A TEST FOR CLINICAL EQUIVALENCY: A PORTABLE CONCENTRATOR WITH INTEGRATED OXYGEN-CONSERVING COMPARED TO CONTINUOUS FLOW OXYGEN DURING NOCTURNAL USE

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Introduction: Small, lightweight (~9.5 lbs) portable oxygen concentrators (POC) are a recent innovation in oxygen therapy. A technical requirement of POCs is the use of an integrated oxygen conserving device (OCD). Despite the large scale use of OCDs in awake and ambulating patients, published data is limited regarding the use of OCDs at night. This study was designed to compare heart rate and saturation of oxygen dependent sleeping patients using a POC with an OCD versus continuous flow oxygen.

Materials: Sleep Screening Device-(3rd Shift); Palmsat oximeter (Nonin Medical); WristOx (Nonin Medical); Inogen One® concentrator (Inogen, Inc.); Salter 1600 cannulas (Salter Labs).

Methods: Ten home oxygen patients on various CF oxygen systems and prescriptions (range 0.75-3 lpm) were studied. Informed consents were obtained in accordance with the IRB. The study group consisted of 4 males and 6 females, each acting as their own control in a crossover design. Nine patients had a primary diagnosis of emphysema and 1 patient had a primary diagnosis of pulmonary fibrosis. Age ranges were from 58 to 75. Each patient was screened to rule out co-morbid OSA. All patients underwent a baseline overnight oximetry study performed on their existing home oxygen system and prescription. Patients were titrated on the POC to determine an appropriate setting for overnight oxygen therapy. Titration was acceptable if the resting SpO_2 was ≥ their baseline SpO_2 on CF O_2. The mean titrated POC oxygen setting was 2.9 (range 1-5). The patients received instruction on the use of the POC. Three patients operated the POC on the default setting (standard OCD sensitivity) and 7 patients set the device to the sensitive OCD setting. Data was compared via paired t-test. A power analysis confirmed the sample size was large enough to detect a difference in SpO_2 of 4% and a difference in heart rate (HR) of 5 beats/min with a power of >0.80.

Results: **All reported results reflect mean values*

Device	SpO_2		Heart Rate	
	CF baseline	Study	CF Baseline	Study
POC- All Patients	95.9	93.7	77	78
POC- Sensitive OCD Setting	96.4	94.9	75	74
POC –Default OCD Setting	94.7	90.9	83	88

There was no statistically significant or clinically significant difference between the baseline and study SpO_2 (95.7% vs 93.2%, $p = 0.064$) or heart rate (76.5/min vs 77/min, $p = 0.70$). Nine out of 10 patients maintained mean SpO_2 and heart rates while sleeping on the POC essentially equivalent to that of their baseline study on CF O_2. Patients using the device on the sensitive setting had less variance in both SpO_2 and heart rate as compared to those on the default setting. One patient in the default setting group had a mean SpO_2 of 86% while on the POC, a 10.9% change from her baseline and below the study threshold of 90%.

Conclusion: This study demonstrated that the Inogen One® POC was able to deliver adequate nocturnal oxygen therapy as evidenced by continuous SpO_2 monitoring in 9 of 10 (90%) of patients studied. The resting daytime oxygen titration and the resultant SpO_2 appears to be a reasonably effective method for determining an appropriate nocturnal oxygen setting.

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MOBILITY, REMOTE ACTIVITY & POWER SUPPLY UTILIZATION AMONG OXYGEN DEPENDENT PATIENTS USING A LIGHTWEIGHT PORTABLE OXYGEN CONCENTRATOR SYSTEM

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Background: The standard of practice for ambulatory home oxygen systems is based on recommendations from the *1999 Fifth Consensus for Long Term Oxygen Therapy* conference, which suggest that all ambulatory/portable oxygen systems weigh less than 10 lbs. and provide the equivalent of 4 hours of oxygen at 2 liters per minute (lpm). This standard was developed via expert consensus; based around serving ambulatory patient needs within the functional limitations of small compressed gas or liquid oxygen systems, which were the standard ambulatory oxygen systems available in 1999. We hypothesized that a new portable oxygen concentrator (POC) technology, which weighs less than 10 lbs. and operates from numerous power sources, including AC, DC and an internal lithium ion battery (capable of 2-3 hours of remote use) may provide improved ambulation and mobility among active oxygen patients. An effectively employed POC may greatly exceed the suggested standard of 4 hours of remote/ambulatory oxygen use.

Method: Ten active, ambulatory and clinically stable home oxygen therapy patients were selected to participate in the study. All patients had current prescriptions for 24-hour home oxygen therapy (1-3 lpm) and utilized oxygen in their residence >1 year. We selected the Inogen One™ (Inogen, Inc., Goleta, CA) as the POC because it weighs approximately 9.7 lbs., operates on all required power sources, uses in integrated oxygen conserving device (OCD) and is designed to function as both a stationary and portable oxygen system. All patients were appropriately titrated to the POC-OCD, insuring a SpO2 of ≥92 % during all activities. Each patient was instructed to keep a detailed diary of their ambulation and activities outside of the home for a 2-week period. Data recorded in the diary included the patient's specific activity, the device O2 setting, the power supply operating the POC and the length using the power supply.

