

A bench evaluation of fraction of oxygen in air delivery and tidal volume accuracy in home care ventilators available for hospital use

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Background: Turbine-powered ventilators are not only designed for long-term ventilation at home but also for hospital use. It is important to verify their capabilities in delivering fraction of oxygen in air ($F_{I}O_2$) and tidal volume (V_T).

Methods: We assessed the $F_{I}O_2$ accuracy and the V_T delivery in four home care ventilators (HCV) on the bench. The four HCV were Astral 150, Elisée 150, Monnal T50 and Trilogy 200 HCV, which were connected to a lung model (ASL 5000). For assessing $F_{I}O_2$ accuracy, lung model was set to mimic an obstructive lung and HCV were set in volume controlled mode (VC). They supplied with air, 3 or 15 L/min oxygen and $F_{I}O_2$ was measured by using a ventilator tester (Citrex H4TM). For the V_T accuracy, the lung model was set in a way to mimic three adult configurations (normal, obstructive, or restrictive respiratory disorder) and one pediatric configuration. Each HCV was set in VC. Two V_T (300 and 500 mL) in adult lung configuration and one 50 mL V_T in pediatric lung configuration, at two positive end expiratory pressures 5 and 10 cmH₂O, were tested. V_T accuracy was measured as volume error (the relative difference between set and measured V_T). Statistical analysis was performed by using one-factor ANOVA with a Bonferroni correction for multiple tests.

Results: For Astral 150, Elisée 150, Monnal T50 and Trilogy 200, $F_{I}O_2$ averaged 99.2%, 93.7%, 86.3%, and 62.1%, respectively, at 15 L/min oxygen supplementation rate ($P < 0.001$). Volume error was $0.5\% \pm 0\%$, $-38\% \pm 0\%$, $-9\% \pm 0\%$, $-29\% \pm 0\%$ and $-36\% \pm 0\%$ for pediatric lung condition ($P < 0.001$). In adult lung configurations, Monnal T50 systematically over delivered V_T and Trilogy 150 was sensitive to lung configuration when V_T was set to 300 mL at either positive end-expiratory pressure (PEEP).

Conclusions: HCV are different in terms of $F_{I}O_2$ efficiency and V_T delivery.

Keywords: Home care ventilators (HCV); intermediate care; tidal volume (V_T); fraction of oxygen in air ($F_{I}O_2$); life support

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Introduction

Ventilators can be used in a large variety of medical settings including operating room, pre-hospital setting, emergency room, pneumology ward, intensive care unit (ICU), and at home for long-term mechanical ventilation. ICU ventilators and home care ventilators (HCV) are fundamentally different.

Comparison of differences of ICU and HCV

Of notice, ICU ventilators are fed by pressurized gas and allow direct setting of accurate inspiratory fraction of oxygen in air ($F_{I}O_2$) over a wide range (21–100%). HCV are piston- or turbine-driven and are limited in their capability to deliver high $F_{I}O_2$. Turbine-driven ventilators can be used in the ICU setting and have been shown to perform in the range of the newest ICU ventilators in terms of triggering sensitivity and quality of pressurization (1). On the bench and in patients dedicated ventilators to noninvasive ventilation were found with a better patient-ventilator synchrony than ICU ventilators even if these latter were set with their specific noninvasive mode (2-4).

Problems of $F_{I}O_2$ and tidal volume (V_T), use and indications of HCV in hospital and ICU

In the hospital setting HCV can be used to provide non-invasive ventilator support to patients with mild to moderate acute respiratory failure (5). Moreover, HCV could be of importance in specific situations e.g., during ICU bed or ICU ventilator shortage during pandemics or other multi-patient situations. It is, therefore, very important to verify that these ventilators have the right capabilities to meet patients' needs. The advantage of a turbine is that it means the ventilator can operate without high-pressure compressed air. The potential limitations of a turbine include the risk of the gas reaching a high temperature at the ventilator outlet, the lack of accuracy in $F_{I}O_2$ when the oxygen is added, and the lack of accuracy V_T delivery for patients with a marked impairment in respiratory mechanics (6). A previous bench study demonstrated acceptable temperatures at the outlets of turbine ventilators, and hence a very low risk of humidifier dysfunction (7). One bench study pointed out heterogeneity in V_T delivery with HCV and mouthpiece (8). $F_{I}O_2$ delivery and V_T accuracy in HCV have received less attention. Thus, we carried out the present bench study to investigate the performance of the HCV, all of them used in our ICU and hypothesized that HCV differed for both $F_{I}O_2$

delivery and V_T accuracy.

