs tested, was best at meeting patients' clinical needs. POC recipients should be appropriately tested during all activities of daily living to ensure adequate oxygenation. The health care provider should provide information and help direct the patient toward the most clinically appropriate oxygen system while being mindful of the patient's preferences and lifestyle. This study was registered with clinicaltrials.gov, trial number NCT01653730. (Word count = 249)

Key words: chronic obstructive pulmonary disease; oxygen inhalation therapy/instrumentation; pulmonary fibrosis; exercise test; ambulatory care; walking

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Introduction

Long-term oxygen therapy (LTOT) is indicated for patients with chronic lung disease (CLD) and is universally accepted for its effect on mortality in patients with chronic obstructive pulmonary disease (COPD) with persistent hypoxemia.[1;2] Studies have demonstrated that giving supplemental oxygen with activity may improve exercise performance, enhance exercise training and reduce dyspnea.[3;4]

Patients with CLD using LTOT benefit from an active lifestyle and portable oxygen systems (POS) are of particular interest to this patient population. The challenge for clinicians is in selecting the most appropriate POS, meeting the patients' current and future clinical and physical needs.[5-13] The 6th long-term oxygen therapy consensus conference recommended that physicians, patients, and home-medical-equipment providers effectively collaborate to ensure LTOT users have access to the most appropriate technologies for their clinical and lifestyle needs.[14]

Portable oxygen concentrators (POCs), whose only daily requirement for maintenance is access to electricity to re-charge batteries, present an attractive option when compared to compressed gas and liquid oxygen systems. However, studies have shown that POCs do not always maintain adequate oxygenation during exercise[5;7;13] and bench studies have shown decreases in fraction of inspired oxygen (FiO_2) in POCs as respiratory rate increases.[9;12] These studies give reason for concern since evidence suggests that maintaining oxygen saturation (SpO_2) $\geq$ 90% offers a survival advantage.[15]

A small number of studies have examined how variations in the technical specifications between POCs affect clinical outcomes in exercising patients. Subramaniam et al.[10] compared 3 POCs

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during a 10 minute treadmill test and found no statistical differences in SpO_2 or walking distance. However, a second group did find a difference between 3 POCs during a treadmill test concluding that higher oxygen delivery capacity was associated with improved exercise outcomes and oxygenation.[5;13]

In an attempt to reconcile the disparity in these results and determine if POCs are capable of meeting patients' oxygen needs during exercise ($SpO_2 \geq 90\%$) we chose to evaluate 3 POCs using a standardized exercise test (6-minute walk test) in patients with CLD with severe exertional oxygen desaturation. We also measured patients' personal POC preferences.

Materials and Methods

Study Design and Setting

A within-subject, repeated-measures design was used to compare 3 POCs during an exercise test. Participants attended 2 sessions at the Respiratory Services, CANVent Program of The Ottawa Hospital Rehabilitation Centre. During the initial screening session, clinical characteristics were measured to determine the participant's eligibility for the study. Eligible participants then returned for a second session where they completed four 6MWTs (1 with their usual portable oxygen source and 1 with each of the 3 POCs being tested).

Exercise measure – 6-minute walk test (6MWT)

The 6MWT is a reproducible, self paced, walk test reflective of activities of daily living.[16] A physiotherapist and a respiratory therapist conducted all of the walks using the American Thoracic Society (ATS) 6MWT standards and script.[17]

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Participants

Oxygen dependent patients with an existing diagnosis of COPD or pulmonary fibrosis (PF) who had completed the pulmonary rehabilitation program at The Ottawa Hospital Rehabilitation Centre between January 30th 2008 and March 31st 2011 were invited to participate in the study. While the pathophysiology of PF is different than COPD and the ability of POC's to maintain oxygenation during exercise may differ, this patient population also benefit from and partakes in an active lifestyle. They therefore need access to and/or guidance on the appropriateness of portable oxygen systems. For these reasons patients with PF were included in the study.

During the screening session participants completed a 6MWT on room air to determine their eligibility for the remainder of the study. Participants who maintained oxygen saturation > 85% during the walk were excluded from further participation (see Figure 1). The study was approved by the Ottawa Hospital Research Ethics Board (#2009845-01H). All patients gave written informed consent before their screening assessment.

Equipment

We selected the 3 POCs with the highest oxygen production capabilities (ml per minute) that were available in our region. They were: EverGo (Respironics Inc.; Murrysville, PA, USA); iGo (DeVilbiss Healthcare; Summerset, PA, USA); and Eclipse 3 (Caire Inc. Ball Ground; GA, USA). Technical specifications can be found in Table 1. The current study aimed to test the upper limit of the POC's ability to meet patient's oxygenation needs. Since POC pulse dose settings are most frequently used by patients on LTOT to conserve battery power, each unit was set at its' maximum pulse-dose setting. For the control walk, participants used their personal portable oxygen device on the setting prescribed for paced exercise (see Table 2).

