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Harms of Unintentional Leaks during Volume Targeted Pressure Support Ventilation

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Running Title: Efficiency of Targeted Volume Mode

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Abstract

Background: Volume targeted pressure support ventilation (VT-PSV) is a hybrid mode increasingly used to maintain a minimal tidal volume (VT) by automatically adjusting the level of inspiratory pressure. The objective of the study was to determine the ability of home ventilators to maintain the preset minimal VT during unintentional leaks in a VT-PSV mode.

Methods: Seven ventilators were tested on a lung bench with different circuit configurations and with different levels of unintentional leaks. Unintentional leaks were generated using calibrated holes.

Results: All the studied ventilators with a single-limb circuit with intentional leak (n=5) were able to maintain the minimal preset VT during unintentional leaks. One ventilator overcompensated VT during unintentional leaks of high intensity. In contrast, all studied ventilators with a single circuit with an expiratory valve (n=2) or a double-circuit (n=3) but one failed to maintain the minimal VT during unintentional leaks. Unintentional leaks generated a decrease in inspiratory pressure, which was responsible for the fall in VT.

Conclusions: Most of the studied ventilators with a single-limb circuit with intentional leak correctly estimate the expiratory VT and therefore successfully maintain the preset minimal VT during unintentional leaks, in contrast to most of the studied ventilators with a double-circuit, which paradoxically are not able to directly measure expiratory VT. Importantly, the VT-PSV mode, when used with most ventilators with expiratory valve or double-circuit, can paradoxically exacerbate the VT drop during unintentional leaks.

Key words: Home ventilators; Pressure support; Unintentional leaks; Volume targeted; Hybrid mode; Ventilatory circuit.

Introduction

Volume-targeted pressure support (VT-PSV) modes, which include average-volume-assured pressure support (AVAPS), are relatively new ventilatory modes which aim to guarantee a minimal tidal volume (VT) via an automatic adjustment of the inspiratory airway pressure. The aim of these modes is to ensure the maintenance of adequate ventilation during changes in pulmonary mechanics such as may occur during sleep.[1-3] An initial randomized-controlled cross-over trial suggested that the addition of AVAPS to pressure-preset non-invasive positive pressure ventilation resulted in better control of nocturnal ventilation compared with pure pressure-preset ventilation in patients with obesity hypoventilation syndrome.[4] Successive trials showed comparable outcomes, even though nocturnal hypoventilation was better controlled in some trials.[5] However, in one study, polysomnographic sleep quality appeared to be reduced during AVAPS.[6] Moreover, one recent randomized-controlled trial in adults with obesity hypoventilation syndrome did not show either any significant difference between a bi-level pressure support or AVAPS modes.[7] Therefore, the evidence for target volume setting remains questionable, and clear benefits and efficiency of these hybrid modes of ventilation remain to be assessed.[5]

The ability to automatically increase the inspiratory pressure during leaks has been evaluated using home ventilators having a “volume guarantee” module.[8] However, the maintenance of a minimal VT during a unintentional leak was more difficult and was associated with large variations in VT, a default of pressure support delivery for some devices, and patient-ventilator dyssynchrony, both during bench and *in vivo* study.[8] The presence of an inspiratory pressure increase during leaks was considered as the indication

that “volume guarantee” ventilation remained effective. However, the unintentional leaks were initiated with the inspiratory pressure set at the minimal level, which precluded the detection of a possible decrease in inspiratory pressure if VT decreased below the target VT.

The VT-PSV mode is increasingly popular and is now available on many home devices, including bi-level ventilators having a single-limb circuit with an intentional leak and ventilators that can be used with an expiratory valve and/or with a double-limb circuit.[3-4-6-7-10-11] It is unclear how these different home ventilator configurations estimate VT. If the ventilator program software equates VT as the volume delivered by the ventilator (VTv), the estimation will be correct only in the absence of unintentional leaks. During pressure-support ventilation with leaks, the inspiratory flow increases to reach the target inspiratory airway pressure.[12] Equating VT to VTv may paradoxically result in inspiratory pressure adjustment to a lower level during unintentional leaks, which may worsen the fall in VT. Moreover, Contal *et al.*[9] recently showed that the simple estimation of VT and leak by home ventilator software is far to be always accurate. Such an inaccuracy is clearly a problem to propose a minimal VT via VT-PSV.

In this study we evaluated in our bench the ability of some home ventilators available in France to maintain the preset minimal VT during unintentional leaks with the VT-PSV mode and different circuit configurations (single-limb and double-limb circuits).