Methods

Present study was not submitted to an IRB because it was a bench study that did not involve and include any patients.

Equipment

The set-up comprised of the following items (*Figure 1*): (I) Four HCV: Astral 150 (ResMed), Elisée 150 (ResMed), Monnal T50 (Air Liquide Medical System), and Trilogy 200 (Philips); (II) the ASL 5000 Active Servo Lung model (IngMar Medical, Pittsburgh, PA, USA); (III) a ventilator tester (Citrex H4TM, imtmedical, Buchs, Switzerland), which contains devices for measuring oxygen concentration in the air, gas temperature and pressure; (IV) a double limb ventilator circuit (Intersurgical, Fontenay Sous-bois, France) of 22 mm internal diameter (ID) and 1.70 m length per limb; (V) a flow-meter (Floval, Air Liquide Médical System, Antony, France) to adjust the rate of oxygen supply delivered from the wall at high pressure (3.5 bars). The four HCV and the ICU ventilator presently investigated were selected because they are used in our unit composed of a 15-bed medical ICU, a 5-bed step down unit, and a 6-bed respiratory medicine unit which is responsible for long-term home ventilated patients. The Astral 150, Elisée 150, Monnal T50 are used in our ICU and were purchased by the institution, and the Trilogy 200 was provided by the manufacturer. However, for the purposes of the present study the four HCV used were all brand-new devices provided by the manufacturers.

Protocol

The experiments were conducted in our laboratory at room temperature. Before the measurements were taken the tester was calibrated then plugged into the ASL 5000 and connected to a laptop computer. The ventilators were submitted to a full test before use according to the manufacturer's recommendations.

The protocol comprised of two parts.

The first part evaluated the delivery of $F_{I}O_2$. The ASL 5000 was set to passive condition, with lung compliance (C) and resistance (R) mimicking obstructive lung: nonlinear C 75 mL/cmH₂O, inspiratory R 15 cmH₂O/L/s and expiratory R 25 cmH₂O/L/s. HCV were used in volume controlled mode (VC) at constant flow inflation and set to V_T 500 mL, positive end-expiratory pressure (PEEP) 5 cmH₂O,

