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The configuration of bi-level ventilator circuits may affect compensation for non-intentional leaks during volume-targeted ventilation

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Abstract Purpose: To assess the behaviour of a pressure-preset volume-guaranteed (V_{TG}) mode of ventilation in the presence of non-intentional leaks in single-limb circuit (SLC) home ventilators. **Methods:** All SLC home ventilators commercially available in Italy can be used in a V_{TG} mode with an intentional leak (“vented”) or a true expiratory valve (“non-vented”) configuration were selected. Using an experimental model consisting of a mannequin connected to an active lung simulator, for each level of leak (15, 25 and 37 l/min) three different conditions of respiratory mechanics (normal, restrictive and obstructive) were simulated using the ventilators in either a “vented” or “non-vented” configuration. **Results:** Three home ventilators were tested: Vivo50 (Breas), PB560 (Covidien) and Ventilologic LS (Weimann). In a “vented” circuit configuration all three ventilators kept

constant or increased inspiratory pressure in all leak conditions to guarantee the V_{TG} . Conversely, in a “non-vented” circuit configuration, all tested ventilators showed a drop in inspiratory pressure in all leak conditions, resulting in a concomitant reduction in delivered tidal volume. The same behaviour was found in all conditions of respiratory mechanics. In the absence of leaks, all the ventilators, independently of circuit configuration, were able to maintain the set V_{TG} in the presence of modifications of the respiratory mechanics. **Conclusions:** The ability of the V_{TG} mode to compensate for non-intentional leaks depends strictly on whether a “vented” or “non-vented” circuit configuration is used. This difference must be taken into account as a possible risk when a V_{TG} mode is used in the presence of non-intentional leaks.

Keywords Volume target · Home ventilators · Non-invasive ventilation · Leaks · Single-limb circuit

Introduction

Bi-level positive pressure ventilators are by far the most widely used ventilators for the majority of patients affected by chronic hypercapnic respiratory failure [1–3]. Although pressure-preset non-invasive positive pressure ventilation (NIPPV) is able to compensate for non-

intentional leaks better than volume-preset NIPPV [4, 5], a constant tidal volume (V_T) may not be guaranteed in the presence of changes in respiratory impedance. To overcome this problem, a volume-guaranteed (V_{TG}) mode has recently been introduced in most bi-level ventilators both in double-limb and in single-limb circuits (SLC) [6–10]. A recent study [11] found that, in the presence of

modifications of respiratory impedance, V_{TG} ventilation was able to guarantee a preset volume. Conversely, the V_{TG} was not always ensured in the presence of non-intentional leaks. However, in that study ventilators with double-limb circuits or SLC with a true expiratory valve (“non-vented”) or with an intentional leak (“vented”) were used indifferently. No study has so far focussed on the differences in leak compensation between a “vented” or “non-vented” SLC configuration. We hypothesized that, in a V_{TG} mode, the ability of a ventilator to compensate for non-intentional leaks is strictly dependent on the type of SLC configuration used. The aim of this study is to compare the behaviour of a V_{TG} mode used with “vented” and “non-vented” SLC in the presence of non-intentional leaks in different conditions of respiratory mechanics.