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(Table 1 about here)

(Table 2 about here)

Screening session

On the day of the screening assessment, the participant's medical history was obtained and force expiratory volume in 1 sec (FEV_1) and force vital capacity (FVC) were measured (CPFS/D spirometer; Medical Graphics Corporation; St Paul, MN, USA). The participant then performed a qualifying room air 6MWT while SpO_2 was monitored.

POC testing session

Qualifying participants returned to the clinic within 3 weeks for a second session. Participants performed a total of 4 separate 6MWTs during this second session. Two walks were completed in the morning followed by a minimum 2-hour lunch break and then 2 walks in the afternoon. The first 6MWT, was a control walk where participants used their usual oxygen system set at their prescribed exertional oxygen flow rate (maximum rate of 4 L/min). Participants then performed a 6MWT with each of the 3 POCs set at the unit's maximum pulse dose setting. The Eclipse 3 was the only device with adjustable rise time and triggering sensitivity features. For all participants the sensitivity was set at "1" (most sensitive) and rise time set at "FAST".

The order in which POCs were used was randomly assigned for each participant using a sequence generator to minimize order effects. Participants completed the walk using their usual mode of ambulation (e.g. walker with basket). Each 6MWT was separated by a minimum 20-minute rest period to allow their SpO_2 to return to baseline during which the participant used their own oxygen system at the prescribed resting setting. Participants were placed on the

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assigned POC 10 minutes prior to the next walk. The therapist terminated a walk if the participant's oxygen saturation reached 85% or less for any length of time. Participants also had the option to terminate a walk at any time based on their own judgement of perceived exhaustion.

(Figure 1 about here)

Outcome Measures

SpO_2 was measured continuously during the walk using a forehead probe (OxiMax Max-Fast; Covidien; Mansfield, MA, USA) with headband and an oximeter (Nellcor OxiMax N-600 and N600x; Covidien; Mansfield, MA, USA). Pulse rate was monitored during the walks to ensure probe connectivity and to ensure patient safety but is not reported. After each walk, oximetry data was downloaded to a computer (Profox Oximetry Software; Profox Associates Inc; Escondido CA, USA). SpO_2 and dyspnea (as measured by the 10 point Borg scale)[18] were manually recorded at the start (pre-) and end (post-) of the walk. Total distance walked (meters) and time spent with $SpO_2 \geq 90\%$ was recorded. Post-walk, participants completed a self-administered questionnaire designed by the researchers to allow them to rate the POCs (Figure 2).

(Figure 2 about here)

Statistical Analysis

Pre- and post- SpO_2 saturations and Borg scores were analysed using a repeated-measures analysis of variance (ANOVA) with timepoint (pre- vs. post-) and POC type as within-subject repeated factors. Pairwise post hoc comparisons applying Bonferonni corrections for multiple

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comparisons were done to further examine significant effects. A second repeated-measures ANOVA was completed for outcomes measured only once (walk distance, time with $SpO_2 \geq$ 90%) with POC type as the within-subject repeated factor. Questionnaire data were examined with descriptive analyses. All analyses were completed with SPSS V-18 or 19 for Windows.

Results

Participant Demographics and Baseline Characteristics

Of the 35 patients who completed the rehabilitation program and were oxygen dependent, 24 agreed to participate. Two of the 24 participants failed to meet the oxygen saturation criteria during the screening room air 6MWT and 1 further participant was excluded due to poor SpO_2 tracking leaving 21 participants in the analyses (12 females). Participants had a mean age of 66.57 (SD 8.36, range 53-82). Eighteen participants were diagnosed with COPD and 3 with PF. The mean FEV_1 % predicted was 32.22 ± 11.67 in patients with COPD and 61.0 ± 7.94 in patients with PF and the mean FEV_1/FVC was 42.22 ± 16.35 in patients with COPD and 85.67 ± 4.04 in patients with PF.

Fifteen participants used a wheeled walker to carry POCs and 6 used the manufacturer provided POC wheeling device.

Pre/post-6MWT measures

6MWT outcome measures and walk terminations are presented in Table 3. Eighty-six percent of participants walked for the full 6 minutes using the Eclipse 3 as compared to 52% using either the iGo or the EverGo. One walk was terminated by the patient, during an EverGo trial; all other terminations were initiated by the therapist due to oxygen desaturation.