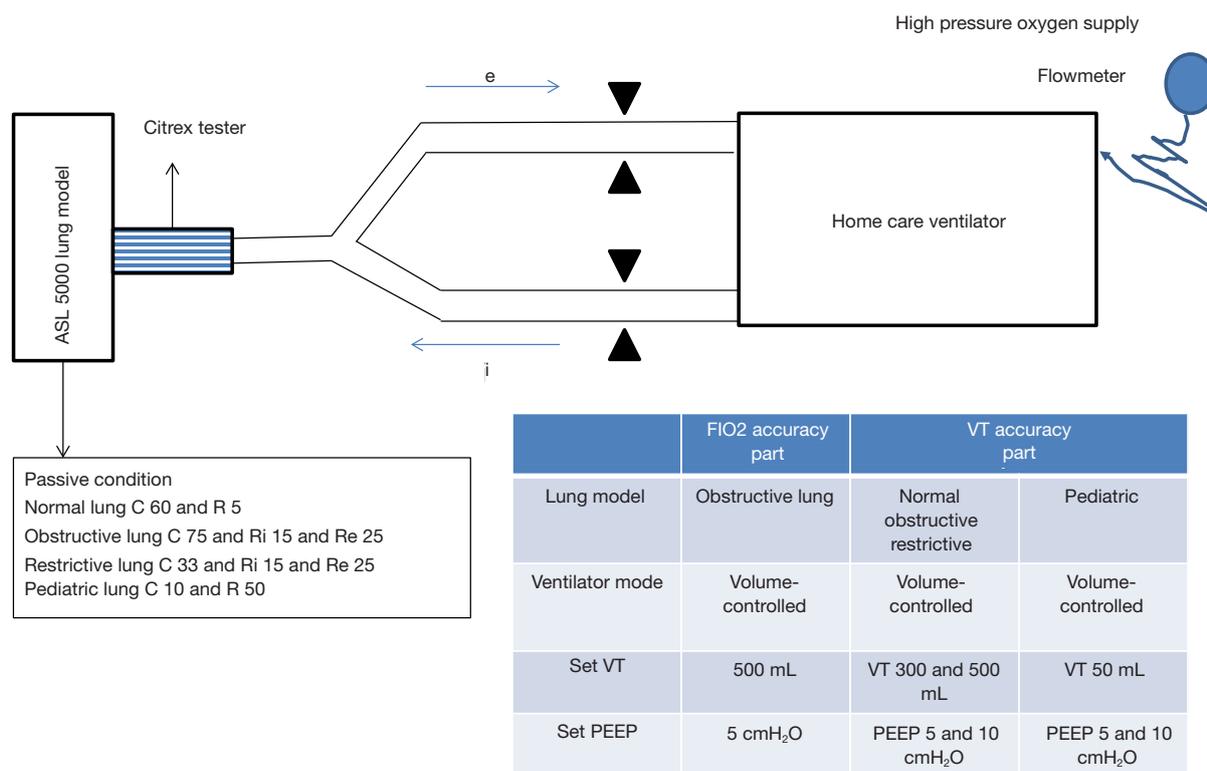


Figure 1 Schematic drawing of the measurement set-up with settings of ASL 5000 lung model and conditions tested. The symbols indicate inspiratory and expiratory valves. C, compliance in mL/cmH₂O; R, resistance in cmH₂O/L/s; i, inspiration; e, expiration; F_IO₂, fraction of oxygen in air; VT, tidal volume; PEEP, positive end-expiratory pressure.

breathing frequency 15 cycles/min and inspiratory time 0.8 s, inspiratory trigger off. The HCV was supplied with room air or pure oxygen from the hospital wall at rates of 3 and 15 L/min. Oxygen was administered to the rear of the HCV via a specific low pressure plug, which was the same across the ventilators. The F_IO₂ signal was recorded at 200 Hz and continuously displayed on the computer screen. Each level of gas was supplied to the ventilator until F_IO₂ reached a plateau.

The second part of the study evaluated the accuracy of V_T delivery. The ASL 5000 was set in passive mode to mimic a normal adult lung (linear C 60 mL/cmH₂O, inspiratory and expiratory R 5 cmH₂O/L/s), an obstructive lung as described above, or restrictive lung (linear C 33 mL/cmH₂O, inspiratory R 15 cmH₂O/L/s and expiratory R 25 cmH₂O/L/s) and to mimic pediatric lungs (linear C 10 mL/cmH₂O, inspiratory and expiratory R set to 50 cmH₂O/L/s). The HCV were set in VC, with triggering off. For the three adult conditions the target V_T was 300 and 500 mL, each tested at both 5 and 10 cmH₂O PEEP. Target V_T of 50 mL was tested for

the pediatric lung conditions at the same PEEP levels. All ventilators were set to body temperature pressure saturated (BTSP). The volume signal was acquired at 200 Hz for 2 min under each condition.

The various settings used to determine the lung configurations at the ASL 5000 lung model were taken from the literature and notably from (9-11) for the obstructive lung, (12) for the restrictive lung and (13-16) for the pediatric lung.

No leak, either intentional or nonintentional, was present in our experimental set-up.

Data analysis

We used Flowlab software (imtmedical, Buchs, Switzerland) to measure both F_IO₂ and V_T because our ASL 5000 was not equipped to measure F_IO₂. The accuracy of the Citrex H4TM device is ±1% for F_IO₂ measurement and ±2% for volume measurement.