Materials and methods

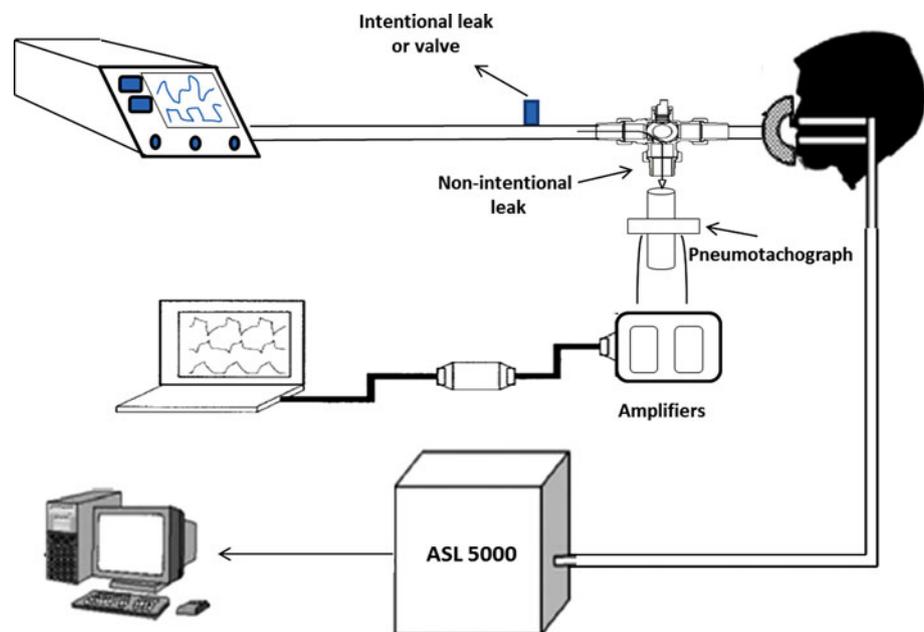
The study was performed in the Respiratory Mechanics Laboratory of the Fondazione Salvatore Maugeri, Pavia, Italy. All SLC home ventilators commercially available in Italy with the possibility of using a V_{TG} mode in either a “vented” or “non-vented” configuration were tested. Ventilators with the V_{TG} mode active only with a “vented” or a “non-vented” SLC or with a double-limb circuit were excluded. The ventilators used in this study were the Vivo 50 (V_{50} ; Breas Medical AB-Molnlycke, Sweden), the Ventilic LS (W_{LS} ; Weinmann-Hamburg, Germany) and the Puritan Bennet 560 (PB_{560} ; Covidien-Mansfield, MA, USA).

The experimental model consisted of a mannequin head (Laerdal Medical AS, Stavanger, Norway) connected to an active test lung (ASL 5000; Ingmar Medical, Pittsburgh, PA, USA) [12] and to a face mask, sealed to the mannequin with plaster to avoid any additional leaks. A heated pneumotachograph (Hans-Rudolph 3700, Kansas, USA) and a differential pressure transducer (± 300 H_2O ; Honeywell, Freeport, IL, USA) were placed between a valve generating the leak and the ventilator circuit to measure the non-intentional leak. Each ventilator was tested using a manufacturer’s standard SLC with an exhalation valve (“non-vented” circuit), and with a standard disposable Whisper Swivel (Philips Respironics, Murraysville, PA, USA) (“vented” circuit). Figure 1 shows the experimental setup.

Study setup

Three different conditions were simulated: (1) normal respiratory mechanics (resistance 5 $cmH_2O/l/s$ and compliance 50 ml/cmH_2O), (2) a restrictive pattern (resistance 5 $cmH_2O/l/s$ and compliance 30 ml/cmH_2O) and (3) an obstructive pattern (resistance 15 $cmH_2O/l/s$ and compliance 50 ml/cmH_2O). Ventilators were set in pressure-controlled ventilation with the following parameters: end positive airway pressure (EPAP) 4 cmH_2O , minimal inspiratory pressure ($IPAP_{min}$), intended as the baseline minimum value delivered by the ventilator, 8 cmH_2O , maximal inspiratory pressure ($IPAP_{max}$), intended as the maximum value delivered by the ventilator, at the highest allowed value, respiratory rate 15 breaths/min, inspiratory time 1.2 s, V_{TG} 500 ml. Whenever available on the

Fig. 1 Experimental setup



ventilator, the pressure ventilator ramp of V_{TG} compensation, namely the speed at which the ventilator increases pressure ($IPAP_{max}$) to reach the set V_{TG} , was set at the fastest value. Three different levels of leak were tested (15, 25 and 37 l/min) for each ventilator in both the “vented” and “non-vented” configurations in the three above-mentioned conditions of respiratory mechanics of the single-compartment lung model. Operatively, in all the simulated types of respiratory mechanics, after a steady-state condition had been reached for at least 2 min, a leak (15, 25 or 37 l/min) was generated in a random order and kept constant for 4 consecutive minutes to allow the different algorithms of the ventilator to stabilize the inspiratory pressure and V_{TG} . After the leak was switched off, the recording was continued for another 4 min.

