What Does Built-In Software of Home Ventilators Tell Us? An Observational Study of 150 Patients on Home Ventilation

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Key Words

Home ventilators • Noninvasive ventilation • Chronic hypercapnic respiratory failure

Abstract

Background: Recent home ventilators are equipped with built-in software which provides data such as compliance, estimations of leaks, tidal volume, minute ventilation, respiratory rate, apnea and apnea-hypopnea indexes, and percentage of inspirations triggered by the patient (or ventilator). However, for many of these variables, there is neither consensus nor documentation as to what is to be expected in a population of stable patients under noninvasive ventilation (NIV). **Objectives:** To document the values and distribution of specific items downloaded from ventilator monitoring software, by diagnostic category. **Methods:** Analysis of data downloaded from home ventilators in clinically stable patients under long-term NIV, during elective home visits by specialized nurses. **Results:** Data were collected from home ventilators of 150 patients with chronic obstructive pulmonary disease (n = 32), overlap syndrome (n = 29), obesity-hypoventilation (n = 38), neuromuscular disorders (n = 19), restrictive disorders (n = 21), and central sleep apnea syndrome (n = 11). On average, leaks were low, being lowest in

patients with facial masks (vs. nasal masks), and increased with older age. Compliance was excellent in all groups. Patients with neuromuscular diseases triggered their ventilators less and tended to be 'captured', while other groups triggered at least half of inspiratory cycles. Most patients had a respiratory rate just slightly above the back-up rate. Residual apneas and hypopneas were highest in patients with central apneas. **Conclusions:** Built-in software of home ventilators provides the clinician with new parameters, some of which are a useful adjunct to recommended tools for monitoring NIV and may contribute to a better understanding of residual hypoventilation and/or desaturations. However, an independent validation of the accuracy of this information is mandatory.

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Introduction

Long-term noninvasive positive-pressure ventilation for chronic hypercapnic respiratory failure (CHRF) became a therapeutic option in the mid 1980s, after the first reports of nasal ventilation in patients with Duchenne's muscular dystrophy. Early home positive-pressure ventilators were volumetric. Bi-level pressure-cycled ventila-

tors appeared in the early 1990s [1] and became, over a 10-year period, the default treatment for most causes of CHRF [2]. Technical advances in bi-level pressure-cycled ventilators have been tremendous over the past 20 years in terms of pressurization (range, compensation of leaks), size, noise, improvement of patient-ventilator synchronization through adjustable inspiratory and expiratory triggers, and, recently, the availability of built-in tools for monitoring the efficacy of home ventilation [3].

Home noninvasive ventilation (NIV) aims to improve quality of life [4], quality of sleep and survival, correct hypoventilation and associated symptoms, and daytime and nocturnal blood gases. Monitoring of the efficacy of home NIV usually relies on daytime arterial blood gases (ABGs) and nocturnal pulse oxymetry (a few centers use polysomnography for monitoring their NIV patients). Although this may suffice in most stable patients or patients with few symptoms, several authors have recently drawn the attention to respiratory events occurring during nocturnal NIV, most often asymptomatic, and often not detected by daytime ABGs and nocturnal pulse oxymetry alone [5–7]. The importance of leaks on sleep structure, for instance, has been well described by Teschler et al. [8]. Many recent bi-level ventilators designed for home care have been equipped with built-in software which supply detailed information about items such as estimated ventilation (tidal volume, V_T , minute ventilation, V_E and respiratory rate, RR), estimated leaks, respiratory cycles triggered by the patient or the ventilator, cycling by the ventilator or the patient, and residual or new apneas/hypopneas [7].

Although this technological advance is welcome, the clinician is faced with two new dilemmas. The first is to determine whether the signals and data recorded are reliable or not: this warrants further independent clinical and bench testing. A study by Rabec et al. [9] suggests that – at least in one commercialized home ventilator – estimation of leaks and V_E is reliable. However, a recent bench study shows that the reliability of ventilator signals is quite variable from one device to another [10]. The second question is what should the clinician expect and consider as ‘usual’ in a population of stable patients under home NIV in terms of respiratory mode, triggering of ventilators, leaks, in different diagnostic groups of patients.