F_IO₂ was measured over the last ten breaths during the

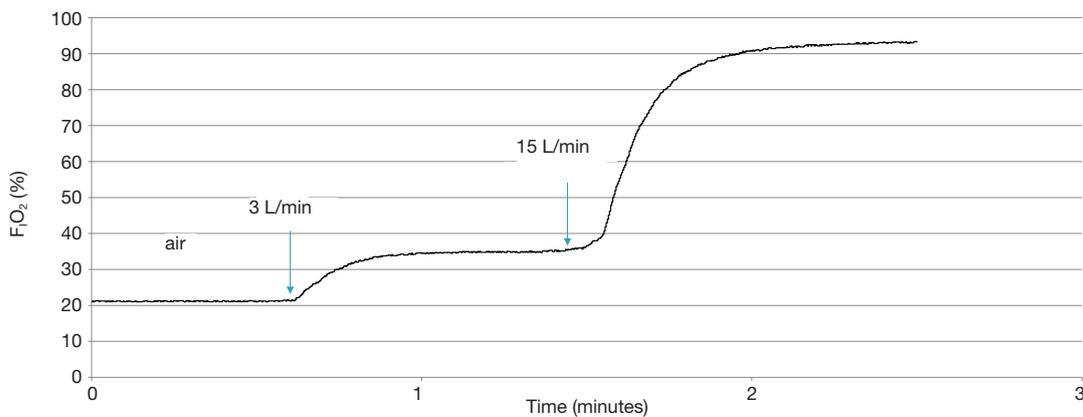


Figure 2 Tracing of fraction of oxygen in air ($F_{I}O_2$) over time at three rates of oxygen supplementation with the Elisée 150 ventilator. Arrows indicate the time at which the rate of oxygen supplementation was changed.

plateau in $F_{I}O_2$. Plateau was defined as an average change in $F_{I}O_2 < 10\%$ as compared to the previous ten breaths. For each ventilator, at each oxygen supply rate and each ventilator circuit, the values of $F_{I}O_2$ were averaged over ten consecutive breaths.

Ten consecutive breaths were used to measure V_T . The volume error was defined as follows:

$$(\text{measured } V_T - \text{targeted } V_T) / \text{targeted } V_T \times 100$$

and expressed as percentage. A positive or a negative value for the volume error indicates overestimation or underestimation, respectively, of the measured volume relative to the value set on the ventilator.

Given the nature of the investigation, i.e., a bench experiment, we expected no or very low within-ventilator variability for the $F_{I}O_2$ and V_T values, for any given ventilator and condition tested. It was therefore decided, a priori to not perform statistical tests if this assumption was verified. Therefore, any observed differences in mean $F_{I}O_2$ and V_T were considered as true. In case of standard deviations different from zero the statistical analysis was done and the comparison between ventilators was performed by using one-factor ANOVA with a Bonferroni correction for multiple tests.

The data are presented as mean \pm standard deviation unless otherwise stated. The accuracy of V_T delivery was defined within a range of $\pm 10\%$ on both sides of the mean value for volume error. This 10% value was chosen because it is the average difference in lung volume between BTPS and ambient temperature pressure dry conditions and, is therefore relevant. It has also been used in previous studies, including one of the recent bench evaluation of ventilators (17).

The statistical analysis was carried out using R software, version 2.15.2 (R Development Core Team. R: A Language and Environment for Statistical Computing. In Vienna, Austria: R Foundation for statistical Computing; 2009).

Results

$F_{I}O_2$ efficiency

Three experiments were performed for each ventilator for this part of the study. A representative tracing of continuous $F_{I}O_2$ measurement at different oxygen supplementation rates is shown in *Figure 2*.

For each given ventilator and condition, the measurements were mostly identical except in two cases with very low variability, namely Monnal T 50 at 3 L/min oxygen flow rate and Astral 150 at 15 L/min flow rate (*Table 1*). According to our statistical strategy we performed the statistical comparisons between ventilators at these oxygen flow rates and used Monnal T50 and Astral 150 as controls (*Table 1*). There were no differences between the ventilators when they were supplemented with air (*Table 1*). Under oxygen supply at 3 L/min flow rate, the $F_{I}O_2$ values delivered with the Astral 150, Elisée 150 and Trilogy 200 were significantly different from those with the Monnal T50. At 15 L/min the values of $F_{I}O_2$ were significantly higher with the Astral 150 than with any other HCV (*Table 1*).

