A Bench Evaluation of Eight Home-Care Ventilators

Sara Martínez Castro, Francisco Javier Belda Nacher, Carlos Delgado Navarro, and Jaume Puig Bernabeu

BACKGROUND: The growing number of patients on home mechanical ventilation has driven considerable progress in the performance and functionality of ventilators, with features comparable with those used in the ICU. However, a publication gap exists in the evaluation and comparison of their performance and each ventilator choice depends on machine characteristics defined by manufacturers. METHODS: We bench tested 8 home-care ventilators that are currently available: Monnal T50, EOVE EO-150, Puritan Bennet 560, Weinmann, PrismaVent 50, Trilogy Evo, Astral 150, and Vivo 60 by using an active lung model. These devices were tested under 18 experimental conditions that combined 3 variables: respiratory mechanics, ventilatory mode, and inspiratory muscle effort. The volume delivered, trigger response, pressurization capacity, and synchronization were analyzed. RESULTS: Significant differences were observed in the performance among the devices. Decreased inspiratory muscle effort caused changes in the delivered volume, which worsened the response-to-trigger time, pressurization capacity, and synchronization. Increased pressure support favored the development of asynchronies. All the ventilators developed asynchronies under at least 1 set of conditions, but the EOVE and Trilogy Evo ventilators showed the fewest asynchronies during the experimental conditions studied. CONCLUSIONS: Great variability in terms of technical performance was observed among the 8 home-care ventilators analyzed. Asynchronies became a major issue when home mechanical ventilation was used under higher pressure-support values and lower muscle efforts. Our results may prove to be useful in helping choose the best suited machine based on a patient's clinical therapy needs. *Key words: mechanical ventilation; noninvasive ventilation; breathing mechanics; computer simulation; home care; ventilator performance; pressure-time product; trigger delay time; asynchrony.* [Respir Care 2021;66(10):1531–1541.

Introduction

Noninvasive ventilation (NIV) began its development in 1927 when Drinker and Shaw designed the iron lung, but it was not until the end of the 20th century when Philips Respironics (Murryville, Pennsylvania) introduced BiPAP to the market. Since then, NIV has become a fundamental therapy for patients with neuromuscular and obstructive pathologies. Guidelines such as the Global Initiative for Chronic Obstructive Lung Disease[1] established the criteria for its indications. In 2000, de Lucas Ramos et al[2] analyzed and documented the implementation of home mechanical ventilation programs in Spanish hospitals. At that time 1,821 patients were treated at home. However, a great variability was observed in terms of indications, ventilators, and interfaces used.

The continuous development of NIV has led to an increase in its use parallel to ventilator technological improvements. Its scope covers the in-hospital and out-of-hospital environments, including transport. Home mechanical ventilation requires out-of-hospital settings, with the consequent increase in the demand for home-care devices.[3] Home mechanical ventilation consists of the intermittent or continuous use of a ventilator at home by using a nasal/facial mask as an interface (NIV), or directly connected to a tracheostomy cannula (invasive ventilation). Its role in neuromuscular pathologies and acute exacerbations of COPD leaves no doubt as, among other things, therapy reduces respiratory work, prevents muscle fatigue, increases tidal volume (V_T), and improves gas exchange. Two mechanical ventilation modes are commonly used: volume control continuous mandatory ventilation (VC-CMV) and pressure support ventilation (PSV). Patients with COPD benefit from pressure support therapies mainly at night; unloading respiratory muscles with high mean positive airway pressure and mandatory high breathing frequencies can improve alveolar ventilation and

thereby reduce chronic hypercapnia.[4] Neuromuscular patients benefit from volume-controlled therapies due to muscle weakness or paralysis, which have demonstrated survival rates similar to pressure support, with a lower number of admissions and greater comfort reported by patients. However, in practice, PSV is also used.

Synchronization and airway pressurization capacity are fundamental requirements to optimize patients' respiratory work; these require adequacy in trigger response, delivered volume, PEEP, and pressure support level. Among the advantages of home mechanical ventilation are decreased mortality rates, a reduced hospital length of stay, and a lower number of admissions. Ventilation optimization leads to improvement in the social conditions and quality of life, better sleep quality, and tolerance of daily physical activity.[5-7] Drawbacks are mainly related to an inadequate ventilatory regime, prescribed settings, and device performance. The growing number of home ventilation users has led to an increased investment in technologic development by manufacturers to improve ventilator performance. Home devices have sophisticated software and are under a continuous process of study and change, and feature functions comparable with ICU ventilators.[2,3] They theoretically fulfill quality and safety criteria, but many bench studies have shown large differences in performance among available home-care ventilators.[8-10]

The present study sought to describe and compare the performance of 8 commonly used home-care devices and to give clinicians information that might help them choose a ventilator, mode, and settings based on individual clinical conditions. The purpose was not to generate a ranking but to describe each ventilator's performance based on a predefined methodology under standardized conditions. We studied the performance in VC-CMV and PSV modes in 3 types of patient mechanics, with 2 levels of inspiratory effort, and evaluated (1) volume delivered, (2) response to trigger and pressurization capacity, and (3) quantity and quality of the asynchronies developed.

QUICK LOOK

Current knowledge

In theory, continuous development and acquisition of modern home ventilators with advanced settings should make it possible for these devices to better meet patient requirements. It is challenging to evaluate and compare these ventilators on the basis of their performance and responsiveness to patient needs. Lung models that feature noninvasive ventilation conditions allow testing of different ventilation scenarios, with the goal of offering general guidance about the choice of devices and settings to meet patient treatment goals.

What this paper contributes to our knowledge

Common themes during in vitro testing among the ventilators studied were that decreased inspiratory effort and increased support pressure worsened ventilator's response time and pressurization, and favored the development of asynchronies. Ventilator choice and settings may have a substantial impact on the ability of a device to meet patient needs and to improve synchrony. Because these ventilators and their interactions with patients and their physiologies vary in many ways, it is important to perform an in vivo clinical evaluation after home ventilation therapy is initiated.

Methods

Eight home-care ventilators available in the European and American markets were evaluated: Monnal T50 and EOVE EO-150 [EOVE] (AirLiquide Healthcare, Pau, France), Puritan Bennett 560 [PB560] (Covidien, Dublin, Ireland), Weinmann (Weinmann, Hamburg, Germany), PrismaVent 50 (Löwenstein Medical, Hamburg, Germany), Trilogy Evo (Philips, Murrysville), Astral 150 (ResMed, San Diego, California), and Vivo 60 (Breas Medical, Mölnlycke, Sweden). All of these were used with the appropriate limbs and connectors in accordance with each manufacturer's guidelines. The ventilators were connected via a single-limb circuit, with intentional leak, to the active lung model ASL 5000 (IngMar Medical, Pittsburgh, Pennsylvania; software version SW3.6 was used with the simulator bypass and leak valve module) already validated in previous ventilator evaluation studies.[10,11] The simulator uses a computer-operated piston to displace a predetermined volume; displacement is controlled by following the equation of motion of the respiratory system and allows adjusting of the values of airway resistance (R_{aw}) and compliance (C_{RS}), simulating different mechanics and inspiratory efforts.