Data analysis

V_{Texp} , defined as the expiratory tidal volume delivered to the simulator, and the actual airway inspiratory pressure ($IPAP_{act}$) were measured during all recording periods by offline analysis with ASL5000 software (version 3.2; Ingmar Medical Ltd., Pittsburgh, PA, USA) [12]. The mean V_{Texp} was calculated as the average of at least 20 consecutive stable breaths at the end of each recording phase (when a steady-state condition was reached), before, during and after the simulated leak. V_{TG} “undercompensation” was arbitrarily defined as the inability to maintain a V_{Texp} of at least 450 ml, while “overcompensation” was defined as a mean V_{Texp} greater than 550 ml. The greatest V_{Texp} among the first three breaths after the end of the leak period was also recorded. A significant “overshoot” [11] was defined as a V_{Texp} at the end of the leak period greater than 20 % of the mean V_{Texp} measured during the leak.

Statistical analysis

The deviation of quantitative variables from the normal distribution was evaluated by Shapiro’s test, under the null hypothesis of normality. The presence of statistically significant differences between quantitative variables was tested by Student’s *t*-test (if the Shapiro *p*-value was >0.05) or by Wilcoxon’s rank-sum test (if the Shapiro *p*-value was <0.05). Statistical analyses were performed using R software.

Results

Table 1 and Fig. 2 present the typical behaviours of each ventilator in their “vented” and “non-vented”

configurations, in all conditions of respiratory mechanics and for all levels of leak.

Irrespective of the mechanical properties set on the test lung, in a “vented” configuration and in the presence of non-intentional leaks, ventilators kept constant or increased the inspiratory pressure in order to guarantee the V_{TG} . Only the V_{50} delivering ventilation to the model set with an obstructive pattern and a leak of 37 l/min was not able to cope with the leak, showing a V_T instability that could not be averaged. In contrast, in a “non-vented” configuration all the ventilators failed to maintain the V_{TG} , showing a pressure drop at all levels of leak and in all conditions of respiratory mechanics. This resulted in a concomitant reduction in V_{Texp} (Table 1 and online supplementary figure). The behaviour of the “vented” SLC ventilators in terms of under- or overcompensation and/or overshooting with respect to the preset V_{TG} in normal, obstructive and restrictive conditions is summarised in Table 1 and described below.

Normal respiratory mechanics

The V_{50} undercompensated the V_{TG} at baseline (448.3 ± 1.2 ml), while the PB_{560} and W_{LS} overcompensated at, respectively, 37 l/min (602.6 ± 1.3 ml) and at all levels of leak (576.1 ± 2.2 ml at 15 l/min, 645.6 ± 2.7 ml at 25 l/min and 721.5 ± 2.9 ml at 37 l/min). An overshoot (739 ml) was found with the PB_{560} after the closure of the leak at 37 l/min.

Obstructive respiratory mechanics

The V_{50} undercompensated the V_{TG} at baseline (428.5 ± 2.4 ml) and after the closure of the leak (436.9 ± 0.5 ml), whereas the PB_{560} and W_{LS} overcompensated at, respectively, 37 l/min (575.4 ± 1.3 ml) and in all leak conditions (602.7 ± 1.2 ml at 15 l/min, 688.8 ± 1.3 ml at 25 l/min, 750.8 ± 2.1 ml at 37 l/min).

An overshoot (831.9 ml) was found with the PB_{560} after closure of the leak at 37 l/min. The V_{50} was not able to cope with a leak of 37 l/min and showed a V_T instability that could not be averaged.