Accuracy of V_T delivery

Twelve and two experiments were performed for each ventilator for the adult lung configuration ($2 V_T \times 2$ PEEP

Table 1 $F_{I}O_2$ results for four HCV at different oxygen supply rates

Ventilator	Oxygen flow rate supply (L/min)		
	0	3	15
Astral 150	21.6±0.0	41.6±0.0*	99.2±0.3
Elisée 150	21.5±0.0	34.8±0.0*	93.7±0.0**
Monnal T 50	20.8±0.0	40.1±0.1	86.3±0.0**
Trilogy 200	22.1±0.0	29.6±0.0*	62.1±0.0**

Values are expressed in %. Values are mean ± standard deviation. *, $P < 0.001$ vs. Monnal T 50; **, $P < 0.001$ vs. Astral 150; $F_{I}O_2$, fraction of oxygen in air; HCV, home care ventilators.

× 3 lung configurations) and for the pediatric lung condition (1 V_T × 2 PEEP × 1 lung configuration), respectively. For each given ventilator and every single condition, the measurements were identical, the standard deviation being nil in every instance. Therefore, according to our statistical approach no statistical comparison was performed.

In the adult configurations the Monnal T50 systematically over-delivered V_T by more than 10% (Figures 3,4), except for target V_T of 500 mL at PEEP 10 (Figure 3). In the normal lung condition the remaining three HCV delivered V_T within the 10% accuracy range and these values were very similar to each other. In the obstructive lung condition the Trilogy 200 delivered V_T above the 10% upper limit of accuracy whilst the Astral 150 and the Elisée 150 were within the 10% bounds and gave very similar values. For the restrictive lung condition, the three HCV Astral 150, Elisée 150 and Monnal T50 produced similar values. These results were consistent for target V_T 300 mL at both PEEP levels (Figure 3). For target V_T 500 mL, the V_T delivered by the HCV was within the 10% range for accuracy (Figure 3), except for the Monnal T50. The three HCV Astral 150, Elisée 150 and Trilogy 200 gave very similar values.

For the pediatric condition, Astral 150 over delivered V_T by less than 1% (0.47%±0%). This is in sharp contrast with the V_T error found with the other HCV. At PEEP 5, it amounted to -38%±0% for Elisée 150, -29%±0% for Monnal 50 and -9%±0% for Trilogy 200 (Figure 4) ($P < 0.001$ between ventilators by using one-factor ANOVA). The results were essentially the same at PEEP 10, except for the Monnal 50 that fell into the range of accuracy (-7%±0%) and was statistically significantly more accurate than the Trilogy (Figure 4). As can also be seen in Figure 4, the reproducibility of V_T from breath to breath was very high.

Discussion

The main findings of the present bench investigation were that the Trilogy 200 and Astral 150 met the 10% standard for V_T delivery and the Astral 150, Elisée 150 and Monnal T50 HCV provided the most efficient use of oxygen.

Our hypothesis of very low variability between $F_{I}O_2$ and V_T values was verified. Hence, no statistical tests were performed when the standard deviation was nil, and the differences in means were considered as true. It should be mentioned that we used ten consecutive breaths in our analysis. Should a much greater number of breaths has been used some variability may have been present but it is unlikely this would have changed the results.

$F_{I}O_2$

HCV are not equipped with gas blender and, hence most of them have a low-pressure inlet for oxygen supplementation. In present study, the $F_{I}O_2$ values reached at the 15 L/min oxygen rate supply were high, in particular with the Astral 150 and Elisée 150 machines. With the BiPAP synchrony device (18) $F_{I}O_2$ averaged 0.60 at best with a 10 L/min oxygen supply. With the Breathe ventilator, delivered $F_{I}O_2$ ranged from 0.36 to 0.45 (19). In contrast, the portable ventilator LTV 1000 (Pulmonetic systems) delivered $F_{I}O_2$ up to 90% when supplied with oxygen at a 10 L/min flow rate (20). Different factors may influence $F_{I}O_2$ values during non-invasive ventilation (21). Leaks are one of them (22). In the present study we did not investigate the effect of non-intentional leaks on $F_{I}O_2$. The site of oxygen injection also influences the value of $F_{I}O_2$. Dai *et al.* (18) measured $F_{I}O_2$ at four different oxygen injection locations, i.e., at the ventilator, the humidifier, the mask or the exhalation valve, and found that the closer the site was to the patient, the higher the $F_{I}O_2$. In the present study oxygen supplementation was administered at the rear of the ventilator in each case. The two ventilators that achieved the highest values of $F_{I}O_2$ (Astral 150 and Elisée 150) are made by the same manufacturer, which suggests that the mixing of air and oxygen that comes from the regulation of the corresponding valves is better than for the other ventilators tested. Another possibility is that these ventilators better accommodate the speed of the turbine facing high rate of oxygen supply, however this is more unlikely. The most likely factors contributing to high $F_{I}O_2$ are low bias flow during expiration and control of the oxygen entering the turbine from a reservoir inside the ventilator. This is how