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Table 1. Eighteen Experimental Conditions that Resulted from the Adjustment of 2 Magnitudes of Inspiratory Muscle Effort

Mechanics	Standard		Obstructive		Restrictive	
$P_{0.1}$	Normal*	Low†	Normal*	Low†	Normal*	Low†
VC-CMV	VSN	VSL	VON	VOL	VRN	VRL
PSV10	P10SN	P10SL	P10ON	P10OL	P10RN	P10RL
PSV20	P20SN	P20SL	P20ON	P20OL	P20RN	P20RL

* $P_{0.1}$ = –2 cm H_2O.
† $P_{0.1}$ = –0.5 cm H_2O.
$P_{0.1}$ = airway occlusion pressure
VC-CMV = volume control continuous mandatory ventilation; PSV10 = pressure support ventilation 10 cm H_2O; PSV20 = pressure support ventilation 20 cm H_2O; VSN = VC-CMV in standard mechanics with normal effort; VSL= VC-CMV in standard mechanics with low effort; VON = VC-CMV in obstructive mechanics with normal effort; VOL= VC-CMV in obstructive mechanics with low effort; VRN = VC-CMV in restrictive mechanics with normal effort; VRL = VC-CMV in restrictive mechanics with low effort; P10SN = PSV10 in standard mechanics with normal effort; P10SL = PSV10 in standard mechanics with low effort; P10ON = PSV10 in obstructive mechanics with normal effort; P10OL = PSV10 in obstructive mechanics with low effort; P10RN = PSV10 in restrictive mechanics with normal effort; P10RL = PSV10 in restrictive mechanics with low effort; P20SN = PSV20 in standard mechanics with normal effort; P20SL = PSV20 in standard mechanics with low effort; P20ON = PSV20 in obstructive mechanics with normal effort; P20OL = PSV20 in obstructive mechanics with low effort; P20RN = PSV20 in restrictive mechanics with normal effort; P20RL = PSV20 in restrictive mechanics with low effort

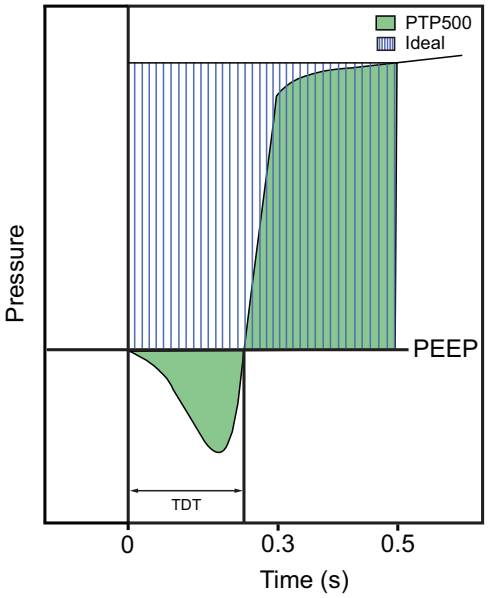

Figure 1. Graphic representation of the pressure time product in the first 500 ms of the respiratory cycle (PTP500) and trigger delay time (TDT). PTP500 represents the net area under the pressure curve for the first 0.5 s. The TDT represents the time from the beginning of the inspiratory effort (pressure drop below zero or the PEEP) until the beginning of the positive inspiratory flow (pressure above zero or PEEP) in seconds.

For this study 3 types of respiratory physiology were simulated by using different combinations of C_{RS} and R_{aw} values: standard (S) (C_{RS} = 50 mL/cm H_2O, R_{aw} = 5 cm H_2O/L/s), obstructive (O) (C_{RS} = 50 mL/cm H_2O, R_{aw} = 20 cm H_2O/L/s), and restrictive (R) (C_{RS} = 20 mL/cm H_2O, R_{aw} = 5 cm H_2O/L/s). By using a scheme similar to previous studies, standard settings were adjusted as follows: spontaneous breathing frequency of 12 breaths/min and PEEP of 5 cm H_2O, with a trigger at maximum sensitivity without developing auto-triggering. Because one of the main characteristics of home ventilation is the constant and inevitable presence of leaks, an additional constant leak of 6 L/min (measured at 10 cm H_2O) was added with the ASL 5000 leak valve in all the experimental conditions.[8,11,12] Ventilators were programmed in the VC-CMV mode with V_T of 500 mL, and in PSV with 2 pressure levels: 10 cm H_2O (PSV10) and 20 cm H_2O (PSV20). Two levels of inspiratory muscle effort were used: normal (N) airway occlusion pressure of –2 cm H_2O and low (L) airway occlusion pressure of –0.5 cm H_2O.[13] By combining these 3 variables (respiratory physiology, ventilatory mode, and inspiratory muscle effort), 18 experimental conditions were tested (Table 1). Rise time settings were adjusted at the beginning of each ventilator trial as the maximum rate of rise (fastest response) allowed by each device. Cycling criteria parameters were left at each ventilator's default settings. When adjustment was mandatory, 20% of peak inspiratory flow was set. In all conditions, a minimum time of 1 min was left for stabilization of the system (clear sequence of cycles with similar morphology), then 10 consecutive respiratory cycles were recorded at each experimental condition for subsequent analysis.

For each experimental condition, data values of muscle pressure, airway pressure, and flow as measured by the ASL 5000 simulator were exported to an Excel (Microsoft, Redmond, CA) spreadsheet. From these data, delivered volume, trigger response, pressurization capacity, and asynchronies (quantity and quality) were calculated. Sampling frequency of the data points was 512 Hz. The delivered V_T was measured in milliliters in representative synchronous respiratory cycles chosen by the investigators. When synchronization was not achieved in any cycle during VC-CMV, V_T was measured in an auto- triggering in which V_T is theoretically equivalent to the V_T delivered in a controlled cycle. The response to a trigger was measured by the trigger delay time, defined as the time from the beginning of the inspiratory effort (drop in muscle pressure below zero) until the beginning of the positive inspiratory flow (higher than the flow triggering value) expressed in milliseconds. Pressurization capacity was evaluated through the pressure time product (PTP) in the first 500 ms of the respiratory cycle (PTP500). For this study, it was measured as the area under the airway- pressure curve from the beginning of the effort (where the muscle pressure values became negative) through 500 ms on each respiratory cycle. Measurements of PTP500 and the trigger delay time are illustrated in Figure 1.

