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Simulated flying altitude and performance of continuous positive airway pressure devices.

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Abstract

Introduction: Continuous positive airway pressure (CPAP) is used in air ambulances to treat patients with impaired oxygenation. Differences in mechanical principles between CPAP devices may affect their performance at different ambient air pressures as will occur in an air ambulance during flight.

Methods: Two different CPAP systems, a threshold resistor device and a flow resistor device, at settings 5 and 10 cm H_2O were examined. Static pressure, static airflow and pressure during simulated breathing were measured at ground level and at three different altitudes (2400 m (8 kft), 3000 m (10 kft) and 10700 m (35 kft)).

Results: When altitude increased, the performance of the two CPAP systems differed during both static and simulated breathing pressure measurements. With the threshold resistor CPAP, measured pressure levels were close to the preset CPAP level. Static pressure decreased 0.71 ± 0.35 cm H_2O, at CPAP 10 cm H_2O, comparing ground level and 35 kft. With the flow resistor CPAP, as the altitude increased CPAP produced pressure levels increased. At 35 kft, the increase was 5.13 ± 0.33 cm H_2O at CPAP 10 cm H_2O.

Discussion: The velocity of airflow through the flow resistor CPAP device is strongly influenced by reduced ambient air pressure leading to a higher delivered CPAP effect than the preset CPAP level. Threshold resistor CPAP devices seem to have robust performance regardless of altitude. Thus, the threshold resistor CPAP device is probably more appropriate for CPAP treatment in an air ambulance cabin, where ambient pressure will vary during patient transport.

Key words: Continuous positive airway pressure, Air ambulance, Threshold resistor, Flow resistor, Bench study

Introduction

During aeromedical transfer and flight, cabin pressure can decrease as the aircraft gains altitude. This effect occurs in aircrafts with both pressurized and non-pressurized cabins [5]. Patients with impaired oxygenation who are being transported by air may benefit from positive airway pressure treatment in flight [13, 14]. For patients with acute hypoxia, related to pulmonary illness or acute pulmonary edema with heart failure, mask-delivered continuous positive airway pressure (CPAP) is a recommended first option for treatment when available [12, 15, 20]. Mask CPAP may also be part of chronic treatment for individuals with chronic lung disease or obstructive sleep apnea (with permission and in cooperation with airline medical services) [1]. Mask CPAP in emergency air ambulance settings is often based on rapid application of disposable CPAP devices, devices that this study will focus on.

The clinical relevance of CPAP device performance in aircraft cabins is that there can be a wide range of cabin pressures, from unpressurized aircraft flying at lower altitudes, to pressurized aircraft flying at higher altitudes, which normally do not maintain sea level cabin pressure. The most clinically common cabin pressures for pressurized fixed-wing air ambulances traveling at cruising altitude are from approximately 1800 m (6 kft) to 3000 m (10 kft) 'altitude'. Also, testing of CPAP devices in the event of rapid decompression at simulated cruising altitude is of interest, both for patients and pilot CPAP in the event of rapid cabin depressurization at high altitude. Rapid decompression is an event which can happen if an aircraft at higher altitude suddenly loses cabin integrity and the pressurized state.

Non-invasive ventilation by CPAP reduces work of breathing [9, 18], re-inflates collapsed alveoli and improves oxygen saturation [3, 10]. In a systematic review, a decrease in the need for endotracheal intubation was observed (-26% risk difference) in patients with cardiogenic pulmonary edema treated with CPAP, compared to standard therapy alone [16].

The design and mechanical principles differ between different CPAP devices. These differences may, in theory, affect how CPAP devices perform at different ambient air pressures as will occur in an air ambulance during ascent, cruising and descent.

The positive expiratory pressure, or the CPAP-level, may be obtained with a threshold resistor or a flow resistor. With a threshold resistor, the CPAP level is obtained with a valve that opens and closes at a preset pressure level. With a flow resistor the CPAP level is obtained with an orifice resistor, restricting airflow [2, 11]. In high flow CPAP devices, the CPAP level is controlled by a high continuous flow of gas through the resistor. To avoid fluctuations in delivered

CPAP level it is important that the flow delivery capacity of the CPAP system is high [4, 7]. A resistor that is held open throughout the breathing cycle indicate that the airflow delivered by the CPAP device is sufficient [8]. During air ambulance flight, where the amount of available gas to operate the CPAP device is limited, it is important that the CPAP device can function at a satisfactory level without using too much gas.

Fromm and coworkers have reported that a reduction in ambient air pressure can affect CPAP devices differently due to differences in mechanical design [6]. Taken their observation into consideration we hypothesized that changes in ambient air pressure will affect the preset CPAP level.

We aimed to test this hypothesis in a bench study by experimentally varying simulated aircraft cruising altitudes/cabin pressures while measuring CPAP delivered pressure- and airflow levels in two disposable CPAP devices, of different mechanical design, one threshold resistor device and one flow resistor device.

