Reliability of Tidal Volume in Average Volume Assured Pressure Support Mode

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BACKGROUND: Remote monitoring is increasingly used in patients who receive home mechanical ventilation. The average volume assured pressure support mode is a target volume pressure preset mode that delivers a given tidal volume (V_T) within a range of controlled inspiratory pressures. In a mode such as this, it is important to verify that the V_T value retrieved from the ventilator SD card is accurate. METHODS: A lung model was set with C (Compliance) 0.075 L/cm H_2O and R_I (Inspiratory resistance)-R_E (Expiratory resistance) 15–25 cm H_2O/L/s (model 1) or with C 0.050 L/cm H_2O and R_I 6 cm H_2O/L/s (model 2) and 6 cm H_2O effort. Three home-care ventilators (A40, PrismaST30, and Vivo40) were set to average volume assured pressure support mode with 0.3 and 0.6 L V_T each at PEEP 5 and 10 cm H_2O, and were connected to the lung model with and without nonintentional leak. The reference airway pressure and flow were measured by a data logger. V_T was expressed in body temperature and pressure saturated. We assessed the difference in V_T between the ventilator SD card and a data logger relative to set V_T and factors associated with its magnitude. RESULTS: For A40, PrismaST30, and Vivo40, the adjusted mean V_T differences between the ventilator SD card and the data logger were −0.053 L (95% CI −0.067 to −0.039 L) ($P < .001$), −0.002 L (95%CI −0.022 to 0.019 L) ($P = .86$), and −0.067 L (95% CI −0.007 to 0.127 L) ($P = .03$), respectively. The partial Spearman correlation coefficients between the ventilator SD card and a data logger were 0.89 ($P < .001$), 0.59 ($P < .001$), and 0.78 ($P < .001$), respectively to the ventilators. The relative variations in measured V_T from the set V_T were 16.0, −12.0, and 6.7% for the ventilator SD card, and were −2.5, −7.5, and −27.2% for the data logger, respectively. The discrepancy in ventilator between SD card and data logger were influenced by PEEP for the PrismaST30 ventilator, nonintentional leak for the Vivo40 ventilator and PEEP, nonintentional leak, and underlying disease, the effect of each depending on the levels of the other factors, for the A40 ventilator. CONCLUSIONS: In the 3 home-care ventilators, the ventilator SD card underestimated V_T. Factors involved in this difference differed among the ventilators. *Key words: home mechanical ventilation; bi-level; average volume assured pressure support mode; noninvasive ventilation.*
[Respir Care 2018;63(9):1139–1146.

Introduction

Caregiver experts in some countries recommend that domiciliary noninvasive ventilation (NIV) for patients with chronic respiratory failure should be initiated on the basis of invasive (arterial blood gas) or noninvasive (capnogra-

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The authors have disclosed no conflicts of interest.

phy) criteria.[1] The main reasons for this recommendation stem from hospital overcrowding and the costs of prolonged hospitalization. Furthermore, following up such patients is time consuming for health-care professionals, which is an additional reason for initiating domiciliary NIV outside the hospital.

Accordingly, respiratory parameters, such as the daily duration of machine use or leaks, which can be derived from built-in ventilator software, are essential when considering monitoring those patients who receive long-term home mechanical ventilation.[2] Caregivers have to inform patients about these respiratory parameters when discussing patient adherence. Furthermore, the collected data can be downloaded from the ventilator SD card at the time of a routine hospital visit by the patient, and, hence, his or her adherence to therapy can be measured. More recently, remote monitoring of the data collected during home mechanical ventilation has been implemented by home care ventilator manufacturers; therefore, respiratory parameters can be directly sent to the home care providers and prescribers, who may eventually remotely change some home mechanical ventilator settings. It, therefore, is essential to verify the reliability of these measurements before adopting the complete remote monitoring platform and remote modifications in home mechanical ventilator settings.