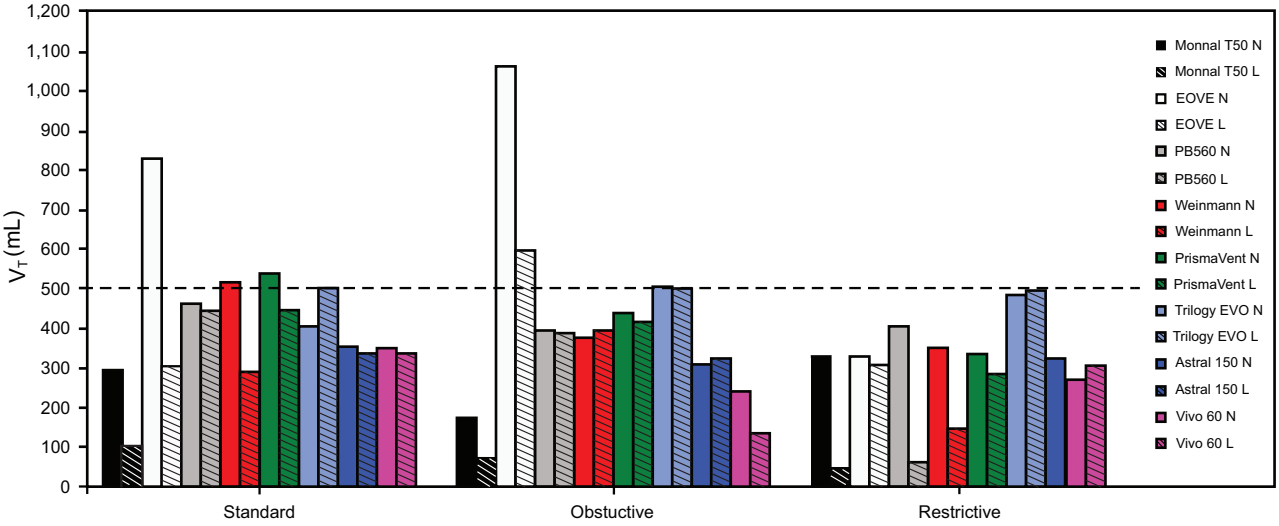

Figure 2. Tidal volume (V_T) measured at 2 levels of inspiratory effort normal (N) and low (L) in the volume control continuous mandatory ventilation (VC-CMV) mode, with a constant leak of 6 L/min in 3 mechanics. The black line corresponds to the V_T set to VC-CMV 500 mL.

When compared with invasive ventilation, the open system nature of the NIV and the fluctuating resistances of the ventilator-lung pairs may lead to patient-ventilator asynchronies. These are defined as the mismatch between the activity of the patient and the inspiratory mechanical cycle.[14] The quantitative and qualitative analysis of asynchronies in the present study was carried out by visual inspection of airway pressure, muscle pressure, and flow curves in the recorded cycles. For each experimental condition, 10 cycles were collected and analyzed as follows: (1) the asynchrony index was calculated as the number of asynchronous events divided by the total number of respiratory cycles (sum of triggered and non-triggered cycles), expressed as a percentage; the asynchrony index took into consideration ineffective efforts, auto-triggering, and double/reverse triggering; when $\geq$ 10%, the asynchrony index was considered clinically relevant[14,15]; and (2) qualitative analysis of asynchronies included time asynchronies (ineffective efforts, auto-triggering, and double/reverse triggering), flow (flow starvation having an impact on airway pressure shape) and inspiration/expiration cycling (premature or delayed).

Statistical Analysis

Each parameter value was represented as the mean of 3 breaths (whenever it was possible); all results were reported as mean ± SD. In general, the SDs of 3 cycles showed very small variations (range, 1- 2%) and was not representative in the presence of a high incidence of asynchronies. Because data collected did not meet the assumption of normality, the Welch analysis of variance was used to compare V_T, trigger delay time, and PTP500 mean values for the 8 ventilators and Student *t* tests to compare pairs of ventilators for each condition; $P < .05$ was considered statistically significant. Asynchrony analysis was performed by visual inspection of respiratory cycle graphs for each experimental condition; the evaluation was carried out individually by 2 researchers on the same traces when agreeing on the type and magnitude of asynchronies. Values taken for reference were based on the safety standards in design and manufacture of ventilators for home use when assuming a negligible variability intracondition that was not considered clinically relevant.[16]

Results

Effort reduction may influence triggering in VC-CMV and PSV, but small effects on delivered V_T were expected. Surprisingly, there were statistically significant differences for all the devices analyzed and decreased respiratory effort caused a decrease in V_T. In VC-CMV (Fig. 2), V_T was reduced significantly in most of the ventilators with low effort. The PB560, PrismaVent and Trilogy Evo ventilators maintained V_T around the prescribed 500 mL, whereas the Monnal T50 ventilator delivered a lower V_T for all conditions. With S mechanics, decreased effort resulted in a drop in V_T for all the devices, except for the Trilogy Evo ventilators. Ventilators with the highest decrease in V_T were the Monnal T50 (64% drop), EOVE (63%), and Weinmann (44%). With O mechanics, a decrease in muscle effort did not change V_T in 5 of 8 ventilators analyzed. With R mechanics, V_T was < 500 mL, despite being in VC-CMV, significantly lower than under S and O mechanics. The lowest V_T values were recorded for all the devices except the Trilogy Evo when R mechanics and L effort were set. V_T for the Astral 150

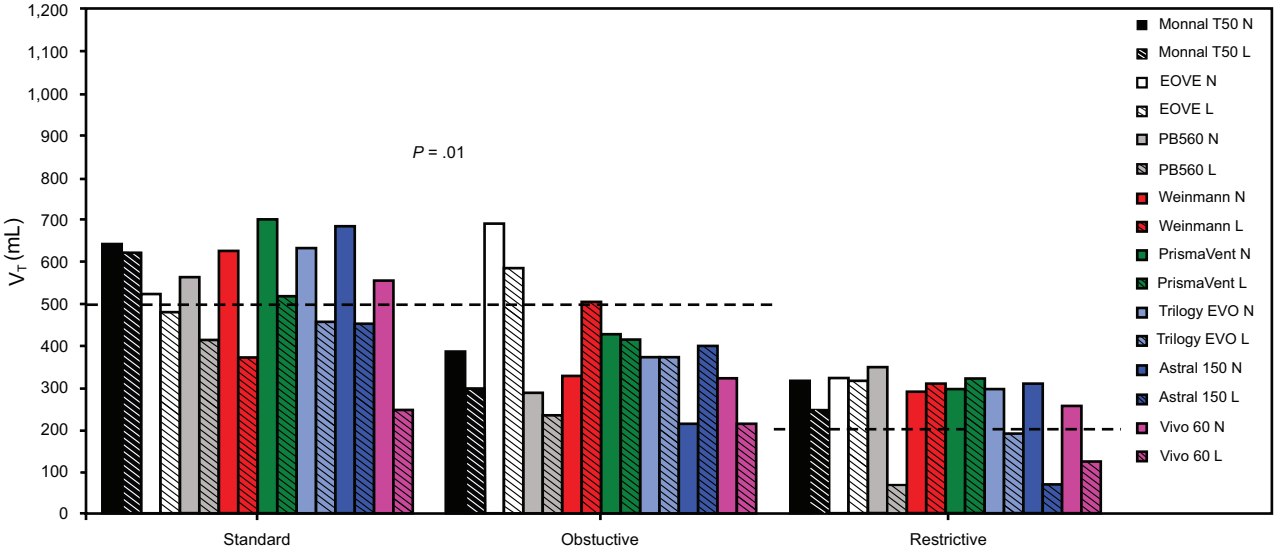

Figure 3. Tidal volume (V_T) measured at 2 levels of inspiratory effort normal (N) and low (L) in the pressure support ventilation 10 cm H_2O (PSV10) mode, with a constant leak of 6 L/min in 3 mechanics. The black lines correspond to the expected V_T.

