Bench Evaluation of Four Portable Oxygen Concentrators Under Different Conditions Representing Altitudes of 2438, 4200, and 8000 m

Vincent Bunel, Amr Shoukri, Frederic Choin, Serge Roblin, Cindy Smith, Thomas Similowski, Capucine Morélot-Panzini, Jesus Gonzalez

Bench evaluation of four portable oxygen concentrators under different conditions representing altitudes of 2,438, 4,200 and 8,000 meters.

Vincent Bunel[1], Amr Shoukri[2,3], Frederic Choin[4], Serge Roblin[4], Cindy Smith[4], Thomas Similowski[1,2] , Capucine Morélot-Panzini[1,2] , Jesus Gonzalez[1,2]

[1] AP-HP, Groupe Hospitalier Pitié-Salpêtrière Charles Foix, Service de Pneumologie et Réanimation Médicale (*Département "R3S"*), F-75013, Paris, France

[2] Sorbonne Universités, UPMC Univ Paris 06, INSERM, UMRS1158 Neurophysiologie respiratoire expérimentale et clinique, Paris, France

[3] Shams University, Cairo, Egypt

[4] Service du centre d'essais d'AIRBUS Defence and Space, TSOEG25 - Components & Synthesis Tests, Les Mureaux, France

Corresponding Author: Vincent Bunel, vincent.bunel@gmail.com

Abstract

Air travel is responsible for a reduction of the partial pressure of oxygen (O_2) as a result of the decreased barometric pressure. This hypobaric hypoxia can be dangerous for passengers with respiratory diseases, requiring initiation or intensification of oxygen therapy during the flight. In-flight oxygen therapy can be provided by portable oxygen concentrators, which are less expensive and more practical than oxygen cylinders, but no study has evaluated their capacity to concentrate oxygen under simulated flight conditions.

We tested four portable oxygen concentrators during a bench test study. The O_2 concentrations (FO_2) produced were measured under three different conditions: in room air at sea level, under hypoxia due to a reduction of the partial pressure of O_2 (normobaric hypoxia, which can be performed routinely) and under hypoxia due to a reduction of atmospheric pressure (hypobaric hypoxia, using a chamber manufactured by *Airbus Defence and Space).*

The FO_2 obtained under conditions of hypobaric hypoxia (chamber) was lower than that measured in room air (0.92 [0.89-0.92] versus 0.93 [0.92-0.94], $p = 0.029$), but only one portable oxygen concentrator was unable to maintain an $FO_2 \geq 0.90$ (0.89 [0.89-0.89]). In contrast, under conditions of normobaric hypoxia (tent) simulating an altitude of 2,438 m, none of the apparatuses tested was able to achieve an FO_2 greater than 0.76. (0.75 [0.75-0.76] versus 0.93 [0.92-0.94], $p = 0.029$).

Almost all portable oxygen concentrators were able to generate a sufficient quantity of O_2 at simulated altitudes of 2,438 m and can therefore be used in the aircraft cabin. Unfortunately, verification of the reliability and efficacy of these devices in a patient would require a non-routinely available technology and no pre-flight test can currently be performed by using simple techniques such as hypobaric hypoxia.

Keywords:

- Equipment evaluation
- Chronic respiratory failure
- Ambulatory oxygen therapy
- Hypoxic challenge test
- Portable oxygen concentrator

INTRODUCTION

The minimum authorized pressure on commercial aircraft simulates an altitude of 8,000 feet (2,438 meters) for passengers. At this altitude, atmospheric pressure is decreased by about 25% compared to sea level, resulting in hypobaric hypoxia: the partial pressure of oxygen in inspired air corresponds to that observed on the ground during inhalation of a gas mixture containing 15% oxygen (Josephs et al., 2013). Although this hypobaric hypoxia has no consequences for passengers without respiratory diseases, it can be harmful in passengers with chronic respiratory diseases, who may require temporary oxygen therapy or more intensive continuous oxygen therapy (Ahmedzai et al., 2011).

