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Portable Oxygen Concentrators versus Oxygen Cylinder during Walking in Interstitial Lung Disease: A Randomized Crossover Trial

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SUMMARY AT A GLANCE:

This is the first crossover trial comparing the clinical performance characteristics of two portable oxygen concentrators (the Inogen One G2 and the Evergo) with that of a compressed oxygen cylinder in patients with ILD, showing comparable performance among the three devices.

ABSTRACT

Background and objective: Ambulatory oxygen therapy is often provided to patients with interstitial lung disease (ILD). Lightweight portable oxygen concentrators (POCs) provide an alternative to traditional portable systems such as compressed oxygen cylinders, however, their efficacy in patients with ILD has not been assessed. This study aimed to evaluate the clinical performance of three ambulatory oxygen systems (two different POCs and a compressed oxygen cylinder) during 6-minute walk tests (6MWTs) in patients with ILD and exertional desaturation.

Methods: Twenty participants with ILD of varying aetiologies who demonstrated exertional desaturation to $<90\%$ on room air during 6MWT were recruited. Each participant performed two 6MWTs while breathing room air. On a subsequent day, two further 6MWTs were performed, in random order: one breathing oxygen via a POC (either the Inogen One G2 POC or the EverGo POC at the setting of 6) and one with a compressed oxygen cylinder (at 5L/minute).

Results: There were no significant differences in nadir oxygen saturation during 6MWTs using different portable oxygen devices (Trial 1 – mean SpO_2 for Inogen One G2 POC: $82.3 \pm 3.5\%$ versus oxygen cylinder: $80.3 \pm 2.2\%$, $p = 0.14$; Trial 2 – mean SpO_2 for EverGo POC: $85.7 \pm 7.7\%$ versus oxygen cylinder: $86.1 \pm 6.1\%$, $p = 0.79$). The mean 6-minute walk distances were not significantly different among the three devices.

Conclusion: The performance of the Inogen One G2 POC and the EverGo POC had comparable performance to that of the compressed oxygen cylinder during walking in patients with ILD and exertional desaturation.

Short title: Portable oxygen concentrators in ILD

Keywords:

- * Exercise
- * Interstitial lung disease
- * Oxygen inhalation therapy
- * Pulmonary fibrosis
- * Quality of life

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INTRODUCTION

Exertional desaturation is thought to contribute to exertional dyspnoea and exercise limitation in patients with interstitial lung disease (ILD). Mechanisms contributing to exertional desaturation in ILD include pulmonary ventilation and perfusion mismatching, oxygen diffusion limitation, low mixed venous oxygen concentration, and increased intra-cardiac and intrapulmonary shunting.[1-6] Although the prevalence of exertional desaturation in ILD is uncertain, a previous study assessing nocturnal desaturation in patients with ILD reported that 47% of participants desaturated to < 88% during 6-minute walk tests (6MWTs).[7] Exertional desaturation may occur even in patients with mild disease, including in those without resting hypoxaemia.[8]

Ambulatory oxygen therapy delivered via compressed oxygen cylinders or liquid oxygen canisters is commonly prescribed for patients with ILD and exertional desaturation. The aim of this treatment is to improve symptoms and functional status, although evidence supporting benefit is limited.[9-12] Adherence to ambulatory oxygen systems is poor in patients with chronic obstructive pulmonary disease (COPD),[13,14] and although adherence data are lacking in patients with ILD, it is likely that some of the same causative factors apply, including poor portability and perceived unreliability and/or lack of efficacy of the oxygen system.[13,14] Portable oxygen concentrators (POCs) are an alternative source of ambulatory oxygen with proven popularity among consumers. Due to differences in technical specifications, the performances of different POCs are variable in bench studies.[15,16] Clinical studies comparing different POCs during exercise tests in patients with COPD revealed inconsistent impacts on clinical parameters with different POCs.[17,18] Currently, POCs deliver oxygen at lower purity than oxygen cylinders, the amount of oxygen delivered varies depending upon several factors including the conserving ratio of the conserver used in the POC, the delivery method of the POC (for example pulse delivery), as well as patient factors. Thus, the dose settings on a POC, frequently labelled in numerals, do not correspond directly to flow rates delivered via oxygen cylinders.