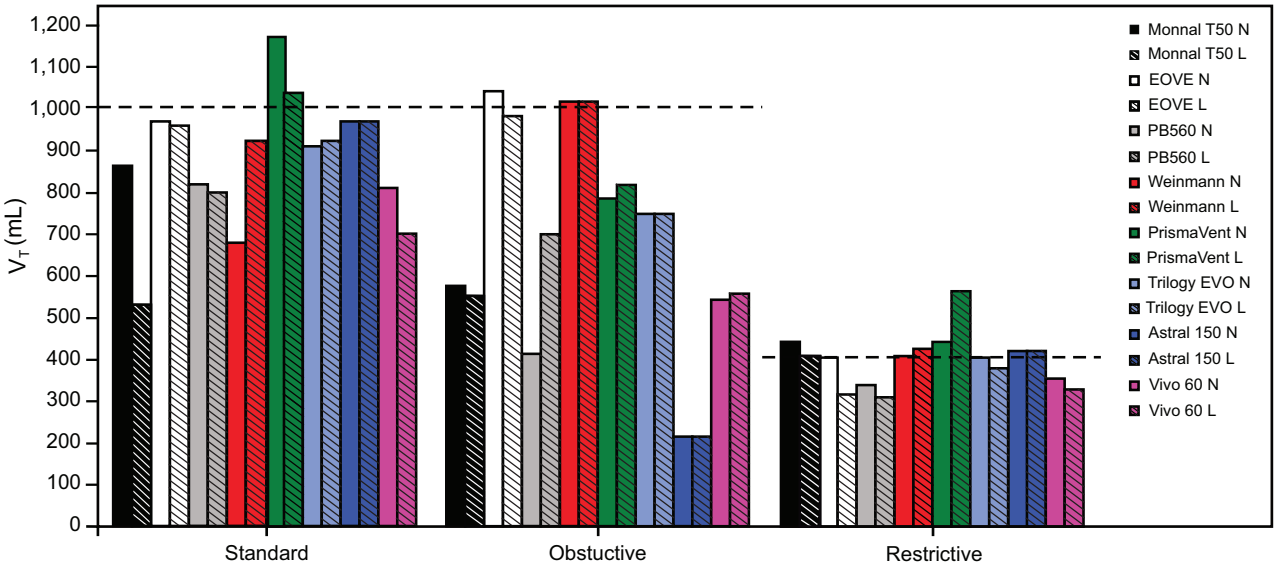

Figure 4. Tidal volume (V_T) measured at 2 levels of inspiratory effort normal (N) and low (L) in the pressure support ventilation 20 cm H_2O (PSV20) mode, with a constant leak of 6 L/min in 3 mechanics. The black lines correspond to the expected V_T.

ventilator in L effort was not measured because the ASL 5000 developed ineffective efforts in all cycles.

When analyzing V_T in PSV, a decrease in muscle effort and increase in pressure support from 10 to 20 cm H_2O made synchronization difficult for all ventilators analyzed, especially with R mechanics. In PSV10 (Fig. 3), with expected V_T of 500 mL with S and O mechanics and 200 mL with R mechanics, effort reduction decreased V_T in all the patterns for the 8 devices. Four of 8 ventilators maintained correct synchronization (cycling in all conditions), despite the changes: EOVE, PB560, Trilogy Evo, and Vivo 60. With S mechanics and L effort, the Vivo 60 ventilator recorded the lowest V_T value (251 mL) and the Monnal T50 ventilator recorded the highest value (631 mL). In PSV20 (Fig. 4), with an expected V_T of 1,000 mL with S and O mechanics, and 400 mL with R mechanics, the EOVE, Trilogy Evo, and Astral 150 ventilators delivered V_T in all conditions, with little variation, despite decreased effort. However, V_T delivered by the Astral 150

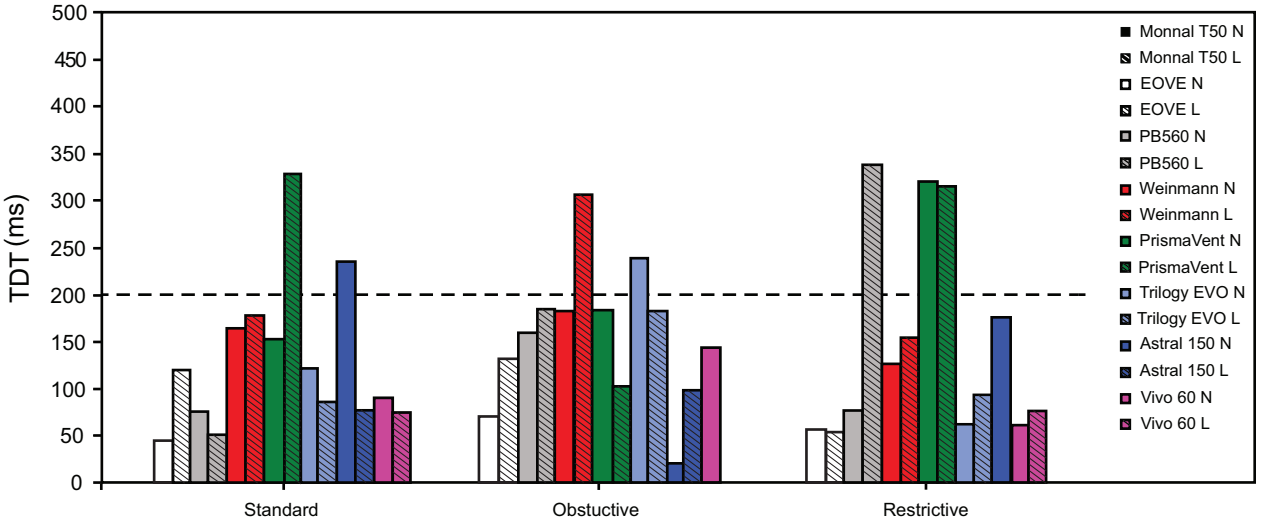

Figure 5. Trigger delay time (TDT) values (ms) of the 8 devices with 2 levels of inspiratory effort normal (N) and low (L) in the volume control continuous mandatory ventilation (VC-CMV) mode for 3 mechanics, a constant leak of 6 L/min. Black line corresponds to the expected value.

