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Evaluation of Over-the-Counter Portable Oxygen Concentrators Utilizing a Metabolic Simulator

Richard Casaburi, Michael Hess, Janos Porszasz, William Clark, Ryan Diesem, Ruth Tal-Singer, and Carrie Ferguson

BACKGROUND: Supplemental oxygen is designed to raise alveolar P_{O_2} to facilitate diffusion into arterial blood. Oxygen is generally delivered by nasal cannula either by continuous or pulsatile flow. Battery-powered portable oxygen concentrators (POCs) facilitate ambulation in patients experiencing exertional hypoxemia. In the United States, the Food and Drug Administration (FDA) clears these devices to be sold by physician prescription. Recently, however, lower-cost devices described as POCs have been advertised by online retailers. These devices lack FDA clearance and are obtained over the counter (OTC) without prescription. This study determined whether a selected group of OTC POCs have oxygen delivery characteristics suitable for use by hypoxemic patients. METHODS: A metabolic simulator, capable of simulating a range of metabolic rates and minute ventilations, determined effects of oxygen supplementation delivered by a variety of devices on alveolar P_{O_2}. Devices tested included 3 OTC POCs, an FDA-cleared POC, and continuous-flow oxygen from a compressed oxygen cylinder. End-tidal P_{ETO_2}, a surrogate of alveolar P_{O_2}, was determined at each of each device's flow settings at 3 metabolic rates. RESULTS: Continuous-flow tank oxygen yielded a linear P_{ETO_2} increase as flow increased, with progressively lower slope of increase for higher metabolic rate. The prescription POC device yielded similar P_{ETO_2} elevations, though with somewhat smaller elevations in pulse-dose operation. One OTC POC was only technically portable (no on-board battery); it provided only modest P_{ETO_2} elevation that failed to increase as flow setting was incremented. A second OTC POC produced only minimal P_{ETO_2} elevation. A third OTC POC, a pulsed-dose device, produced meaningful P_{ETO_2} increases, though not as great as the prescription device. CONCLUSIONS: Only one of 3 OTC POCs tested was potentially of use by patients requiring ambulatory oxygen. Physicians and respiratory therapists should inform patients requiring portable oxygen that OTC devices may not meet their oxygenation requirements.
Key words: exertional hypoxemia; portable oxygen concentrator; supplemental oxygen; metabolic simulator; long-term oxygen therapy; online store; nasal cannula. [Respir Care 2023;68(4):445–451.

Introduction

The purpose of supplemental oxygen is to increase alveolar P_{O_2}. This facilitates diffusion of oxygen into the pulmonary capillary blood and improves arterial P_{O_2}. More than a million people in the United States require supplemental oxygen for treatment of a variety of lung diseases.[1]

Outside of hospital settings, supplemental oxygen is almost always delivered to the patient via nasal cannula. Oxygen can be delivered by stationary or portable devices. Portable devices are designed to provide oxygen supplementation during ambulation and travel. In the 1980s, oxygen conservation strategies were developed.[2] Rather than delivery by continuous gas flow (in which flow during expiration is wasted) oxygen is delivered in a pulsatile manner usually only during the early part of inspiration, allowing more economical gas utilization. In the 20th century, portable oxygen delivery systems were either small compressed oxygen tanks or liquid oxygen reservoirs. More recently, battery-powered portable devices have become available (portable oxygen concentrators [POCs]).[3] Designed to enhance mobility, these devices draw in air from the atmosphere and concentrate the oxygen component, which is then provided to the patient at a selected flow (continuously or in pulses) via nasal cannula.