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SpO_2 – There was a significant interaction between POC type and pre- vs. post-measurements of SpO_2 ($P = .006$). Post hoc tests showed that SpO_2 was higher pre walk ($P < .001$) and was highest when the Eclipse 3 was used ($P < .001$ for all contrasts comparing the Eclipse 3 to the other POC types). Examination of the means indicates that the Eclipse 3 had higher SpO_2 values both pre- and post-walk and the decrease in SpO_2 between pre- and post-walk was the smallest of all the POC models (see Figure 3). In this study the oxygen levels of the 3 participants with PF during walks were within the distribution of all participants. With the Eclipse 3, 2 out of 3 participants with PF maintained oxygen levels ≥90% for the duration of the walk while the 3rd participant maintained oxygen levels >85%. Participants with PF did not maintain oxygen levels >85% (nor did 7 out of 18 participants with COPD) for both the iGo and EverGo walks.

Borg score – While Borg score was significantly higher post-walk when compared to pre-walk ($P < .001$) there was no significant difference between POCs ($P = 0.201$).

(Table 3 about here)

Other 6MWT measures

There was a significant difference between POCs for time spent with $SpO_2 \geq 90\%$ ($P < .001$) and total distance walked ($P = .001$). Post hoc analyses indicated that participants using the Eclipse 3 walked further (Control contrast, $P = .013$; EverGo contrast, $P = .009$; iGo contrast, $P = .008$) and spent more time with $SpO_2 \geq 90\%$ (Control contrast, $P < .001$; EverGo contrast, $P < .001$; iGo contrast, $P = .001$). In fact, the Eclipse 3 was the only POC to maintain a mean $SpO_2 \geq 90\%$ for the duration of the walk.

(Figure 3 about here)

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Questionnaire Responses

Participants consistently gave 'neutral' (3) or 'disagree' (1 or 2) responses to the questionnaire statements for the iGo. Participants rated the EverGo most favorably for questions about the device's physical characteristics (86% of patients gave a 4 or 5 rating for each statement) while the Eclipse 3 received the most favorable response to the device's ability to respond to breathing (95% of patients gave a rating of 4 or 5). The EverGo and the Eclipse 3 received comparable responses to the remaining statements with ratings of 4 or 5 in 81% and 76% of patient for "easy to use while walking", 50% and 48% for "felt comfortable with device", and 52% and 43% for "would consider for future use". See Table 4 for a summary of questionnaire response rates.

(Insert Table 4 about here)

Discussion

This study compared the ability of 3 POCs to maintain adequate oxygenation during a 6MWT in a well defined group of patients with CLD. Despite using the maximum pulse-dose setting for each device, the Eclipse 3 was the only POC to maintain a mean $SpO_2 \geq 90\%$ for the duration of the exercise and showed significantly better performance on all outcome measures. The difference in walk distance between the Eclipse 3 and the other 2 POCs was also clinically significant.[19] Furthermore, participants rated the Eclipse 3 as the best to respond to their own spontaneous breathing patterns during exercise.

Although the Eclipse 3 and the iGo shared the same high oxygen production capability (3000 ml/min), they did not demonstrate equivalent performance. This is in contrast with results found by McCoy et al.[5;13] who concluded that having a POC with a greater oxygen production capacity

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improved oxygen saturation and exercise outcomes. Instead, we found that Post-walk SpO_2 and walk distance were more similar between the EverGo and the iGo than the Eclipse 3 despite the fact that the EverGo has a published oxygen production capability almost one third that of the other 2 POCs (1050 ml/min). Based on the technical specifications of the POCs used in the current study we speculate that the most probable characteristic contributing to the performance differences was the O_2 pulse dose bolus volume. While the bolus volume range of the iGo and EverGo are similar, the Eclipse 3 is much larger (see Table 1). In line with results reported by Chatburn and Williams[9], we suggest that the larger O_2 pulse bolus volume of the Eclipse 3 was an important contributing factor enabling it to better meet patients' oxygen needs during exercise.

In spite of the Eclipse 3's superior performance for meeting clinical needs, participants rated the EverGo and the Eclipse 3 similarly when asked if they would use the device in future. Clearly the physical characteristics of the EverGo, as the lightest and smallest POC, were important to participants. Clinicians should educate patients that the goal of supplementary oxygen is to satisfy blood oxyhemoglobin needs and that this should be the first consideration in selecting a POC. The current study tested 3 specific POC models and although technology will change, the recommendations and principles for determining the best POC for patients will remain. It is important to consider not only production capability but also bolus volume when helping patients choose the right POC.

During the control 6MWT we found that most patients desaturated to unacceptable levels. It is clear that patients' usual paced walking prescription and oxygen device were unable to meet the oxygen requirements of strenuous exercise. During rehabilitation, patients are instructed in how

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to pace themselves during exercise in order to minimize oxygen desaturation. Clinicians should ensure that patients are aware of the limitations of their devices and have appropriate oxygen prescriptions for all activity levels. This study raises awareness of POCs variability and should encourage clinicians to focus on clinical outcomes under conditions as close to real life as possible. Clinicians and patients should test any potential new device to ensure it meets their clinical needs during activities of daily living. Patient preferences (ie. for lighter, smaller, or more convenient devices) should only be considered once potential devices have demonstrated to meet their oxygen needs.