This descriptive study thus aims to analyze information that can be downloaded from home bi-level pressure-cycled ventilators, in a large group of stable patients under long-term NIV and its potential relevance for monitoring and follow-up of these patients in clinical practice.

Patients and Methods

The outpatient section of Geneva University Hospital’s Division of Pulmonary Diseases follows a group of patients under home NIV for CHRF ($n = 179$ at the time of the study) [11]. Specialized nurses pay regular home calls to patients under NIV and record clinical symptoms, SpO_2 , and spirometry, during their visits. They also download data recorded over the previous 4 weeks from home ventilators on a PC. This information is stored in a computerized database. Medical consultations are organized according to clinical stability and the results of these home visits, and include measurement of arterial blood gases and nocturnal pulse oximetry.

Among the ventilators used for home NIV in our area, the following were equipped with a built-in software allowing downloading on a PC and analysis of ventilator performance over the previous weeks or months: VPAP III, VPAP IV (ResMed™; North Ryde, N.S.W., Australia, with ResScan™ software) and Synchrony I and II ventilators (Philips Respironics™; Murrysville, Pa., USA, with Encore Pro™ software). Items given by the ResScan software include: ventilator settings, leaks (data provided are unintentional leaks only averaged over the respiratory cycle: ‘intentional’ leak of mask is subtracted when using ResMed masks), V_T , total V_E , RR, percentage of spontaneous inspirations and expirations, apnea-hypopnea index (AHI), and detailed report of compliance on a daily basis (fig. 1). The Encore Pro software also provides ventilator settings, leaks (readings give sum of ‘intentional’ (mask) and ‘unintentional’ leaks), RR, V_T , V_E , maximal inspiratory flow, and percentage of respiratory cycles triggered by patient. V_T , V_E , leaks and AI were estimated for all these home ventilators. Data downloaded covered the previous 4 weeks.

Data analyzed were included prospectively over a 2 1/2-year period from April 1, 2007 to September 30, 2009. All patients had been put on home NIV at Geneva University Hospital either electively or after an acute episode of hypercapnic respiratory failure. Implementation of NIV was performed according to prevailing recommendations [12], with the aim of optimizing nocturnal SpO_2 , nocturnal $PtcCO_2$, daytime ABGs [2], patient comfort and to minimize leaks. Initiation of home NIV was performed by specialized chest therapists, under the supervision of a pulmonologist. It is our practice to pay special attention to the presence of unintentional leaks [11]; we thus use facial masks either as default interface, or whenever leaks through the mouth are problematic with nasal masks; 73% ($n = 110$) of patients in this study had a facial interface.

Statistics

Values are expressed as median (interquartile range) or as mean $\pm$ SD according to their distribution. To compare data downloaded from the ventilator software between diagnostic categories, we used the Kruskal-Wallis test. A p value <0.05 was considered significant. Multivariate regression analysis was performed to determine whether specific items (age, gender, BMI, diagnostic group, ventilator settings, nasal vs. facial mask) were predictive of leaks. Statistical analyses were carried out with Stata version 11 (StataCorp, College Station, Tex., USA).

The study protocol was approved by the Ethics Committee for Medical Research of Geneva University Hospital.

Fig. 1. a Graphic transcription of daily compliance and pattern of use of ventilator provided by ventilator software in a patient who is well adapted to his ventilator, with excellent compliance. Use of ventilator during the night is continuous, without interruption, suggesting acceptable quality of sleep. **b** Graphic transcription of daily compliance and pattern of use of ventilator provided by ventilator software in a patient who tolerates his treatment poorly, revealing multiple interruptions during the night, and days without ventilator use.