Portable oxygen (O_2) concentrators are now approved by the Federal Aviation Administration (FAA) and consequently by all airlines (International Air Transport Association, 2015). They are increasingly used due to their considerable advantages in terms of cost, simplicity and safety compared to the oxygen cylinders conventionally provided by airline companies. Portable oxygen concentrators comprise a zeolite sieve, which binds nitrogen allowing the production of O_2 according to a continuous mode or a pulsed mode (triggered by breathing, less energy-consuming). To our knowledge, only one study has tested the capacity of these apparatuses under hypoxic conditions, but under alpine conditions in COPD patients (Fischer et al., 2013). These apparatuses have never been evaluated on a test bench simulating hypoxia in an aircraft cabin. An hypoxic atmosphere is difficult, expensive and tedious to reproduce and often requires the assistance of military scientists (Dillard et al., 1995; Naughton et al., 1995). To address this issue, we verified whether portable oxygen concentrators were still able to generate O_2 in an hypoxic atmosphere and then studied the possibility of testing these devices by means of a simpler hypoxia test. To answer these questions, we tested the oxygen concentrating capacities of four FAA-approved portable oxygen concentrators (Federal Aviation Administration, 2016) in the laboratory under 2 different conditions of simulated hypoxia: normobaric hypoxia and, more simply, hypobaric hypoxia, ((Dine and Kreider, 2008; Edvardsen et al., 2012; Kelly et al., 2008), as this method has been shown to be equivalent to a hypobaric hypoxia test (Dillard et al., 1995; Dine and Kreider, 2008). These two hypoxia conditions simulate different altitudes: 2,438 m (the lowest pressure authorized in an aircraft cabin), and, by curiosity, we also tested a simulated altitude of 4,200 m (the limit for the release of oxygen masks in flight) and 8,000 m (close to the summit of Mount Everest).

METHODS

We conducted a bench test study on four FAA-approved portable oxygen concentrators: SimplyGo (Philips Respironics Inc., Murrysville, PA, USA), Eclipse 3 (Chart Sequal Technologies Inc., Ball Ground, GA, USA), Solo2 (Invacare Corporation, Elyria, OH, USA), iGo (deVilbiss Healthcare Inc., Somerset, PA, USA).

The normobaric hypoxic test was performed with an hypoxic generator (decreasing O_2 and increasing nitrogen content) connected to an airtight tent (HYPOXICO Inc., Jalhay, Belgium).

The hypobaric hypoxic test was performed with an altitude chamber specifically designed in order to test a portable oxygen concentrator, in collaboration with *Airbus Defence and Space*, based on the principle of generating low pressure in the chamber by means of a rotary vane pump and piloting the chamber with air renewal via a calibrated valve **(Figure 1)**. The targeted pressure, measured by an absolute pressure transducer, was 753 mbar (equivalent to the atmospheric pressure at an altitude of 2,438 m. This set-up was also used to perform tests at 450 mbar (atmospheric pressure at 4,214 m) and 356 mbar (atmospheric pressure at 8,000 m). An airtight outlet tube from the chamber was used to reliably measure the O_2 concentration (FO_2), ($MaxO_2$+, MAXTEC Inc., Utah, USA). A special oxygen monitor that can be used at low atmospheric pressure (Tetra 3, Crowcon Ltd, Abingdon, UK) was used to ensure that the FO_2 inside the chamber remained stable at 0.209.

Each portable oxygen concentrator was tested first in room air (Airbus Defence and space laboratory, altitude: 28 m, atmospheric pressure: about 1000 mbar) and then under conditions of normobaric hypoxia (tent) and hypobaric hypoxia (chamber). Measurements were performed on the same day to limit variations in temperature, relative humidity and atmospheric pressure that could influence the measurement. For each condition, we calculated the median of 30 FO_2 measurements performed over 15 minutes in order to assess the stability of FO_2. Each portable oxygen concentrator was used in continuous mode, because the pulsed mode did not allow reliable measurement of FO_2, and at the possible maximum flow rate, in order to simulate the most unfavorable situation for these apparatuses corresponding to a worst-case scenario. All 3 concentrators were therefore tested at 3 l/min, and one concentrator (SimplyGo) was tested at 2 l/min.

Due to the non-normal distribution of the data, the results were expressed as median [q1-q3] and differences between conditions were tested by a Mann-Whitney test.