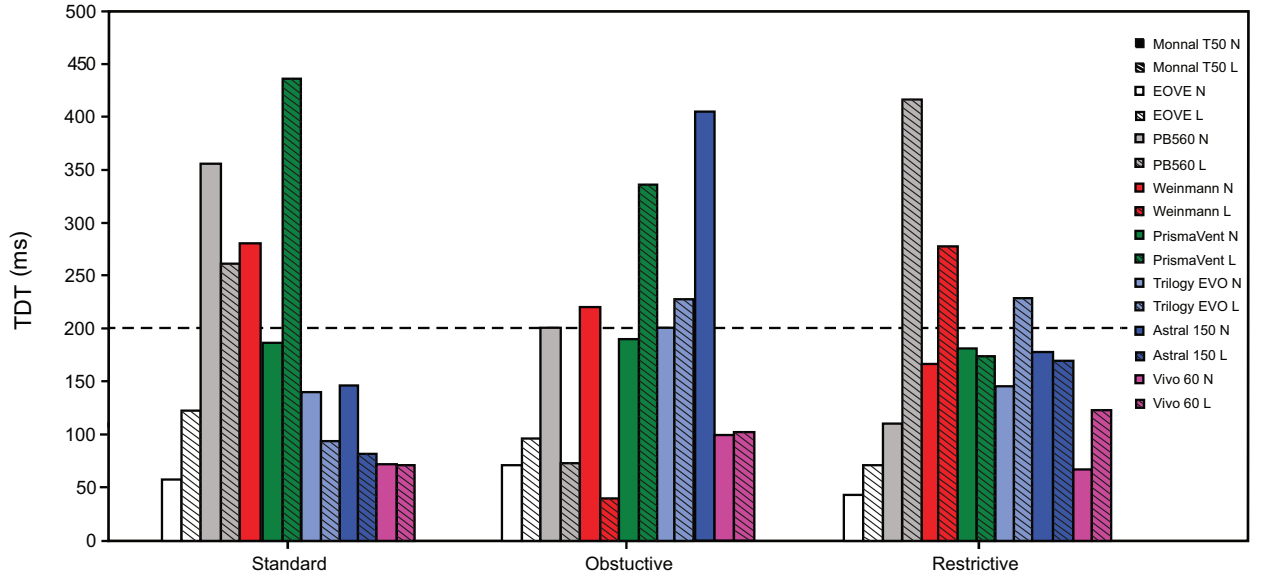

Figure 6. Trigger delay time (TDT) values (ms) of the 8 devices with 2 levels of inspiratory effort normal (N) and low (L) in pressure support ventilation 10 cm H_2O (PSV10) for 3 mechanics, a constant leak of 6 L/min. Black line corresponds to the expected value.

ventilator with O mechanics was remarkably low (215 mL). Synchronization difficulties were a factor for ventilators when used with the model with O mechanics. The Weinmann ventilator remained as the ventilator with the highest intracondition variability and developed asynchronies (mainly auto-triggering and ineffective efforts) in all the conditions.

Effort decrease did not cause significant differences in trigger response times, although there was a trend toward slightly higher times in almost all devices tested. Lowest trigger delay time variations with changes in mechanics were recorded for the PB560, EOVE, and Vivo 60 ventilators. Ventilatory mode modification from VC-CMV to PSV did not cause changes in the trigger response time for the EOVE, Trilogy Evo, and Vivo 60 ventilators. Missing bars in Figures 5–7 correspond to unmeasured values due to the lack of synchronous cycles. The trigger delay time could not be assessed for the Monnal T50 ventilator due to numerous and heterogeneous asynchronies, mainly related to ineffective efforts and flow starvation. In general, decreased inspiratory effort meant an increase in the trigger delay time and exceptions, for example, the Weinmann ventilator,

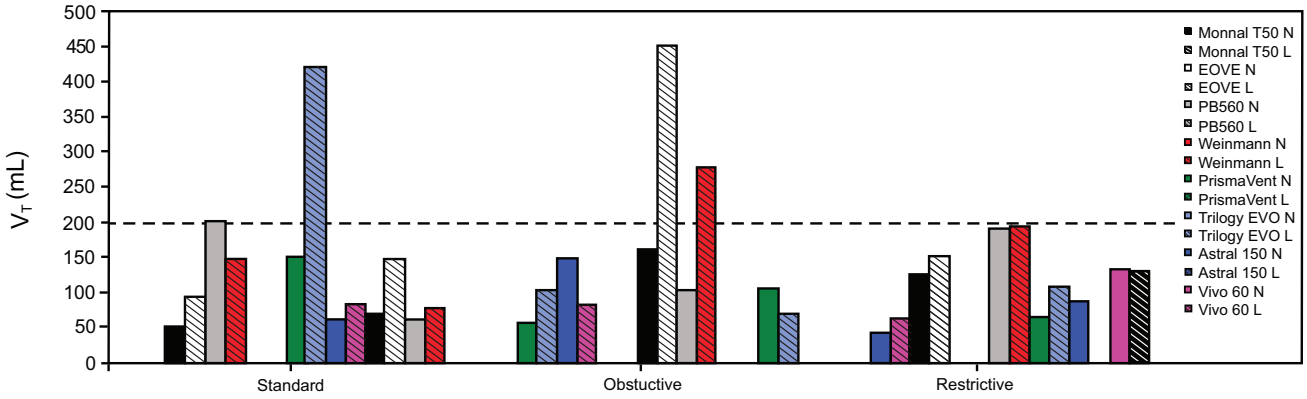

Figure 7. Trigger delay time (TDT) values (ms) of the 8 devices with 2 levels of inspiratory effort normal (N) and low (L) in pressure support ventilation 20 cm H_2O (PSV20) for 3 mechanics, a constant leak of 6 L/min. Black line corresponds to the expected value.

corresponded to conditions in which only one synchronous cycle was analyzed (which might be a coincident cycle).

In VC-CMV (Fig. 5), and with the N effort, 5 of 7 ventilators represented (except the PrismaVent and Astral 150) had a response time to trigger of <200 ms. The fastest responses (lowest trigger delay times) were achieved by the EOVE and Vivo 60 ventilators. Decreased effort led to a marked increase in the trigger delay times for the PrismaVent (with S mechanics), Trilogy Evo (with O mechanics), and PB560 (with R mechanics) ventilators. With PSV10 (Fig. 6), the EOVE and Vivo 60 ventilators had trigger delay time values of <200 ms for all the conditions. Decreased (L) effort resulted in an increase in trigger delay time (being the largest for the PrismaVent ventilator with S and O mechanics, and for the PB560 ventilator with R mechanics). With PSV20 (Fig. 7), the trigger delay time decreased in almost all the devices that were studied, regardless of the lung mechanics. The EOVE and Vivo 60 ventilators did not show significant differences with effort decrease or with changes in mechanics, again with trigger delay time values of <200 ms. The trigger delay time increased markedly with O mechanics for the PrismaVent ventilator (165 ms with the N effort versus 605 ms with the L effort). The Weinmann ventilator failed to synchronize under any condition for any of the tested mechanics, and the Astral 150 ventilator failed to synchronize with O and R mechanics.