Results

Of 179 patients under home NIV at the beginning of the study, 19 were under servo-assisted bi-level pressure support, 7 were under volumetric ventilators, 1 was under pressure support ventilation (Breas PV403), and 2 under bi-level positive-pressure ventilation without any incorporated software. The present analysis focuses on the 150 patients (83 male, 67 female, aged 66 ± 14 years), treated with either ResMed (VPAP III, VPAP IV, $n = 103$, 69%), or Philips Respironics ventilators (Synchrony 1 or 2, $n = 47$, 31%), with facial ($n = 110$, 73%) or nasal masks ($n = 40$, 27%) for an average of 4.1 ± 2.6 years. Ventilator mode was spontaneous/timed (ST: pressurization is triggered by the patient unless spontaneous respiratory rate decreases under preset back-up respiratory rate) for all patients but 3 who were on AVAPS/ST (automated volume pressure support) mode.

Patients were treated for CHRF resulting from moderate to severe chronic obstructive pulmonary disease (COPD, graded according to GOLD recommendations, $n = 32$, 21%, BMI (kg/m^2): 26 ± 8), overlap syndrome, defined as COPD and obstructive sleep apnea syn-

drome, documented by polygraphy or polysomnography, $n = 29$, 19%, BMI: 40.9 ± 7.8), obesity-hypoventilation syndrome ($n = 38$, 25%, BMI: 45.4 ± 7.5), neuromuscular disorders ($n = 19$, 13%, BMI: 24.8 ± 6.1), chest wall or parenchymal restrictive disorders ($n = 21$, 14%, BMI: 24.2 ± 5.8) and central sleep apnea syndrome (CSAS; $n = 11$, 7.3%, BMI: 26.9 ± 2.7). Fifty-four (36%) patients received supplemental oxygen during their nocturnal ventilation.

Results of home pulse oximetry (Minolta Pulsox 300i®) were: SpO_2 $92.5 \pm 3\%$; oxygen desaturation index $11 \pm 14/\text{h}$; percentage of recording spent with $\text{SpO}_2 < 90\%$ $19 \pm 26\%$.

Results of spirometry and ventilator settings are listed in table 1. Values for time to peak, minimal inspiratory time ($\text{TI}_{\min}$) and maximal inspiratory time ($\text{TI}_{\max}$) only apply to patients using ResMed ventilators, since Philips Respironics ventilators rely on the automated 'AutoTrak' system. Inspiratory and expiratory triggers (ResMed ventilators only) were set on default values ('medium') in 82 and 88% of patients, respectively.

Data downloaded from ventilators are listed in table 2.

Table 1. Spirometry and ventilator settings

	COPD	Overlap syndrome	Obesity hypoventilation	Neuromuscular disorders	Restrictive disorders ¹	CSAS
Patients, n	32	29	38	19	21	11
<i>Pulmonary lung functions</i>						
FEV ₁ % predicted, %	30 (25–44)	58 (46–66)	75 (62–94)	57 (41–62)	43 (36–67)	87 (80–131)
FVC % predicted, %	59 (51–75)	75 (57–86)	79 (64–94)	53 (37–61)	50 (39–64)	92 (83–125)
FEV ₁ /FVC	56 (44–62)	81 (76–83)	99 (95–103)	102 (93–116)	94 (86–103)	96 (91–101)
<i>Ventilator settings</i>						
IPAP, cm H ₂ O	19 (16–22)	20 (18–22)	20 (18–22.5)	14 (13–18)	16 (14–18)	15 (11–16)
EPAP, cm H ₂ O	5 (5–6)	8 (6–10)	8 (7–10)	4 (4–6)	4 (4–6)	6 (5–8)
Back-up RR, n	14 (13.5–16)	14 (12–15)	14 (12–14)	14 (12–16)	14 (14–16)	14 (12–14)
Time to peak, ms	150 (100–200)	150 (100–200)	150 (100–200)	150 (150–250)	125 (100–250)	150 (150–250)
TI _{min} , s	0.6 (0.5–0.7)	0.8 (0.6–0.8)	0.7 (0.7–0.8)	0.8 (0.7–0.8)	0.7 (0.5–0.8)	0.6 (0.5–0.8)
TI _{max} , s	1.2 (1.1–1.3)	1.4 (1.3–1.6)	1.4 (1.2–1.5)	1.3 (1.1–1.6)	1.5 (1.35–1.6)	1.3 (1.2–1.4)