Restrictive respiratory mechanics

The V_{50} undercompensated the V_{TG} at baseline (420.4 ± 3.2 ml) and after the closure of the leak (420.5 ± 0.5 ml) after 15 l/min, 436.5 ± 0.4 after 25 l/min, 436.9 ± 0.24 after 37 l/min). The PB_{560} and W_{LS} overcompensated at, respectively, 37 l/min (620.7 ± 1.45 ml) and in all leak conditions (632.4 ± 1.6 ml at 15 l/min, 661.7 ± 1.7 ml at 25 l/min, 722.1 ± 1.7 ml at 37 l/min). An overshoot

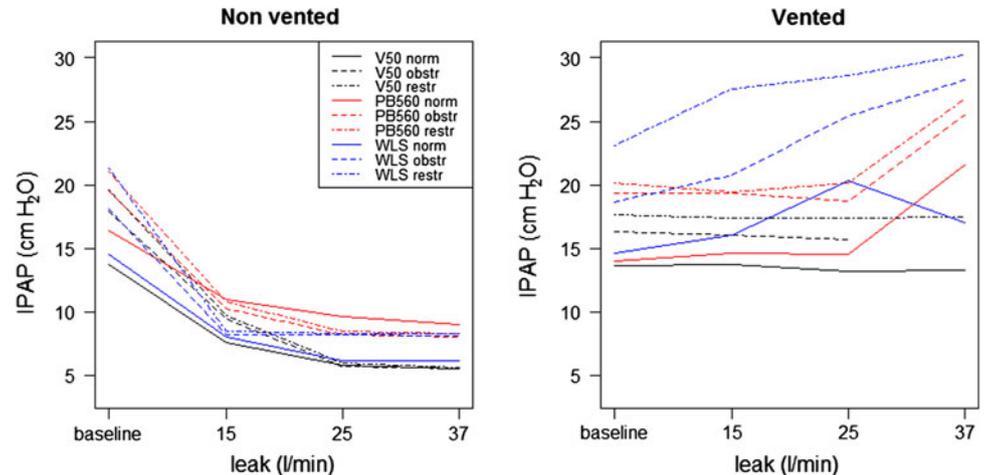
Table 1 Modification of measured expiratory volume (V_{Texp}) circuit in the three different tested respiratory mechanics conditions at baseline, during leak (15, 25 and 37 l/min) and after leak closure in all tested ventilators in “vented” and “non-vented” configuration