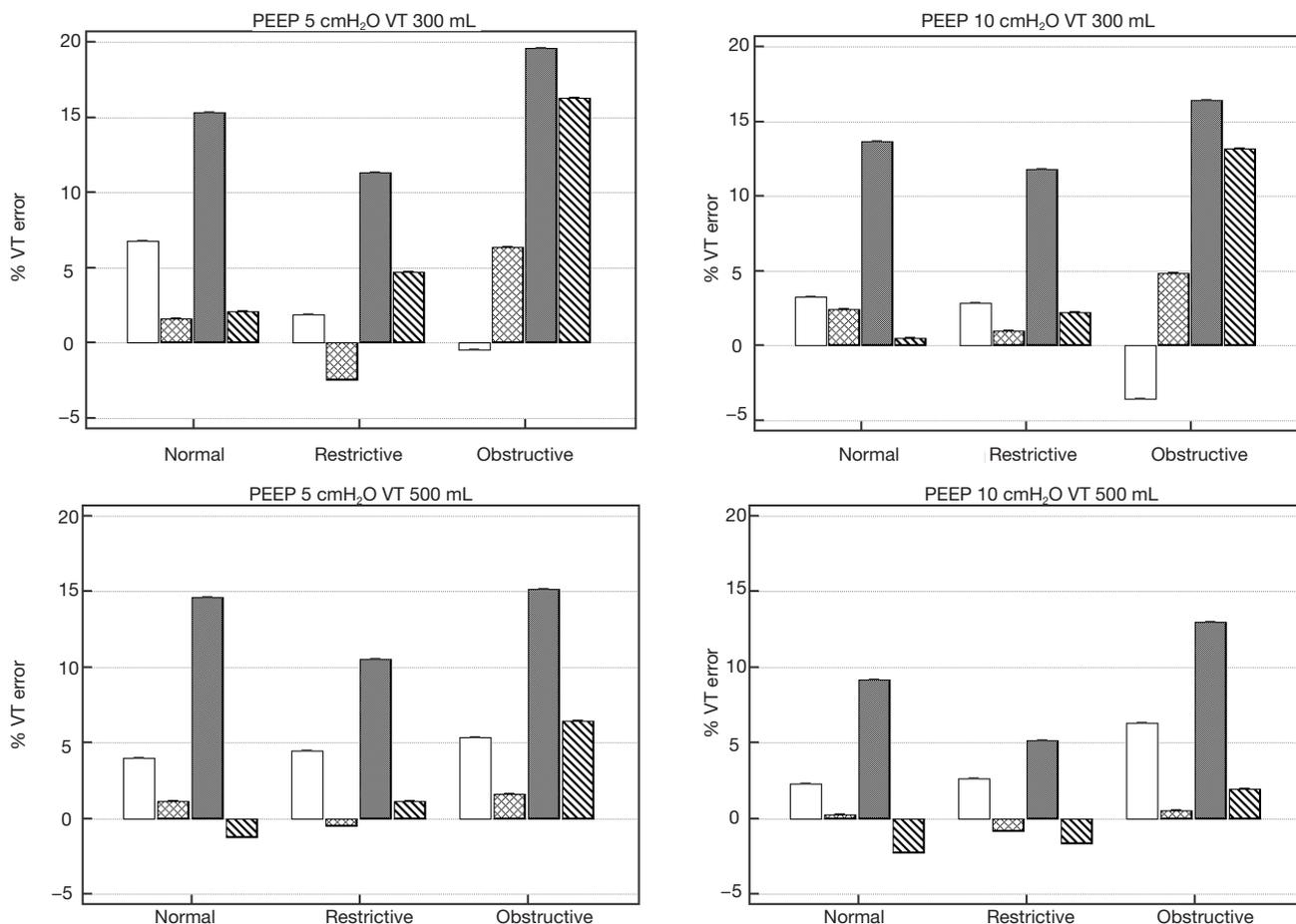


Figure 3 Values for the percentage error in tidal volume (V_T) delivery for V_T set to 300 and 500 mL across all ventilators for normal, obstructive and restrictive lung at both 5 and 10 cmH₂O positive end-expiratory pressure (PEEP). Rectangles are the mean. Horizontal bars are standard deviations if greater than mean. White rectangles Astral 150, crossed-marked rectangles Elisée 150, grey rectangles Monnal 50 and hatched Trilogy 200 ventilator.

the LTV achieves high $F_{I}O_2$. Finally, although high $F_{I}O_2$ can be achieved with turbine ventilators, the stability of $F_{I}O_2$ is not guaranteed as changes in respiratory rate and minute ventilation may influence $F_{I}O_2$ (20). $F_{I}O_2$ with HCV is also influenced by the inspiratory flow rate or inspiratory time of the spontaneous breath because the mixing rate of air and O_2 can change with circuit flow. This situation was not explored in the passive setting used in this study. As our study was designed for the bench it allowed us to focus solely on the operational performance of the machine itself.

V_T

V_T delivery must match the physician's prescription as