Methods

Equipment

This bench study was performed in a hypobaric chamber (SAAB, Linköping, Sweden).

The threshold resistor CPAP (O2-RESQ^{TM} System, IM-Medico, Saltsjö-Boo, Sweden) has a preset spring loaded valve that can be adjusted to deliver a CPAP level of 5, 7.5 or 10 cm H_2O. This CPAP device is a fixed flow venturi device that can be connected directly to a gas source (using a quick connector included in the device package) or to a flowmeter with a minimum delivery rate of 15 L/min.

The flow resistor CPAP device (Boussignac CPAP, Vygon, Skellefteå, Sweden) consists of a 5.5 cm long plastic tube open to the atmosphere. There are four micro channels in the wall of the plastic tube. With a flowmeter, air or oxygen flow is directed into the micro channels. Gas flow accelerates through the micro channels and creates a virtual valve on the patient side of the plastic tube. The speed of gas flow through the micro channels determines the size of the virtual valve and thereby the CPAP level, making this CPAP device flow dependent.

Outside the hypobaric chamber (figure 1), compressed air was filtered and guided through a 4.5 bar pressure regulator (Norgren Ltd, Lichfield, United Kingdom). Inside the pressure chamber the air was then guided through a 3.5 bar pressure regulator (Norgren Ltd, Lichfield, United Kingdom) and further to a gas panel with four outlets (©AGA Gas AB - Linde Healthcare, Solna, Sweden). We chose 3.5 bar since it is the supply pressure level used in fixed wing air ambulances

in Sweden. We initially had the pressure regulator outside the hypobaric chamber, but to mimic actual flying conditions, the pressure regulator was moved inside the hypobaric chamber.

The flow resistor CPAP device was connected to the gas panel through a rotameter (QMT care, Kalmar, Sweden) and the threshold resistor CPAP device was connected directly to the gas panel (i.e. using the quick connector). Each CPAP device was then connected to a flow sensor (Novametrix medical systems Inc., Wallingford, Connecticut), which in turn was connected to a pressure sensor (Freescale semiconductor Inc., Austin, Texas) located outside the hypobaric chamber. The pressure sensor was configured using different settings for pressure or airflow measurements. Pressure or airflow was recorded continuously at 200 Hz using a MP30 system (Biopac Student Lab Pro 3.7.7, Biopac Systems Goleta, California).
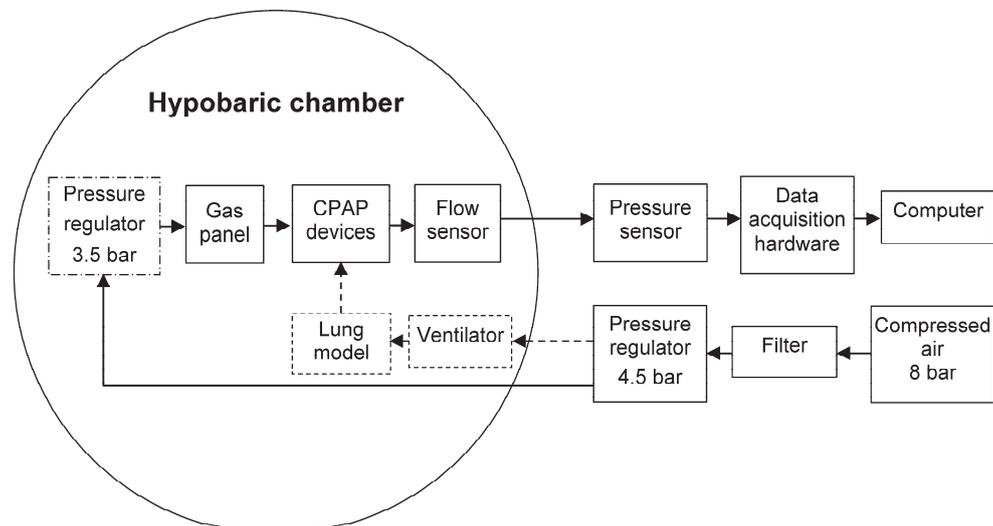
Figure 1. Experimental setup. According to the protocol, the 3.5 bar regulator was placed outside or inside the hypobaric chamber. Outside the hypobaric chamber compressed air was guided through a 4.5 bar pressure regulator. Inside the pressure chamber the air was then guided through a 3.5 bar pressure regulator and further to a gas panel with four outlets. The flow resistor CPAP device was connected to the gas panel through a rotameter and the threshold resistor CPAP device was connected directly to the gas panel. Each CPAP device was then connected to a flow sensor which in turn was connected to a pressure sensor located outside the hypobaric chamber. The dotted lines show equipment (lung model and ventilator) used only during simulated breathing measurements.

The experimental protocol was divided into two different test conditions, static measurements and simulated breathing, as described below. The static condition was further divided into three sub conditions; 1) static pressure; 2) static airflow;

and 3) static pressure and airflow measurements using different flow selectors (see below). During both static measurements and simulated breathing, the threshold resistor CPAP was tested with the spring-loaded valve in a horizontal position.