Patients with ILD have more severe exertional desaturation compared to patients with COPD,[19] and often require higher oxygen flow rates during exertion to prevent desaturation. Whether adequate oxygenation can be maintained using a POC in the setting of the high exertional oxygen demands occurring in patients with ILD is unclear. This study aimed to compare the performance of two commonly used POCs (the Inogen One G2 POC and the EverGo POC) with the compressed oxygen cylinder in patients with ILD during exercise.

METHODS

A randomized crossover study was conducted at two tertiary hospitals, Austin Health (Trial 1) and Alfred Health (Trial 2). Eligible participants were patients aged over 18 years with a confirmed diagnosis of ILD of any aetiology and exertional desaturation (defined as desaturation < 90% on room air during the 6MWT). Exclusion criteria included significant communication or locomotor difficulty, primary diagnosis of a respiratory condition other than ILD, and pregnancy. Patients with resting hypoxaemia were not excluded. Potential participants were recruited from ILD clinics at both hospitals. This study was approved by the Austin Health Human Research Ethics Committee (HREC/15/Austin/330) and the Alfred Hospital Ethics Committee (187/13).

We selected two POCs with high oxygen delivery capacity and good portability features which were available in our region: Inogen One G2 POC (Inogen, Goleta, California) and EverGo POC (Respironics, Murrysville, Pennsylvania). Technical specifications of the POCs are listed in Table 1. The compressed oxygen cylinders used at both trial sites were type CH cylinders, weighing 4.2 kg with a volume of 470 L and a height of 52 cm.

Study Design

Eligible participants performed four 6MWTs, conducted by senior clinicians according to current field test guidelines,[20] over two consecutive days (as shown in Figure 1). On Day 1, two 6MWTs, with at least 30 minutes of rest between tests, were performed breathing room air in order to determine participants' eligibility for the study. Eligible participants then returned for a second session on the subsequent day.

On Day 2, participants had an arterial blood gas (ABG) taken on room air after 30 minutes of rest. Then, participants undertook two 6MWTs in random order as determined using sealed envelopes: one with a compressed oxygen cylinder, and one with either the Inogen One G2 POC (Trial 1 at Austin Health) or the EverGo POC (Trial 2 at Alfred Health). Both POCs delivered pulse flow on their maximum setting of 6, whilst the oxygen cylinder was set on 5 L/min with continuous flow. Prior to each 6MWT, participants breathed oxygen from the allocated device using nasal prongs for at least 30 minutes, after which time the resting oxygen saturation (SpO₂) and ABG were obtained. Between tests, participants rested for at least 30 minutes breathing room air prior to switching to the alternate device for the second test.

Additional weight was added to each POC to match for the weight of the oxygen cylinder. Participants pulled the devices themselves using a trolley. Familiarisation with the different portable oxygen devices took place prior to the first test on Day 2. Nadir SpO₂, maximum heart rate and the distance walked were recorded. Dyspnoea and fatigue were measured before the start and at the end of each test using the 10-point Borg scale.[21]

Statistical Analysis

Statistical analysis was performed using GraphPad Prism (v5, Graphpad Software, USA). A sample size of 10 participants for each trial was calculated to detect a difference of at least 3% in nadir SpO₂ between tests for each of the POCs, with a statistical power of 80%, assuming a within-patient standard deviation nadir SpO₂ of 2% based on data from a previous trial using 6MWTs in patients with ILD.[22] Standard descriptive data were expressed as mean and standard deviation (range). Categorical data were presented as counts and

percentages. For parametric data, t tests or analysis of variance followed by the Tukey post-test were used for two or multiple comparisons, respectively. Parametric correlations were assessed using Pearson's test. Non-parametric data were analysed with Mann-Whitney or Kruskal-Wallis tests followed by Dunn's post-test for two or multiple comparisons. Non-parametric correlations were assessed using Spearman's test. Statistical significance was accepted as p-values below 0.05.