PTP500 values were obtained only from the synchronous cycles, despite the fact that these were a low percentage of the total number of cycles analyzed. Conditions in which negative or near zero values were obtained were due to the lack of synchrony because of insufficient inspiratory flow (flow starvation). To show the effect of synchronization on PTP500 values, the asynchrony index, expressed in percentages for each condition, was included in the x-axis in Figures 8 and 9. Synchrony, an important factor in reducing the inspiratory workload during assisted ventilation, was a determining factor in the lower pressurization capacity observed. Pressurization capacity varied considerably among the devices (PSV10: range, –3.56 to 77.37%; PSV20: range, –2.38 to 75.56%). For each ventilator studied, there were no significant differences in PTP500 when comparing PSV10 (Fig. 8) and PSV20 (Fig. 9). PTP500 increased with R mechanics compared with O (N effort) for all the devices except the EOVE ventilator (% PTP500 with S: 60%, with O: 77%, and with R: 0%). The EOVE, PrismaVent, and Astral 150 ventilators registered PTP500 values > 50% of the ideal pressurization with N effort and S mechanics at both levels of PSV, but PTP500 decreased with the L effort. The Weinmann ventilator with both levels of support showed PTP500 values of <16%. Asynchronies developed by the ventilators studied were cataloged by wave analysis of the trigger delay time and PTP500 because they affected these variables by prolonging the trigger delay time and decreasing pressurization capacity with lower PTP500 values.

Discussion

In an evidence-based medicine world, there is little knowledge about ventilators targeted for use in home care. Our group performed a bench analysis to evaluate the performance of 8 home-care devices by using a lung model (ASL 5000) under 18 experimental conditions that were intended to mimic the clinical scenarios that might be encountered for home mechanical ventilation. These evaluations are necessary and useful because they provide information about performance under clinical conditions that are

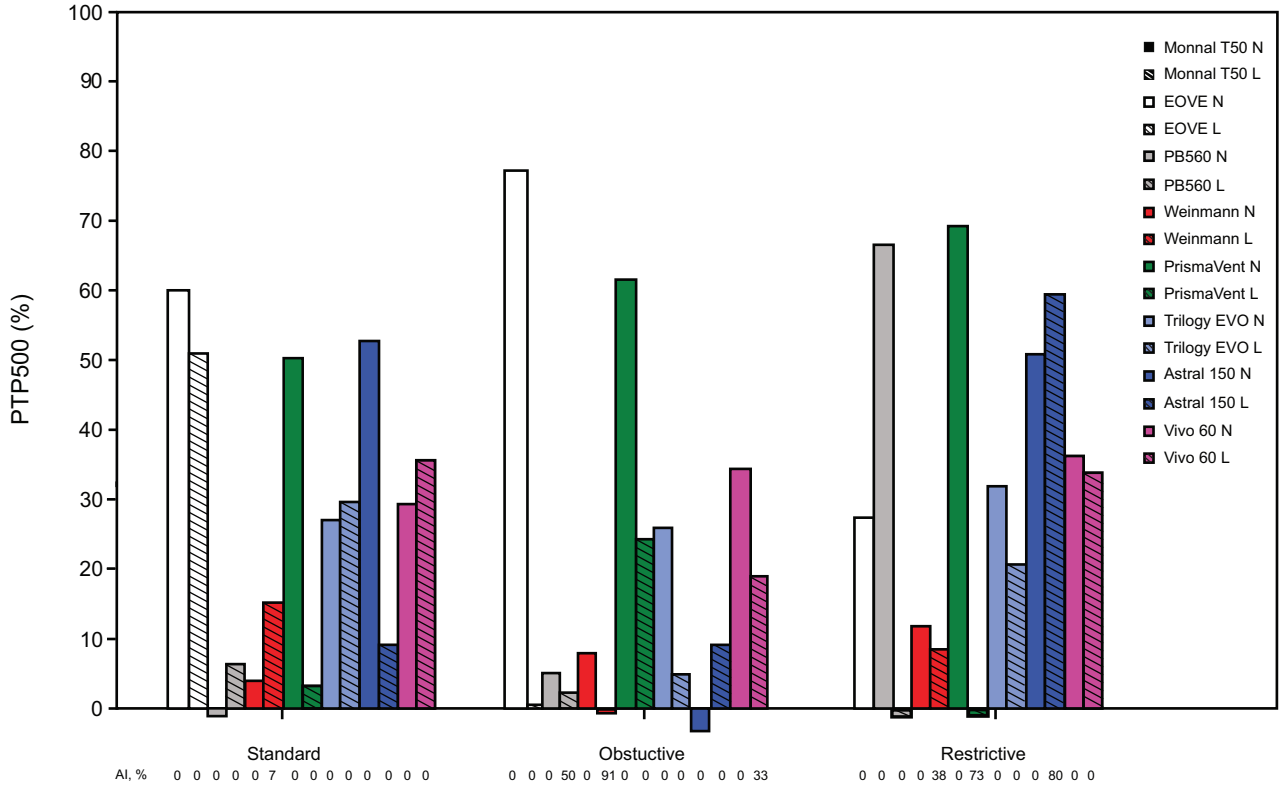

Figure 8. Pressure time product (PTP) in the first 500 ms of the inspiratory effort (expressed in percentages) at 2 levels of airway occlusion pressure ($P_{0.1}$) normal (N) and low (L) in pressure support ventilation 10 cm H_2O (PSV10) for 3 mechanical patterns, a constant leak of 6 L/min. The x-axis (mechanics) includes the value of the asynchrony index (AI) (%).

not covered in the user guides provided by the manufacturers. These results may help guide decisions about home ventilation management, particularly with respect to the choice of a device and its primary settings. One would expect the newest devices with newer turbines and advanced software to be able to compensate for changes in respiratory conditions to maintain a stable performance that meets patient needs.

However, our results showed that it is not the case for most devices. The present study illustrated the great variability observed in performance among devices that may require clinicians to account for device differences in their patient management. Our findings were consistent with those reported in previous publications.[17-20] On the one hand, decreased inspiratory effort caused an increase in the trigger delay time. Even if this effect should be negligible in high-quality triggering systems, increases in the trigger delay times were the main cause for decreases in pressurization capacity and synchronization in previous studies.[17,18] On the other hand, synchronization worsened while increasing pressure support from 10 to 20 cm H_2O. This effect might be related to an insufficient pressurization ramp slope after inspiratory onset, failure to meet higher inspiratory flow demand, or an increase in inspiratory and/or expiratory times.[17,19,20] It is worth noting the variability and lack of accuracy in the delivered volume, as previously shown.[5,21] In VC-CMV, no large variations were observed, performance worsened whenever adverse conditions developed (increased pressure support and restrictive physiology). Inspiratory effort reduction caused a greater impact on the volume delivered, up to a 50% decrease in some cases.[9,11,22] In our study, the Monnal T50 ventilator showed good results, contrary to previous published studies.[23]