Material and Methods

Experimental bench

We tested seven home ventilators with the VT-PSV mode, available in France (table 1). Each ventilator was connected via its standard circuit (single-limb circuit with intentional leak or expiratory valve, double-limb circuit) to a chamber Michigan test lung (MII Vent Aid TTL, Michigan Instruments, Grand Rapids, MI, USA) (Figure 1). To simulate the mechanical characteristics of the respiratory system, the compliance of the testing chamber was adjusted to 100 mL/cmH_2O and a parabolic resistance (Pneuflo® Airway Resistors, Rp5, Michigan Instruments; 2.7 cmH_2O/L·s^{-1} at 1 L·s^{-1} and 10.8 cmH_2O/L·s^{-1} at 2 L·s^{-1}) was added between the chamber and the ventilator.

Airway pressure (Paw) and flow were measured at the end of the ventilator circuit using a pressure transducer (Validyne DP 45±56 cmH_2O, Northridge, CA, USA) and a pneumotachograph (Fleisch n°2, Lausanne, Switzerland) with a pressure differential transducer (Validyne DP 45±3.5 cmH_2O), respectively. VT was obtained by integration of the flow signal. A short tube open to atmosphere and connected to a second pneumotachograph was placed between the ventilator and the pneumotachograph placed on the ventilatory circuit. Calibrated holes (RMT Valves, Ambu®, Le Haillan, France: 2 mm, 2.2 mm, 2.5 mm, 3.5 mm, 4.5 mm, and 5 mm of diameter) were fixed successively at the short tube ending to simulate inspiratory and expiratory unintentional leaks (Figure 2). A manual valve was present at the short tube entry in order to close the leakage. Simulated unintentional leaks were quantified using the second pneumotachograph. Signals were digitised at 200 Hz using an analogic/digital system (MP100, Biopac Systems, Goleta, CA, USA) and recorded on a microcomputer for further analysis.

Procedure

In pressure support ventilation (PSV) mode minimal inspiratory positive airway pressure (IPAP) was first adjusted to obtain a VT around 500 mL. Then, the VT-PSV mode was switched on and the minimal target VT was set to 700 mL in order to obtain an IPAP above the pre-set level. Positive end-expiratory pressure (PEEP) was set at 4 cmH_2O independently of the type of circuit in order to compare the ventilators under the same conditions. The back-up respiratory rate was set at 15/min and the inspiratory trigger was switched off when possible. Maximal IPAP was set as the maximum value possible. Table 1 summarised the different settings.

The protocol consisted of successive periods with increasing levels of unintentional leaks using the calibrated holes of increasing diameter, separated by periods without leaks. The unintentional leak and non-unintentional leak periods were maintained for a minimum of 2 minutes, until Paw achieved a steady state according to the ventilators algorithm. The following parameters were computed from each pressure and/or flow traces: level of Paw, VTv, inspiratory VT (VTi).

Results

The seven ventilators were tested with all their available circuits, which resulted in 10 different conditions (table 1). The VIVO 50 was the only ventilator that could be used with a single-limb circuit with intentional leak and with an expiratory valve.

Figure 3 shows the mean delivered VTi at each condition. Five ventilators could be used with a single-limb circuit with intentional leak. Among those, only the BiPAP AVAPS

and VIVO 50 ventilators when used with a single-limb circuit with intentional leak were able to adequately maintain VTi at its target value during unintentional leaks. PB560 tended to slightly undercompensate the target VTi with leak holes over 3.5 mm. BiPAP A30 and Trilogy 100 ventilators maintained VTi at the target value for leak holes ≤ 2.5 mm but then increased the VTi above the targeted VT as the unintentional leaks increased. Three ventilators could be used with a double-limb circuit. Among those, only the Monnal T50 overcompensated VTi levels as the unintentional leaks increased while in the 2 other ventilators, VTi fell below the preset minimal value during unintentional leaks. In the 2 ventilators with a single-limb circuit with expiratory valve, VTi fell below the preset minimal value during unintentional leaks, decreasing to the baseline value set before activating the VT-PSV mode (i.e. about 500 mL).

Figure 4 shows the changes in mean Paw during the different unintentional leaks. The trend of Paw followed the same pattern than VTi, explaining why the ventilators tended to under, overcompensate or maintain the target VTi.

Overshooting in VTi (increase of VTi > 20%) at the closure of the leak holes over 3.5 mm was observed in the Monnal T50 with the double-limb circuit, and the PB560 and VIVO 50 with single-limb circuit with intentional leak.