Ventilators	Leak (l/min)	Normal respiratory mechanics				Obstructive respiratory mechanics				Restrictive respiratory mechanics			
		Baseline (V_{Texp} , ml)	Leak (V_{Texp} , ml)	After leak (V_{Texp} , ml)	Overshoot (V_{Texp} , ml)	Baseline (V_{Texp} , ml)	Leak (V_{Texp} , ml)	After leak (V_{Texp} , ml)	Overshoot (V_{Texp} , ml)	Baseline (V_{Texp} , ml)	Leak (V_{Texp} , ml)	After leak (V_{Texp} , ml)	Overshoot (V_{Texp} , ml)
V_{50}	15	449.3 ± 2.5 [§]	453.9 ± 0.39 ^{**}	448.3 ± 0.4 ^{††}	517	419.8 ± 0.4 [#]	404.8 ± 0.5 ^{**}	437 ± 0.5 ^{††}	419.3	404.8 ± 0.6 [#]	398.9 ± 0.6 ^{**}	420.5 ± 0.6 ^{††}	420.4
	25	448.6 ± 1.7 [§]	425.6 ± 0.73 ^{**}	448.9 ± 0.5 ^{††}	518	436.9 ± 0.4	391.1 ± 0.4 ^{**}	436.9 ± 0.3 ^{††}	471.2	420.5 ± 0.6 [#]	397.6 ± 0.5 ^{**}	436.5 ± 0.4 ^{††}	451.4
	37	448.6 ± 0.5	424.9 ± 0.7 ^{**}	448.9 ± 0.5 ^{††}	519	∞	∞	∞	∞	436.6 ± 0.7 [#]	395.2 ± 0.9 ^{**}	436.9 ± 0.2 ^{††}	468.1
V_{50}	15	462.2 ± 1 [§]	166.3 ± 6.9 ^{**}	482.7 ± 8.9 ^{††}	188	478.8 ± 0.5	180.9 ± 0.2 ^{**}	478.9 ± 0.3 ^{††}	197.2	465.3 ± 0.4 [#]	165.6 ± 0.2 ^{**}	464.8 ± 0.3 ^{††}	197.3
	25	485.5 ± 0.5	81.3 ± 0.4 ^{**}	485.5 ± 0.4 ^{††}	99	478.9 ± 0.3	52 ± 0.6 ^{**}	478.8 ± 0.4 [†]	67.5	465.1 ± 0.4 [#]	54.1 ± 0.2 ^{**}	465.2 ± 0.7 [†]	78.2
	37	485.8 ± 0.9 [#]	70.2 ± 1.9 ^{**}	461.8 ± 0.4 ^{††}	506	478.7 ± 0.3	46.9 ± 0.4 ^{**}	476.2 ± 7.0 [†]	67.2	465.1 ± 0.6 [#]	48.9 ± 0.1 ^{**}	465.4 ± 0.3 [†]	90.6
PB ₅₆₀	15	503.9 ± 1.2	488.7 ± 1.4 ^{**}	504.5 ± 1.1 ^{††}	506	474.1 ± 0.9	457.2 ± 2.3 ^{**}	473.3 ± 0.7 ^{††}	473.9	482.9 ± 0.9 [#]	459.9 ± 0.5 ^{**}	482.7 ± 0.7 ^{††}	471.2
	25	504.6 ± 1.1 [#]	477.1 ± 0.76 ^{**}	523.7 ± 1.1 ^{††}	524	514.2 ± 1.0	467.1 ± 0.7 ^{**}	516.3 ± 0.8 ^{††}	456	483.1 ± 0.7 [#]	474.7 ± 0.8 ^{**}	482.6 ± 0.1 ^{††}	522.4
	37	490.1 ± 1 [#]	602.6 ± 1.3 ^{**}	455.2 ± 0.8 ^{††}	739 [§]	507.5 ± 6.7 [#]	575.4 ± 3.8 ^{**}	490.2 ± 1.2 ^{††}	831.9 [§]	482.8 ± 0.8 [#]	620.7 ± 1.5 ^{**}	482.9 ± 0.4 ^{††}	848.4 [§]
PB ₅₆₀	15	554.5 ± 1.5 [#]	234.5 ± 0.8 ^{**}	575.2 ± 1.5 ^{††}	242	525.4 ± 0.6	206.7 ± 1.3 ^{**}	526.0 ± 1.2 ^{††}	216	533.7 ± 1.1 [#]	222.7 ± 0.7 ^{**}	533.8 ± 1.5 ^{††}	242
	25	553.4 ± 1.1 [#]	299 ± 3 ^{**}	552.1 ± 1.1 ^{††}	328	525.7 ± 0.8 [§]	148.3 ± 4.5 ^{**}	526.7 ± 1.8 ^{††}	167	534.1 ± 1 [#]	156.1 ± 2.8 ^{**}	533.8 ± 0.7 ^{††}	169
	37	552.8 ± 1.5 [#]	215.2 ± 9.3 ^{**}	497.3 ± 2.9 ^{††}	501	525.3 ± 0.8	139.9 ± 3.3 ^{**}	526.1 ± 3.6 ^{††}	157	533.8 ± 0.7 [#]	152.6 ± 1.4 ^{**}	529.6 ± 3 ^{††}	186
W _{LS}	15	511.4 ± 1.0	576.1 ± 2.2 ^{**}	511 ± 1.4 ^{††}	507	524.7 ± 0.7 [#]	602.7 ± 1.2 ^{**}	527.5 ± 1.1 ^{††}	555	531.4 ± 0.5 [#]	632.4 ± 1.6 ^{**}	538.2 ± 1.9 ^{††}	579
	25	510.2 ± 1.4 [§]	645.6 ± 2.7 ^{**}	511 ± 0.6 ^{††}	558	522.1 ± 1.3 [#]	688.8 ± 1.3 ^{**}	525.8 ± 1.4 ^{††}	632	532 ± 0.8 [#]	661 ± 1.7 ^{**}	527 ± 1.6 ^{††}	519
	37	519 ± 1.2 [#]	721.5 ± 2.9 ^{**}	521 ± 0.8 ^{††}	736	523.6 ± 0.9 [#]	750.8 ± 2.1 ^{**}	528.6 ± 2.3 ^{††}	759	530.9 ± 1 [#]	722.1 ± 1.7 ^{**}	532.4 ± 1.4 ^{††}	774
W _{LS}	15	498.8 ± 1.5 [§]	181.2 ± 0.6 ^{**}	502.1 ± 4 ^{††}	186	498.6 ± 2.2	147.1 ± 0.3 ^{**}	499.2 ± 2 ^{††}	205	504.2 ± 1.1 [#]	127.3 ± 0.5 ^{**}	501.2 ± 1.1 ^{††}	130
	25	497.7 ± 1.5 [#]	96.9 ± 0.94 ^{**}	495.3 ± 0.8 ^{††}	133	501.1 ± 1.4 [#]	144.8 ± 1.1 ^{**}	493.5 ± 3.8 ^{††}	178	502.1 ± 2 [#]	122.7 ± 0.8 ^{**}	498.3 ± 2.8 ^{††}	138
	37	493.8 ± 0.9 [§]	95 ± 0.3 ^{**}	492.6 ± 0.9 ^{††}	134	499 ± 2.1 [§]	143.7 ± 0.6 ^{**}	493.8 ± 5 ^{††}	177	501 ± 1.2 [#]	119.2 0.4 ^{**}	496.5 ± 4 ^{††}	129

