Influence of Dynamic Leaks in Volume-Targeted Pressure Support Noninvasive Ventilation: A Bench Study

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INTRODUCTION: The effect of leaks on volume-targeted pressure support noninvasive ventilation mode has only been tested with continuous simulated leaks. The objective of the study was to assess the influence of random leaks occurring either during inspiration or expiration. METHODS: Analysis of the volume-targeted pressure support mode in 6 commercial ventilators with single-limb circuits and intentional leak in a bench study (restrictive model). Unintentional leaks were introduced through a mechanical system during inspiration (threshold valve with 2 levels of leaks) or during expiration (active valve). Results of delivered tidal volume (V_T) and pressure support were externally recorded. A pre-set V_T of 550 mL was programmed, with a wide range of pressure support values. RESULTS: All the ventilators showed a deviation of delivered versus programmed V_T below 10% in the period without unintentional leaks. In the model with unintentional inspiratory leaks, a progressive drop in delivered V_T and pressure support was observed for all ventilators. The reduction in the delivered V_T for the highest inspiratory leak ranged between 21 and 40%, corresponding to a decrease in pressure support between 3.09 and 10.15 cm H_2O after 5 min. Conversely, in the expiratory model, increases in delivered V_T and pressure support were observed, ranging between 16 and 33% and between 2.7 and 6.5 cm H_2O, respectively. CONCLUSIONS: The introduction of random leaks influences the performance of commercial ventilators with single-limb circuits and intentional leak. The decrease in delivered V_T with inspiratory leaks reaches a magnitude that may have clinically important impacts. *Key words: dual-control mode; noninvasive ventilation; leaks; volume-targeted pressure support.* [Respir Care 2015;60(2):1–•. © 2015 Daedalus Enterprises]

Introduction

Modern noninvasive ventilators for domiciliary and in-hospital use provide the clinician with a wide spectrum of ventilation modes for the treatment of patients with respiratory failure. Manufacturers have introduced dual-control ventilation modes based on pressure support (volume-targeted pressure support), in which the ventilator increases or decreases the level of support as a function of the targeted tidal volume (V_T) set by the clinician.

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In clinical practice, the use of volume-targeted pressure support in noninvasive ventilation (NIV) has produced controversial results. Initial reports demonstrated a benefit mainly in patients with obesity-hypoventilation syndrome,[1] but later analyses in which pressure support was carefully titrated and monitored did not show this effect.[2] Other studies focusing on patients with COPD[3-5] also demonstrated modest benefits for this dual-control mode.

To simplify the management of ventilators by both clinicians and patients, single-limb circuits with exhalation leak port have been the most frequently used systems for providing a gas mixture from the ventilator to the patient and for preventing rebreathing from the patient's exhaled gas. One of the main drawbacks of this system, however, is that certain essential values (for instance, V_T and unintentional leaks) are estimated rather than directly measured. Focusing on this issue, several bench studies have demonstrated that the estimation of V_T by home ventilators may be modified by the leak. In a model of continuous leaks simulated through a calibrated orifice, 2 studies have shown underestimations of V_T of different magnitudes by commercial devices,[6,7] and, in a dynamic leak model, with excess leaks during inspiration or expiration, Sogo and colleagues[8] found that the increase in inspiratory leaks led to an overestimation of the V_T. Inaccurate V_T estimations may also manifest in the volume-targeted pressure support modes. In a model of continuous leaks, 2 studies have demonstrated that single-limb circuits with an exhalation leak port provided the targeted V_T, even when continuous additional unintentional leaks were introduced in the circuit.[9,10] However, Fauroux and colleagues[11] demonstrated that some ventilators were not able to guarantee the pre-set V_T when unintentional leaks were introduced, a phenomenon that the authors attributed mainly to the development of asynchronies (autotriggering) rather than to an inaccurate estimation of V_T. The behavior of leaks may be different in clinical practice, however, in which poorly fitted masks may generate leaks only during inspiration, or during exhalation in patients wearing nasal masks who exhale through the mouth. In this setting, we performed a bench study with a model of dynamic leaks (predominant in inspiration or expiration) to determine their influence in volume-targeted pressure support modes.

Methods

Study Design

This study was performed in the Hospital de Sabadell, Sabadell, Barcelona, Spain. The experiment was conducted under simulation conditions in a mechanical ventilation laboratory equipped with a breathing simulator (series 1101, Hans Rudolph, Inc., Shawnee, Kansas), which was used to test the ventilators. As a signal acquisition system, an external polygraph (16Sp Powerlab, ADInstruments, Sydney, Australia), equipped with 2 pressure transducers (1050 model) and 2 pneumotachographs (S300, instrumental dead space = 70 mL, resistance = 0.0018 cm H_2O/L/s) was used. Sampling frequency was set to 200 Hz, and the polygraph was connected to a personal computer equipped with Chart 7.0 software for Windows.