RESULTS

Under conditions of hypobaric hypoxia (chamber), the FO_2 obtained was lower than that measured in room air (0.92 [0.89-0.92] versus 0.93 [0.92-0.94], $p = 0.029$), but one of the four apparatuses was unable to achieve an $FO_2 \geq 0.90$ (0.89 [0.89-0.89]) **(Table 1)**. At simulated altitudes of 4,200 m and 8,000 m in the altitude chamber, none of the apparatuses was able to maintain an $FO_2 \geq 0.9$, but three portable oxygen concentrators were still able to concentrate O_2 to achieve an FO_2 of 0.88 [0.88-0.90] ($p = 0.0498$, $n = 3$) at a simulated altitude of 4,200 m and one portable oxygen concentrators achieved an FO_2 of 0.83 [0.73-0.84] at 8,000 m **(Figure 2)**. In contrast, under conditions of normobaric hypoxia (tent) simulating an altitude of 2,438 m, none of the apparatuses tested was able to achieve an FO_2 greater than 0.76. Overall, FO_2 was 0.17 lower than that measured in room air (0.75 [0.75-0.76] versus 0.93

[0.92-0.94], p = 0.029). As indicated by the interquartile range, FO_2 measurements remained stable over the 15-minute test period regardless of the condition tested.

DISCUSSION

Measurements performed in an altitude chamber showed that the majority of portable oxygen concentrators tested achieved lower but satisfactory FO_2 under hypobaric hypoxia equivalent to the minimum pressure authorized in an aircraft cabin.

Our study confirms the results of a previous study conducted in an alpine environment that demonstrated the capacity of portable oxygen concentrators to produce FO_2 greater than 0.94 at altitudes of up to 3,250 m (Fischer et al., 2013). Our simulator showed that O_2 production was still possible at 4,000 m and 8,000 m with some portable oxygen concentrators, which could be useful in contexts such as alpine rescues or hot-air balloons. Portable oxygen concentrators are effectively able to concentrate O_2 even under conditions of hypobaric hypoxia, as all 4 apparatus tested comprise an air compressor before the air enters the zeolite cylinders.

However, under simulated conditions of hypobaric hypoxia, the performance of the portable oxygen concentrators was lower than that previously reported (Fischer et al., 2013) and one of the portable oxygen concentrators was unable to generate an FO_2 greater than the recommended 0.90 to be classified as an "oxygen concentrator" (ISO 80601-2-69:2014). These discordant results could be due to the fact that our simulation more closely resembled the conditions of air travel than those of previously published tests or that this new generation of portable oxygen concentrators is less efficient than those previously tested (Fischer et al., 2013). The fact that none of the oxygen concentrators was able to generate an FO_2 greater than 0.94 at sea level (**Table 1**) tends to suggest the decreased performance of this new generation of portable oxygen concentrators, possibly related to miniaturization. However, all of the apparatuses tested were FAA-approved (Federal Aviation Administration, 2016). It should be noted that FAA approval does not comprise any recommendation to test the FO_2 under in-flight conditions, although such testing is implied as portable oxygen concentrators are defined as "*small, portable devices that work by separating oxygen from nitrogen and other gasses in the air and providing the user with oxygen at a concentration of more than 90 percent*" (US Department of Transportation - Federal Aviation Administration, 2016).

Consequently, in order to reassure users, the capacity of a portable oxygen concentrator to concentrate O_2 under the hypoxic conditions of altitude should be tested prior to authorization of the use of the device in the aircraft cabin, even when FAA approval has been obtained. Unfortunately, the present study shows that testing under conditions of hypobaric hypoxia would require excessively complex technology (compressor, resistant chamber, adapted transducers) and we had to seek the assistance of space and military research (*Airbus Defence and Space),* as in other countries (Dillard et al., 1995; Naughton et al., 1995). In view of these constraints, we tried to validate a simpler test, such as the normobaric hypoxia test, which can be performed routinely or even with a patient, but, unfortunately, this test provided inaccurate measurements. The inability of portable oxygen concentrators to achieve satisfactory FO_2 in the tent could be due to an excessively high nitrogen concentration in the gas mixture used, as functioning of portable oxygen concentrators is based on the principle of rapid pressure-modulated adsorption of nitrogen on a zeolite molecular sieve, the capacity of which may be insufficient under the conditions tested here.

Verification of the efficacy of the device and/or titration of the O_2 flow rate before a flight therefore cannot be performed by an hypoxia test with the currently available portable oxygen concentrators, which raises an additional doubt concerning the value of pre-flight hypoxia tests (Howard, 2013; Naeije, 2000), as recommended and performed at the present time (Ahmedzai et al., 2011). We know that titrating supplemental oxygen during a hypoxia challenge test is uncertain due to accumulation of O_2 under the face mask (Akerø et al., 2011). We also know that the HCT is good to predict in-flight PaO_2, but not in-flight symptoms (Edvardsen et al., 2013). Therefore, the recommendation to give 2 l/min of supplemental oxygen in-flight is in most cases could be the only practical choice.