Procedure, static measurements

The two different CPAP devices were simultaneously tested in duplicate (i.e. two of each) at ground level (52 m above sea level) and at three different simulated altitudes, 2400 m (8 kft), 3000 m (10 kft) and 10700 m (35 kft), in accordance with RTCA/DO-160 recommendations [19]. Initially, the time frame at each altitude was set to 10 minutes. An analysis of the first recording showed that the altitude effect on the recording was stabilized within one minute. The time frame at each altitude was therefore decreased to three minutes. With a rotameter, the flow resistor device CPAP level was adjusted to 5 and 10 cm H_2O (clinically often applied pressure levels), as guided by a manometer (Astra Tech, Mölndal, Sweden). The spring-loaded valve in the threshold resistor device was adjusted to the same CPAP levels. Measurements were performed with the 3.5 bar pressure regulator both outside and inside the hypobaric chamber (see above).

By obstructing the airflow through the flow sensor, a static pressure (i.e. the pressure generated by the CPAP device) could be measured which was the result of the pressure difference between the inside of the flow sensor and the ambient pressure in the hypobaric chamber.

The flow sensor was also used for measuring airflow. Non-obstructed airflow at the output of the different CPAP devices was measured. To calculate airflow, relative pressure across the flow sensor was recorded and transformed into airflow measurements by the BioPac system.

As a separate part of the protocol, four different flow selectors, (flow selector 1: Mediflow® Ultra ll, GCE Holding AB, Malmö, Sweden), (flow selector 2: Gloor Jetflow, © AGA Gas AB - Linde Healthcare, Solna, Sweden), (flow selector 3 and 4: LSP L-233-50 and LSP L-233-20 respectively, Life Support Products, St Louis, Missouri) , were separately connected to the flow resistor CPAP device, and were compared in terms of resulting pressure and airflow. The rationale for testing these flow selectors was to ensure that the rotameter, when used together with the flow resistor CPAP device, did not influence the flow resistor CPAP performance.

These flow selectors delivered gas at fixed flow levels and can therefore, when connected to the flow resistor CPAP device, not be adjusted to deliver gas flow to a desired CPAP level. The delivered gas flow was 25 L/min (flow selector 1), 26 L/min (flow selector 2), 25 L/min (flow selector 3) and 15 L/min (flow selector 4). We used high airflow levels in order to achieve predefined CPAP levels.

Comparisons between these four flow selectors were performed with the 3.5 bar pressure regulator outside the hypobaric chamber, at the same simulated altitudes as described above.

Procedure, simulated breathings

A ventilator (Oxylog, Drägerwerk, Lübeck, Germany) connected to a lung model (Vent Aid Training test lung, Michigan instruments, Inc., Grand Rapids, Michigan) was used to simulate breathing. The 4.5 bar pressure regulator outside the hypobaric chamber operated the ventilator (figure 1). To measure pressure and airflow simultaneously, two flow sensors were positioned between the lung model and the CPAP device. Simulated breathing measurements were conducted at a preset tidal volume of 700 ml and a ventilator frequency of 12 breaths per min. In addition, the pressure and airflow produced by the ventilator and the lung model per se was measured without connecting the lung model to a CPAP device (0 cm H_2O). All measurements were performed with the 3.5 bar pressure regulator inside the hypobaric chamber, at the same altitudes and CPAP levels as during the static measurements.

Statistical analysis and data processing

Before measurements a 2-point calibration procedure of pressure and airflow sensors was performed. Pressure was calibrated at 0 and 10 cm H_2O using a manometer and airflow was calibrated at 0 and 1 L using a 1 L calibration syringe.

Since the airflow sensors have a slight non-linear property, the airflow sensor was further calibrated at different airflow levels using a VT plus Gas flow analyzer BIO-TEK® (Bio-Tek Instruments Inc., Winooski, VT). In this calibration, airflow was stepwise increased with 0.2 L/s in the interval between 0 and 3.2 L/s. These calibration values were used in the data processing described below.

Pressure and airflow data were analyzed in Matlab (R2007b, Mathworks, Inc., Natick, MA). If baseline pressure and airflow levels (measured during a period with no airflow) differed from zero, these discrepancies were removed before performing subsequent analysis. The recalculated airflow signal was interpolated with a cubic spline algorithm using data from the calibration of non-linear effects described above. The pressure and airflow signals were then down sampled to 10 Hz and exported to Excel. At each ambient air pressure level (ground level and the three different simulated altitudes), data from three different 15-30 seconds periods were analyzed.