The average volume-assured pressure support mode is the target volume during the pressure-preset mode that allows the delivery of the target tidal volume (V_T) within a range of controlled inspiratory pressure. NIV with the average volume assured pressure support mode has been used in obesity-hypoventilation syndrome and, compared with the fixed pressure support, found to be associated with some beneficial effect on nocturnal P_{aCO_2}[3] but with more sleep impairment.[4] However, no difference between the average volume assured pressure support mode and fixed pressure-support ventilation was found in the subjects who were morbidly obese,[5] in a mixed population of chronic respiratory failure[6] and in subjects with stable COPD.[7,8]

The average volume assured pressure support mode has been found to be feasible in subjects with COPD who are in acute respiratory failure.[9] Because the average volume assured pressure support mode can be used in patients who are using mechanical ventilation at home, the V_T information can be sent to the caregivers, as previously mentioned. Therefore, it is as important to verify that the V_T retrieved from the ventilator SD card is as reliable as the target V_T delivered by the ventilator. Indeed, a previous bench study on home bi-level ventilators used in fixed pressure support found significant bias between the set and the recorded V_T by the ventilator SD card.[10] Even though the average volume assured pressure support mode is systematically found in any new home mechanical ventilator (Level 1 and Level 2 when following the new Haute Autorité de Santé rules), it has not been widely investigated.

In line with the above considerations, we underwent the present bench study to assess the size of V_T value retrieved from the ventilator SD card of home ventilators set to the average volume assured pressure support mode with the hypothesis that it was different from the V_T measured with a reference measurement device. This hypothesis was based on the previously mentioned bench result with fixed inspiratory pressure support.[10]

QUICK LOOK

Current knowledge

Caregivers involved in home ventilation use data retrieved from the internal card of the ventilators to adjust settings. The average volume assured pressure support mode is a target volume pressure–preset mode that delivers a given tidal volume (V_T) within a range of controlled inspiratory pressures. The measurement or calculation of V_T in this mode has a variable accuracy.

What this paper contributes to our knowledge

The V_T significantly correlated between the internal card and the data logger but was systematically underestimated by the former. The factors involved in the discrepancy between the internal card and the data logger were different among the ventilators.

Methods

Setup

The experimental setup is schematically represented in Figure 1 and comprised the following items: (1) ASL 5000 Lung Model (Ingmar, Pittsburgh, Pennsylvania); (2) a data logger (Biopac 150; Biopac, Goleta, California) used to collect pressure and flow; (3) 2 pneumotachographs (Hans Rudolph 3830 series pneumotachograph; Hans Rudolph, Pawnee, Kansas) (the pneumotachograph 2 in Fig. 1 was used to perform the measurements presented in the results section); (4) a standardized leak that mimicked continuous nonintentional leak (20 L/min at 15 cm H_2O pressure); (5) 3 home care ventilators (A40 [Philips, Amsterdam, the Netherlands], PrismaST30 [Weinmann, Hamburg, Ger-