Figure 5 shows the changes in Paw during leakage through the 2.5-mm hole. The time-course of Paw differed across ventilators and circuit conditions. Paw remained quite stable with the ventilators with single-limb circuit with an intentional leak, during the unintentional leakage (maximal variation, 1 cmH_2O). However, Paw changed immediately with the ventilators with the double-limb circuit and expiratory valve,

increasing gradually with the Monnal T50™ and a double circuit and dropping rapidly with the others ventilators.

Discussion

This study shows that VT-PSV mode is effective during constant unintentional leaks in the studied ventilators that can be used with a single-limb circuit with an intentional leak. In contrast, all studied ventilators with a double-limb circuit but one (Monnal T50) and all studied ventilators with an expiratory valve misinterpreted leaks as an increase in VT and therefore decreased their inspiratory pressure to the minimal preset level, thereby paradoxically exaggerating the fall in VT.

In theory, when using a double-limb circuit, the simplest way to estimate the patient's VT during unintentional leaks should be to measure expiratory VT and to consider that VT is underestimated in case of expiratory leakage,[12] as occurs during speaking with mechanical ventilation.[13] By definition, ventilators with an expiratory valve have no expiratory circuit and no pneumotachograph connected to the patient interface. Consequently, these ventilators cannot measure expiratory VT and, therefore, the patient's real VT during unintentional leaks.

By measuring pressure and flow inside the ventilator, while taking in account the ventilator turbine speed throughout the entire respiratory cycle, and detecting the beginning and end of inspiration, the ventilators with circuit with intentional leak are able to rebuild the patient's flow pattern and to establish a "baseline" breathing pattern corresponding to the patient's zero flow (to obtain an expiratory VT equal to the VTi). As a result, all these ventilators but two almost adequately estimated expiratory VT during a

constant leak.[12-14] However, these devices may perform less well when the level of leakage varies, as occurs in clinical practice. The exceptions were the BiPAP A30 and Trilogy 100 ventilators, which overcompensated during severe leakage.

Surprisingly, two of the ventilators with a double-limb circuit tested in our study (Elisée 150 and PB560) did not measure the expiratory VT but the VTv, as observed by the VT values displayed on the ventilator screen (data not shown), which explain why they were therefore not able to compensate for unintentional leaks. Accordingly, we observed that changing the double circuit by single tubing and an expiratory valve did not modify the Elisée 150 behaviour (unpublished data). However, another double-limb circuit ventilator (Monnal T50) overestimated VT, because it equated expiratory VT to its target VT. By checking the expiratory leak, we confirmed that the excessive VT delivery by the Monnal T50 ventilator was due to expiratory leaks inducing underestimation of VT. However, the degree of underestimation was limited: for example, with leaks through the 2.5-mm hole, the volume returned to the expiratory circuit was only 545 mL but was considered by the ventilator to be 700 mL. In addition, with the Monnal T50 ventilator, the inspiratory pressure increase during leaks was very gradual (as was the inspiratory pressure decrease after discontinuation of the unintentional leaks, data not shown). This probably decreases the risk of “over” ventilation during leaks in clinical practice. In contrast, for the other devices producing inspiratory pressure decreases during unintentional leaks, the decreases occurred very early, within the first five cycles following leak initiation. The result may be an exaggerated risk of hypoventilation when the minimal inspiratory pressure is set at a low level.

As previously shown,[8] three ventilators were not able to rapidly decrease airway pressure at the end of a perturbation, leading therefore to an overshoot in pressure and VTi. Unfortunately we do not have any explanation for this important overshoot effect at high level of leaks. Like autotitrating continuous positive airway pressure devices,[15] VTPS systems are classic examples of a "black box". In essence, a black box is only known in terms of its output for any particular input; how that output is determined remains unknown. Under US and European administration regulations, marketing approval for a home ventilator device does not seem to require detailed descriptions of the current algorithms that determine the response of the machine to changes in respiratory system mechanics and leaks. Therefore, they are not explicitly disseminated, and when requested are said to be proprietary. Clinically, an overshoot of VT may cause hyperventilation and a decrease in the patient's respiratory effort, causing patient-ventilator dyssynchrony and eventually air leak injury.[8-16] Moreover, these overshoots with high pressure levels may lead to a low carbon dioxide tension crossing the apnea threshold, favoring the occurrence of periodic breathing, oxygen desaturations and microarousals.[17-18]