These results place the physician in a difficult situation, as IATA international requirements (International Air Transport Association, 2015) specify that "*the passenger has talked with his/her physician regarding fitness to fly and the requirement that an individual who wishes to use a portable oxygen concentrator provide a written statement signed by a licensed physician that verifies that: The passenger is able to operate the device and to respond to any alarms. The treating physician has prescribed the oxygen flow rate*". A potential clinical solution would be to prescribe the highest flow rate of the portable oxygen concentrator and to encourage patients to titrate the necessary flow rate by means of a pulse oximeter during the flight, especially in order to lower the flow rate and prolong the battery life, but this method could be anxiogenic and, most importantly, a pre-flight test cannot formally guarantee the inflight efficacy of the portable oxygen concentrator. Under these conditions and in view of the results obtained with our simulator, manufacturers should be required to provide technical validation of portal oxygen concentrators proposed for air travel under conditions of hypobaric hypoxia, especially by verifying the capacity to produce a FO_2 90% in flight.

In conclusion, our study shows that some but not all portable oxygen concentrators are able to concentrate oxygen under conditions of altitude-related hypoxia and, as this study also demonstrates that flight conditions with a portable oxygen concentrator cannot be easily reproduced on the ground without a disproportionate use of technology, manufacturers should be required to verify the efficacy of the portable oxygen concentrator by means of a hypobaric hypoxia test before proposing their apparatus for use in an aircraft cabin.

REFERENCES

Ahmedzai, S., Balfour-Lynn, I.M., Bewick, T., Buchdahl, R., Coker, R.K., Cummin, A.R., Gradwell, D.P., Howard, L., Innes, J.A., Johnson, A.O.C., et al. (2011). Managing passengers with stable respiratory disease planning air travel: British Thoracic Society recommendations. Thorax *66*, i1–i30.

Akerø, A., Edvardsen, A., Christensen, C.C., Owe, J.O., Ryg, M., and Skjønsberg, O.H. (2011). COPD and air travel: oxygen equipment and preflight titration of supplemental oxygen. Chest *140*, 84–90.

Dillard, T.A., Moores, L.K., Bilello, K.L., and Phillips, Y.Y. (1995). The preflight evaluation. A comparison of the hypoxia inhalation test with hypobaric exposure. Chest *107*, 352–357.

Dine, C.J., and Kreider, M.E. (2008). HYpoxia altitude simulation test*. Chest *133*, 1002–1005.

Edvardsen, A., Akerø, A., Christensen, C.C., Ryg, M., and Skjønsberg, O.H. (2012). Air travel and chronic obstructive pulmonary disease: a new algorithm for pre-flight evaluation. Thorax *67*, 964–969.

Edvardsen, A., Ryg, M., Akerø, A., Christensen, C.C., and Skjønsberg, O.H. (2013). COPD and air travel: does hypoxia-altitude simulation testing predict in-flight respiratory symptoms? Eur. Respir. J. *42*, 1216–1223.

Federal Aviation Administration (2016). Acceptance Criteria for Portable Oxygen Concentrators Used On Board Aircraft.

Fischer, R., Wanka, E.R., Einhaeupl, F., Voll, K., Schiffl, H., Lang, S.M., Gruß, M., and Ferrari, U. (2013). Comparison of portable oxygen concentrators in a simulated airplane environment. Respiratory Medicine *107*, 147–149.

Howard, L.S. (2013). Last call for the flight simulation test? Eur. Respir. J. *42*, 1175–1177.

International Air Transport Association (2015). Guidance on Managing Medical Events ISBN 978-92-9252-698-6 ©.

Josephs, L.K., Coker, R.K., Thomas, M., BTS Air Travel Working Group, and British Thoracic Society (2013). Managing patients with stable respiratory disease planning air travel: a primary care summary of the British Thoracic Society recommendations. Prim Care Respir J *22*, 234–238.

Kelly, P.T., Swanney, M.P., Seccombe, L.M., Frampton, C., Peters, M.J., and Beckert, L. (2008). Air travel hypoxemia vs. the hypoxia inhalation test in passengers with COPD. Chest *133*, 920–926.

Naeije, R. (2000). Preflight medical screening of patients. Eur. Respir. J. *16*, 197–199.

Naughton, M.T., Rochford, P.D., Pretto, J.J., Pierce, R.J., Cain, N.F., and Irving, L.B. (1995). Is normobaric simulation of hypobaric hypoxia accurate in chronic airflow limitation? Am. J. Respir. Crit. Care Med. *152*, 1956–1960.