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RESULTS:

Subjects

Twenty eligible participants were recruited from two specialised ILD clinics, 10 from each site. Demographic and clinical characteristics of the participants are shown in Table 2. Their mean age was 69 years. They had moderate-to-severe lung function impairment, which was worse in the Trial 1 population. In Trial 1, 40% of participants had idiopathic pulmonary fibrosis (IPF) and 40% had chronic hypersensitivity pneumonitis. Only one participant had connective tissue disease-related ILD (amyotrophic dermatomyositis), without musculoskeletal involvement. Most participants in Trial 2 (80%) had IPF.

6-Minute Walk Test

There were no significant differences in nadir SpO₂ during walking among different portable oxygen devices (Mean SpO₂: Trial 1 – Inogen One G2 POC: $82.3 \pm 3.5\%$ versus oxygen cylinder: $80.3 \pm 2.2\%$, $p = 0.14$; Trial 2 – EverGo POC: $85.7 \pm 7.7\%$ versus oxygen cylinder: $86.1 \pm 6.1\%$, $p = 0.79$). In Trial 1 more participants desaturated to less than 80% during 6MWTs using the oxygen cylinder (80%) compared to the Inogen One G2 POC (20%) ($p = 0.16$). In trial 2, there was an equal number of participants (20%) who desaturated to less than 80% during 6MWTs using either devices.

The mean 6MWDs improved with all devices, although there was significant heterogeneity of response between individual participants and the improvement was not statistically significant compared to the distances walked on room air (mean difference in 6MWD [95% confidence interval]: Inogen One G2 POC versus room air = 14 m [-7 to 34 m]; EverGo POC versus room air = 31 m [-62 to 124 m]; oxygen cylinder versus room air = 26 m [-21 to 73 m]). Maximum heart rates and Borg scores for both dyspnoea and fatigue post-walk were not significantly different among the devices (Table 3).

Arterial Blood Gases

There was no significant difference in resting SpO₂ between the devices for Trial 1, while the resting SpO₂ on EverGo POC was lower than on the oxygen cylinder ($p = 0.02$, Table 4). However, both POCs provided adequate oxygenation based on PaO₂, which was comparable to the oxygen cylinder at rest (mean PaO₂: Trial 1 – Inogen One G2 POC: 116.1 ± 30.2 mmHg versus oxygen cylinder: 102.4 ± 23.9 mmHg, $p = 0.12$; Trial 2 – EverGo POC: 126.3 ± 36.2 mmHg versus oxygen cylinder: 151 ± 42.7 , $p = 0.08$). There were no significant differences in pH and PaCO₂ among different devices (Table 4).

Patient Preferences

For Trial 1, five participants preferred using the Inogen One POC as they felt that it was easier to negotiate during exertion with more favourable physical characteristics. Four participants expressed no preference, while one favoured the compressed oxygen cylinder due to less operating noise. In Trial 2 five participants preferred the EverGo POC over the oxygen cylinder, as it was perceived to be more user friendly, in addition to having improved portability. Three participants preferred the oxygen cylinder, with two of these mentioning better oxygen flow as the reason for this preference and one suggesting the oxygen cylinder was easier to manoeuvre. Two participants indicated no preference for POC or cylinder.

DISCUSSION

This is the first crossover trial comparing the clinical performance characteristics of two POCs with that of a compressed oxygen cylinder in patients with ILD. The results reveal similar performance on all outcome measures during exercise with both the Inogen One G2 POC and the EverGo POC compared to the oxygen cylinder, the portable oxygen device currently prescribed for delivering ambulatory oxygen therapy in many countries, including Australia. Furthermore, 80% of participants either preferred the POC or had no preference while only 20% preferred the oxygen cylinder.