Two linear mixed effects models were used to compare the two different CPAP devices. Since the interval between the simulated altitudes (ground level, 8, 10 or 35 kft) differed, a mixed model was chosen to enable simulated altitude to be used as a covariate scaling variable. In the first model pressure or airflow were used as outcome variables. Fixed factors were CPAP device type (threshold resistor CPAP

device or flow resistor CPAP device), CPAP level (5 or 10 cm H_2O) and the interaction between CPAP device type, 3.5 regulator (placed inside or outside the hypobaric chamber) and simulated altitude (0, 8, 10 or 35 kft), where altitude was set as a covariate. A random effect for baseline variations between different unique CPAP-units was included in the model. The covariance matrix was set to diagonal with separate estimates for random effects for the two CPAP types.

In the second model the outcome variable was the noise-level in the static pressure measurements. Fixed factors were CPAP type and CPAP level. A random effect for baseline variations between different unique CPAP-units was included in the model. The covariance matrix was set to diagonal with separate estimates for random effects for the two CPAP types.

Comparisons between measured pressures or airflow at the investigated simulated altitudes are presented as mean ± SD. Results from the statistical analyses, are presented as estimate, standard error of estimate and confidence intervals. A p-value < 0.05 was considered statistically significant. Statistical analyses were performed with SPSS statistics software (IBM SPSS Statistics 22.0, IBM, Armonk, New York).

Results

With the threshold resistor CPAP device, at the respective preset CPAP level (5 and 10 cm H_2O), corresponding static measured pressure levels were in accordance with the preset CPAP level regardless of simulated altitude. With the 3.5 bar regulator inside the hypobaric chamber, the decrease in measured pressure between ground level and 2400 m was 0.02 ± 0.02 cm H_2O at CPAP level 5 cm H_2O and 0.18 ± 0.34 cm H_2O at CPAP level 10 cm H_2O. Between ground level and 10700 m, measured pressure decreased with 0.13 ± 0.00 and 0.71 ± 0.35 cm H_2O at CPAP level 5 and 10 cm H_2O, respectively. With the threshold resistor CPAP device, for every kft increase in altitude the estimated pressure level decreased 0.0024 ± 0.0039 cm H_2O (p =0 .539) and 0.0140 ± 0.0030 cm H_2O (p ≤ 0.001) with the 3.5 bar regulator placed outside or inside the hypobaric chamber, respectively (table I, figure 2, panel A).

With the flow resistor CPAP device however, there was a strong relation between the simulated altitude and the CPAP generated pressure level. As the simulated altitude increased the flow resistor CPAP device generated higher pressure levels. With the 3.5 bar regulator inside the hypobaric chamber, the increase in measured pressure between ground level and 2400 m was 0.63 ± 0.01 cm H_2O at CPAP level 5 cm H_2O and 1.18 ± 0.29 cm H_2O at CPAP level 10 cm H_2O. Between ground level and 10700 m, measured pressure increased with 4.09 ± 0.19 and 5.13 ± 0.33 cm H_2O at CPAP level 5 and 10 cm H_2O respectively.

Increases in measured pressure levels were higher when the 3.5 bar pressure regulator was outside the hypobaric chamber. With the flow resistor CPAP device, for every kft increase in altitude the estimated pressure level increased 0.2475 ± 0.0038 H_2O (p $\leq$ 0.001) and 0.1368 ± 0.0030 cm H_2O (p $\leq$ 0.001) with the 3.5 bar regulator placed outside or inside the hypobaric chamber, respectively. Small differences in measured pressure levels at ground level were observed between the two CPAP devices (table I, figure 2, panel A).

The variance between the threshold resistor CPAP devices was 0.640 (cm $H_2O)^2$ and between the flow resistor CPAP devices 0.004 (cm $H_2O)^2$.

The noise-level in the static pressure measurements did not differ between the threshold resistor CPAP device compared to the flow resistor CPAP device but the noise-level was lower at CPAP level 5 cm H_2O compared to CPAP level 10 cm H_2O.

The complete results from the mixed effects models are presented in Tables I and II.

Table I. Statistical analyses. Estimates of fixed effects with pressure as outcome variable.

Model terms	Model (N)[†]	Variable	Estimate	Std. Error	95% Confidence Interval Lower	95% Confidence Interval Upper	P-value
CPAP type	144	Flow resistor	10.21	0.0601	10.08	10.34	< 0.001
	144	Threshold resistor	9.13	0.3314	8.29	9.98	< 0.001
CPAP level	96	5 cm H_2O	-5.46	0.0573	-5.57	-5.35	< 0.001
	192	10 cm H_2O	0[*]	0			
CPAP type*	48	Flow resistor*Outside*Altitude	0.2475[**]	0.0038	0.2401	0.2550	< 0.001
[‡]Regulator*	96	Flow resistor*Inside*Altitude	0.1368[**]	0.0030	0.1310	0.1427	< 0.001
[§]Altitude	48	Threshold resistor*Outside*Altitude	-0.0024[**]	0.0039	-0.0010	0.0052	0.539
	96	Threshold resistor*Inside*Altitude	-0.0140[**]	0.0030	-0.0199	-0.0081	< 0.001

[*] This parameter was set to zero because it is redundant. [†]Effective sample size. [‡]3.5 bar regulator was outside or inside the hypobaric chamber. [§]Altitude: 0, 8, 10, 35 kft. [**]Variable estimate depict change per kft.