Limitations

In the current study, these commercially available POCs were not tested to ensure they met advertised product specifications. Our interpretation therefore assumes that no product defects or anomalies were present. Further, although patients with COPD and PF were included in the sample, there were insufficient patients with PF to do group analyses. Despite this, visual inspection of the data suggests that patients with PF's patterns of performance were similar on the different POCs to the patients with COPD. Future studies should aim to recruit more patients with PF to determine if their needs are different from patients with COPD. Additionally, due to methodological constraints, we did not measure respiratory rate, a factor that could have potentially affected the ability of devices to meet patient's oxygen needs. Future studies should seek to find ways of reliably measuring respiratory rate during ambulation. Inhaled medication use was also not specifically monitored during the study. Although none of the participants was observed taking rescue inhaled medication, participants were not always visible to the therapists completing the testing, in particular during lunch breaks and between walks. Nevertheless, since

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measurements for the study were made within patients and the order in which POCs were used was randomly assigned it is unlikely that there would be an effect of bronchodilator use that would have affected any one POC more than another. Finally it should be recalled that this study involves selected patients who desaturated below 85% during a room air walk test. The results of the current study therefore do not preclude the possibility that any of the POC devices tested could provide adequate oxygenation with for patients who have lesser degrees of desaturation.

Conclusions

These findings suggest that patients with CLD exhibit considerable improvement in their ability to maintain oxygen saturation when exercising with the Eclipse 3. We have shown that bolus size can be an important factor in determining the effectiveness of a POC device and health care professionals should be mindful of patients' current and future oxygen needs at all activity levels when guiding them in the selection of their own POC.

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Author contributions

CL, LL and DM contributed to conception and design of the study; analysis and interpretation of the data; and drafting and revision of the manuscript. CL and LL collected the data and are the guarantors of the paper. JK: contributed to the ethics application; interpretation of the data; and revision of the manuscript. RT-S and AW contributed to the analysis and interpretation of the data; and RT-S contributed to the drafting and revision of the manuscript.

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Other contributions

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Figure Legends

Figure 1. CONSORT flowchart diagram.

Figure 2. Self-administered questionnaire for POC preferences.

Figure 3. Comparison of pre and post exercise SpO_2 for the control and POC 6MWTs. *Indicates there was a significant difference in SpO_2 levels when the Eclipse 3 was used compared to all other POCs.

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Table 1. Technical specifications of the 3 POCs tested in the study

	DeVilbliss iGo (model 306D S-A)	SeQual Eclipse 3	Philips Respironics EverGo
Maximum O_2 capacity (ml/min.)	3000	3000	1050
O_2 pulse dose bolus volumes (ml)	14-84	16-192	12-70
Purity of O_2 (%)	91±3	90±3	89±3
Pulse setting	1-6	1-6	1-6
Trigger sensitivity (cmH_2O)	(-) 0.05 – (-) 0.12	(-) 0.15 – (-) 0.45	(-) 0.2
O_2 delivery method	Continuous up to 3 L/min; PD max setting 6	Continuous up to 3 L/min; PD max setting 6	PD max setting 6
FAA approval status	Yes (up to 4000m)	Yes (up to 4000m)	Yes (up to 2450m)
Noise level (dB(A))	40 at pulse dose setting 3	<49	<50
Weight (kg)	8.6 with one battery	8.4 with one battery	4.5 with two batteries
Dimensions	49.0 H x 31.2 W x 18.0 D	49.0 H x 31.2 W x 18.0 D	21.6 H x 15.25 W x 30.5 D
Battery duration (hrs.)	3.0 with PD of 6 (bolus 84ml) and RR 20/min.	3.5 with PD 6 (bolus 96ml) and RR 12/min.	4.0 with PD of 6 (bolus 70ml) and RR 20/min.
Battery recharge time (hrs.)	3/battery	2-3/battery	2-3/battery

PD = pulse dose

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Table 2 – Number of patients using different oxygen delivery systems during the control walk and range of pulse/continuous flow settings used.

Device type	# participants using pulse-dose mode (pulse setting range)	# participants using continuous flow mode (range of L/min. setting)
Compressed gas oxygen cylinder (E or D size)	4 (1-5)	1 (3 L/min)
Liquid oxygen	1 (1.5)	9 (1-4 L/min)
EverGo POC	3 (2-2.5)	0
Sequal Eclipse POC	1 (4)	1 (2 L/min)
Inogen POC	1 (4)	0