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DOI: 10.4187/respcare.05917

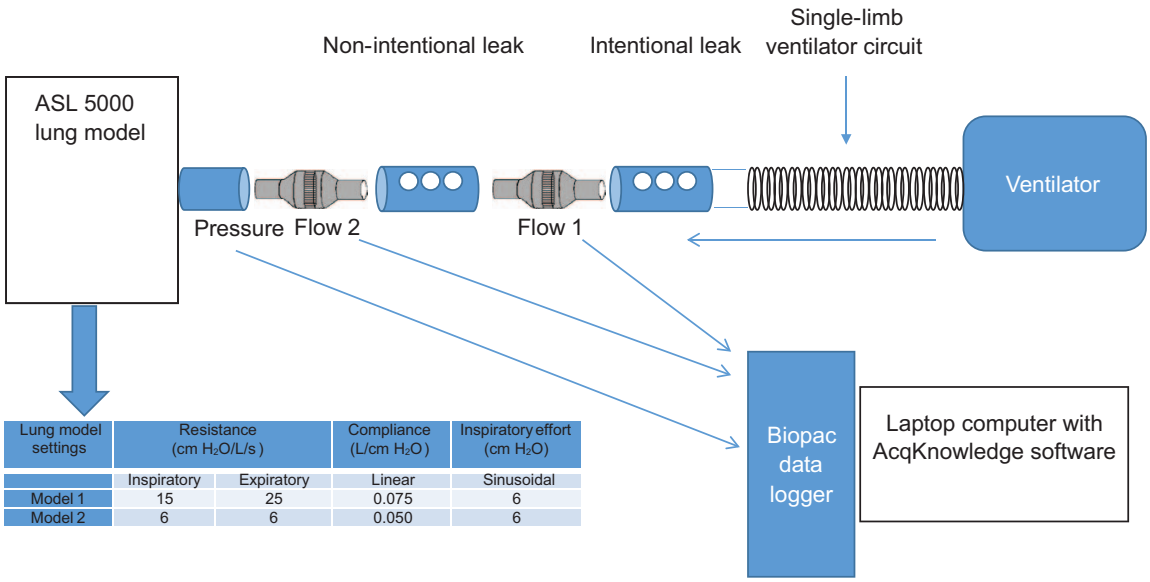

Fig. 1. The experimental setup. The pneumotachograph 2 was used for the measurements performed in the study and presented in the results section.

many], Vivo40 [Breas]), validated for use in patients; and (6) a single-limb ventilator circuit (Intersurgical, Fontenay-sous-bois, France). The inclusion criteria of home mechanical ventilators for this study were the following: integrated ventilator SD card, the average volume assured pressure support mode available, and the availability of the device in France. Ventilators characterized as "life support" were excluded from this research.

Protocol

Before the experiments, both the pressure transducer and pneumotachographs were calibrated at room air temperature and pressure. The pneumotachographs calibration consisted in comparing, in the steady condition, the flow measured by the pneumotachographs with the flow from a reference flow meter, which was a rotameter (Houdec glass [Houdec Innovation SAS, Abrest, France]) specially designed for use in air. The ASL 5000 Lung Model was set to mimic COPD (model 1) and obesity hypoventilation syndrome (model 2) (Fig. 1). A fixed inspiratory effort of 6 cm H_2O with a sinusoidal profile was selected (Fig. 1). The frequency of effort was fixed at 12 breaths/min. The muscular effort lasted 16% of total breath duration, followed by a 2% pause and a 40% release time. Henceforth, the total duration of effort was 1 s. The ventilator was set in the pressure preset S (Spontaneous)/T (timed) mode at predetermined settings (Table 1).

For model 1 or model 2, each ventilator was run to target 0.300 and 0.600 L V_T, each at PEEP 5 and 10 cm H_2O. Experiments were performed with and without a nonintentional leak (Fig. 1). Recordings were started simultaneously with the ventilator and the data logger. To analyze exactly the same breaths with the ventilator SD card and the data logger, the ASL writings included a single large breath after completion of 30 breaths. This signal was easily recognized by both the ventilator SD card and the data logger. After this signal, 30 consecutive breaths were recorded.

Table 1. Predetermined Ventilator Settings in Models 1 and 2

Variable	Result
EPAP, cm H_2O	5 or 10
IPAP, minimum-maximum, cm H_2O	2–20
Target V_T, L	0.600 or 0.300
Slope of rising pressure to reach target V_T, cm H_2O/s	0.5–0.7
Inspiratory trigger	Highest sensitivity without auto-triggering
Cycling	25% maximal inspiratory flow
Frequency, breaths/min	10
Inspiratory time, minimum-maximum, s	0.3–2.0
Pressurization slope, ms	Mini (<90 ms)

EPAP = expiratory positive airway pressure
IPAP = inspiratory positive airway pressure
V_T = tidal volume
Mini = minimal value setting

Data Analysis

The last 10 breaths over these 30 breaths were manually analyzed backward from the very last breath in the ventilator SD card and data logger device. The assessors of the

breaths were blinded in that the investigator who analyzed the data from the ventilator SD card (AS) was not the same one who analyzed the data from the data logger (CG). Inspired V_T was read directly on the ventilator SD card, and it was obtained from numerical integration of the flow signal in the data logger by using Acqknowledge software version 4.0 (Biopac 150). The A40 and Vivo40 ventilators expressed the volume in body temperature pressure saturated and the Prisma ST30 ventilator expressed volume in saturated temperature and pressure dry, while the data logger measured volume in ambient temperature dry conditions. Therefore, to make the V_T comparable across ventilators, the values V_T measured by both the ventilator SD card and data logger were expressed in body temperature pressure saturated conditions according to the following formula:

$$V_T(BTPS) = V_T(ATPrh) \times \frac{310.15}{T} \times \frac{((P_A + PEEP) - rh \times P_{sat}[T])}{((P_A + PEEP) - P_{sat}\{310.15°\})}$$