Table II. Statistical analyses. Estimates of fixed effects with noise-level in the static pressure measurements as outcome variable.

| Model terms | Model (N)[†] | Variable | Estimate | Std. Error | 95 % Confidence Interval | | P-value |
					Lower	Upper	
Intercept			0.0577	0.0063	0.0370	0.0783	0.003
CPAP type	144	Flow resistor	-0.0101	0.0188	-0.0557	0.0355	0.610
	144	Threshold resistor	0[*]	0			
CPAP level	96	5 cm H_2O	-0.0534	0.0067	-0.0666	-0.0403	<0.001
	192	10 cm H_2O	0[*]	0			

[*] This parameter was set to zero because it is redundant. [†]Effective sample size.

CPAP produced airflow levels were lower at CPAP level 5 cm H_2O compared to 10 cm H_2O with both CPAP systems. With the threshold resistor CPAP device, at the preset CPAP level 10 cm H_2O, the measured airflow was higher at ground level when the 3.5 bar pressure regulator was inside the hypobaric chamber compared to the 3.5 bar pressure regulator being outside the hypobaric chamber. When the simulated altitude was higher, airflow decreased when the 3.5 bar pressure regulator was inside the hypobaric chamber, but was unchanged when the 3.5 bar pressure regulator was outside the hypobaric chamber. With the 3.5 bar regulator inside the hypobaric chamber, the measured airflow level was not changed (0.00 ± 0.02 L/s) when the simulated altitude increased from ground level to 2400 m at CPAP level 5 cm H_2O but decreased with 0.08 ± 0.06 L/s at CPAP level 10 cm H_2O. Between ground level and 10700 m, measured airflow decreased with 0.08 ± 0.05 and 0.33 ± 0.03 L/s at CPAP level 5 and 10 cm H_2O, respectively. With the threshold resistor CPAP device, for every kft increase in altitude the estimated airflow level decreased 0.0033 ± 0.0016 L/s (p = 0.034) and 0.0023 ± 0.0018 L/s (p = 0.203) with the 3.5 bar regulator placed outside or inside the hypobaric chamber, respectively (table III, figure 2, panel B).

With the flow resistor CPAP device, similar to static pressure measurements (see above), every time the simulated altitude increased, the measured airflow increased. With the 3.5 bar regulator inside the hypobaric chamber, the increase in measured airflow between ground level and 2400 m was 0.10 ± 0.02 L/s at CPAP level 5 cm H_2O and 0.19 ± 0.11 L/s at CPAP level 10 cm H_2O. Between ground level and 10700 m, measured airflow increased with 0.76 ± 0.04 and 0.53 ± 0.22 L/s at CPAP level 5 and 10 cm H_2O, respectively. With the flow resistor CPAP device, for every kft increase in altitude level, the estimated airflow increased 0.0273 ± 0.0016 L/s (p ≤ 0.001) and 0.0142 ± 0.0018 L/s (p ≤ 0.001) with the 3.5 bar regulator placed outside or inside the hypobaric chamber, respectively (table III, figure 2, panel B).

The complete results from the mixed effects model are presented in Table III.

Table III. Statistical analyses. Estimates of fixed effects with airflow as outcome variable.

Model terms	Model (N)[†]	Variable	Estimate	Std. Error	95 % Confidence Interval		P-value
					Lower	Upper	
CPAP type	120	Flow resistor	2.180	0.1258	0.772	3.589	0.032
	120	Threshold resistor	1.707	0.6634	1.159	2.256	0.012
CPAP level	96	5 cm H_2O	-0.603	0.0259	-0.6536	-0.5515	< 0.001
	144	10 cm H_2O	0[*]	0			
CPAP type*	72	Flow resistor*Outside*Altitude	0.0273[**]	0.0016	0.0242	0.0304	< 0.001
[†]Regulator*	48	Flow resistor*Inside*Altitude	0.0142[**]	0.0018	0.0107	0.0178	< 0.001
[§]Altitude	72	Threshold resistor*Outside*Altitude	-0.0033[**]	0.0016	-0.0064	-0.0003	0.034
	48	Threshold resistor*Inside*Altitude	-0.0023[**]	0.0018	-0.0058	0.0012	0.203

[*] This parameter was set to zero because it is redundant. [†]Effective sample size. [‡]3.5 bar regulator was outside or inside the hypobaric chamber. [§]Altitude: 0, 8, 10, 35 kft. [**]Variable estimate depict change per kft.