The ventilators tested were connected to the simulator through a single standard 2-m tube with a commercial leak port (Swivel, Philips Respironics, Murrysville, Pennsylvania) placed at their distal end. The equation defining the mathematical relationship between pressure and baseline intentional leak for this port was as follows: leak = $-0.034p^2 + 2.253p + 6.264$ ($R^2 = 0.999$). The leak port was maintained during the entire experiment, simulating the intentional leak used in clinical practice in NIV with single-limb configuration. A T-piece was inserted after this leak port to simulate the dynamic unintentional leaks during the inspiratory or expiratory phases.

In the model for inspiratory leaks, a 7.5 cm H_2O PEEP threshold valve (Whisperflow, Philips Respironics) was attached to this T-piece. Three levels of leak were added: (1) no leak, with the distal end of the T-piece occluded, maintaining only the port leak (Swivel valve) in the circuit; (2) baseline leak (Swivel valve) + additional leak 1, a calibrated hole with a diameter of 2 mm at the distal end; and (3) baseline leak (Swivel valve) + additional leak 2, a calibrated hole with a diameter of 3 mm (Fig. 1).

In the model for expiratory leaks, an active valve (Philips Respironics) was attached to the T-piece, with their opening and closure mechanically controlled by a standard tube connected to the proximal end of the tubing (Fig. 2).

QUICK LOOK

Current knowledge

Leak compensation during noninvasive ventilation (NIV) is essential to assure patient comfort and tolerance. The ability to trigger and cycle the breath in the face of a leak avoids asynchrony and improves NIV success.

What this paper contributes to our knowledge

The presence of dynamic, unintentional leaks during NIV using a single-limb circuit with a leak port circuit interferes with ventilator performance in the volume-targeted pressure support mode. Inspiratory leaks result in a reduction in pressure support, with no guarantee of delivered tidal volume. A minimal level of pressure support may be required to avoid insufficient support.
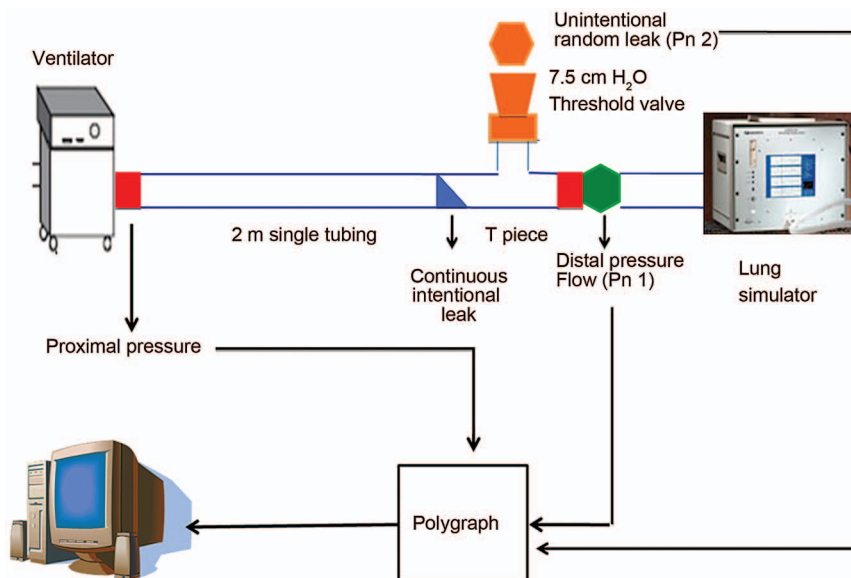
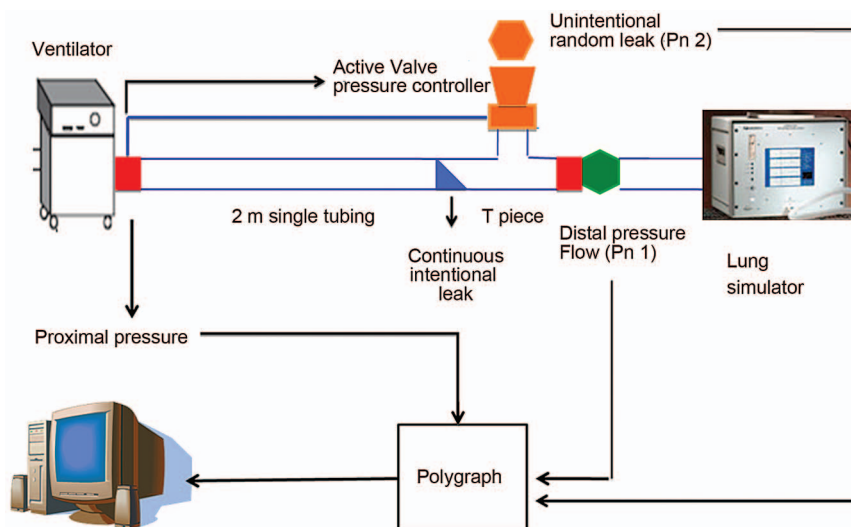Fig. 1. Design of the experiment in the inspiratory model.