Ambulatory oxygen therapy is commonly offered to patients with ILD who desaturate during exertion and demonstrate symptomatic benefit from oxygen on a 6MWT. A fall in SpO₂ to less than 90% during a 6MWT has previously been shown to be an important predictor of mortality in patients with certain forms of ILD.[23,24] Previously, single assessment studies comparing performance during functional exercise tests using oxygen cylinders and air in patients with ILD have suggested improvements in exercise capacity and symptoms with oxygen, although results across studies are inconsistent.[10-12,25] In the current study, there were improvements in both degree of oxygen desaturation and 6MWD with oxygen delivered via a POC and a compressed oxygen cylinder compared to room air, although these improvements did not reach statistical significance and patients were not blinded.

According to the Sixth Oxygen Consensus Conference, a portable device should be of a size and weight that allows the patient to perform activities of daily living suitable to his or her own lifestyle while maintaining proper oxygen saturation.[26] Internationally, compressed oxygen cylinders and liquid oxygen canisters are the common sources of ambulatory oxygen therapy. In Australia compressed oxygen cylinders are the predominant government-funded source. A POC provides an attractive alternative, with improved portability due to operating on rechargeable batteries and lighter weight. Medical grade oxygen in compressed oxygen cylinders and liquid oxygen canisters is at least 99.6% pure.[17] On the other hand, POCs deliver oxygen at concentrations between 85 and 95% purity depending on flow rate. In

addition, POCs only deliver oxygen via pulses at higher flow settings. Differences in pulse timing and peak pulse flow between POCs may affect the fraction of inspired oxygen that is delivered. A previous bench study showed that POCs provide a lower relative fraction of inspired oxygen compared to constant-flow pure oxygen, with decrements in fraction of inspired oxygen in all devices when respiratory rate is increased.[16] The clinical implications of these differences are particularly important in patients with ILD. Patients with ILD typically adopt a rapid shallow breathing pattern, which worsens with exertion, and desaturate more severely than patients with other chronic lung diseases such as COPD.[1, 19] Previous studies in COPD showed that pulsed flow oxygen may be inferior to continuous flow oxygen in providing oxygenation during exertion.[27,28] Thus, continuous flow was used for the compressed oxygen cylinders as the optimal comparator to the POCs in this study. Our findings revealed that all three portable systems tested had comparable clinical performance during exercise, although none were able to maintain saturation > 90%.

There were significant differences in the weight of each portable oxygen system in this study, which resulted in different loads that may have affected both the outcomes during 6MWTs and participants' device preference. Additional loads were added to the POCs in our study to match for the weight of the oxygen cylinders. This was done in order to ensure that any differences found could be attributed to the methods of oxygen delivery rather than the differences in weight of the devices. However, despite weight matching, 80% of participants either preferred the POC or had no preference while only 20% preferred the oxygen cylinder. In those who preferred the POC, the physical characteristics of the portable oxygen devices were an important factor in influencing their preference. Given the comparable clinical performance characteristics in meeting oxygen requirement, both the Inogen One G2 and the EverGo POCs provide a viable alternative approach to oxygen cylinders that may be more favourable to certain patients with ILD who require ambulatory oxygen therapy. In order to maximise the potential therapeutic benefits of ambulatory oxygen therapy, it is important to ensure patients' adherence to the therapy in addition to ensuring the portable oxygen device provides adequate oxygenation.

There are a few limitations with this study. Firstly, the sample size was small and may not reflect the range of patients with ILD. However, we included patients with varying types of ILD and different levels of lung function impairment. Secondly, adequate oxygenation during the 6MWTs was not achieved using either the POCs or the oxygen cylinder despite using the maximal flow rates of the different portable oxygen devices. This suggests that currently available sources of ambulatory oxygen therapy may be inadequate to meet the increased oxygen demands occurring during physical activities in patients with ILD. The findings from this study should not be generalised to other types of POCs as different POCs vary significantly in their technical specifications. More importantly, the clinical translation of the findings from a single assessment study to physical activity in daily life is uncertain. However, the 6MWT is an optimal field test which closely simulates daily function and is commonly used for ambulatory oxygen therapy assessment and prescription. It is reassuring that both POCs had clinical performance similar to that of the oxygen cylinder. This may allow the use of POCs as the source of ambulatory oxygen for any future long-term studies on the effects of ambulatory oxygen in patients with ILD.