Where BTPS is body temperature pressure saturated; T is the ambient temperature expressed in kelvin (295.65K); P_A is the ambient pressure (770.6 mm Hg); Rh is the relative humidity of the ambient air (27%); P_{sat} is the saturation pressure of water (or equilibrium pressure vapor); P_{sat} 37°C (310.15K) = 47 mm Hg; P_{sat} 21.85°C (295.65K) = 20.4 mm Hg; PEEP is expressed in mm Hg. In this formula, rh was set to 0 and T was 21°C (294.15K) to transform saturated temperature and pressure dry into the BTPS condition. The experiment generated 480 measurements (2 PEEP × 2 leaks × 2 clinical models × 2 target V_T × 3 ventilators × 10 breaths with each measurement device). Data were expressed as median (first and third quartiles).

The primary end point was the comparison of V_T between the ventilator SD card and the data logger taken as the reference value. The correlation between the 2 measurements was quantified by a partial Spearman rank correlation coefficient with its 95% CI (the estimate of the correlation coefficient was adjusted on the ventilator, clinical model, target V_T, PEEP, and leak). The bias between the V_T measured by the ventilator SD card and the reference was quantified and tested by a linear mixed model that modeled all the measurements (ventilator SD card and reference) and quantified the device effect (ventilator SD card or data logger) adjusted for the interaction among the different conditions (ventilator, clinical model, target V_T, PEEP, and leak). A random effect was added to take into account the correlation between the ventilator SD card and reference measurements obtained at the same time.

The secondary end point was the assessment of factors involved for each ventilator in the V_T difference between the ventilator SD card and data logger. We first computed the relative variation between the target and measured V_T (V_T set − V_T measured)/V_T set for the ventilator SD card and the data logger, and expressed this variation as a percentage. This was done to make the computation independent of the size of the V_T value. Then, we computed the absolute difference of the relative variation between the data logger and the ventilator SD card as follows:

$$\left(\frac{V_T\,set - V_T\,data\,logger}{V_T\,set}\right) - \left(\frac{V_T\,set - V_T\,ventilator\,SD\,card}{V_T\,set}\right) = \left(\frac{V_T\,ventilator\,SD\,card - V_T\,data\,logger}{V_T\,set}\right)$$

If the difference is positive, then the ventilator SD card overestimates V_T compared with the V_T data logger. The opposite is true if the difference is negative. The role of factors that may be involved in the V_T difference between the ventilator SD card and the data logger were underlying disease (model 1 or model 2), nonintentional leak (absent of present), and PEEP level (5 and 10 cm H_2O) was investigated by adjusting a linear model separately for each ventilator. All the factors were included in the model, with their double and triple interactions, which led to 8 coefficients. If the interactions were not significant at the .05 level, then they were discarded from the model one by one, starting from the least significant one. The final model was used to calculate the difference between the V_T ventilator SD card and the data logger relative to the V_T set for the different combinations of the levels of factors analyzed. The data analysis was performed by using R software (R, R Foundation for Statistical Computing, Vienna, Austria).

Results

V_T Over All the Ventilators

Overall measurements of the median values of V_T were 0.372 L (0.280, 0.571 L) for the ventilator SD card and 0.473 L (0.350, 0.674 L) for the data logger. The partial Spearman correlation coefficient was 0.46 (0.36, 0.54) ($P < .001$). The adjusted mean difference between the ventilator SD card and the data logger was −0.074 L (95% CI −0.118 to −0.031 L) ($P < .001$). Overall, the ventilator SD card underestimated V_T (Fig. 2). The median value of the relative difference between the target V_T and the ventilator SD card was 6.7% (−10.9%, 13.7%) and was −15.3% (−23.5%, 1.2%) for the data logger, which indicated that, as a whole, the ventilator SD card underestimated and the data logger overestimated V_T relative to