Fig. 2. Design of the experiment in the expiratory model.

In both cases (inspiratory and expiratory leaks), a second pneumotachograph monitored the inspiratory unintentional leaks.

Before each session, both pneumotachographs 1 and 2 and the pressure transducers were calibrated following the manufacturer's instructions, using a 3-L syringe and against a water column.

Parameters Used in the Study

Parameters of the simulator. Spontaneous breathing frequency was programmed at 15 breaths/min in the simulator (-6 cm H_2O of effort level/20% of the respiratory cycle). As volume-targeted pressure support is most frequently used in restrictive patients, compliance was set at 25 mL/cm H_2O, and resistance at 7.5 cm H_2O/L/s.[12]

Parameters of the ventilator. Parameters selected for each ventilator are summarized in Table 1.

Ventilators Tested

Six commercial ventilators were tested: (1) Vivo 50 (General Electric, Mölnlycke, Sweden), (2) Stellar 150 (ResMed, North Ryde, Australia), (3) Trilogy 100 (Philips Respironics), (4) Puritan Bennett (PB) 560 (Covidien,

Table 1. Parameters Selected for Each Ventilator for the Bench Study

Ventilator	Targeted Volume*	Minimum IPAP (cm H_2O)	Maximum IPAP (cm H_2O)	EPAP (PEEP) (cm H_2O)	Rise Time	Inspiratory Trigger†	Cycle-off Criterion (%)	Maximum Inspiratory Time (s)
Vivo 50	550	8	40	5	2‡	9‡	7‡ (30)	1.5
Stellar 150	6.5	8	40	5	150§	Very low	Low	1.5
Trilogy 100	550	8	34	5	2‡	9‖	30	NA
PB 560	550	8	40	5	1‡	5‡	30	1.5
Carina	550	NA	NA	5	200§	Normal	NA	1.5
V60	550	8	40	5	2‡	NA	NA	NA

Backup breathing frequency was programmed at 12 breaths/min in the ventilators.
* Measurements are given in mL for targeted volume, except for Stellar 150, which is given in L/min (minute ventilation).
† Inspiratory trigger was set at the lowest sensitivity to avoid autotriggering.
‡ In analogic scale.
§ Measurements are given in ms.
‖ Measurement is given in L/min.
IPAP = inspiratory positive airway pressure
EPAP = expiratory positive airway pressure
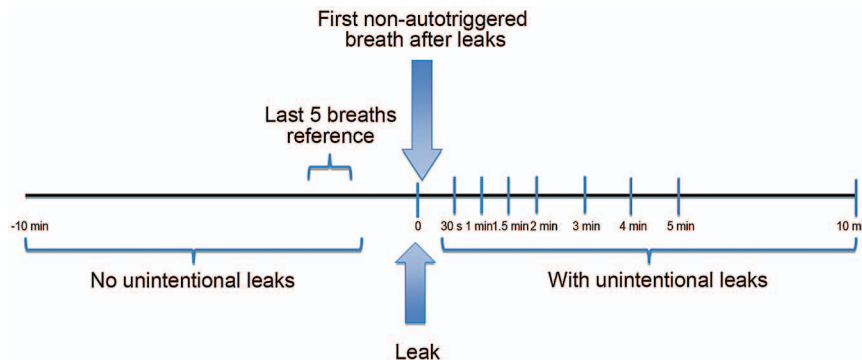PB = Puritan Bennett
NA = not available

Fig. 3. Measurement protocol.

Mansfield, Massachusetts), (5) Carina (Dräger, Lübeck, Germany, and (6) V60 (Philips Respironics).

Measurement Protocol

To reach stability with targeted volume and only the leak port circuit, an initial period of 10 min was recorded. After that, a 10-min period was scheduled for each tested condition (lower and higher inspiratory leak, and expiratory leak). The 4 last breaths of the initial 10-min period with only the leak port circuit (stability period), the first non-autotriggered breath after valve opening (to ensure that the results were not influenced by a lack of compensation of unintentional leaks and labeled as "after leaks"), and the 5 last breaths of each 30-s period (until minute 2) and 1-min period (until minute 5) were recorded. If the variation in V_T or pressure support was < 5% after min 5, only values until this minute were analyzed. The measurement protocol is summarized in Figure 3.

To standardize the analysis of true V_T entering the respiratory system, the V_T obtained by the pneumotachograph was converted to BTPS (body-temperature-and-pressure-saturated) conditions[13] as detailed elsewhere.[7] At the same time, dynamic (unintentional) leak values were monitored (pneumotachograph 2) and registered.