Recently, Carlucci *et al.*[14] also pointed out the differences found with the VT-PSV mode in case of unintentional leaks, using different circuit configurations in three single-limb circuit ventilators. They concluded that the ability to compensate for unintentional leak was determined only by the circuit configuration. However, they did not assess ventilators with double-limb circuit. Moreover, contrarily to our study, they fixed the minimal inspiratory pressure as the minimal value delivered by the ventilator. In our study, we chose the minimal inspiratory pressure as the value required to reach a preset VT of 500 mL. In that condition, we were able to check that in case of leak, the

ventilators were able to maintain this preset inspiratory pressure and therefore guarantee the minimal VT of 500 mL. This finding is important as it highlights the fact that minimal preset inspiratory pressure should be selected in order to always guarantee the minimal VT necessary for the patient, and therefore avoid hypoventilation in case of unintentional leak.

The first limitation of our study was that our leakage procedure was somewhat artificial considering that we used different sized resistors during both inspiration and expiration like in previous bench[8-19] and clinical studies.[12] The advantage of a constant leak is that it impedes irregular cycles which may avoid some ventilators to take into account leakage occurrence. Leaks are less marked during expiration than during inspiration, because upper-airway pressure decreases markedly when mechanical insufflation switches off to permit expiration. However, positive end-expiratory pressure may promote expiratory leaks. Conceivably, the expired-volume method for measuring tidal volume might underestimate the tidal volume if leaks occur during expiration and therefore may induce overcompensation such as we observed with the Monnal T50 when this device was equipped with double circuit, whereas there was no compensation when the device was equipped with single tubing and an expiratory valve. To our knowledge the measurement of leaks during expiration is only possible if the expiratory volume obtained by a pneumotachograph is compared to another method such as inductive plethysmography.[20] However our present results suggest that using few bi-level pressure devices with intentional leak seem to be a simpler and accurate alternative. Secondly, the implemented software aimed at correcting the missing volume is known to be highly different between

various devices. Some of them provide only a very small pressure change within one minute. However, considering the rapid effects of leakage on blood gases during mechanical ventilation and sleep,[21] one can suppose that, to be efficient, adaptation to leakage occurrence needs to be as fast as possible. Finally, the tests were performed during passive conditions without spontaneous respiratory activity. In the presence of spontaneous effort, we may observe patient-ventilator asynchronies (autotriggering, ineffective trigger…) as well as the effect of the unintentional leaks on the breathing cycles such as increases in inspiratory time and overshoots. However because spontaneous breathing can affect VT we decided to evaluate the volume targeted modes in the simplest condition.

To conclude, our study shows that the studied ventilators, with double-limb circuit or single-limb circuit with expiratory valve, providing the VT-PSV mode are unable to maintain the preset minimal VT during unintentional leaks. VT-PSV mode is not recommended when using an expiratory valve. Theoretically, double-limb circuit ventilators should be preferred, but most of the currently available ventilators with a double-limb circuit fail to accurately measure the patient's expiratory VT and are therefore not sufficiently reliable. Finally, ventilators that can be used with a single-limb circuit with intentional leak outperform the other devices. However, further work is needed to test the performance of these ventilators during a variable level of unintentional leak, as observed in clinical practice.

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Table 1. Ventilatory settings and circuits.

	MODE	CIRCUIT	IPAPmin (cmH_2O)	IPAPmax (cmH_2O)	PEEP (cmH_2O)	F (b/min)	TI (s)	TRIG I (L/min)	TRIG E	SLOPE
ELISEE 150 (ResMed SA, Saint Priest, France)	AI VS	D	10		4	15	1.3	5	25%	1
MONNAL T50 (Air Liquide, Antony, France)	AI VS	S	10	34	4	15	1.3	10	30%	1
	AI VS	D	10	34	4	15	1.3	10	30%	1
PB560 (COVIDIEN Courtaboeuf, France)	AI FR	D	10	30	4	15	--	5	35%	1
	AI FR	S+leak	10	30	4	15	--	5	35%	1
VIVO 50 (Breas Medical Saint Priest, France)	VS-Vtcibl	S	10	20	4	15	1.3	9	9 L/min	1
	VS-Vtcibl	S+leak	11	20	4	15	1.3	9	9 L/min	1
TRILOGY 100 (Respironics France Carquefou, France)	ST-AVAPS	S+leak	10	34	4	15	1.3	9	30%	1
BIPAP A30 (Respironics France Carquefou, France)	ST-AVAPS	S+leak	10	25	4	15	1.3	auto	auto	1
BIPAP AVAPS (Respironics France Carquefou, France)	ST-AVAPS	S+leak	10	25	4	15	1.3	auto	auto	1

Abbreviations: IPAP: Inspiratory positive airway pressure; min: minimal; max: maximal; PEEP: positive end-expiratory pressure; F: respiratory rate; TI: inspiratory time; TRIG I: inspiratory trigger; TRIG E: expiratory trigger; S: single-limb circuit with expiratory valve; D: double-limb circuit; S+leak: single-limb circuit with intentional leak.