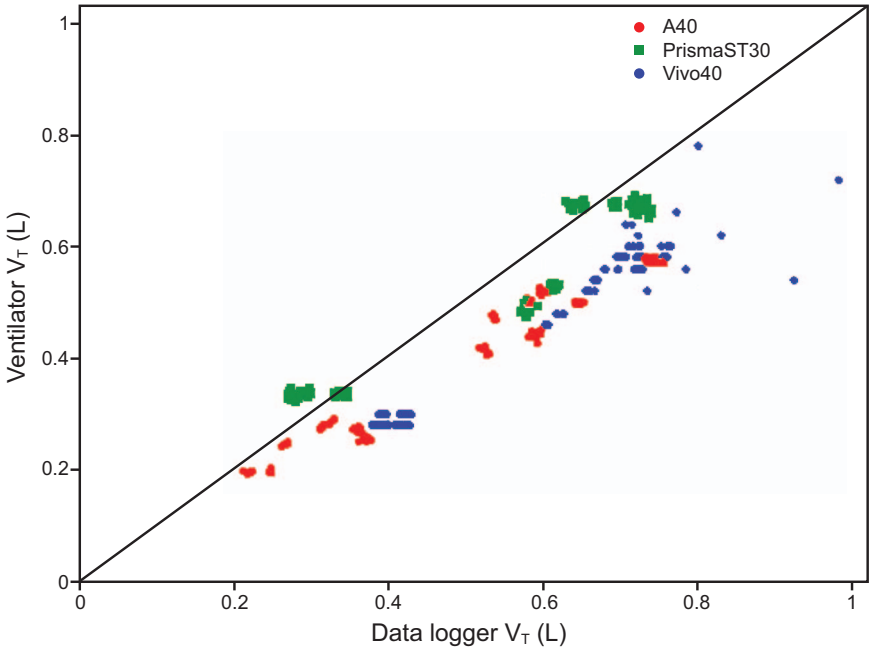

Fig. 2. The relationship of tidal volume (V_T) measured on the ventilator SD card and the data logger in each ventilator over all the conditions (480 measurements).

the target set V_T. The A40 ventilator seemed acceptable at low V_T but systematically underestimated V_T to be >0.4 L. The Vivo40 ventilator systematically underestimated V_T. The Prisma ST30 underestimated V_T in the vicinity of 0.6 L.

V_T for Each Ventilator

A40 Ventilator. For 160 measurements for the A40 ventilator, the adjusted mean difference between the ventilator SD card and the data logger was −0.053 L (95% CI −0.067 to −0.039 L) ($P < .001$). The partial Spearman correlation coefficient was 0.89 (0.83, 0.93) ($P < .001$). The ventilator SD card underestimated V_T compared with the data logger (Fig. 2). The relative difference between the target V_T and ventilator SD card was 16.0% (−9.0%, 22.6%) and was −2.5% (−21.2%, 10.6%) for the data logger, which indicated that the ventilator SD card underestimated and the data logger overestimated V_T relative to the target set V_T.

PrismaST30 Ventilator. For all 160 measurements with the PrismaST30 ventilator, the adjusted mean difference between the ventilator SD card and the data logger was −0.002 L (95% CI −0.022 to 0.019 L) ($P = .86$). The adjusted Spearman correlation coefficient was 0.59 (0.44, 0.71) ($P < .001$). The ventilator SD card underestimated V_T compared with the data logger (Fig. 2). The relative difference between the target V_T and the ventilator SD card was −12.0% (−12.9, −10.9) and was −7.5% (−15.6, 3.4) for the data logger, which indicated that both ventilator SD card overestimated the target set V_T.

Vivo40 Ventilator. For all 160 measurements with the Vivo40 ventilator, the adjusted the mean difference between the ventilator SD card and the data logger was −0.067 L (95% CI −0.007 to 0.127 L) ($P = .03$). The partial Spearman correlation coefficient was 0.78 (0.61, 0.87) ($P < .001$). The ventilator SD card underestimated V_T compared with the data logger (Fig. 2). The relative difference between the target V_T and the ventilator SD card was 6.7% (0%, 6.7%) and was −27.2% (−37.0%, −19.2%) for the data logger, which indicated that the ventilator SD card underestimated, and the data logger overestimated the V_T relative to the target set V_T.