Currently, several manufacturers make POCs for use by patients with respiratory diseases. They are United States

Food and Drug Administration (FDA) cleared for this purpose and require a physician's prescription. Many are cleared by the Federal Aviation Administration for use in air flight; POCs are the only oxygen system accepted for air travel. They range in price; an average might be near $2,000 (https://www.thoracic.org/patients/patient-resources/resources/portable-concentrators-garvey.pdf. *Accessed August 6, 2022*). Recently, however, devices have been marketed as POCs in

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online stores (eg, Amazon, eBay). Purchase of these devices does not require a prescription (ie, they are provided over the counter [OTC]). The advertisements for these devices carefully avoid stating that they are for medical use but, for example, may feature a picture of a white-coated individual carrying a stethoscope in the online marketing brochure. By one review, prices of these devices are generally in the $400–750 range: much cheaper than the prescription devices.

We were concerned that uninformed patients with pulmonary disease might reason that these non-prescription devices would be suitable lower-cost substitutes for the more expensive prescription POCs. It was our aim to determine whether these OTC POC devices might pose a hazard to pulmonary disease patients who require oxygen supplementation in that they might be incapable of elevating alveolar P_{O_2} to a useful extent.

The ability of these devices to raise alveolar P_{O_2} depends not only on the concentration of oxygen in the gas provided via the nasal cannula and the gas flow setting (whether continuous or pulsatile) but also on the patient's metabolic rate. Higher rates of alveolar ventilation are required for the higher metabolic rates associated with physical exertion.

We utilized a metabolic simulator, capable of simulating a range of known metabolic rates at any given choice of minute ventilation, to determine the efficacy of the oxygen supplementation delivered by a variety of devices on the alveolar P_{O_2}. Three OTC POC devices were tested and compared to a marketed prescription device and to continuous-flow oxygen from a compressed gas source. The results provide a cautionary note for physicians and other health care professionals advising their patients on the wisdom of acquiring these OTC POC devices.

QUICK LOOK

Current knowledge

Portable oxygen concentrators (POCs) provide patients experiencing exertional hypoxemia the ability to better tolerate ambulatory activities. Food and Drug Administration–cleared devices, obtained by prescription, are widely used but are costly. Cheaper devices, labeled as POCs and not requiring a prescription, are advertised on online stores. Whether these over-the-counter (OTC) devices have characteristics suitable for use by patients with exertional hypoxemia is unclear.

What this paper contributes to our knowledge

Using a metabolic simulator, we determined the ability of 3 OTC POCs to increase simulated alveolar oxygen partial pressure. Only one of 3 OTC POCs tested was found to be potentially of use by patients requiring ambulatory oxygen. Physicians and respiratory therapists should inform patients requiring portable oxygen that OTC devices may not meet their oxygenation requirements.

Methods

Experimental Apparatus

In 1990, a metabolic simulator was described, designed for use in calibrating systems that measure metabolic rate from pulmonary gas exchange.[4] It was subsequently manufactured for sale (VacuMed, Ventura, California) (Fig. 1). It consists of a reciprocating pump whose volume and stroke rate can be adjusted. To simulate metabolic consumption of O_2 and production of CO_2, the inspirate of the pump is supplied with a calibrated flow of gas consisting of 21% CO_2 and 79% nitrogen (and no O_2); a reservoir bag and a one-way valve assure that this gas flow enters the system only during inspiration. The pump will, thereby, exhale gas at any desired metabolic rate: O_2 uptake = CO_2 output = 0.21 × gas flow.

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Dr Casaburi discloses relationships with Inogen, Boehringer-Ingelheim, GlaxoSmithKline, and Regeneron. Mr Hess discloses relationships with the COPD Foundation and Inogen. Dr Porszasz discloses relationships with United Therapeutics, Genentech, and Regeneron. Dr Tal-Singer discloses relationships with GlaxoSmithKline, ENA Respiratory Board on behalf of the COPD Foundation, Teva, ImmunoMet, Vocalis Health, and ENA Respiratory. Dr Ferguson discloses relationships with United Therapeutics, Genentech, and Regeneron. The remaining authors have disclosed no conflicts of interest.