* Leak versus baseline; [§] $p < 0.05$; ^{**} $p < 0.001$; [†] After leak versus leak; ^{††} $p < 0.05$, ^{†††} $p < 0.001$; [§] Baseline versus after leak; [§] $p < 0.05$, ^{††} $p < 0.001$; [§] Significant overshoot

∞ Missing data due to the inability of the ventilator to cope with this level of leak

Fig. 2 Mean value of inspiratory pressure (IPAP) from all ventilators in all mechanics conditions, at baseline and during each level of leak in “non-vented configuration” (*left panel*) and “vented configuration” (*right pane*). Data from the V_{50} in the “vented” configuration at leak rate of 37 l/min are missing because of the ventilator’s inability to cope with this level of leak



(848.4 ml) was found with the PB_{560} after closure of the leak at 37 l/min.

Discussion

The major finding of this study was that the behaviour of SLC ventilators in the V_{TG} mode in the presence of non-intentional leak differs. All ventilators in the “vented” configuration, with the exception of the V_{50} in a simulated obstructive condition and a leak of 37 l/min, kept constant or increased the inspiratory pressure in all leak conditions to maintain the V_{TG} . Conversely, the same ventilators with “non-vented” circuit configuration failed to maintain the V_{TG} , showing a clinically relevant fall in inspiratory pressure and V_{Texp} compared with the baseline value.