For assisted modes, the effort required to trigger the ventilator theoretically represents 10–20% of the respiratory effort. Higher trigger sensitivity leads to shorter response times, which should lead to less dyspnea, but there is no evidence that a variation of 100 ms among devices has a clinically significant impact.[24] The current trend is toward the development of devices with a shorter trigger delay time. Our results showed that the trigger delay time was heterogeneous among the ventilators and longer than observed in previous studies.[17] In general, the trigger delay time increased with decreased inspiratory muscle effort. The EOVE, Vivo 60, and Trilogy Evo ventilators did not have much variation in trigger delay times under any conditions, with values in

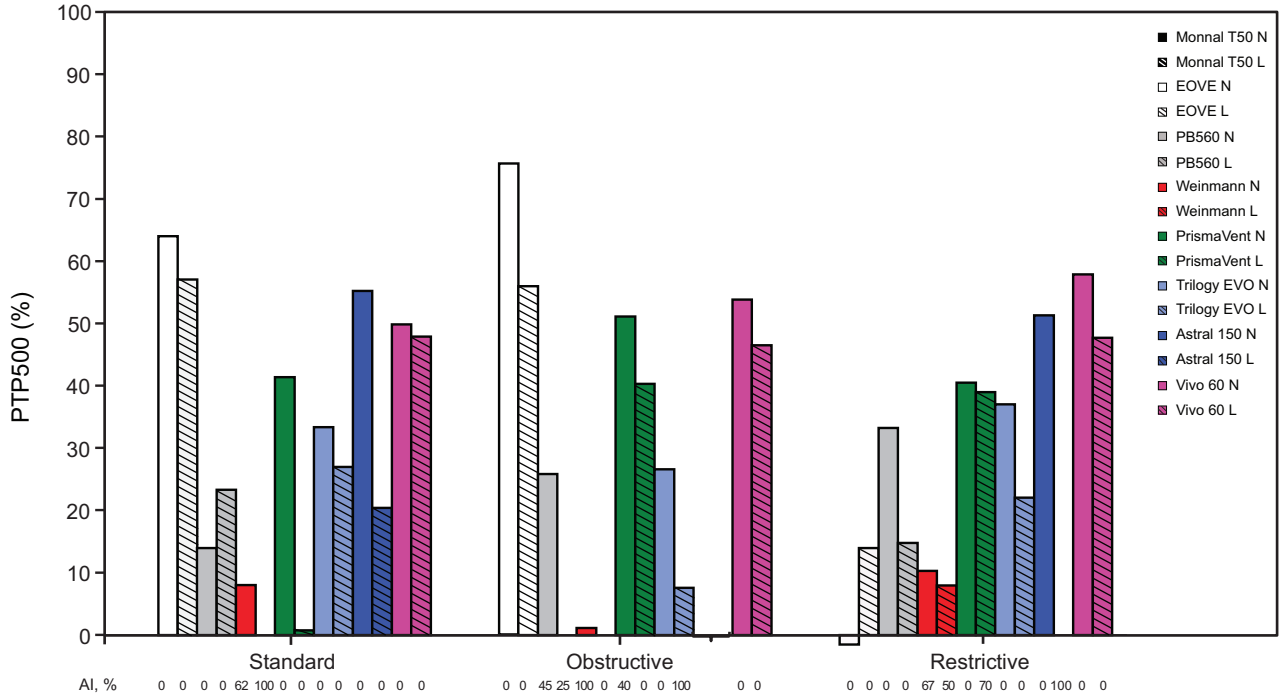

Figure 9. Pressure time product (PTP) in the first 500 ms of inspiratory effort (expressed in percentage) at 2 levels of airway occlusion pressure ($P_{0.1}$) normal (N) and low (L) in pressure support ventilation 20 cm H_2O (PSV20) for 3 mechanics, a constant leak of 6 L/min. The x-axis (mechanics) includes the value of the asynchrony index (AI) (%). See the Figure 8 legend.

the tolerated range of around 200 ms or below. The PrismaVent ventilator showed increased trigger delay times with decreased inspiratory effort. In other studies, the Astral 150 ventilator showed good performance despite changes in leak and muscle effort, contrary to what we found in this research.[10] Because of asynchronies, the trigger delay time could not be assessed for the Monnal T50 ventilator (ineffective efforts and flow starvation) or the Weinmann ventilator (auto-triggering and ineffective efforts).

In spite of a patient's inspiratory effort at a given pressure-support level, ventilators must deliver a high initial flow that meets individual demand. An insufficient inspiratory flow rate can be considered the most distressing form of dyspnea. It influences home mechanical ventilation, especially for those patients with severe kyphoscoliosis and obesity, for whom a ventilator's ability to pressurize is necessary for comfort, optimal gas exchange, and tolerance of activity.[8] In our study, there was much variability observed in terms of pressurization capacity, ranging from 0 to 77% of the ideal. It improved with normal inspiratory effort, which suggested that the ventilators studied did not compensate with decreases in inspiratory effort, as seen in previous studies.[8] This parameter must be interpreted with caution because of the great variability associated with the trigger delay time. Previous investigations showed that low PTP500 values in home-care ventilators were more likely due to increases in the trigger delay time as opposed to deficiencies in pressurization capacity. No significant differences were found when comparing PSV10 and PSV20, consistent with L'Her et al[11] but in contrast to Chiumello et al,[18] who found that lower PTPs were associated with increases in pressure support. PTP500 improved with R mechanics (N effort) in all the devices except the EOVE. Inspiratory muscle effort changes had a highly variable impact on the PTP500 as reported previously.[8,25] PTP500 is measurable only in cycles synchronous with patient effort, which thus explains the poor response seen with the Weinmann device.[18] The best pressurization range for comfort and synchronization, both closely related characteristics, is still under question.

Synchrony is important for patient comfort and work of breathing, but it is also related to hospital and ICU admissions and to mortality.[26] Proper adjustments of main settings to meet patient demands will reduce the development of asynchronies. Expiratory trigger settings, often underappreciated, can cause premature cycling in patients with restrictive characteristics or delayed cycling in obstructive cases. All the ventilators evaluated in this study developed asynchronies at least once, but the EOVE and Trilogy Evo ventilators remarkably showed synchronization under almost all the experimental conditions tested. The Weinmann ventilator developed frequent asynchronies that increased when inspiratory effort was reduced and pressure support was increased.

The main limitation of our study, similar to that of previous bench tests, is the difficulty of extrapolating our results to real clinical situations. Advantages of the ASL 5000 ventilator include standardization of mechanical characteristics, reproducibility of experiments, and the ability to simulate a wide range of conditions. The lung model replicates patients' inspiratory effort during assisted mechanical ventilation. However, there are several factors that our model could not emulate: (1) the imperfect fit of the mask interface to a patient's facial characteristics, (2) variable activity of respiratory muscles along the day, and (3) multifocal and irregular leaks during home mechanical ventilation. Moreover, the parameters chosen to define patient mechanics and inspiratory muscle effort are similar to those used in previous publications but they vary inter- and intra-subject breath-to-breath in real life, so they may not always represent our population. For example, in the case of airway occlusion pressure, variations may be as high as 50%.[27] The clinical relevance of these findings is difficult to determine and may depend on patient status (eg, trigger delay time variation, from 150 to 250 ms). In addition, delivered V_T, response-to-trigger time, and pressurization capacity characterize only some of the ventilator response during assisted modes.