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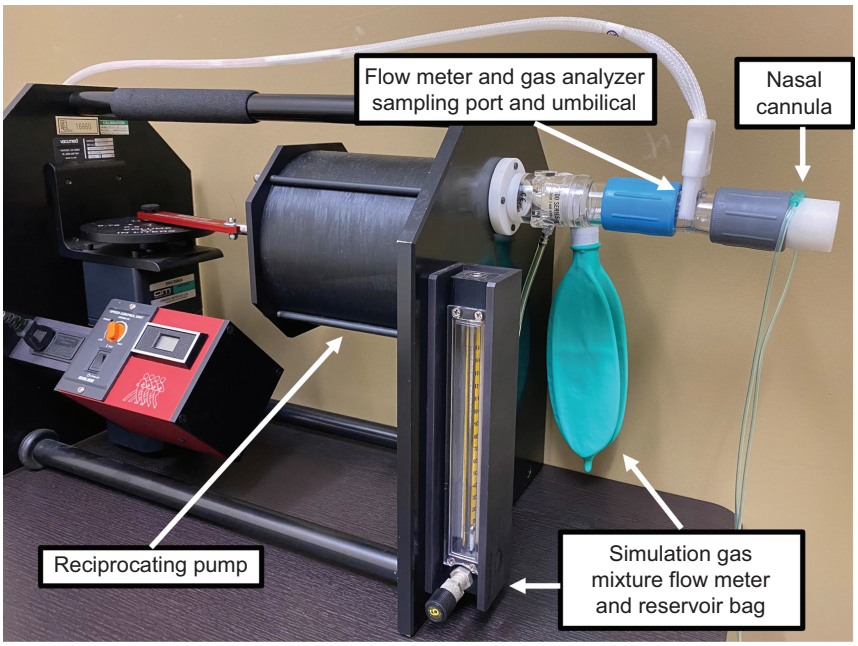

Fig. 1. Experimental apparatus.

For this experiment, tubing with dead space of ~175 mL volume (simulating anatomic pulmonary dead-space volume) was connected to the exhaled port of the metabolic simulator (Fig. 1). The flow meter and gas sampling port of a breath-by-breath gas exchange analysis system (CardiO2, MGC Diagnostics, St. Paul, Minnesota) were interposed in the tubing. On the distal side, a short segment of tubing was constructed with a standard nasal cannula penetrating the tubing to the midstream of the respired gas flow. Providing gas flow from any given oxygen source will raise the inspired oxygen concentration above the ambient 21% and will increase the simulated alveolar oxygen concentration. This will be reflected in the end-expiratory (end tidal) oxygen concentration measured by the gas exchange system.

Oxygen Systems Tested

As it was not our purpose to evaluate specific devices, but only to provide information on what might be expected from a typical OTC POC purchase or an FDA-cleared purchase, we do not identify devices by manufacturer, rather we define them by characteristics. For the OTC POC devices, we identified devices from a search of an online retail site for "portable oxygen concentrators" and selected 3 devices whose description specifically emphasized the device's ability to supply concentrated oxygen via nasal cannula and that the device was portable. Listed prices (with shipping) ranged from $400–730. These devices were purchased by the COPD Foundation. The FDA-cleared POC device was a currently marketed device and was obtained from a durable medical equipment provider by rental. It should be noted that systems were tested only for ability to raise alveolar P_{O_2}. Other aspects, such as battery life or durability, were not evaluated.

Over-the-Counter POC Devices

1. OTC1: Though advertised as portable, this device weighed 13.8 lb and had no on-board battery. Power was obtained via wall plug. The device did, however, feature a carrying handle. Gas flow was provided by continuous flow from 1–7 L/min in 1 L/min increments.
2. OTC2: Weighing 4.0 lb, this device featured an external battery, which could be recharged from wall or automobile (12 V) sources. It featured a single flow setting, stated as 3 L/min, with no adjustments.
3. OTC3: Weighing 6.6 lb, this device featured an on-board battery with capabilities for recharging from wall or automobile sources. It featured pulse-dose settings from 1–5.