Statistical Analysis

Statistical analyses were performed using SPSS 19 (SPSS, Chicago, Illinois). Quantitative values for each experimental condition were expressed as means ± SD. To compare the behavior of the ventilators at different steps of the protocol, the general model for repeated measures was used. When the sphericity of the model could not be assumed (Mauchly's test with P value < .05), the significance of the model was assessed with the Greenhouse-Geisser correction. Inter-subject differences between ven-
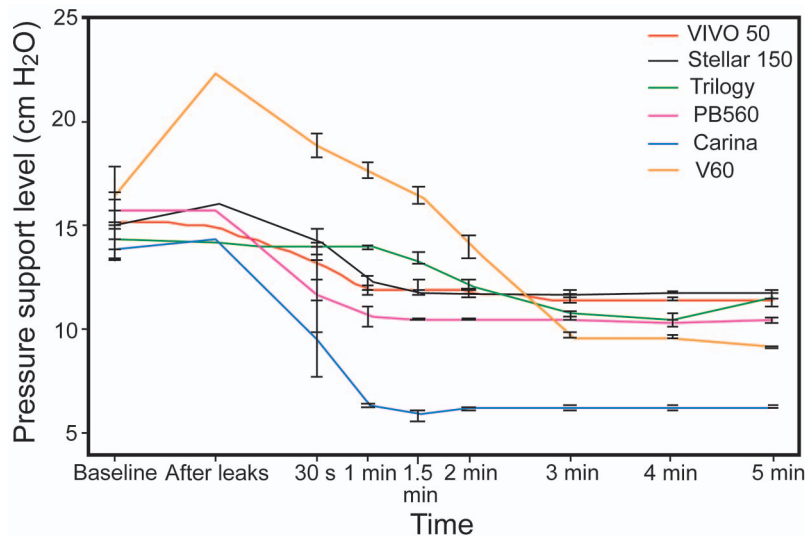
Fig. 4. Changes in the pressure support level after the introduction of unintentional leaks (lower inspiratory leak). Significant intra- and inter-subject differences were found for all ventilators ($P < .01$). Data are shown as mean ± SD.

Table 2. Mean Level of Leaks (Measured [Unintentional] and Estimated [Intentional]) at 30 s After the Valve Opening

Ventilator	Excess of Inspiratory Leaks (Lower Leak)* (L/min)	Excess of Inspiratory Leaks (Higher Leak)* (L/min)	Excess of Expiratory Leaks (L/min)	Estimated Intentional Baseline Leaks† (L/min)	
				Inspiratory (peak)	Expiratory (mean)
Vivo 50	20.76 ± 1.72	30.63 ± 3.17	10.12 ± 0.06	37.72	16.2
Stellar 150	24.72 ± 0.88	32.86 ± 1.88	13.41 ± 0.57	37.90	17.05
Trilogy 100	21.66 ± 0.24	31.90 ± 1.01	14.96 ± 0.83	37.22	17.1
PB 560	21.48 ± 2.95	28.30 ± 2.7	13.09 ± 0.09	38.37	16.8
Carina	20.20 ± 2.06	25.40 ± 3.85	11.05 ± 0.05	36.89	17.2
V60	27.67 ± 1.45	41.50 ± 1.14	14.80 ± 0.16	38.81	16.6

* Lower and higher leaks were simulated trough calibrated holes (2 and 3 mm, respectively), placed after the threshold valve.
† Estimated in the period without unintentional leaks.
PB = Puritan Bennett

tilators were assessed by Bonferroni post hoc analysis. Statistical significance was set at a P value of $< .05$.

Results

The protocol was completed for all tested ventilators, which reached stability in pressure support and predetermined V_T values at the end of 10 min with the leak port circuit, and before minute 5 in the periods with dynamic unintentional leaks. Differences in targeted and measured volume at the end of the period with baseline leak (only the exhalation port) were below 10% for all the ventilators studied, although there were some differences between the pressure support levels reached by each ventilator (Fig. 4).

In the period with dynamic leaks (valve open), the amount of leaks varied according to the level of pressure support attained by the devices. Mean level of leaks (measured [unintentional] and estimated [intentional]) at 30 s after the valve opening are displayed in Table 2. As shown in the higher leak, leaks during the inspiratory phase accounted for up to 70 L/min.