Explanation of the results

In SLC, the “vented” system is not a “true expiratory valve”. A “vented system”, incorporated in the mask or in the proximal part of the respiratory circuit, allows the expiratory flow and carbon dioxide to be flushed in an amount proportional to the end expiratory airway pressure (EPAP) [13] and to the flow through the “vented system” at a given pressure. Minimal re-breathing may be possible [13]. In contrast, in the “non-vented” configuration a true expiratory valve allows unidirectional expiratory flow, thus avoiding any possible carbon dioxide re-breathing. Our findings could be explained by the different algorithms used by “vented” and “non-vented” SLC to compute additional leaks. In the “non-vented” configuration the monitored V_T is always a real measurement of inspiratory V_T . The values are computed at the beginning of inspiration, so that in the presence of leaks, the leaks are considered as part of the delivered V_T . Consequently, the

greater the leak, the higher the “measured” inspiratory V_T . Differently, in the “vented” configuration the monitored V_T is just an estimation based on different manufacturers’ algorithms. Measurements of intentional and any non-intentional leaks are made at the end of expiration and considered as the baseline from which the “estimated” V_T is calculated. For this reason, in the presence of non-intentional leaks, the V_T shown by the ventilator remains constant because overall leak flow is subtracted from the overall turbine flow. In the ventilators studied, the V_{TG} mode is based either on the detection of the measured inspiratory V_T in “non-vented” SLC or on the V_T estimation in “vented” SLC. When the V_T monitored from the ventilator falls below the set V_{TG} , the ventilator progressively increases the inspiratory pressure to reach the target V_{TG} . As shown in Fig. 3, in the “non-vented” configuration, at each level of leak, the V_T displayed by all ventilators (V_{Tvent}) increased, becoming significantly higher than the set V_{TG} . Consequently, the inspiratory pressure decreased, causing a fall in V_{Tesp} . On the other hand, in the “vented” configuration, V_{Tvent} did not change when the leak was opened or decreased slightly in presence of the greatest leak. In fact, the ventilator kept constant or increased the inspiratory pressure to reach the V_{TG} . In a similar study, Oscroft et al. [10] found that additional leaks, ranging from 8.3 to 32.8 l/min, had a minimal effect on delivered ventilation. Their findings were also confirmed by Fauroux et al. [11], who showed that only “vented” SLC ventilators were able to cope with non-intentional leaks. Moreover, our results, in agreement with those of Fauroux et al. [11], showed that all ventilators, in the absence of non-intentional leaks and independently of the SLC configuration, were able to cope with different modifications of respiratory mechanics. In our study one ventilator showed an “overshoot” after a leak of 37 l/min in all the simulated conditions of respiratory mechanics. This means, as previously observed [11], that the ventilator was not able to reduce airway pressure promptly at the end of the perturbation.