FDA-Cleared POC Device

1. RX: Weighing 9.8 lb, this device featured an on-board battery with capabilities for recharging from wall or automobile sources. It featured both continuous flow (at 1 or 2 L/min) as well as pulse-dose flow setting from 1–6 (in 0.5 setting increments).

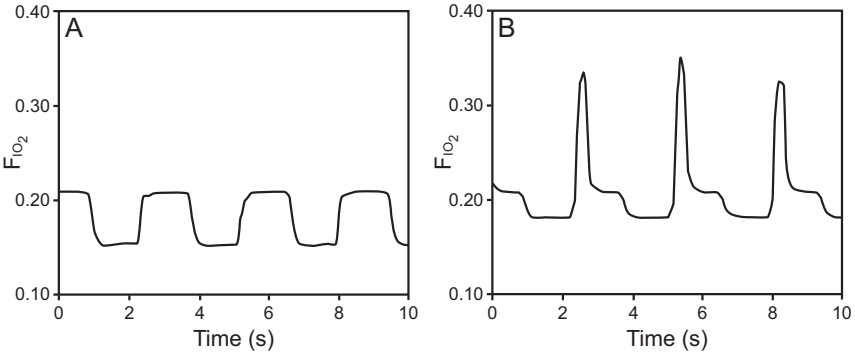

Fig. 2. Time course of respired oxygen fraction during simulation at moderate metabolic rate (oxygen uptake = 850 mL/min). A: Oxygen fraction with no nasal cannula flow. B: Oxygen flow by pulsed dose from the prescription portable oxygen concentrator at a setting of 3. Note that the pulse of oxygen early in inspiration yields a spike upward in oxygen concentration. Pulsed-dose oxygen elevates expired oxygen fraction; oxygen fraction is constant during the expiration.

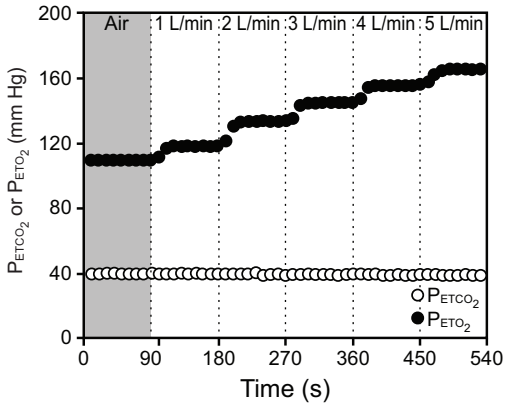

Fig. 3. Time course of P_{ETO_2} and P_{ETCO_2} for the moderate metabolic rate simulation as continuous-flow tank oxygen was progressed from 0–5 L/min in 1 L/min increments every 90 s.

Compressed Oxygen Tank

1. COM: An oxygen H cylinder fitted with a rotameter was used to provide continuous flow of 100% O_2 at 1–5 L/min in 1 L/min increments.

Experimental Protocol

The metabolic simulator was set to one of 3 metabolic rates: 350 mL/min (simulating minimal exertion), 850 mL/min (simulating moderate exercise), and 1,200 mL/min (simulating heavy exercise), as a patient with moderate exercise limitation might tolerate. The metabolic simulator features discrete tidal volume settings; tidal volumes of 0.75, 1, and 1.5 L were chosen for the progressively higher simulated metabolic rates. Breathing frequency was then adjusted at each metabolic rate to achieve a physiologically appropriate P_{ETCO_2} of 40 mm Hg; resultant minute ventilation was 8.9, 21.3, and 29.4 L/min, respectively.

The study was conducted in 3 sessions, one for each of the 3 simulated metabolic rates. In each session, each device was tested in the same manner. For each device, starting with no cannula flow, cannula flow was increased through each of the device's settings. At each setting, a 1–3 min stabilization period was allowed, and a steady measurement of a whole number value of P_{ETO_2} in mm Hg was recorded. After completion of a given device's series of measurements, we moved on to the next device.