The results of the model with inspiratory leaks are displayed in Figure 4 (for pressure support) and Figure 5 (for V_T) for the lower leak, and in Figures 6 and 7 for the higher leak. As can be observed, the addition of inspiratory dynamic leaks caused a progressive decrease both in the pressure support and in the delivered V_T, falling clearly below the programmed targeted values. The progression of the decrease differed between the devices, with some ventilators (Carina and PB 560) reaching stability before minute 2 and others (Trilogy and V60) showing a slower decrease. At the end of the 5-min period, differences in the
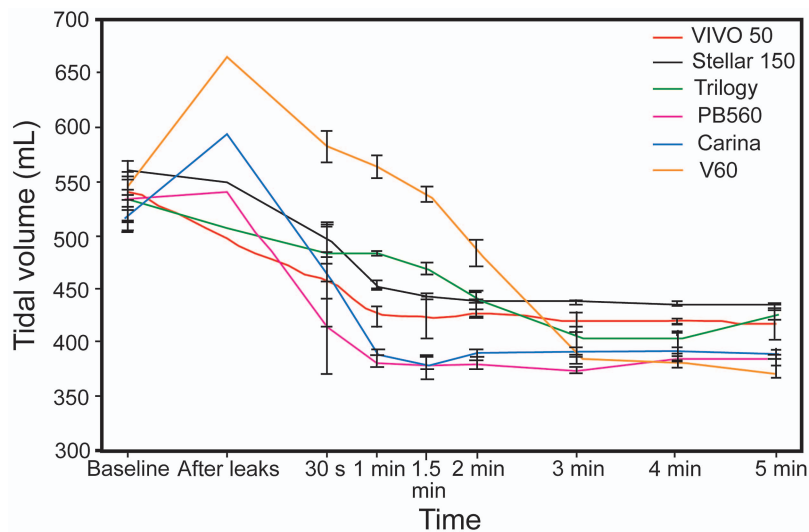
Fig. 5. Changes in the delivered tidal volume after the introduction of unintentional leaks (lower inspiratory leak). Significant intra- and inter-subject differences were found for all ventilators ($P < .01$). Data are shown as mean $\pm$ SD.
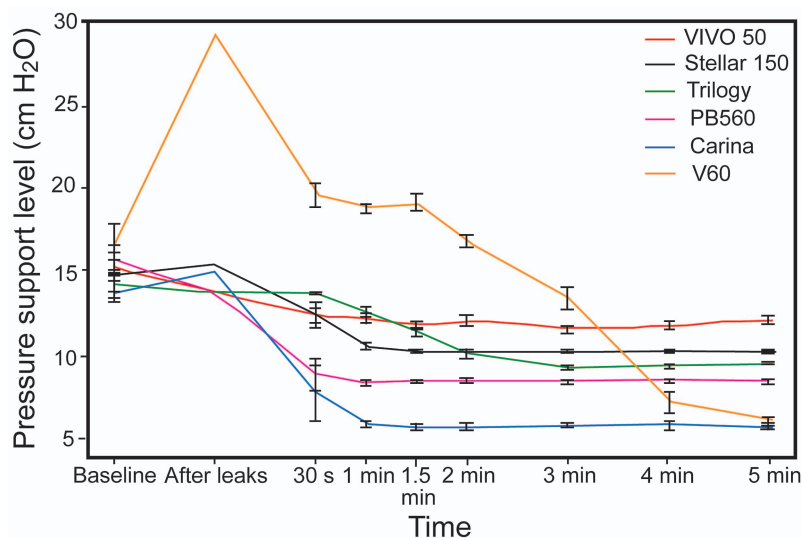

Fig. 6. Changes in the pressure support level after the introduction of unintentional leaks (higher inspiratory leak). Significant intra- and inter-subject differences were found for all ventilators ($P < .01$). Data are shown as mean $\pm$ SD.

mean delivered V_T comparing the periods with and without dynamic leaks ranged from 21 to 31% for lower leak and from 21 to 40% for higher leak. Regarding the pressure support level, the differences ranged between 2.82 and 7.28 cm H_2O for lower leak and between 3.09 and 10.16 cm H_2O for higher leak. Interestingly, 2 ventilators (Carina and V60) showed an increase both in pressure support levels and in delivered V_T immediately after valve opening. The other 4 ventilators showed minimal differences (Stellar 150) or only modest decreases (Vivo 50, Trilogy, and PB 560) in these 2 variables. Statistically significant intra-subject (ventilator) differences were found as a function of time for all tested ventilators ($P < .01$ by

Greenhouse-Geisser test). Similarly, significant differences between the different ventilator models were observed (Bonferroni post hoc test $< .01$). The influence of the level of leak in the delivered V_T by each ventilator is shown in Figure 8. As displayed, all ventilators presented significant differences ($P < .01$) when the 2 levels of dynamic leaks were compared, with the exception of Vivo 50.