Similar to static pressure and airflow measurements described above, as simulated altitude increased, the measured CPAP produced pressure (figure 2, panel C) and airflow levels (figure 2, panel D) increased for the four investigated flow selectors, separately connected to a flow resistor CPAP device. The measured pressure and airflow levels at ground level differed between the four different flow selectors, and amounted to 5.47, 3.14, 5.56 and 2.62 cm H_2O and 1.59, 0.96, 1.44 and 0.84 L/s for flow selector 1, 2, 3, and 4, respectively.

During simulated breathing with the threshold resistor device, at the respective preset CPAP level (5 and 10 cm H_2O) corresponding measured mean pressure levels were in accordance with the respective preset CPAP level regardless of the altitude. There was no difference in measured mean pressure between ground level and 2400 m at CPAP level 5 and 10 cm H_2O, respectively. Between ground level and 10700 m measured mean pressure decreased with 0.21 cm H_2O at CPAP level 10 cm H_2O. With the flow resistor CPAP device, similar to described above for the static pressure measurements, every time the altitude increased the measured mean pressure levels increased concomitantly. The increase in measured mean pressure between ground level and 2400 m was 0.62 cm H_2O at CPAP level 5 cm H_2O and 1.33 cm H_2O at CPAP level 10 cm H_2O. Between ground level and 10700 m mean pressure increased with 4.03 cm H_2O and 5.18 cm H_2O at CPAP level 5 and 10 cm H_2O, respectively (figure 3).
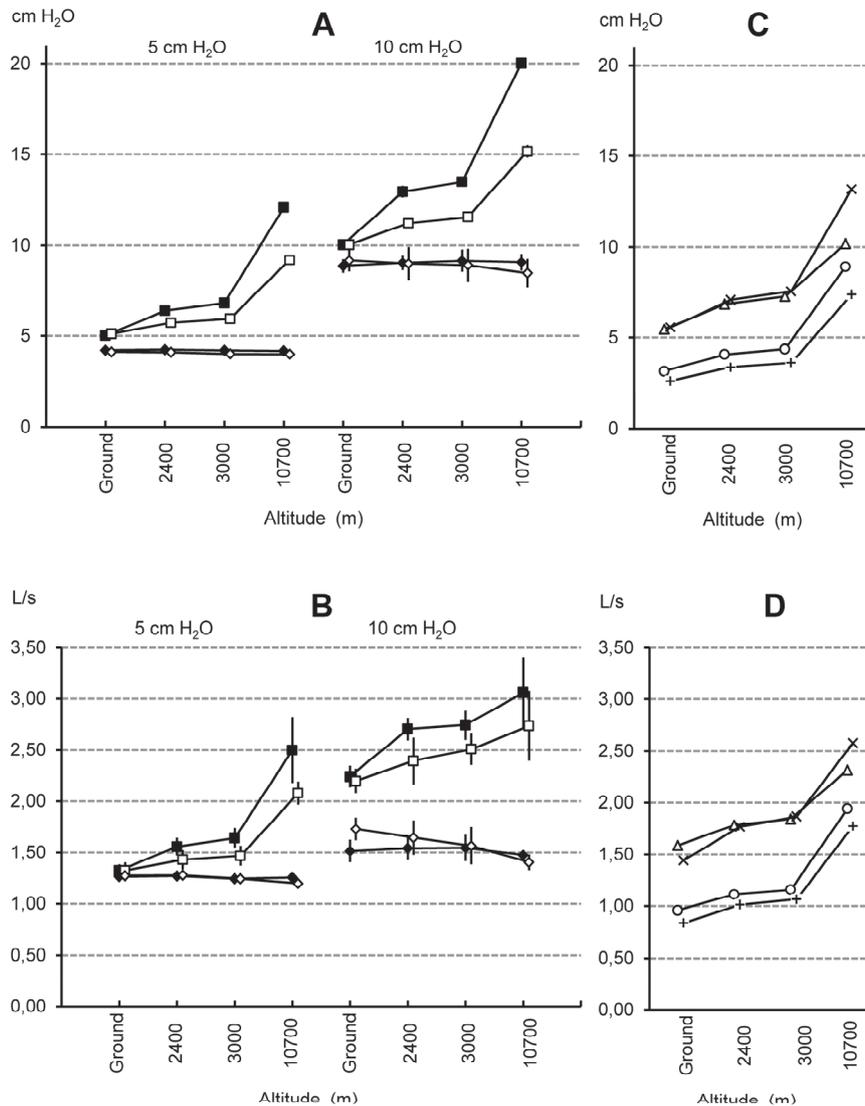
Figure 2A-D. Static pressure at CPAP levels 5 and 10 cm H_2O (panel A). Static airflow at CPAP levels 5 and 10 cm H_2O (panel B).

Flow resistor CPAP device - regulator outside the hypobaric chamber (filled square), flow resistor CPAP device - regulator inside the hypobaric chamber (open square), threshold resistor CPAP device - regulator outside the hypobaric chamber (filled diamond), threshold resistor CPAP device - regulator inside the hypobaric chamber (open diamond). Data are presented as mean ± SD.
Static pressure with different flow selectors, single measurement (no statistical test performed) (panel C) and static airflow with different flow selectors, single measurement, (no statistical test performed) (panel D).

