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Bench testing of a new hyperbaric chamber ventilator at different atmospheric pressures

Received: 29 December 2011
Accepted: 18 April 2012
Published online: 17 May 2012
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Electronic supplementary material

The online version of this article (doi:10.1007/s00134-012-2590-4) contains supplementary material, which is available to authorized users.

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Abstract Purpose: Providing mechanical ventilation is challenging at supra-atmospheric pressure. The higher gas density increases resistance, reducing the flow delivered by the ventilator. A new hyperbaric ventilator (Siaretron IPER 1000) is said to compensate for these effects automatically. The aim of this bench test study was to validate the compensation, define its limits and provide details on the ventilator's output at varied atmospheric pressures. **Methods:** Experiments were conducted inside a multiplace hyperbaric chamber at 1, 2.2, 2.8 and 4 atmospheres absolute (ATA), with the ventilator connected to a test lung. Transducers were recalibrated at each ATA level. Various ventilator settings were tested in volume and pressure control modes. Measured tidal volumes were compared with theoretical predictions based on gas laws. **Results:** Results confirmed the ventilator's ability to provide

compensation, but also identified its limits. The compensation range could be predicted and depended on the maximal flow attainable, decreasing linearly with increasing atmospheric pressure. With settings inside the range, tidal volumes approximated set values (mean error $10 \pm 5\%$). With settings outside the range, the volume was limited to the predicted maximal value calculated from maximal flow. A practical guide for clinicians is provided. **Conclusion:** The IPER 1000 ventilator attempted to deliver stable tidal volume by adjusting the opening of the inspiratory valve in proportion to atmospheric pressure. Adequate compensation was observed, albeit only within a predictable range, which can be reliably predicted for each setting and ATA level combination. Setting a tidal volume outside this range can result in an unwanted decrease in minute ventilation.

Keywords Hyperbaric oxygen therapy · Mechanical ventilation · Ventilator · Volume-control · IPER 1000 · Gas density

Introduction

Hyperbaric oxygen therapy (HBOT) is used in the treatment of several acute medical conditions, including

decompression sickness, carbon monoxide poisoning and necrotizing infections [1]. In recent years, technical advances and a better understanding of mechanical ventilation under hyperbaric pressure have contributed to the

increasing use of HBOT in the treatment of critically ill patients. Nevertheless, applying HBOT to mechanically ventilated patients remains challenging because of safety and technical reasons [2]. Devices used in the hyperbaric chamber must resist the crushing effect of pressurization, while electronic components must operate at low voltage to mitigate the risk of fire hazard in the oxygen-enriched environment, precluding the use of conventional ventilators [1, 3]. The higher gas density at supra-atmospheric pressure increases resistance, reducing the flow delivered by the ventilator [4, 5]. This is frequently worsened by the suboptimal performance of hyperbaric-approved ventilators [2, 5, 6].

A hyperbaric ventilator combining safety and acceptable performance, mostly in terms of sufficient and stable minute ventilation (V_E), is clearly needed. Ideally, it should be portable, user friendly, with adequate alarms and various ventilation modes, notably assisted ones (as opposed to fully controlled ventilation). To our knowledge, the recently released Siaretron IPER 1000 (Siare, Bologna, Italy; distributed by Haux Life-Support, Karlsbad-Ittersbach, Germany) is the only ventilator approved for use inside the chamber that offers assisted modes of ventilation and automatic adjustment of the inspiratory valve opening to provide stable flow regardless of the ambient pressure.

The IPER 1000 has never been bench tested independently under hyperbaric pressure. This study was carried out to evaluate the performance and operational characteristics of the IPER 1000. Since this ventilator is said to compensate for the effects of increased gas density automatically, we compared the measurements obtained in supra-atmospheric conditions with theoretical calculations based on gas laws. This allowed us to (1) estimate the amount of compensation provided by the ventilator; (2) test and understand its limits; and (3) provide users with practical information about its operational range.

Materials and methods

The IPER 1000 is a portable electropneumatic ventilator, functioning with a low-tension electrical circuit and compressed medical gases. Volume-assist control (VC) and pressure-assist control (PC) modes are available, in addition to pressure support (PS). There is no integrated volume/flow monitoring (nor alarms), but the airway pressure (P_{aw}) is displayed on a bar graph, and there is a low/high P_{aw} alarm. The device is CE certified in accordance with European regulations, but is not yet available in the US, pending FDA approval.