Results

For illustration, Figure 2 presents the time course of P_{O_2} recordings over several breaths for no oxygen flow and pulsatile nasal cannula flow. These recordings were made at the moderate metabolic rate using the RX device at a pulse flow setting of 3. Note the short pulse of elevation in inspired P_{O_2} related to the nasal cannula oxygen pulse. Moreover, expired P_{O_2} is constant throughout expiration in both situations, with a flat alveolar plateau. The flat plateau indicates that end-tidal values are representative of the entire alveolar gas exhalate.

Figure 3 presents the time course of a typical data collection run. It presents P_{ETO_2} and P_{ETCO_2} for the moderate metabolic rate simulation as continuous-flow tank oxygen (COM) was progressed from 0–5 L/min in 1 L/min increments. Note that, after a short transient, P_{ETO_2} increased to a progressively higher steady state. P_{ETO_2} increased from 110 mm Hg at zero flow to 167 mm Hg at 5 L/min. Also note that, as expected, P_{ETCO_2} did not vary as a function of supplemental oxygen flow.

Figure 4 presents the progression of end-tidal P_{ETO_2} at progressively higher device settings for each of the 3 simulated metabolic rates for each of the 5 supplemental oxygen devices (2 panels are presented for the RX device, one forits continuous-flow settings [RX-CON], one for its pulsatile flow settings [RX-Pulse]). In general, for a given device setting, higher metabolic rates yielded