FIGURE LEGENDS

Fig. 1 Lung bench model used for the study.

V': airflow; P: airway Pressure.

Fig. 2 Pressure-flow curves of the calibrated holes used to generate unintentional leaks.

Paw: airway pressure.

Fig. 3 Variations in tidal volume (VT) during various levels of unintentional leakage. The left panel shows results with bi-level pressure ventilators and intentional leaks and the right panel results with the pressure-support devices and a double-limb circuit or expiratory valve. The VIVO 50 with expiratory valve and the Monnal T50 with double-limb circuit were not able to cope with leaks over 3.5 and 4.5 mm, respectively.

Each point represents the mean value of at least 10 stable cycles. Vertical bars represent the standard deviation.

Fig. 4 Variations in airway pressure (Paw) during various levels of unintentional leakage. The left panel shows results with bi-level pressure ventilators and intentional leaks and the right panel results with the pressure-support devices and a double-limb circuit or expiratory valve. The VIVO 50 with expiratory valve and the Monnal T50 with double-limb circuit were not able to cope with leaks over 3.5 and 4.5 mm, respectively.

Each point represents the mean value of at least 10 stable cycles. Vertical bars represent the standard deviation.

Fig. 5 Variations in airway pressure (Paw) during the first five cycles and the first cycle with a Paw steady state, during unintentional leakage through a 2.5-mm hole. The left panel shows results with ventilators with a single-limb circuit with an intentional leaks and the right panel, results with the double circuit or expiratory valve.

The Paw steady state was obtained in 24 and 84 seconds for VIVO50 and BiPAP A30 with a leak circuit respectively; in 32, 48 and 32 seconds for Elisée 150, Monnal T50, and PB560 with a double circuit respectively; in 24 and 21 seconds for VIVO 50 and Monnal T50 with an expiratory valve respectively. While for the PB560, Trilogy 100 and BiPAP AVAPS with a leak circuit, Paw constantly varied between two values with a maximal variation of 0.5, 0.2 and 0.4 cmH_2O, respectively.

Figure 1.

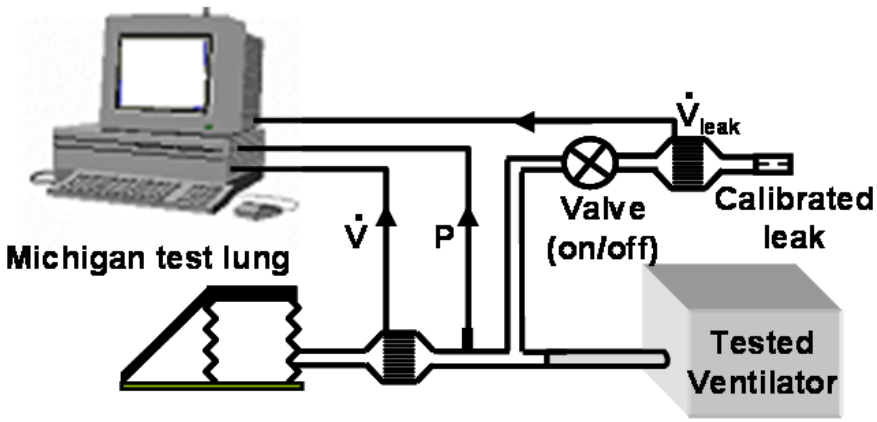


Figure 2.