All the experiments were conducted inside a multi-place hyperbaric chamber (Haux-Starmed 2400, Haux Life-Support, Germany) at 1, 2.2, 2.8 and 4 atmospheres

absolute (1 ATA = atmospheric pressure). The IPER 1000 was connected to a passive Michigan test lung (Michigan Instruments, Grand Rapids, MI, USA) using an 8-mm endotracheal tube and a double-limb circuit [7, 8]. Compliance was set at $50 \text{ ml cmH}_2\text{O}^{-1}$, without additional resistance. The ventilator, test lung and sensors were placed inside the chamber, while the data collecting units were kept outside for safety reasons. Four set tidal volume (V_T ; 250, 500, 750 and 1,000 ml) and inspiratory pressures (P_{insp} ; 5, 10, 15, 20 cmH_2O) were tested in VC and PC, respectively, with the following settings: respiratory rate (RR) 15 cycles min^{-1} , no inspiratory pause, positive end-expiratory pressure (PEEP) 5 cmH_2O and FiO_2 21 %. The inspiratory time was modified by varying the inspiratory:expiratory ratio (I:E): 1:2, 1:3, 1:4. Detailed methods are presented in the online supplement.

Theoretical predictions

Due to compression, gas density increases linearly with ambient pressure, with density being doubled at 2 ATA [2, 9]. This higher density increases resistance to gas flow. Since ventilators control flow through the proportional opening of the inspiratory valve, greater resistance results in decreased flow across the valve for a given aperture [4, 10].

The difference in gas density determines the impact on flow and hence on delivered V_T . We calculated the theoretical V_T predicted by the effects of gas laws only, using a volume correction factor detailed in the online supplement:

$$\text{Volume correction factor} = \sqrt{\frac{\text{gas } \rho (1 \text{ ATA})}{\text{gas } \rho (x \text{ ATA})}} = \sqrt{\frac{1}{x}}$$

where $\text{gas } \rho$ = gas density; x = current ATA level. Since they are linearly correlated, the ATA level can directly replace gas density in the equation.

The IPER 1000 compensates for hyperbaric pressure by adjusting the opening of the inspiratory valve in proportion to the ambient pressure. This should function until the maximal valve opening area is attained; the flow then generated dictates the upper limit of the compensation range. According to the manufacturer, the maximal flow (flow_{max}) at 1 ATA is 99 l min^{-1} , and we hypothesized a direct linear decrease with increasing ATA level (e.g., 25 l min^{-1} at 4 ATA). We subsequently determined the predicted maximal V_T attainable ($V_{T\text{max}}$) for each experimental condition by multiplying the flow_{max} by the set inspiratory time. The $V_{T\text{max}}$ fixed the upper limit of the compensation range. In theory, the decline in V_T should be less of an issue with PC, since the ventilator should intrinsically compensate for the decrease in flow to attain the target P_{insp} [4].

Results

As predicted, peak flow was progressively limited with higher ambient pressures, decreasing linearly by a factor proportional to the ATA level, confirming our hypothesis of a predictable flow_{max} (Fig. 1). The area under the flow_{max} values delineates the range of compensation, the ventilator being unable to generate higher flow for a given ATA level. The complete results obtained in VC are displayed in Table 1. The mean error of the delivered V_T was only 5 ± 4 % at 1 ATA. Performances were progressively less accurate with increasing ambient pressure, but the results can be dichotomized according to theoretical predictions of the compensation range. At supra-atmospheric pressures, for settings inside the range (i.e., under V_{Tmax}), the V_T did not decrease as predicted based on gas laws, but remained roughly stable (mean error of 10 ± 5 %), confirming adequate compensation. Conversely, with settings outside the range (bold-italic values in Table 1), the delivered V_T differed widely from the set values, but were in close agreement with our predicted V_{Tmax} (3 ± 3 %), indicating the inability of the ventilator to exceed V_{Tmax}. As the experimental results confirmed our theoretical predictions, we produced a practical user's guide, fixing the range of compensation of the IPER 1000 at frequently used settings (Table 2).

A progressive loss of PEEP of 2–3 cmH₂O was revealed (40–60 % of the set value) for all experimental settings, without being significantly influenced by the ATA level. Importantly, an aberrant insufflation, with

high delivered V_T, was frequently noticed immediately after setting modifications during ventilation (e-figure 5). The results obtained in PC are detailed in the online supplement (e-table 1). In short, large discrepancies were frequently found between the measured and the predicted V_T. This can be mainly attributed to the flow limitation at higher ATA levels, preventing the ventilator from attaining the target P_{insp} (e-table 1 and e-figure 1).