Results: All patients tolerated the POC as their home oxygen system. Data reported in the table below reports the total hours of use during ambulation or travel by power source, along with mean results (SD):

Patient	O2 Setting	AC Power Use	DC Power Use	Internal Battery Use
1	2.0	22.50	0.00	1.50
2	2.0	20.25	0.50	0.50
3	3.0	23.00	0.00	0.25
4	2.0	19.75	2.00	2.25
5	1.5	17.25	3.50	1.75
6	2.0	21.50	0.25	2.00
7	2.0	24.00	0.00	0.00
8	2.5	21.25	0.25	1.00
9	1.0	21.75	0.50	1.75
10	2.0	19.50	0.25	1.50
Mean (SD)		*21.08 (2)*	*0.73 (1.1)*	*1.25 (0.8)*

Conclusion: Data from the patient diaries indicated that ambulation and mobility was effectively achieved using all 3 power sources. Despite significant ambulation during the study period (mean = 23.05 hrs), AC power was the primary power supply used (91.4%) followed by internal battery (5.4%). Diary data suggests actual internal battery use occurred multiple times per day with a mean of ~15 min. per use. All patients stated that 2-3 hour battery duration did not prevent participation in any activity and none expressed difficultly finding adequate AC or DC power to operate the POC while in the community. These results suggest a POC capable of operating from various power supplies, including an internal battery, may prove to be an ideal oxygen system for clinically appropriate, active and ambulatory home oxygen patients. Further investigation among a larger cohort may prove beneficial, helping to validate these preliminary findings.

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USE OF A PORTABLE OXYGEN CONCENTRATOR WITH A FIXED MINUTE VOLUME OXYGEN CONSERVING DEVICE TO DELIVER OXYGEN TO EXERCISING PULMONARY REHABILIATION PATIENTS

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Background: The use of oxygen conserving devices (OCD) in conjunction with home long term oxygen therapy (LTOT) is an accepted standard of practice. Prior literature suggests there is significant variability in performance specifications among OCDs. Key OCD performance variables include trigger sensitivity, bolus volume and bolus flow/speed. Emphasis has been placed on the bolus volume, as OCDs can be more accurately described as oxygen dosing devices, each delivering a predetermined volume (dose) of O2 per setting. A common OCD dose range is 1 to 5 with the O2 dose per setting amounts, ranging from 6ml to 18ml. Many OCDs deliver a volume of O2 per minute based on a simple minute volume formula (RR x O2 dose). It has been suggested that this formula plays a major role in assuring effective OCD O2 delivery in the face of increasing respiratory rates (RR) and physiologic workloads. A new portable oxygen concentrator (POC) with an integrated OCD produces a fixed volume of O2 per setting (150ml/setting, 1-5 settings) and adjusts the bolus volume per breath to the RR. We tested the Inogen One™ POC (Inogen, Inc., Goleta, CA) on exercising patients in an outpatient pulmonary rehabilitation setting to determine if the fixed minute volume of O2 was clinically effective in the face of increased respiratory and physiologic demand among a group of LTOT patients.

Method: Eight patients participating in a Phase III pulmonary rehabilitation maintenance program volunteered to participate in the device trial. Mean age 71 (range 60-80). Four male and 4 female. Six with COPD, 2 with IPF. Seven patients are prescribed continuous LTOT at home and all 8 are prescribed O2 with exercise. During the program patients exercise on a variety of devices, including treadmills, exercise bikes, steps, arm cranks, rowers and free weights to a target heart rate (HR) of 70-75% of their age predicted maximum and a target SpO2 of ≥90% (+/-3%). Patient HR, SpO2 and dyspnea scale scores are monitored pre, during and post exercise. Patients may stop exercising at anytime, for any reason. Baseline clinical data was collected over 4 previous sessions on the patient's usual continuous flow (CF) O2 prescription for crossover comparison. Each patient was titrated to a POC setting during exercise that yielded the target SpO2.

Results: All patients clinically tolerated the POC during exercise. Data reported below represents mean results from all exercise activity during the 50-minute session:

Patient	Age	CF O2 Setting	CF SpO2	POC Setting	POC SpO2	SpO2 Δ
1	78	3.0	94%	5.0	89%	5%
2	64	5.0	92%	5.0	90%	3%
3	79	2.0	97%	4.0	95%	2%
4	80	5.0	92%	5.0	91%	1%
5	61	3.0	91%	4.0	90%	1%
6	62	4.0	96%	4.0	92%	4%
7	75	4.0	90%	5.0	90%	0%
8	60	5.5	93%	5.0	90%	4%
Mean (SD)		*3.9 (1.3)*	*93% (2%)*	*4.7 (0.5)*	*91% (2%)*	*2% (2%)*

Conclusion: All patients were able to tolerate the POC during all exercise activities as demonstrated by a mean SpO2 of 91% (range 89-95%). No patient had HR changes and none stopped exercising while using the POC. There was no appreciable clinical difference between the patient's SpO2 on CF vs. the POC (93% vs. 91%). This preliminary data suggests that appropriately evaluated and titrated LTOT patients can be effectively oxygenated during vigorous exercise using a POC with an integrated OCD and a fixed volume of oxygen production per minute.

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