Flow selectors: flow selector 1 (open triangle), flow selector 2 (open circle), flow selector 3 (X), flow selector 4 (+).
Variable estimate: flow resistor CPAP × regulator outside × altitude $p \leq 0.001$. Variable estimate: flow resistor CPAP × regulator inside × altitude $p \leq 0.001$. Variable estimate: threshold resistor CPAP × regulator outside × altitude $p = 0.539$. Variable estimate: threshold resistor CPAP × regulator inside × altitude $p \leq 0.001$ (panel A).
Variable estimate: flow resistor CPAP × regulator outside × altitude $p \leq 0.001$. Variable estimate: flow resistor CPAP × regulator inside × altitude $p \leq 0.001$. Variable estimate: threshold resistor CPAP × regulator outside × altitude $p = 0.034$. Variable estimate: threshold resistor CPAP × regulator inside × altitude $p = 0.203$ (panel B).

At CPAP level 0 cm H_2O, when the ventilator and lung model was not connected to a CPAP device, measured mean pressure was slightly below zero regardless of altitude (figure 3).

Data from measurements at 10700 m (35 kft) are missing for the dynamic test with the threshold resistor CPAP device at CPAP level 5 cm H_2O due to technical problems that occurred with the hypobaric chamber.
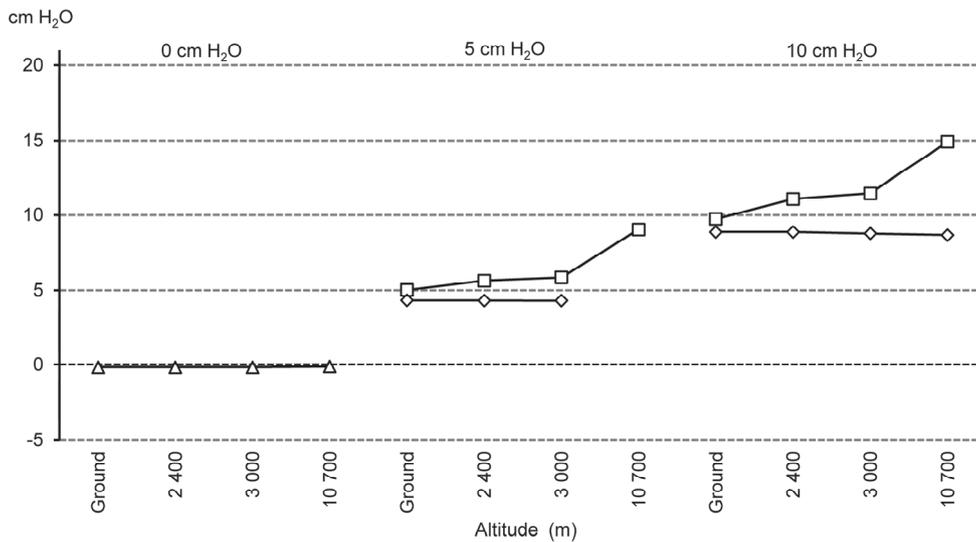
Figure 3. Mean pressure at CPAP levels 0, 5 and 10 cm H_2O during simulated breathing measurements. Flow resistor CPAP device (open square), threshold resistor CPAP device (open diamond), ventilator (open triangle). Single measurement, no statistical test performed.

Discussion

During both static and simulated breathing pressure measurements, performance of the two disposable CPAP systems differed when the simulated altitude increased. The threshold resistor CPAP device performed much closer to its own calibrated setting than the flow resistor CPAP device, especially at higher altitudes. With the threshold resistor CPAP device, measured pressure levels were in accordance with the preset CPAP level regardless of the altitude. With the flow resistor CPAP device, every time the altitude increased the measured mean pressure levels increased. Similar results were obtained during simulated breathing. To ensure that the rotameter was not causing the findings related to the flow resistor CPAP device, four different flow selectors were tested. Whether a rotameter or any of the different flow selectors were connected to the flow resistor device, as the altitude increased measured pressure levels increased concomitantly.

Our main findings, and the observed effect size of altitude on CPAP device performance, indicate that there can be quite a substantial discrepancy in-flight between the CPAP device setting and the actual delivered CPAP level. This could lead to more than anticipated CPAP pressure delivery for the flow resistor CPAP device, when in lower environmental pressures. This means that, as aircraft take off and ascend, and cabin pressure decreases progressively, CPAP treatment can vary from its setting and clinical goal, particularly for a flow resistor CPAP device. This can disturb the optimal application of CPAP. For patients with hypoxic respiratory problems as well as possible increased work of breathing, this possible unintentional increase in delivered level of CPAP would increase the work of breathing for an already compromised patient, leading to a potentially dangerous and life-threatening iatrogenic problem. The utility of CPAP in the urgent respiratory insufficient patient situation is always based on careful titration, and rapid assessment of a changing patient and environmental situation. Although the increase in CPAP level with the flow resistor CPAP was quite small between ground level and 3000 m (10 kft), these findings should alert clinicians to be particularly vigilant when administering CPAP to a respiratory insufficient patient during changing cabin pressures, and particularly with flow resistor CPAP devices. It is also important for air ambulance personnel to be aware of effects on CPAP device performance, and risks to patients using CPAP devices, in the unlikely event of a rapid decompression situation in a pressurized aircraft cabin at cruising altitude.