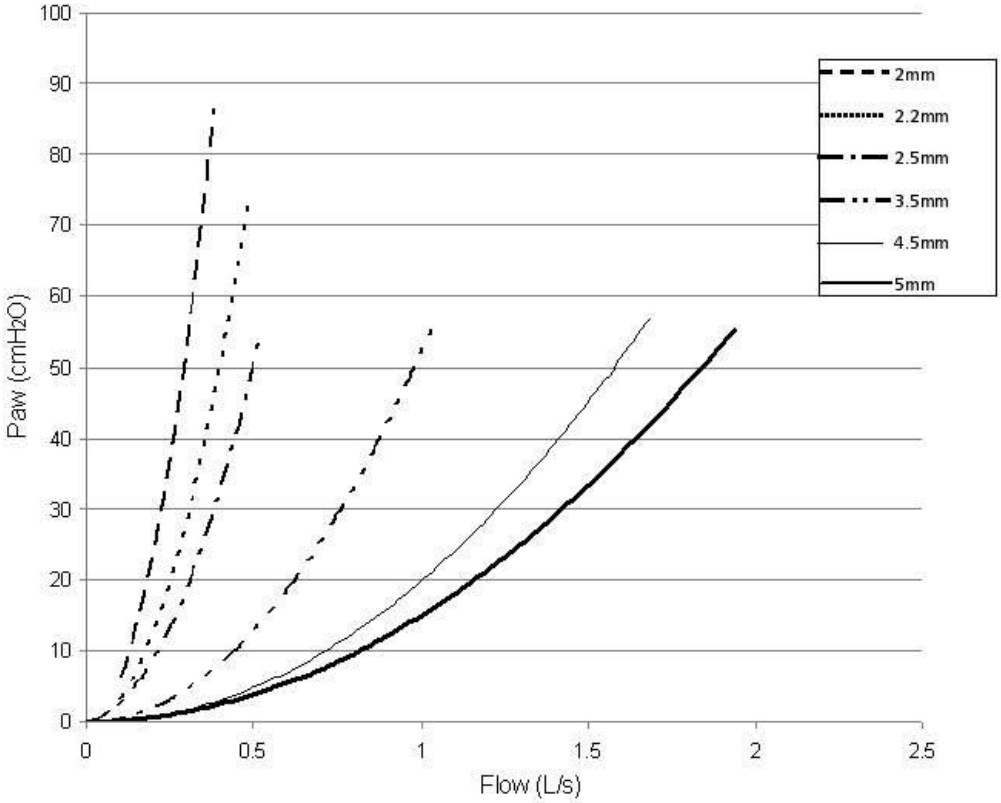


Figure 3.