In the model with expiratory leaks, as observed in Table 3, the addition of the leaks caused an increase in both the delivered V_T and pressure support. As in the inspiratory model, the progression of the increase differed between the ventilators studied, and, at the end of the 5-min period, the increase in V_T ranged between 16 and 33%, compared
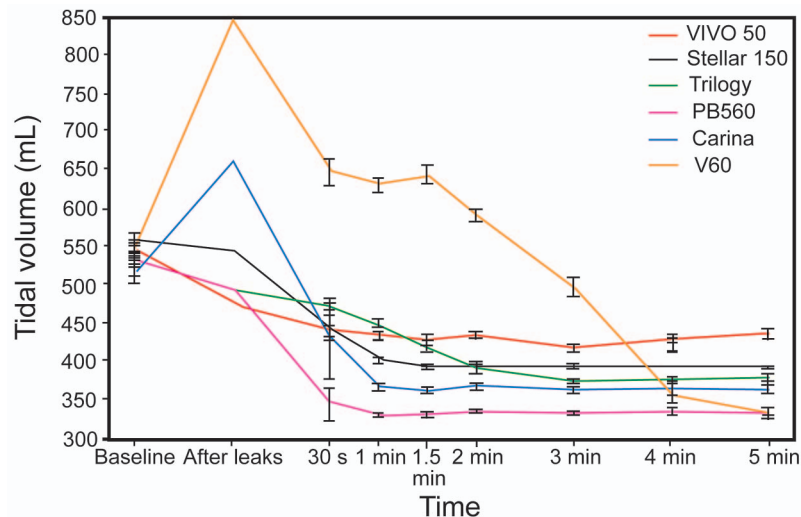
Fig. 7. Changes in the delivered tidal volume after the introduction of unintentional leaks (higher inspiratory leak). Significant intra- and inter-subject differences were found for all ventilators ($P < .01$). Data are shown as mean ± SD.

with the volume delivered at the end of the stability period without unintentional leaks. Finally, the increase in pressure support level ranged between 2.7 and 6.5 cm H_2O. As occurred with the inspiratory model, significant intra-subject differences in V_T as a function of time were found for all the devices studied ($P < .01$ Greenhouse-Geisser test), and inter-subject differences were found also for all ventilators, with the exception of the comparison between Vivo 50 and Stellar 150 ventilators.

Interestingly, the results of V_T displayed by the ventilators able to download this information from internal memory (all of them with exception of Carina and V60) showed a transient overestimation when inspiratory leaks were introduced and a underestimation when expiratory leaks were introduced (Fig. 9).

Discussion

The most important findings of the study are that, in NIV and with single-limb and leak port circuit, the presence of dynamic unintentional leaks altered the delivered V_T during volume-targeted pressure support mode in both inspiratory and expiratory phases. From the clinical point of view, the most feasible model is the excess inspiratory leak model: in this condition, the delivered V_T fell by 40% compared with the values without unintentional leak. This decrease may lead to significant hypoventilation in clinical practice.

The influence of leaks in dual-control modes has been assessed in 2 studies. Carlucci and colleagues[9] studied the influence of the configuration of bi-level ventilator circuits on the compensation of leaks during volume-targeted ventilation. In their study, when unintentional leaks were in-

troduced, the ventilators were able to compensate for them, but only when a vented circuit (leak port circuit) was used. When a non-vented (active expiratory valve) circuit was used, the authors observed a decrease in delivered V_T. Similarly, Khirani and colleagues[10] studied 3 double-limb circuit ventilators and 2 ventilators with a single circuit and exhalation leak port and demonstrated that these devices were unable to maintain the pre-set minimal V_T during unintentional leaks; however, the same ventilators studied with a single-limb circuit and leak port were able to do so. Both studies introduced unintentional leaks as a continuous parameter through a calibrated hole of variable diameter. Based on the results of these previous studies, the volume-targeted pressure support mode was suggested to be safe with a single-limb and leak port circuit.

The model with excess leaks during inspiratory or expiratory phases was first explored by Storre et al[14] in a patient model and generating excess leaks in the circuit with manual occlusion of a T-piece inserted in the circuit. In a similar way, Carteaux et al[15] designed a model of excess of inspiratory unintentional leaks using a water column of variable height to study the frequency of asynchronies at different leak levels. However, the implications of this kind of leak in volume-targeted pressure support mode have not been addressed.