Conclusions

Heterogeneous results from previous publications and lack of guidelines leave the choice of NIV device to physicians who routinely care for patients at home and on ventilation. This bench model study demonstrated a wide heterogeneity of performance among the 8 tested ventilators. Some devices showed asynchronies in almost all the experimental conditions, which, in clinical practice, would be addressed by manual adjustment. These results may help clinicians in choosing portable ventilators for their potential performance based on their patients' respiratory mechanics and ability to trigger ventilatory support. Further studies should aim at assessing device performance and optimal patient-ventilator interactions, both for medical knowledge and to enable manufacturers to improve their machines.

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REFERENCES

1. Agusti A, Vogelmeier C, Beasley R, Celli B. GOLD Report 2020. Global Initiative for Chronic Obstructive Lung Disease 2020. Fontana, WI, USA.
2. de Lucas Ramos P, Rodríguez González-Moro JM, Paz González L, Santa-Cruz Siminiani A, Cubillo Marcos JM. Current status of home mechanical ventilation in Spain: results of a national survey. Arch Bronconeumol 2000;36(10):545-550.
3. Selim BJ, Wolfe L, Coleman JM III, Dewan NA. Initiation of noninvasive ventilation for sleep related hypoventilation disorders: advanced modes and devices. Chest 2018;153(1):251-265.
4. Coleman JM III, Wolfe LF, Kalhan R. Noninvasive ventilation in chronic obstructive pulmonary disease. Ann Am Thorac Soc 2019;16 (9):1091-1098.
5. Mehta S, Mccool FD, Hill NS. Leak compensation in positive pressure ventilators: a lung model study. Eur Resp J 2001;17(2):259-267.
6. Mokhlesi B, Masa JF, Afshar M, Pacheco Almadana, Berlowitz V, Borel DJ J-C, et al. The effect of hospital discharge with empiric noninvasive ventilation on mortality in hospitalized patients with obesity hypoventilation syndrome. An individual patient data meta-analysis. Ann Am Thorac Soc 2020;17(5):627-637.
7. Kolodziej MA, Jensen L, Rowe B, Sin D. Systematic review of noninvasive positive pressure ventilation in severe stable COPD. Eur Respir J 2007;30(2):293-306.
8. Battisti A, Tassaux D, Janssens J-P, Michotte JB, Jaber S, Jolliet P. Performance characteristics of 10 home mechanical ventilators in pressure-support mode: a comparative bench study. Chest 2005;127(5):1784-1792.
9. Luján M, Sogo A, Pomares X, Monsó E, Sales B, Blanch L. Effect of leak and breathing pattern on the accuracy of tidal volume estimation by commercial home ventilators: a bench study. Respir Care 2013;58 (5):770-777.
10. Zhu K, Rabec C, Gonzalez-Bermejo J, Hardy S, Aouf S, Escourrou P, Roisman G. Combined effects of leaks, respiratory system properties and upper airway patency on the performance of home ventilators: a bench study. BMC Pulm Med 2017;17(1):145.
11. L'Her E, Roy A, Marjanovic N. Bench-test comparison of 26 emergency and transport ventilators. Crit Care 2014;18(5):506.
12. Ueno Y, Nakanishi N, Oto J, Imanaka H, Nishimura M. A bench study of the effects of leak on ventilator performance during noninvasive ventilation. Respir Care 2011;56(11):1758-1764.
13. Telias I, Junhasavasdikul D, Rittayamai N, Piquilloud L, Chen L, Ferguson ND, et al. Airway occlusion pressure as an estimate of respiratory drive and inspiratory effort during assisted ventilation. Am J Respir Crit Care Med 2020;201(9):1086-1098.
14. Thille AW, Rodriguez P, Cabello B, Lellouche F, Brochard L. Patient-ventilator asynchrony during assisted mechanical ventilation. Intensive Care Med 2006;32(10):1515-1522.
15. Vitacca M, Bianchi L, Zanotti E, Vianello A, Barbano L, Porta R, Clini E. Assessment of physiologic variables and subjective comfort under different levels of pressure support ventilation. Chest 2004;126 (3):851-859.
16. ISO 80601-2-72:2015 Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients 2015. Available from https://www.iso.org. *Accessed 28 August, 2021*.
17. Thille AW, Rodriguez P, Brochard L. Patient-ventilator asynchrony during assisted mechanical ventilation. Intensive Care Med 2006;32 (10):1515-22.
18. Chiumello D, Pelosi P, Croci M, Bigatello LM, Gattinoni L. The effects of pressurization rate on breathing pattern, work of breathing, gas exchange and patient comfort in pressure support ventilation. Eur Respir J 2001;18(1):107-114.
19. Thille AW BL. Promoting patient ventilator synchrony. Clin Pulm Med 2007;14:350-359.
20. Georgopoulos D, Prinianakis G, Kondili E. Bedside waveforms interpretation as a tool to identify patient-ventilator asynchronies. Intensive Care Med 2006;32(1):34-47.

21. Lofaso F, Fodil R, Lorino H, Leroux K, Quintel A, Leroy A, Harf A. Inaccuracy of tidal volume delivered by home mechanical ventilators. Eur Respir J 2000;15(2):338-341.
22. Chen Y, Cheng K, Zhou X. Performance characteristics of seven bilevel mechanical ventilators in pressure-support mode with different cycling criteria: a comparative bench study. Med Sci Monit 2015;21:310-317.
23. Khirani S, Louis B, Leroux K, Delord V, Fauroux B, Lofaso F, et al. Harms of unintentional leaks during volume targeted pressure support ventilation. Respir Med 2013;107(7):1021-1029.
24. Fresnel E, Muir J-F, Letellier C. Performances of domiciliary ventilators compared by using a parametric procedure. EPJ Nonlinear Biomed Phys. 2016;4(6).
25. Rittayamai N, Beloncle F, Goligher EC, Chen L, Mancebo J, Richard J-CM, Brochard L. Effect of inspiratory synchronization during pressure-controlled ventilation on lung distension and inspiratory effort. Ann Intensive Care 2017;7(1):100.
26. Goligher EC, Dres M, Fan E, Rubenfeld GD, Scales DC, Herridge MS, et al. Mechanical ventilation-induced diaphragm atrophy strongly impacts clinical outcomes. Am J Respir Crit Care Med 2018;197 (2):204-213.
27. Jonkman AH, de Vries HJ, Heunks LMA. Physiology of the respiratory drive in ICU patients: implications for diagnosis and treatment. Crit Care 2020;24(1):104.