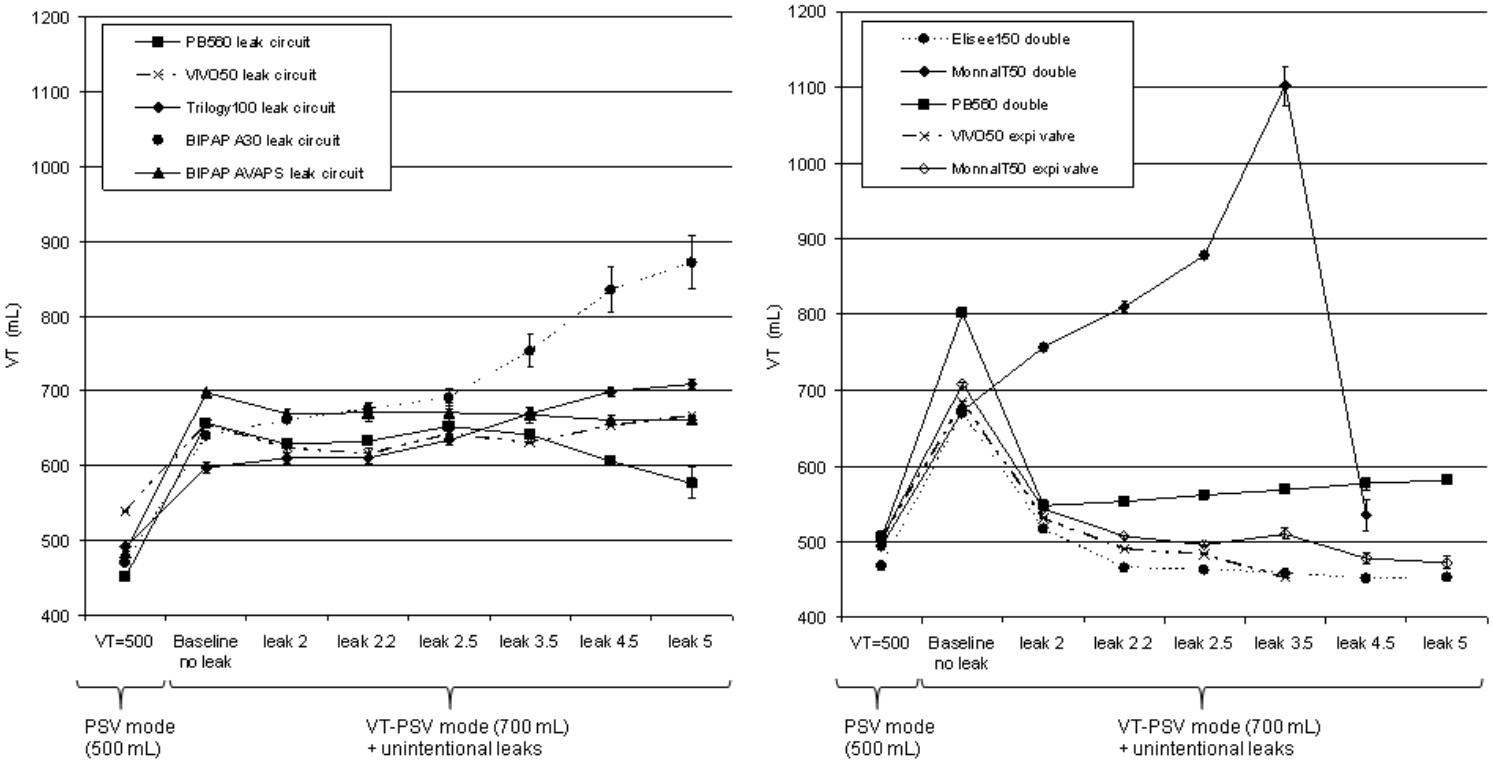


Figure 4.