Discussion

Our results confirmed that the IPER 1000 compensated for the greater resistance induced by higher gas density, apparently by increasing the opening of the inspiratory valve in proportion to the ATA level. However, this compensation only takes place inside an operational range, which becomes narrower at higher ATA levels. This range was shown to be reliably predicted using the theoretical flow_{max} for each ATA level. Users must be aware of this range to prevent an unnoticed decrease in V_E, as there is no built-in volume monitoring. The practical guide presented in Table 2 might give a good estimate of the V_{Tmax} for a given condition. Clinicians should not expect delivered V_T to be higher than V_{Tmax}. The highest attainable V_E is quite low at the higher ATA levels (6.2 l min⁻¹ at 4 ATA; 4.2 l min⁻¹ at 6 ATA, with a 1:3 ratio), which could be insufficient for patients with moderate-high ventilatory needs.

In clinical practice, it is recommended that the IPER 1000 be used with an independent volumeter. Since results are more predictable in VC, this mode should be used preferentially, especially as predictions in PC would be even harder because of the patient's variable respiratory mechanics. Ventilator settings should correspond to the predicted values in Table 2. If the clinical adequacy of the maximal V_E is doubtful, one should consider evaluating its impact on the patient before attempting HBOT with the IPER 1000. Using a 1:2 instead of 1:3 I:E ratio increases the maximal V_E, but this should be done carefully because of the risk of dynamic hyperinflation, further magnified by the relatively high resistance of the exhalation apparatus (online appendix). To limit the impact of ventilating the fixed dead space, the use of a respiratory frequency in the low range (≈ 10/min) along with a relatively high V_T (limited by the V_{Tmax}) should be considered, at least for higher ATA levels.

With respect to study limitations, only one ventilator unit was tested, but the concordance between predicted and measured values suggests reproducible results. Even if a systematic decrease in PEEP is supposed to occur for every set value, only one PEEP level was formally tested. Theoretical predictions were not confirmed at 6 ATA because such a depth is not possible with our chamber. Also, gas mixtures other than air, such as heliox, were not

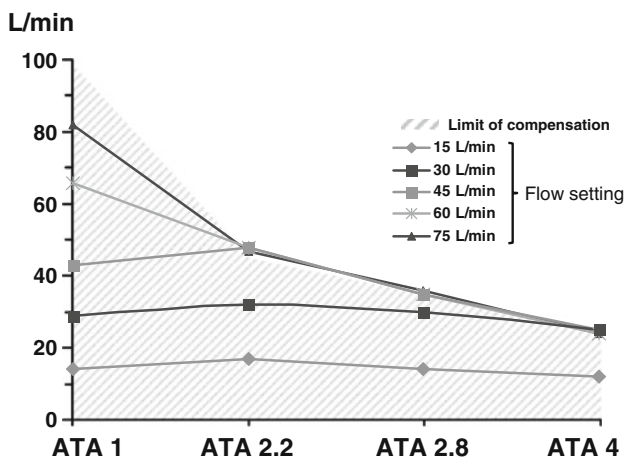


Fig. 1 Changes in peak flow with increasing atmospheric pressure. The figure shows the change in measured peak flow at various flow settings and ambient pressures. The IPER 1000 maintains a stable flow despite increasing atmospheric pressure, but only up to the point where the predicted flow_{max} is reached. This flow_{max} decreased with increasing ATA level. From the flow_{max} values at each ATA level (99 l min⁻¹ at 1 ATA, 45 l min⁻¹ at 2.2 ATA, 35 l min⁻¹ at 2.8 ATA and 25 l min⁻¹ at 4 ATA), a schematic zone of compensation can be represented (hatched area). ATA absolute atmosphere, flow_{max} predicted maximal attainable flow

Table 1 Evaluation in volume control of the delivered tidal volume at various atmospheric pressures (ATA level)