US Department of Transportation - Federal Aviation Administration (2016). Portable oxygen concentrators - AC 120-95.

DECLARATIONS:

Competing interests

There is no financial and non-financial competing interests for any authors of this manuscript.

Authors' contributions

Conception and design: VB, AS, FC, SR, CS, CMP, JG

Analysis and interpretation: VB, TS, JG

Drafting the manuscript for important intellectual content: VB, TS, JG

Acknowledgments:

Caroline Sevoz-Couche for contacts with AIRBUS Defence and Space.

Dr Vincent Feuillie, Medical VP, Air France for in-flight recommendations

François Thomassin, Afnor, for ISO recommendations

FIGURES

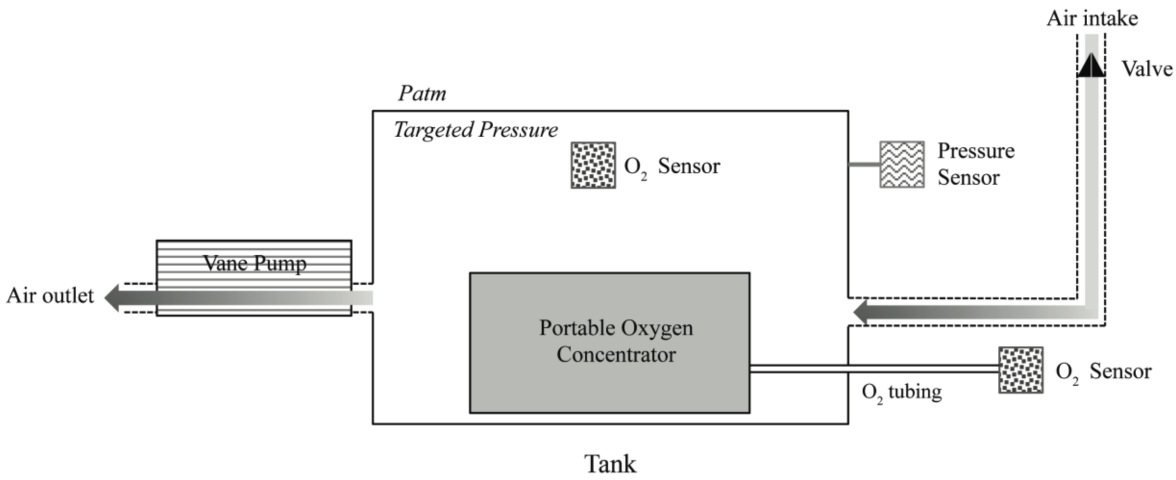

Figure 1: Description of the hypoxic chamber.

Generation of low pressure (targeted pressure) in the chamber by means of a rotary vane pump and piloting the chamber with air renewal via a calibrated valve. The target pressure P, was measured by an absolute pressure transducer. An airtight outlet tube from the chamber was used to reliably measure the O_2 concentration, (MaxO_2+, MAXTEC Inc., Utah, USA). A special oxygen monitor that can be used at low atmospheric pressure (Tetra 3, Crowcon Ltd, Abingdon, UK) was used to ensure that the FO_2 inside the chamber remained stable at 0.209. Patm: atmospheric pressure.