We hypothesize that the findings in our study are more probably due to monitoring inaccuracies than to a lack of compensation of the unintentional leaks. Even with the highest inspiratory leak, only a modest decrease ($< 10\%$) in delivered V_T immediately after the valve's opening was detected in some of the ventilators; in fact, 2 of them, frequently used in clinical practice for the acute setting (Carina and V60), showed a transient overshoot phenom-
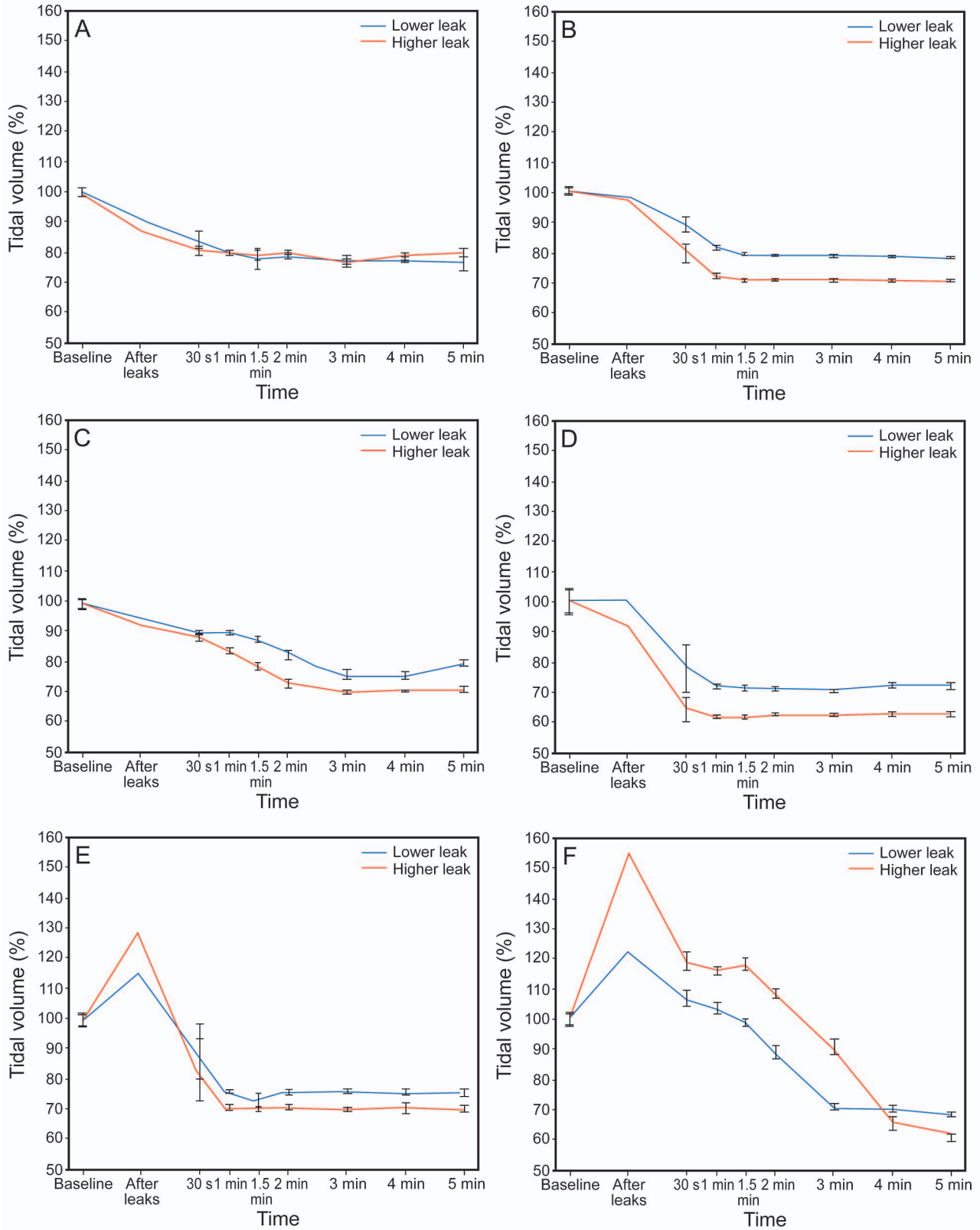
Fig. 8. Comparison of delivered tidal volume (% from baseline) between lower and higher inspiratory leak for all ventilators. $P < .01$ for all ventilators except the Vivo 50. A: Vivo 50, B: Stellar 150, C: Trilogy 100, D: Puritan Bennett 560, E: Carina, and F: V60. Data are shown as mean ± SD.

Table 3. Changes in the Delivered Tidal Volume and Pressure Support After the Introduction of Unintentional Leaks (Expiratory Leak)

Stage	Vivo 50		Stellar 150		Trilogy		PB 560		Carina		V60	
	Mean V_T	Mean PS	Mean V_T	Mean PS	Mean V_T	Mean PS	Mean V_T	Mean PS	Mean V_T	Mean PS	Mean V_T	Mean PS
No leak	545	15.2	561	15.0	533	14.2	536	15.7	515	13.8	544	16.3
After leaks	550	14.4	500	12.1	495	10.6	514	12.5	513	14.7	525	13.9
30 s	608	16.9	568	14.5	504	11.6	705	21.4	633	18.2	536	13.9
1 min	640	18.5	637	17.0	526	12.8	719	21.8	634	18.1	532	14.1
1.5 min	660	19.4	651	17.6	560	14.5	721	21.8	626	17.8	542	15.5
2 min	670	19.6	653	17.6	597	15.8	723	22.0	629	18.0	597	18.0
3 min	669	19.6	656	17.7	660	18.6	721	21.9	632	17.9	704	22.2
4 min	669	19.6	654	17.6	704	20.6	718	21.9	647	18.5	722	23.0
5 min	668	19.6	654	17.7	705	20.8	716	22.0	670	19.3	694	22.1