In conclusion, these studies showed that ambulatory oxygen delivered via both the Inogen One G2 POC and the EverGo POC had similar effects on nadir exertional oxygen saturation as did compressed oxygen delivered via cylinders in patients with ILD during 6MWTs. In addition, there were no significant differences in exercise capacity or symptoms between different portable oxygen devices. Our findings suggest that both POCs may be considered as alternative means of delivering ambulatory oxygen in patients with ILD.

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Table 1. Technical specifications of the Inogen One G2 POC and EverGo POC.

	Inogen One G2 POC	EverGo POC
Maximum oxygen delivery, mL/min	1260	1050
Purity of oxygen, %	90%± 3-6%	89% ± 3%
Dimensions, cm (Length x width x height)	27 x 10 x 24	30.5 x 15.3 x 21.6
Weight (kg)	3.3	3.9
Pulse-dose setting	1 – 6 [#]	1 – 6 [#]
Battery duration, hours	2 hours at pulse-dose setting of 5*	2 hours at pulse-dose setting of 6 and respiratory rate of 20 breaths/min
Operating altitude (feet)	Up to 10000	Up to 8000

* Battery duration is not affected by change of breathing rate.

[#] The pulse-dose settings of each POC are not comparable to that of other POCs and not equivalent to the respective flow rates on compressed oxygen cylinders (for examples, setting of 6 via a POC is not equivalent to a flow rate of 6 L/min via a compressed oxygen cylinder).

Table 2: Participant Characteristics

	Trial 1 (n = 10)	Trial 2 (n = 10)	Combined (n = 20)
Age (years)	69 ± 6 (57-79)	70 ± 6 (56-78)	69 ± 6 (56-79)
Gender (F:M)	0:10	4:6	4:16
Diagnosis of ILD, (n):			
• Chronic hypersensitivity pneumonitis	4	-	4
• Connective tissue disease-related ILD:			
Amyotrophic dermatomyositis	1	-	1
• Fibrotic non-specific interstitial pneumonia	1	-	1
• IPF	4	8	12
• Unclassifiable ILD	0	2	2
Use of corticosteroid			
• Number of participants	4	-	4
• Dosage, mg/day	15 (5-25)		15 (5-25)
FVC (L)	2.29 ± 0.56 (1.42-3.11)	2.64 ± 0.87 (1.80-4.18)	2.44 ± 0.71 (1.42-4.18)
FVC (% predicted)	59.1 ± 15.3 (40-81)	71.9 ± 13.4 (53-92)	64.8 ± 15.5 (40-92)
TLCO (ml/min/mmHg)	11.09 ± 1.94 (8.1-14.7)	12.51 ± 3.80 (5.9-17.4)	11.72 ± 2.91 (5.9-17.4)

TLCO (% predicted)	39.5 ± 7.4 (29-53)	52.9 ± 12.7 (37-70)	45.4 ± 11.9 (29-70)
PaO ₂ on room air at rest (mmHg)	78.0 ± 8.2 (67-89)	79.6 ± 14.5 (54-92)	78.8 ± 11.7 (54-92)
SpO ₂ on room air at rest (%)	94.0 ± 2.2 (91-97)	95.5 ± 1.4 (93-98)	94.8 ± 2.0 (91-98)
6-minute walk distance on room air (m)*	410 ± 95 (277-596)	405 ± 206 (94-674)	407 ± 156 (94-674)

Data are expressed as mean and standard deviation (range) except where indicated.

* 6-minute walk distance values used were the mean of the measurements of two 6MWTs performed on room air

Abbreviations: FVC, forced vital capacity; ILD, interstitial lung disease; IPF, idiopathic pulmonary fibrosis; PaO₂, partial pressure of oxygen in blood; SpO₂, oxyhaemoglobin saturation; TLCO, transfer factor for carbon monoxide.