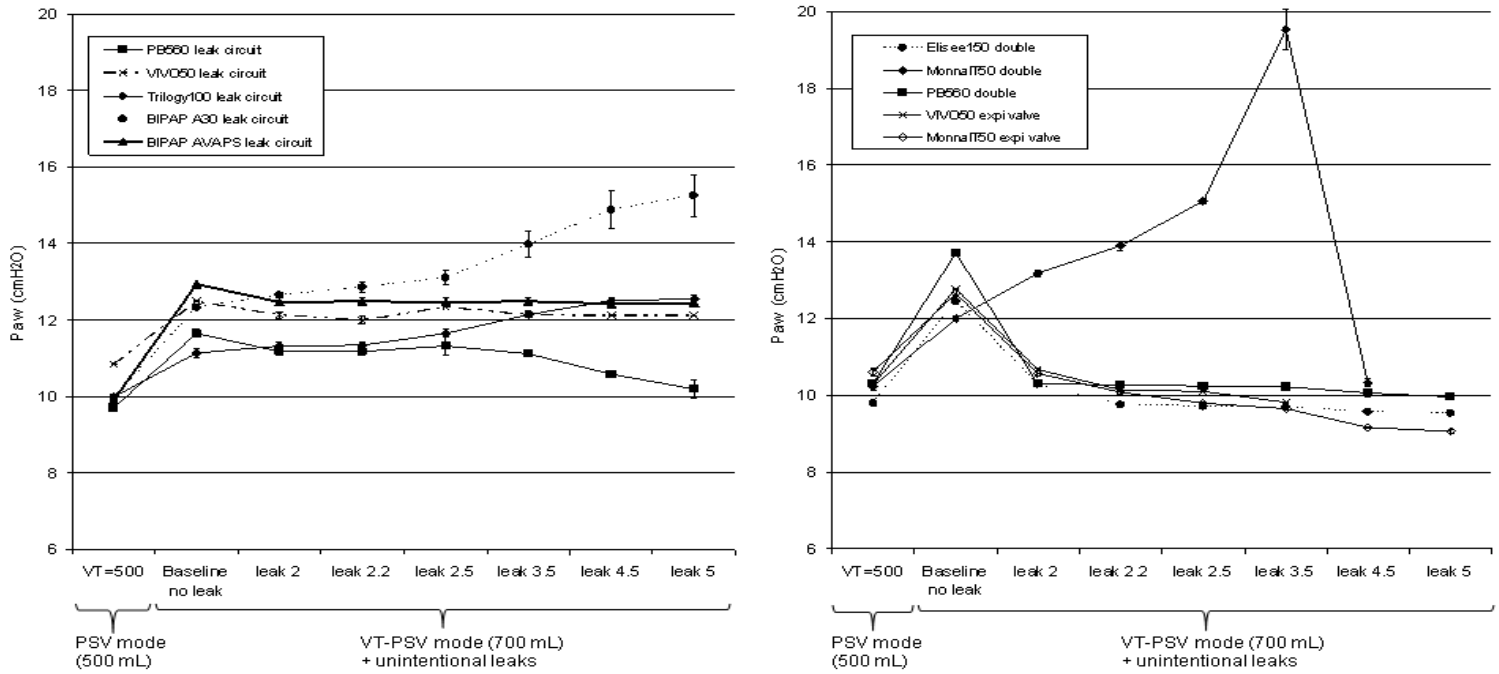
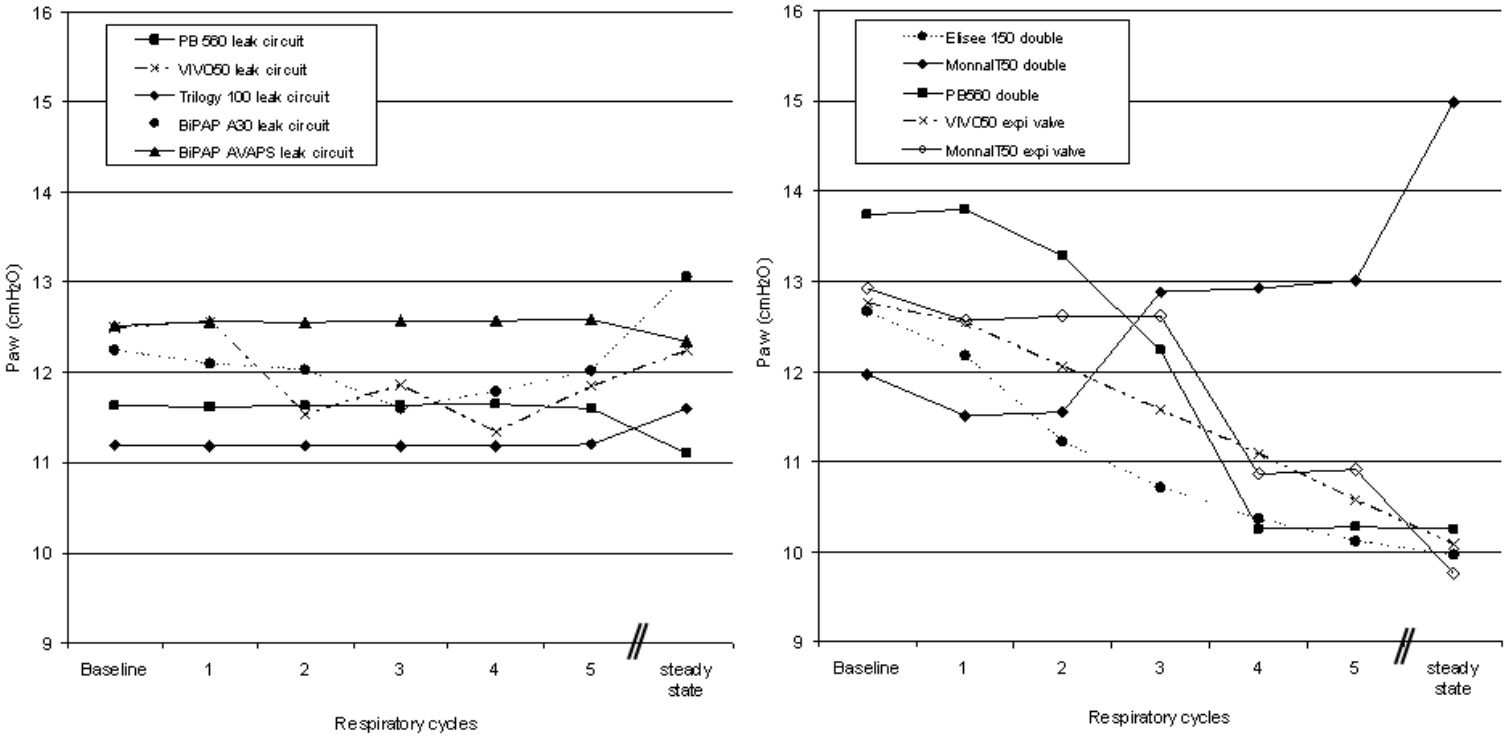


Figure 5.


PB 560 leak circuit
VIVO50 leak circuit
Trilogy 100 leak circuit
BiPAP A30 leak circuit
BiPAP AVAPS leak circuit
Paw (cmH2O)
16
15
14
13
12
11
10
9
Baseline
1
2
3
4
5
steady state
Respiratory cycles
Elisee 150 double
MonnalT50 double
PB560 double
VIVO50 expi valve
MonnalT50 expi valve
Paw (cmH2O)
16
15
14
13
12
11
10
9
Baseline
1
2
3
4
5
steady state
Respiratory cycles