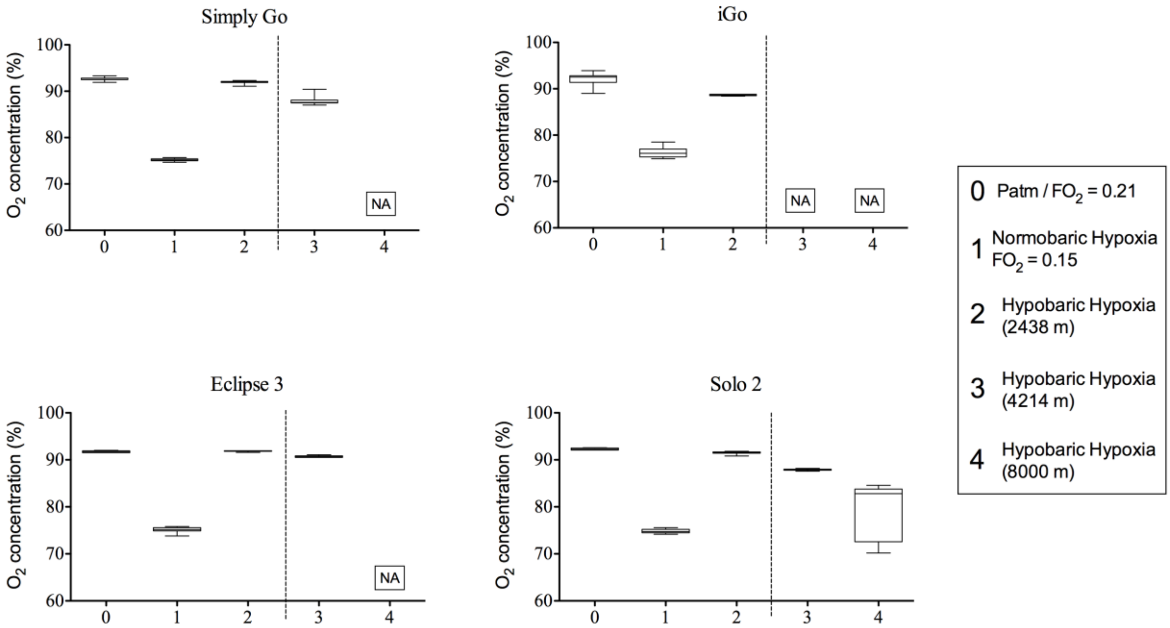

Figure 2: Measurement of the oxygen fraction provided by four portable oxygen concentrators under various pressure and ambient FO_2 conditions. Results expressed with median and interquartile range.

A: SimplyGo, continuous mode, 2 l/min. **B**: iGo, continuous mode, 3 l/min. C: Eclipse3, continuous mode, 3 l/min. D: Solo2, continuous mode, 3 l/min.

0: Measurement outside of the chamber/tent (P = 1.013 mbar, FO_2 = 0 .209); **1**: Measurement in the normobaric hypoxic tent (P = 1.013 mbar, FO_2 = 0.15); **2**: Measurement in hypobaric chamber (FO_2 = 0.209) at 753 mbar (8,000 ft/ 2,438 m); **3:** Measurement in hypobaric chamber (FO_2 = 0.209) at 450 mbar (14,000 ft/ 4,214 m); **4:** Measurement in hypobaric chamber (FO_2 = 0.209) at 356 mbar (26,247 ft/ 8,000 m). NA: Not Applicable: inefficacy of the portable oxygen concentrators to provide O_2: measured FO_2 = 0.21.

Supplemental figure: Set-ups used for measurements. On the left, a portable oxygen concentrator in an hypoxic tent (hypoxic generator at the back of the room). On the right, portable oxygen concentrator in the altitude chamber.

	Room Air 28 m	Normobaric hypoxia 2,438 m	p	Hypobaric hypoxia 2,438 m	p	Hypobaric hypoxia 4,214 m	p	Hypobaric hypoxia 8,000 m	p
SimplyGo median [Q1-Q3]	0.92 [0.90-0.93]	0.75 [0.75-0.75]	< 0.001	0.92 [0.92-0.92]	0,583	0.88 [0.87-0.88]	< 0.001	NA	NA
iGo median [Q1-Q3]	0.93 [0.91-0.93]	0.76 [0.75-0.76]	< 0.001	0.89 [0.89-0.89]	< 0.001	NA	NA	NA	NA
Eclipse3 median [Q1-Q3]	0.94 [0.95-0.96]	0.75 [0.75-0.76]	< 0.001	0.92 [0.92-0.92]	< 0.001	0.91 [0.91-0.91]	< 0.001	NA	NA
Solo2 median [Q1-Q3]	0.93 [0.93-0.93]	0.75 [0.74-0.75]	< 0.001	0.92 [0.91-0.92]	< 0.001	0.88 [0.88-0.88]	< 0.001	0.83 [0.73-0.84]	< 0.001
TOTAL median [Q1-Q3]	0.93 [92-94]	0.75 [0.75-0.76]	0,029	0.92 [0.89-0.92]	0,029	0.88 [0.88-0.91]	0,0498	0.83 [0.73-0.84]	NA

Table 1: Median and interquartile range of O_2 concentrations produced by four portable oxygen concentrators under the various conditions tested. N=30 measurements for room air, normobaric hypoxia (2,438 m) and hypobaric hypoxia (2,438 m) conditions; N=10 measurements for hypobaric hypoxia at 4,214 m and 8,000 m conditions. Each hypoxic condition was compared to the reference condition (room air, 28 m) by a Mann-Whitney test. NA: Not applicable (oxygen concentrators no longer generated O_2, identical measurements making comparison impossible).