closely as possible. As well as the ventilator's ability to achieve the target V_T , gas compression in the ventilator circuit, and gas expansion under increased temperatures may also influence the amount of V_T and hence should be properly taken into account by the algorithms (2).

For the adult lung configuration in the present study three ventilators consistently delivered V_T within the 10% accuracy range, in almost all instances, namely the Astral 150, Elisée 150 and Trilogy 200. The Monnal T50 systematically departed from the 10% upper bound for accuracy indicating over delivery of V_T . The Trilogy 200 was above the 10% upper bound for accuracy in the obstructive lung configuration. In the normal lung condition, the volume error was similar for the Elisée and Trilogy, but lower with

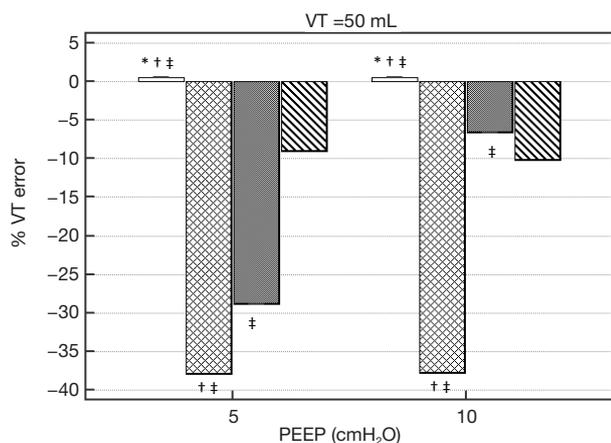


Figure 4 Values of percentage error in tidal volume (V_T) delivery for V_T set to 50 mL across all ventilators for pediatric condition at both 5 and 10 cmH₂O positive end-expiratory pressure (PEEP). Rectangles are the mean. Horizontal bars are standard deviations if greater than mean. White rectangles Astral 150, crossed-marked rectangles Elisée 150, and grey rectangles Monnal 50 and hatched rectangles Trilogy 200 ventilator. *, $P < 0.05$ vs. Elisée; †, $P < 0.05$ vs. Monnal; ‡, $P < 0.05$ vs. Trilogy.