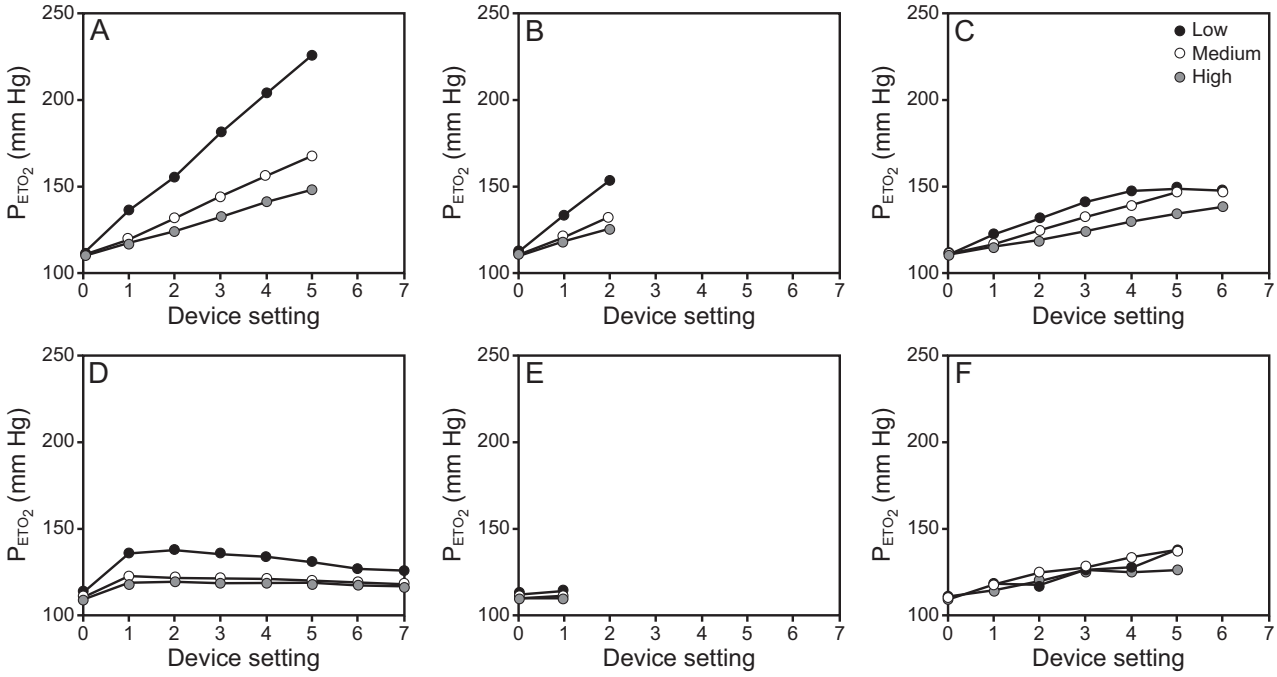

Fig. 4. Progression of end-tidal oxygen P_{ETO_2} at progressively higher flow settings for each of the 3 simulated metabolic rates (low, medium, high) for each of the 5 supplemental oxygen devices. A: COM denotes continuous flow from a compressed oxygen gas tank. Two panels are presented for the Food and Drug Administration–cleared (RX) device, one for continuous-flow settings (B), and one for pulsatile-flow settings (C). Data obtained from the 3 over-the-counter (OTC) oxygen concentrators OTC1 (D), OTC2 (E), and OTC3 (F).

lower P_{ETO_2}, a result of the supplemental oxygen delivered by the device being diluted by the higher minute ventilation. For COM, P_{ETO_2} increased approximately linearly at progressively higher liter flow; for RX with continuous flow, P_{ETO_2} increased similarly, though only through 2 L/min (its highest liter flow setting). For RX with pulsatile flow, P_{ETO_2} increased progressively at each metabolic rate, though there appeared to be some plateauing at the higher pulse settings.

In contrast, OTC1 exhibited the highest end-tidal P_{O_2} at the lowest setting, with modest decreases at higher flows. An indicator on the face of the device indicated the percent O_2 at each flow, which decreased from 90% at setting 1 to 30% at setting 7. It is likely that the quantity of oxygen produced by the OTC1 device is approximately constant across settings. OTC2, which features a single continuous-flow setting (stated as 3 L/min), elevated P_{ETO_2} minimally (2, 1, and 0 mm Hg at progressively higher metabolic rates). For OTC3, which features pulse settings only, P_{ETO_2} increased progressively, though with some evidence for plateauing at higher flow settings.

Figure 5 allows comparison of P_{ETO_2} among devices and across flow settings for a single metabolic rate: the moderate exercise setting. Differences among devices can be seen. The horizontal dashed line demarks the P_{ETO_2} evoked with 2 L/min continuous-flow oxygen (131 mm Hg) to facilitate comparisons among devices (see Discussion).

Discussion

We employed a metabolic simulator to evaluate the ability of several POCs to increase alveolar P_{O_2} in comparison to continuous-flow oxygen provided from a compressed gas tank. An FDA-cleared POC device (that can only be obtained by patients with a prescription) was found to provide elevations in P_{ETO_2} that would be clinically useful in comparison to continuous-flow oxygen. Of 3 POC devices purchased OTC (and without a prescription), only one performed in a manner that might be considered clinically useful, and that device provided less P_{ETO_2} elevation compared to the FDA-cleared POC.

Recent publications support the concept that long-term oxygen patients in the United States are suboptimally serviced and informed. A survey of 1,926 oxygen users revealed "frequent and varied problems, particularly a lack of access to adequate instruction and adequate portable systems."[5] Patients reported that their oxygen system instruction came most often from the driver of the truck delivering their equipment. Complaints about oxygen system portability were common.[5] Patients may seek online information regarding their oxygen therapy, but a recent analysis revealed that content of these online resources is sometimes of low quality and suitability with a reading grade too high for the level of health literacy of the general population.[6,7] The frequency of reassessment of patient oxygen needs by health care professionals has been found to be suboptimal.[8]