Factors Involved in the Difference Between the Target and Measured V_T

The complete model for each ventilator was simplified according to our statistical strategy (see supplementary materials). Overall, for the PrismaST30 ventilator, only the PEEP level influenced the difference between the ventilator SD card and the data logger, whereas only the nonintentional leak influenced the difference for the Vivo40 ventilator (Table 2). For the A40 ventilator, the PEEP level, nonintentional leak, and the underlying disease influenced the difference between the ventilator SD card and the data logger, but the effect of each of these factors

Table 2. Coefficients of Error (95% CI) in Every Condition Tested in Each Ventilator

Combination	A40*	PrismaST30*	Vivo40*
NIL + model 1 PEEP 5 cm H_2O	−33.0 (−34.6 to −31.4)	−3.3 (−8.4 to 1.7)	−35.3 (−37.7 to −33.2)
NIL + model 2 PEEP 5 cm H_2O	−29.5 (−31.1 to −27.9)		
NIL + model 1 PEEP 10 cm H_2O	−30.9 (−32.5 to −29.3)	5.2 (2.7–7.8)	
NIL + model 2 PEEP 10 cm H_2O	−26.6 (−28.2 to −24.9)		
NIL − model 1 PEEP 5 cm H_2O	−9.22 (−10.8 to −7.6)	−3.3 (−8.4 to 1.7)	−27.7 (−29.8 to −25.7)
NIL − model 2 PEEP 5 cm H_2O	−13.2 (−14.8 to −11.6)		
NIL − model 1 PEEP 10 cm H_2O	−17.5 (−19.1 to −15.9)	5.2 (2.7–7.8)	
NIL − model 2 PEEP 10 cm H_2O	−9.9 (−11.6 to −8.3)		

Values are percentages.
* $P <$ .001 vs 0.
NIL = nonintentional leak

depends on the levels of the other factors (the interactions were all statistically significant, as shown in the supplementary materials). For the A40 ventilator, the magnitude of underestimation was more important with than without a nonintentional leak (Table 2). It was almost −20% for model 1 and −17% for model 2, regardless of the level of PEEP when nonintentional leak was present. When the nonintentional leak was absent, the underestimation was less than −10%. The PrismaST30 ventilator was associated with underestimation at PEEP 5 cm H_2O and overestimation at PEEP 10 cm H_2O. For the Vivo40 ventilator, underestimation was >10% with and without nonintentional leak.

Discussion

The main findings of our bench study were that the ventilator SD card underestimated the delivered V_T compared with the data logger taken as the reference and that different factors across ventilators were associated with the magnitude of this difference. To our knowledge, this was the first bench study that compared the average volume assured pressure support mode across these 3 homecare ventilators. As caregivers experts in NIV mentionned, the remote monitoring of respiratory parameters recorded by the built-in ventilator software is a step forward for patients on long-term ventilation at home, and its results should have a role in the decision-making process.[4] Our choice of ventilators for the present experiment was driven by the fact that non–life-support ventilators represent the large majority of the devices used to deliver NIV at home.

The main end point of the present investigation on the average volume assured pressure support mode was V_T. We did that in line with Pasquina et al[11] that emphazised on the direct relationship between alveolar hypoventilation and V_T and the V_T variability in the pressure preset pressure-limited mode. Both resulted from respiratory mechanics impairment, inspiratory effort intensity, and intentional and nonintentional leaks. Therefore, it is worth investigating V_T delivery in the average volume assured pressure support mode.[3-7]

It should be noted that, even though NIV is the standard of care for patients with COPD in acute hypercapnic ventilatory failure, the beneficial effect of long-term use of NIV in these patients is not supported by the evidence. However, quality of life has been improved by long-term use of NIV in patients with COPD and the patients with obesity hypoventilation syndrome.[12,13] The justification of the selected set V_T was to match the range of V_T used in recent trials on average volume assured pressure support.[3-7] For expiratory positive airway pressure, the level of 10 cm H_2O is used specifically in patients with respiratory sleep disorders at the same rate as in patients with obesity-hypoventilation syndrome[14] as in overlap syndrome. The average volume assured pressure support mode gives a better V_T estimation with a single limb circuit and intentional leak than with a double-limb circuit or an exhalation valve, with appropriate pressure adaptation during nonintentional leaks.[15] Apart from V_T, the Minute ventilation is another key element in NIV. Minute ventilation depends on the product of the V_T and the breathing frequency, which is much easier to calculate. The study by Contal et al[10] showed a good correlation between the breathing frequency measured by the test lung and by the ventilator SD card in the fixed pressure preset mode.