This discrepancy in results between CPAP systems may be explained by differences in design and mechanical construction.

In a study by Fromm et al [6], the performance of four different fan driven CPAP machines used for treating sleep apnea were tested at different simulated altitudes. One CPAP machine was equipped with a pressure-sensor and the three others were non-pressure compensated CPAP machines. As in our study, the CPAP

machine equipped with a pressure-sensor (i.e., threshold resistor) maintained the pressure level regardless of altitude and preset CPAP level. In contrast to our study, where the flow resistor CPAP device increased the pressure level at increasing altitudes, the pressure level decreased with increasing altitudes for non-pressure compensated CPAP machines.

The collective fan laws describe how fan driven CPAP machines function when the gas density changes. With constant power to the fan and reduced air density, the fan laws predict a reduction in airflow through the fan. The fan laws also state that with a decrease in air density, the power to the fan has to increase if the flow rate is to remain constant [6]. As a consequence of the results from the study by Fromm et al, today most CPAP machines used for treating sleep apnea come with the option of altitude adjustment [17].

With the flow resistor CPAP device used in our study, an increase in simulated altitude resulted in increased CPAP produced airflow and pressure. Air density is lower at higher altitudes. According to Poiseuille's law, with constant temperature, constant pressure and reduced air density, airflow through a fixed tube will increase. In our study a 3.5 bar pressure regulator delivered airflow at a constant pressure level to the CPAP devices. As air density decreased (i.e., simulated altitude increased) the resistance through the rotameter and the flow resistor CPAP device decreased resulting in increased airflow through the device. As a consequence, the measured pressure level will also increase.

During some tests the 3.5 bar regulator was placed outside the hypobaric chamber. The pressure regulator adjusts its pressure level against the surrounding air pressure (i.e., 3.5 bar above the surrounding pressure). Therefore, when altitude increased, the pressure level inside the hypobaric chamber was lower than the pressure level surrounding the 3.5 bar regulator causing the driving pressure from the 3.5 bar regulator to the CPAP devices to increase. This may explain the higher CPAP produced airflow and pressure levels with the flow resistor CPAP device when the 3.5 bar regulator was outside the hypobaric chamber compared to the 3.5 bar regulator being inside the hypobaric chamber.

As a separate part of the study, the performance of the flow resistor CPAP device was tested when connected to four different flow selectors. These flow selectors have distinct flow rate settings and do not allow titration of airflow to an exact CPAP level, as illustrated by differences in measured ground level pressures. One of the flow selectors, flow selector 1, has a built in regulator. In theory, a regulator should be better at maintaining airflow when ambient pressure changes. However, the CPAP produced airflow and pressure increased similarly whether the flow selector had a regulator or not.

We suspected that the construction of the spring loaded valve in the threshold resistor CPAP device could cause vibrations affecting the performance of this

CPAP device. This suspicion could not be confirmed since there was no difference in the noise-level in the pressure measurements between the two different CPAP devices However, there was a difference in the noise-level between CPAP level 5 and 10 cm H_2O.

Some methodological considerations have to be addressed. This is a bench study which needs to be confirmed in actual inflight working conditions. Since the aim was to evaluate two mechanically different CPAP devices, we had to be able to titrate airflow to the desired CPAP level for the flow resistor CPAP device. This cannot be done if the flow meter has fixed settings as the four flow selectors. We therefore were obliged to use a rotameter, since it provides the opportunity to titrate airflow to an exact CPAP level. With the threshold resistor CPAP, measured pressure levels were a little lower than the calibrated setting of the spring-loaded valve at both CPAP level 5 and 10 cm H_2O. During the static measurements the spring-loaded valve in the threshold resistor CPAP devices was horizontally oriented. If the spring-loaded valve had been vertically oriented, the self-weight of the spring-loaded valve would have increased measured pressure levels. This could explain why the measured pressure levels at ground level were below the calibrated settings.

In summary, performance of the two different types of disposable CPAP devices differed when simulated altitude increased. Based on these findings, we conclude that threshold resistor CPAP devices would be expected to perform closest to device setting calibration, especially at higher altitudes and lower cabin pressures. These findings indicate that flow resistor devices are less reliable for CPAP breathing in aircraft. Furthermore, CPAP device design must be considered when assessing possible use of patient-owned CPAP devices in flight.

Acknowledgement

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