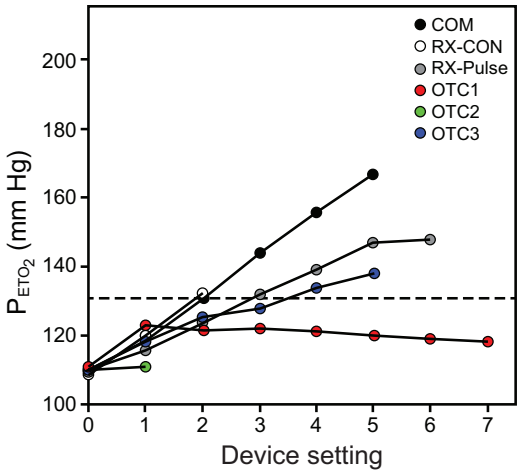

Fig. 5. Comparison of simulated P_{ETO_2} among devices and across flow settings for a single metabolic rate: the moderate metabolic rate setting (oxygen uptake = 870 mL/min). The 5 devices tested are compressed oxygen tank (COM), continuous and pulsatile flow from the FDA–cleared device (RX-CON and RX-pulse), and the 3 over-the-counter devices. The horizontal dashed line has been placed at the P_{ETO_2} obtained with 2 L/min continuous-flow oxygen (131 mm Hg), as this is a common oxygen prescription.

Because of the high cost and inadequate reimbursement for FDA-cleared POCs, patients and their caregivers may seek alternative devices that would allow them the mobility they seek. Internet searches may lead them to non–FDA-cleared medical devices offering a favorable price point. While these OTC units are not FDA cleared, their advertising, while not specifically labeling them for medical use, often misleadingly insinuate medical capability using pictures of supposed medical professionals in the device's marketing materials. While specifying liter flow, they often neglect to specify oxygen purity. The potential result is that the patient may acquire a device that may not only confer no benefit but might endanger health because an important medical need is not met.

Patients who experience hypoxemia with exertion benefit from oxygen supplementation: exercise tolerance is improved, and dyspnea is reduced.[9] The increase in oxygen partial pressure in the lungs necessary to increase arterial oxygen partial pressure differs substantially depending on the cause of hypoxemia; for example, a pulmonary arteriovenous shunt will require greater elevation of alveolar P_{O_2} to increase P_{O_2} than will ventilation-perfusion imbalance. Oxygen supplementation, therefore, needs to be prescribed individually.

Technological advances have evolved the approach to the provision of portable oxygen. Previously, small, compressed oxygen tanks and liquid oxygen reservoirs were the predominant modalities. These devices could provide high oxygen flow (and, thereby, high alveolar P_{O_2}), though use of high flow settings yielded a shorter time until the supply was exhausted. These devices also were disadvantaged in that compressed gas tanks and liquid oxygen generally required home delivery, an economically undesirable model. POC devices enable the more desirable non-delivery model.

We elected to study 3 simulated metabolic rates: 350, 850, and 1,200 mL/min. For a 70 kg individual, the first is a little higher than resting metabolic rate; the second approximately corresponds to walking at 3 mph, and the third roughly equates to mowing the lawn with a power mower.[10] These are exercise levels that might be tolerated by individuals with moderate to severe respiratory impairment (though the highest exercise level may be aspirational for some patients with exercise-induced hypoxemia).

The study results show that continuous-flow oxygen from a compressed gas tank yields progressive, and substantial, increases in P_{ETO_2} at all 3 metabolic rates. The RX device in continuous-flow mode provides similar P_{ETO_2} increase but is limited to 2 L/min. In pulse-dose mode, progressive increases in P_{ETO_2} are seen, though with somewhat lower P_{ETO_2} than with CON; a higher numerical setting would be required to achieve an equivalent P_{ETO_2}.