the Astral and Monnal ventilators. This comparison holds true for both V_T and both PEEP levels. In the obstructive lung configuration, the volume error for the Astral was lower than the Monnal and Trilogy. In the restrictive lung configuration, the volume error for the Astral, Elisée and Trilogy was similar and departed markedly from the Monnal, which over delivered V_T . Blakeman *et al.* compared V_T delivery in VC in seven turbine-driven ventilators in a lung model set to 50 mL/cmH₂O C and 10 cmH₂O/L/s R (23). For a target V_T of 400 mL, Trilogy 200 delivered 362 mL on average, which was exactly the same as the V_T delivered by this ventilator in present study. These results were obtained in a configuration close to our normal condition so this finding is consistent with the present results. Unfortunately for the purposes of comparison, obstructive and restrictive lung configurations were not used in the study by Blakeman *et al.* (23). In our study we found that HCV tended to over deliver V_T in the obstructive lung as compared to the normal or restrictive lung condition. This was particularly true for target V_T of 500 mL. Given the configurations used in our study, it appears that the over delivery of V_T in the obstructive lung profile by the HCV may result from higher C. For the pediatric lung configuration, apart from the Astral 150 that delivered V_T within less than 1%, the other ventilators systematically delivered V_T up to 40% below

target. Present results showed that some HCV can achieve very low V_T accurately. The importance of lowering V_T in patients receiving mechanical ventilation is now largely supported by the evidence, showing improved outcomes as compared to higher V_T , not only for patients with ARDS (24) but also for patients with normal lungs both in the ICU (25) and in the operating room for elective surgery (26). Therefore, a ventilator's ability to accurately deliver V_T goes hand in hand with the clinician's ability to select low V_T for the patients under her/his responsibility. When doing so, the clinician must also have complete confidence in the performance of the ventilator used.

In a previous bench study the Trilogy was tested at low target V_T (23) and was found to accurately deliver V_T For 50 ml target V_T , measured V_T averaged 51 mL with the Trilogy, a result which is in sharp contrast with the present finding. Two reasons might explain the discrepancy between the two studies. One is the lung model used, as the previous study used the Training Test Lung pneumatic model. The second is that in the study by Blakeman *et al.* (23) lung C was set to 25 mL/cmH₂O (*vs.* 10 mL/cmH₂O in our study) and R to 20 cmH₂O/L/s (*vs.* 50 cmH₂O/L/s). We observed in present study that V_T error differs significantly across the lung configurations for a given ventilator. This was particularly the case for the Trilogy regarding obstructive lung configuration at V_T 300 mL (*Figure 3*). This finding is a concern as in volume control the ventilator should deliver a target V_T , with little variation as specified by the manufacturer. Thus, if there is a noticeable difference, the reasons could be either the followings: (I) the ventilator is not performing as stated by the manufacturers; (II) leaks, which were lacking in our study as discussed below; (III) circuit compensation, which is unlikely because the C of circuit was measured before the experiment for each ventilator, this option was activated during the experiment and the same circuit was used for every ventilator; (IV) accuracy of flow meter used for the working processing in the ventilator; (V) variability across ventilators (we tested at random one specimen); (VI) the difference in pressure generated by the different lung configurations that can impact on the measurement of flow depending on the flowmeter used in each ventilator. To address the issues IV to VI, a specific study should be done.

Limitation and strengths

The main limitation of the present study is that it is a bench study and hence our results cannot be extrapolated

to patients. Furthermore, different results might have been obtained if different settings had been used in the lung model. However, the results of present study do support the interest of conducting *in vivo* investigations in patients. Another limitation is the absence of leak in our experimental set-up. This could be seen as a weakness of present study because results would be different in presence of leaks, either intentional or nonintentional, which limits the generalizability of present findings. This concern applies for V_T , $F_{I}O_2$ and also PEEP. In a study on ICU ventilators, Garnier *et al.* recently found that leaks made less accurate the values of V_T and PEEP shown at the ventilator (17). We did not use any leak in our study because we aimed at making the clearest assessment as possible of the accuracy of both $F_{I}O_2$ and V_T delivery avoiding any other confounding factor.

Conclusions

The Astral 150, Elisée 150 and Monnal T50 were able to deliver high enough $F_{I}O_2$ than the Trilogy 200. The Astral 150 delivered low V_T accurately in the condition of very low lung C and high lung R, Monnal 50 systematically over delivered V_T and Trilogy 150 was sensitive to lung configuration when V_T was set to 300 mL at either PEEP.

Acknowledgements

None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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