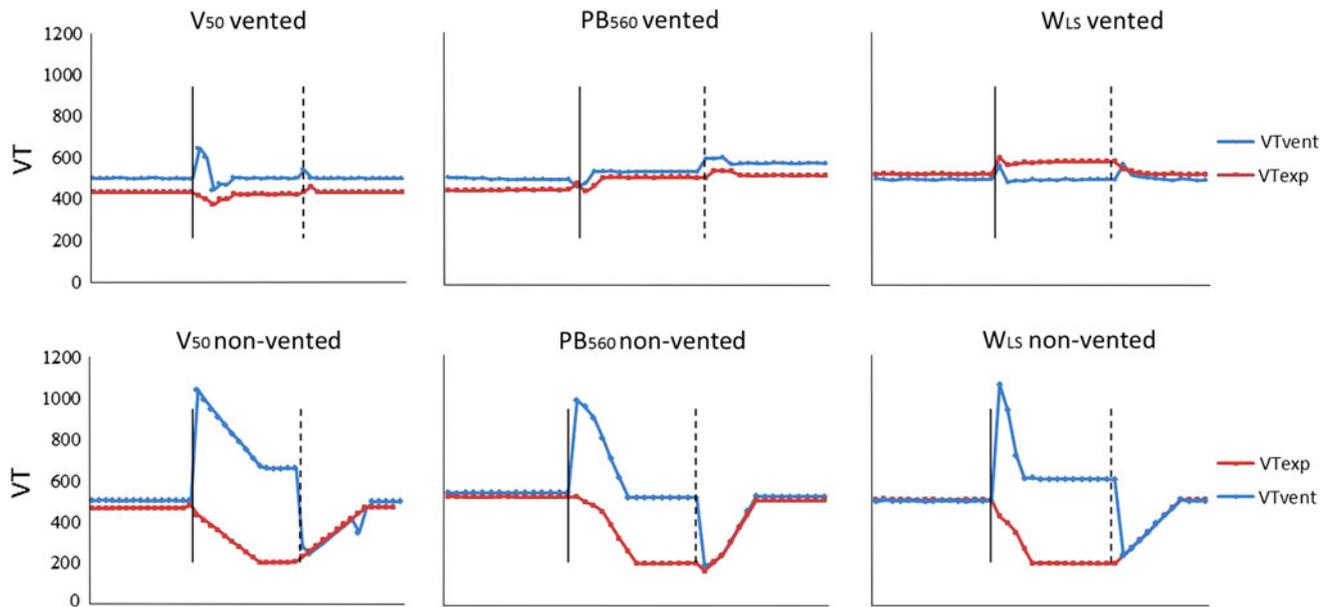


Fig. 3 Trend of expiratory tidal volume (V_{Texp}) and tidal volume displayed by the ventilator monitoring system (V_{Tvent}) at *baseline*, during a leak of 15 l/min and after the closure of the leak. The *solid*

line indicates the opening of the leaks. The *dotted line* indicates the closure of the leaks

Clinical implications

The ability of the V_{TG} mode to ensure a constant tidal volume in the presence of changes of respiratory system impedance has several possible fields of application such as sleep-related hypoventilation in patients with neuromuscular disease, obesity or chronic obstructive pulmonary disease, during both non-invasive and invasive ventilation [6–11]. In particular, in tracheotomised patients, V_{TG} could guarantee a minimal VT during ventilation through a plain, uncuffed tracheostomy tube where the amount of leakage around the tube can vary and can, sometimes, be large [14]. In this application, as well as during non-invasive ventilation in which leaks are almost inevitable, use of a SLC in a “non-vented” configuration should be avoided. The sudden onset of non-intentional leaks could, in fact, lead to clinically significant hypoventilation because of a decrease in inspiratory pressure to the minimum set value.

Limitations of the study

Firstly, our study was a bench study and our results may not, therefore, be completely applicable in clinical practice [15]. In particular, the ability of “vented” configuration to provide the preset V_{TG} in the presence of a non-intentional leak may not necessarily be true in vivo.

In fact, leaks during non-invasive ventilation at the bedside are not constant and can increase as the inspiratory pressure increases. As indicated in Fig. 2, the ventilator can reach inspiratory pressures as high as 30 cmH₂O or otherwise equal to the upper limit set, to guarantee the preset V_{TG} . A clinical study would be useful to strengthen our results. Secondly, to better understand the algorithm governing a V_{TG} mode in coping with leaks, we used controlled time-cycled ventilation to avoid auto-triggering and cycling-off asynchronies [16]. However, in a real-life setting these latter phenomena could significantly affect the correct behaviour of ventilators in the presence of leaks, even when a “vented” configuration is used.

In conclusion, the results of our study make the operator aware of the differences between SLC ventilators in “vented” and “non-vented” configurations and of the possible risks of using invasive or non-invasive V_{TG} ventilation if a non-intentional leak should occur. In this condition, in ventilators with a SLC, a “non-vented” circuit configuration should not be used. Further clinical studies are needed to test the in vivo behaviour of “vented” circuits in the presence of non-intentional leaks.

Conflicts of interest This work has not been funded by any external source. Dr. Gregoretti consults for companies that make or deliver ventilators or interfaces, specifically Covieiden, Smith Ind, Koo Ind, Vivilsol and Sapio Life and is compensated for these consultations. We thank Medicaire Italy srl that provided us with the equipment used to test ventilators.

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