The OTC1 device cannot be considered portable in the sense of facilitating ambulation. Whereas measurable increases in P_{ETO_2} were seen at the lowest setting (roughly approximating the level seen with 1 L/min continuous flow), further setting increases yielded no further increases in P_{ETO_2}. OTC2, the lightest-weight device, produced no appreciable elevation in P_{ETO_2}. We considered that the device might be malfunctioning, but we felt obligated to include it in our analysis because the end user might well have no way to assess the malfunction. To be considered though is that the product literature states that the device produces 28% O_2. Three L/min of 28% O_2 would have the same ability to raise pulmonary P_{O_2} as 0.27 L/min of pure O_2; even if operating as advertised, the device would only be predicted to raise P_{ETO_2} by only ~3 mm Hg at the moderate metabolic rate (Fig. 5). OTC3, a pulse-dose device, features a plateauing of P_{ETO_2} at the higher flow settings for all but the high metabolic rate. At the moderate metabolic rate, OTC3 provided P_{ETO_2} roughly equivalent to continuous-flow oxygen at 1 L/min at a setting of 2, equivalent to continuous-flow oxygen at 2 L/min at setting of 3–4, and could not provide a P_{ETO_2} equivalent to continuous-flow oxygen at 3 L/min. Though somewhat inferior to RX at equivalent pulse flow settings, OTC3 might be considered capable of providing useful oxygen supplementation during ambulation for some patients.

As facilitated by Figure 5, a relevant comparison is to determine, at a moderate metabolic rate, the ability of the devices tested to produce the P_{ETO_2} evoked with 2 L/min continuous-flow oxygen (131 mm Hg, dashed horizontal line), which is a common oxygen prescription. The FDA-cleared POC (RX), when utilizing continuous flow, provides this P_{ETO_2} at a setting of 2 and when using pulse flow at a setting of 3. The OTC3 device provides this P_{ETO_2} at a setting of 4, and neither OTC1 nor OTC2 provide this P_{ETO_2} at any setting.

It might be considered whether this evaluation would have better been performed in a patient population. Consider though that we studied 96 combinations of gas flow, metabolic rates, and devices. Given that patients will typically require a minimum of 6 min to reach a steady state for each of these combinations, this would have required roughly 10 h of measurement time. Day-to-day variability in ventilatory response and gas exchange would have introduced variability, likely requiring study of a group of subjects to achieve reliable comparisons among devices. In contrast, the precisely reproducible characteristics of the gas exchange simulator provided reliable measurements in a single set of measurements, with only ~90 seconds required to obtain each measurement. Consider too that measurement of alveolar P_{O_2} in the human subject when continuous nasal oxygen flow is utilized is difficult. Avoiding contamination of the alveolar sample by the nasal cannula oxygen flow cannot be accomplished unless the subject performs the respiratory gymnastics of breathing in through the nose and breathing out through the mouth. The positioning of the gas sampling probe in the experimental apparatus would be equivalent to positioning it in the trachea of the human subject.

Limitations of this study include certain dissimilarities in the simulation from physiologic conditions. Though anatomic (series) dead space was simulated, alveolar dead space of the calibrator pump was zero. Further, unlike the physiologic situation, CO_2 accumulation and O_2 uptake do not proceed during the exhalation. Therefore, P_{ETCO_2} and P_{ETO_2} remain constant throughout the exhalation (once the anatomic dead space is cleared). This implies that the end-tidal values reflect mean alveolar values during the exhalation. Finally, the gas respired by the calibrator pump is dry gas at ambient temperatures. None of these differences are expected to influence the comparisons made among the devices tested.

Another limitation is that we did not perform a comprehensive examination of all POCs available for sale OTC. However, we made attempts to select representative devices; specifically, we did not find (or exclude) any more expensive POCs that might have been more capable. Further, we limited our evaluation to a single FDA-cleared POC; other devices might have different capabilities and response characteristics.

Conclusions

We conclude that 2 of the 3 POCs sold OTC we tested are not suitable for use by pulmonary patients to facilitate ambulation by providing clinically relevant increases in P_{ETO_2}. Though these devices are not explicitly advertised for this purpose, the marketing material and documentation associated with these devices may suggest the possibility of medical use, which may be confusing and/or misleading to consumers. Physicians and other health care professionals caring for patients requiring portable supplemental oxygen should inform their patients of the potential unsuitability of some OTC POC devices.

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