Significant intra- and inter-subject differences were found for all ventilators ($P < .01$).
PB = Puritan Bennett
V_T = tidal volume
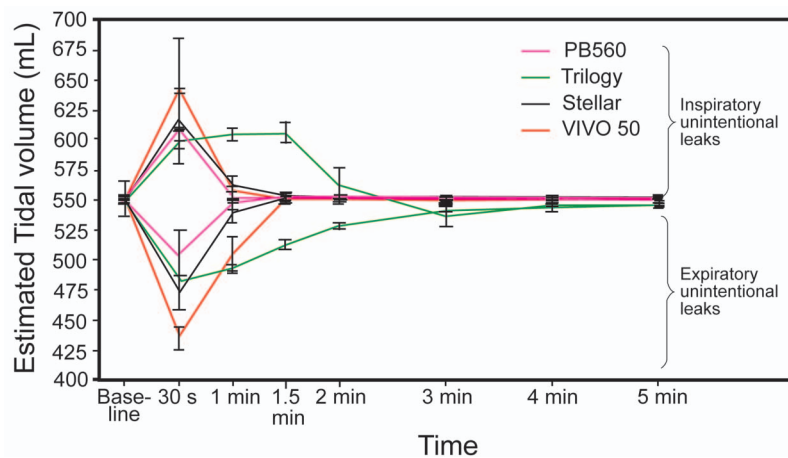PS = pressure support

Fig. 9. Estimated tidal volume the ventilators displayed, downloaded from internal memory.

enon with increases both in the pressure support and in the delivered V_T after the sudden introduction of unintentional leaks. This overshoot has been described by other authors,[11] and, although it suggests that the level of compensation of the leaks was adequate, it might be uncomfortable for some patients.[16]

In a previous study by our group,[8] introduction of unintentional dynamic leaks only during one phase of the respiratory cycle affected the accuracy of the estimation of leak and V_T values. Those findings seem to suggest that the estimation of leak and V_T by built-in software, or by the ventilators themselves, is based on the assumption that there is a proportional relationship between leaks during expiration and inspiration; in clinical practice, however, it may be that leaks occur only in one phase of the respiratory cycle, mostly during inspiration. The algorithms based on these assumptions overestimated delivered V_T in the unintentional leak setting, and underestimated it in the

case of expiratory leaks. These previous findings reinforce the hypothesis that the changes observed in delivered V_T after introducing unintentional leaks are probably a consequence of a deviation in its estimation.[17]

Another interesting result derived from the present study was the different period of time elapsed by the ventilators to reach stability after the introduction of dynamic leaks. In some ventilators, the stability is reached after a few breaths, whereas, in others, it was attained later. This observation might be explained by the different algorithms of increases and decreases in pressure in response to the changes in estimated V_T. Whereas in some ventilators (eg, Carina, Stellar 150, or PB 560) the changes in pressure support to ensure the targeted volume are achieved in few breaths, in others (V60, Trilogy, and even Vivo 50), these changes are more progressive (maximum changes between 1 and 2 cm H_2O of pressure support/min) for improving the patient's tolerance. The initial overshoot observed in

some ventilators after the introduction of unintentional inspiratory leaks may be also related to the features of internal algorithms in each model.

The findings of the present study may have important clinical implications. First of all, if the clinician chooses a volume-targeted pressure support mode, it seems reasonable to set a minimum pressure support level, corresponding to a minimum safe volume. Our data confirm that, in the presence of large leaks and a wide range of pressures, delivered V_T may fall by up to 40% in 5 min, placing the patient at risk of severe hypoventilation. Second, the influence of leaks has not been addressed in clinical studies of the efficacy of dual-control modes, and the potential benefits of these hybrid modes have not been consistently demonstrated in the literature.[18]

Some limitations of the study should be pointed out. Even after introducing unintentional dynamic leaks during an entire phase of the cycle, the design may not reflect the wide spectrum of possibilities of patient-interface interactions, because leaks may appear only during small periods of time in each cycle (only at end inspiration, or during the second half of the inspiratory cycle, for example). Similarly, patient-ventilator interactions may be much more complex than the present model allows for, with changes in respiratory drive, compliance, and ventilatory pattern. Finally, the evaluation was performed in a restrictive model, and it may be questionable whether these findings are of application in an obstructive model.

Conclusions

In NIV using a single-limb with leak port circuit, the presence of dynamic unintentional leaks may interfere with the performance of the ventilators in volume-targeted pressure support modes. The observation that inspiratory leaks may reduce pressure support values, with no guarantee that the pre-set values of V_T are delivered, may have clinical relevance. In this situation, it seems reasonable to recommend a minimum pressure support level corresponding to a minimum safe V_T.

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