ATA	Set V_T (ml)	V_T predicted by gas laws (ml)	Inspiratory:expiratory ratio		
			1:2 V_T (ml)	1:3 V_T (ml)	1:4 V_T (ml)
1	250	250	<i>V_{Tmax} 2,200</i> 245	<i>V_{Tmax} 1,650</i> 245	<i>V_{Tmax} 1,320</i> 240
	500	500	485	485	485
	750	750	740	760	815
	1,000	1,000	1,070	1,110	1,120
2.2	250	168	<i>V_{Tmax} 1,000</i> 300	<i>V_{Tmax} 750</i> 290	<i>V_{Tmax} 600</i> 280
	500	335	545	550	550
	750	502	830	830	655
	1,000	670	1,065	815	645
2.8	250	150	<i>V_{Tmax} 785</i> 235	<i>V_{Tmax} 590</i> 240	<i>V_{Tmax} 475</i> 245
	500	300	495	520	470
	750	450	770	590	475
	1,000	600	775	590	495
4	250	125	<i>V_{Tmax} 550</i> 205	<i>V_{Tmax} 415</i> 210	<i>V_{Tmax} 330</i> 220
	500	250	445	420	325
	750	375	535	405	330
	1,000	500	550	405	330

Measured V_T s are depicted and compared to set V_T . Data in black indicate the proper compensation with settings inside the compensation range of the ventilator (set V_T under V_{Tmax}). With settings outside the range, the V_T decreased with increasing ATA level (italic values). When the range was exceeded, close agreement was

observed between the measured V_T and predicted V_{Tmax} , confirming our calculations

ATA absolute atmosphere, V_T tidal volume, V_{Tmax} predicted maximal V_T for a given setting and ATA level

Table 2 Practical user's guide for the IPER 1000 in volume-control mode

I:E ratio	Predicted V_{Tmax} (mL)											
	2.2 ATA			2.8 ATA			4 ATA			6 ATA		
	1:2	1:3	1:4	1:2	1:3	1:4	1:2	1:3	1:4	1:2	1:3	1:4
Rate												
10	1500	1125	900	1180	885	705	825	620	495	550	415	330
15	1000	750	600	785	590	470	550	415	330	365	275	220
20	750	565	450	590	440	355	415	310	250	275	205	165
V_{Emax} (l min ⁻¹)	15.0	11.3	9.0	11.8	8.9	7.1	8.3	6.2	5.0	5.5	4.2	3.3

Based on theoretical predictions and experimental measurements, the predicted V_{Tmax} is presented according to the ATA level and frequently used combinations of the respiratory rate and inspiratory:expiratory ratio. The predicted V_{Emax} is also shown in bold

ATA absolute atmosphere, V_{Tmax} predicted maximal V_T in given conditions, V_{Emax} predicted maximal minute ventilation

tested because their use is not approved with the IPER 1000, but wide variations in V_T should be expected.

It can be appreciated that a hyperbaric environment poses a challenge for manufacturers; the alternatives to the IPER 1000 also have limitations. With monoplace chambers, the ventilator unit is kept outside of the chamber. The Sechrist 500A and the Omni-vent have been used in this context, but limited performances and capabilities (control mode only) were shown by Weaver et al. [11, 12]. For multiplace chambers, the ventilator must be placed in the enclosure, allowing manipulations by the caregivers. Most of the ventilators tested in one

report have shown unacceptable performance, mainly because of insufficient V_E [5]. Some older devices, such as the Monaghan 225, have also been used in the past, but technical support is now difficult with these devices [13]. Modified standard ICU ventilators have been bench tested with variable results, but none are currently approved for use in clinical practice [4]. Despite not being approved for hyperbaric use, the Impact UNI-VENT Eagle 754 ventilator was shown to provide a stable V_E under various supra-atmospheric pressures [14]. The recently FDA-approved Atlantis ventilator also has generated a lot of interest, but also suffers from several drawbacks as it

provides only control ventilation and is devoid of alarms, and the compensation mechanism is not in function when used in a multiplace chamber. Interestingly, a hyperbaric-compatible version of the Servo-i (Maquet, Solna, Sweden) is expected on the market by mid-2012.

Conclusion

The Siaretron IPER 1000 ventilator attempts to maintain a constant V_T at various ambient pressures by adjusting the

inspiratory valve opening. Clinicians should be aware of the range of compensation, which is predictable for each ATA level. Setting a V_T outside the range can result in an unwanted decrease in V_E with adverse clinical consequences. The maximal V_E provided by the ventilator may be insufficient, especially at high ATA levels and for patients with lung injuries and moderate-high ventilatory needs. The manufacturer should consider restricting the settings to those within the operational range of the ventilator.

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