Table 3: 6MWT results

	Trial 1				Trial 2			
	Room Air	Oxygen Cylinder	Inogen One G2 POC	p-value*	Room Air	Oxygen Cylinder	EverGo POC	p-value*
SpO ₂ , %								
• At rest	94 ± 2.2	96 ± 1.8	96.9 ± 1.8	0.09	95.5 ± 1.4	99.2 ± 0.9	97.6 ± 1.5	0.02
• Nadir during 6MWT	78.6 ± 3.2	80.3 ± 2.2	82.3 ± 3.5	0.14	81.4 ± 6.7	86.1 ± 6.1	85.7 ± 7.7	0.79
6-minute walk distance, m	410 ± 95	420 ± 81	424 ± 76	0.52	405 ± 206	446 ± 153	436 ± 154	0.09
Heart rate, bpm								
• At rest	82.9 ± 8.9	79.4 ± 10.5	79.0 ± 11.7	1.00	77.6 ± 16.4	72.5 ± 13.2	72.6 ± 12.4	0.96
• Maximum	130.5 ± 13.0	127.5 ± 15.0	125.3 ± 14.5	0.27	106.9 ± 23.0	106 ± 28.1	111.9 ± 19.0	0.15
Borg dyspnoea score								
• Pre-walk	1.30 ± 1.01	0.85 ± 1.18	0.85 ± 1.18	-	0.65 ± 0.67	0.4 ± 0.97	0.70 ± 1.06	0.50
• Post-walk	5.05 ± 2.02	4.8 ± 2.78	4.65 ± 2.98	0.78	3.70 ± 2.21	3.6 ± 1.96	3.80 ± 1.75	0.34
Borg fatigue score								
• Pre-walk	0.85 ± 0.88	0.35 ± 0.47	0.30 ± 0.48	1.00	0.10 ± 0.32	0.3 ± 0.95	0.50 ± 1.08	1.00
• Post-walk	3.65 ± 2.29	3.05 ± 2.39	3.15 ± 2.87	0.85	1.25 ± 1.44	1.9 ± 1.91	2.00 ± 1.70	1.00
Percentage of subjects who								

desaturated to a nadir SpO ₂ of less than 80%, %	60	50	20	0.16	30	20	20	1.00
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Data are expressed as mean and standard deviation except where indicated.

* Comparison between oxygen cylinder and the POC

Abbreviations: 6MWT, 6-minute walk test; POC, portable oxygen concentrator; SpO₂, oxyhaemoglobin saturation

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Table 4: ABG results

	Trial 1				Trial 2			
	Room Air	Oxygen Cylinder	Inogen One G2 POC	p-value*	Room Air	Oxygen Cylinder	EverGo POC	p-value*
Resting SpO ₂ , %	94 ± 2.2	96 ± 1.8	96.9 ± 1.8	0.09	95.5 ± 1.4	99.2 ± 0.9	97.6 ± 1.5	0.02
PaO ₂ , mmHg	78.9 ± 8.2	102.4 ± 23.9	116.1 ± 30.2	0.12	79.6 ± 14.6	151 ± 42.7	126.3 ± 36.2	0.08
PaCO ₂ , mmHg	35.8 ± 5.6	34.4 ± 7.1	36.5 ± 5.9	0.18	37.1 ± 4.0	39.5 ± 4.9	38.5 ± 3.1	0.72
pH	7.42 ± 0.02	7.43 ± 0.05	7.42 ± 0.02	0.93	7.44 ± 0.03	7.42 ± 0.02	7.43 ± 0.02	0.20

Data are expressed as mean and standard deviation except where indicated.

* Comparison between oxygen cylinder and the POC

Abbreviations: PaCO₂, partial pressure of carbon dioxide in blood; PaO₂, partial pressure of oxygen in blood; POC, portable oxygen concentrator; SpO₂, oxyhaemoglobin saturation.

Figure 1: Schematic outline of study.

Wash-out period of at least 30 minutes between Test 1 and Test 2

* ABG was performed prior to each 6MWT, after breathing oxygen from the allocated device using nasal prongs for at least 30 minutes

Abbreviations: 6MWT, 6-minute walk test; ABG, arterial blood gas; POC, portable oxygen concentrator.

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