The present study found that each of the 3 ventilators underestimated V_T, as already pointed out,[10,16] in the fixed pressure preset mode. The difference between the ventilator SD card and Biopac 150 for V_T measurement was not homogeneous and depended on ventilator and test lung conditions. Of interest for the practitioner in charge of the patient, our study provided factors that were associated with the magnitude of the difference between the ventilator SD card and Biopac 150, each relative to the set V_T (see supplementary materials). Except for model 1 PEEP 5 cm H_2O and model 2 PEEP 10 cm H_2O both without

nonintentional leak, the 6 other combinations challenged the A40 ventilator card compared with the Biopac 150 (Table 2). Only PEEP (5 vs 10 cm H_2O) for the PrismaST30 ventilator and nonintentional leak for the Vivo40 ventilator were associated with the inaccuracy of the ventilator SD card (Table 2). The magnitude of the difference for each significant combination can be found in the supplementary materials. Taken together, these results showed that, as expected, nonintentional leaks and PEEP are the common factors that led to underdelivering V_T. Leak compensation can be more efficient with a pressure increase, but the risk of leaks increases.[6] Because the data retrieved from the ventilator SD card tended to underestimate the size of V_T, the caregiver would be keen to increase V_T with the subsequent risk of higher leaks.

This hybrid ventilation mode was expected to overcome the lack of strict V_T control with pressure-limited ventilation. Clinical studies on the average volume assured pressure support mode showed contrasting results on sleep quality and efficacy on CO_2 correction. Storre et al[3] and Janssens et al[4] demonstrated a better nocturnal transcutaneously measured partial pressure of carbon dioxide correction. Murphy et al[5] found no difference between ST (spontaneous timed) and the average volume assured pressure support modes on diurnal P_{aCO_2}. A key issue is the range of driving pressure that results in a better ventilator adaptation during nonintentional leaks or high airway resistances, as shown by Ambrogio et al.[6]

The present study also showed that, even though the V_T delivered was underestimated with the ventilator SD card, it was close to the target V_T according to Biopac 150, which may suggest that the prescribed setting was actually delivered. Only clinical studies would be able to demonstrate it. This outcome is crucial because adjustment of V_T based on the ventilator SD card measurement is necessary to offer to the patient receiving NIV a better follow-up with more reliable adaptation. Therefore, the accuracy of V_T measurement should be part of manufacturers' specifications. The difference in the results between the Vivo40 ventilator (an older machine) and the PrismaST30 ventilator (the most recent machine) tested in the present study may indicate an improvement in the technology from the manufacturers. However, the algorithm in the PrismaST30 ventilator led to an excessively high V_T at the higher PEEP.

Limitations

We did not assess the leaks. Leaks which is another key parameter for NIV efficacy and tolerance evaluation.[17] As pointed out by Fauroux et al[16] leaks could compromise V_T delivery more than the increase in resistance. This is a more-complicated parameter to estimate according to the bench test study by Contral et al,[10] due to different manufacturer specifications: the ventilators that were presently investigated measured the amount of both intentional and nonintentional leaks. Other ventilators measure only nonintentional leak, which requires indicating the type of interface.

We used a fixed nonintentional leak but in clinical practice leaks are unstable, and may appear suddenly or progressively, which will not have the same impact on V_T measurement. However, it is difficult to induce random nonintentional leaks with variable intensity in a lung model. Furthermore airway resistances fluctuate, particularly in the upper airways during sleep; consequently, the lack of ability to program these modifications on the test lung limits the efficacy evaluation of the average volume assured pressure support mode.

Conclusions

Of the 3 home-care ventilators tested in our study, the ventilator SD card underestimated V_T but the correlation with reference value was high. Factors involved in this difference varied among the ventilators.

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