All values are expressed as medians and interquartile ranges. FEV₁ = Forced expiratory volume in 1 s; FVC = forced vital capacity; TI_{min} and TI_{max} only apply to subjects using ResMed ventilators since Philips Respironics ventilators rely on the automated

AutoTrak system (not adjustable). Inspiratory and expiratory triggers (ResMed ventilators) were set at default values (Medium) in 82 and 88%, respectively.

¹ Includes 1 case with diffuse bronchiectasis.

Table 2. Data downloaded from ventilator software

	COPD	Overlap syndrome	Obesity hypoventilation	Neuromuscular disorders	Restrictive disorders ¹	CSAS	p value
Patients, n	32	29	38	19	21	11	
ResMed ventilator/Philips Respironics ventilator, n	25/7	19/10	21/17	17/2	16/5	7/4	
Compliance, min/24 h	478 (362–599)	433 (289–527)	436 (348–490)	518 (327–591)	359 (300–448)	314 (283–458)	0.098
Leaks, median, liters/min ²	6 (3–9.6)	8.4 (1.2–16.8)	8.4 (6–10.8)	7.8 (2.4–28)	10.5 (1.2–16.5)	3.6 (1.2–14.4)	0.939
Leaks, 95th percentile, liters/min ²	17.4 (12–34)	18.4 (9.6–48)	19.2 (12–27)	21.6 (4.8–48)	24 (10.2–34.5)	8.4 (2.4–45.6)	0.921
V _T , ml/kg	7.1 (5.7–9.3)	5.9 (4.8–7.5)	4.9 (3.7–6.2)	5.7 (5.0–8.0)	7.0 (5.9–8.6)	7.4 (5.2–8.7)	<0.001
V _E , liters	10 (8.6–11.6)	11.8 (8.4–12.8)	9.6 (8.1–12.0)	8.0 (6.6–8.7)	8.2 (6.7–10.4)	7.9 (6.6–10.7)	<0.001
RR – back up RR, n	1 (0–3.5)	1 (0–3)	2 (1–5)	0 (1–4)	2 (1–4)	3 (1–4)	0.258
Spontaneous inspirations, %	56 (17–77)	52 (18–80)	57 (23–85)	23 (12–60)	50 (18–79)	65 (18–81)	0.557
AHI, n/h ²	1.3 (0.6–4.4)	4.9 (2.2–10.3)	3.4 (2.1–7.7)	6.1 (1.0–11.4)	0.9 (0.1–3.0)	12.5 (5.0–19.7)	0.001
AI, n/h ²	0 (0–0)	0 (0–0.4)	0 (0–0.1)	0 (0–0.3)	0 (0–0.1)	0.4 (0–1.7)	0.405

All values are expressed as medians and interquartile ranges. p values relate to the Kruskal-Wallis test.

¹ Includes 1 case with diffuse bronchiectasis.

² Data collected only from ResMed software (n = 105).

Leaks

As mentioned, leaks were monitored differently in the two types of ventilators (in both cases, leaks are averaged over the whole respiratory cycle; intentional leaks of masks – based on characteristics of ResMed masks – are subtracted in ResMed ventilator reports, but not in Philips Respironics reports; values are reported as either mean, or median with 95th percentile); taking into account these differences, average leaks were low in most

patients. They were significantly lower in patients with facial versus nasal masks [difference between masks: 8.0 liters/min (95% CI: 4.1–11.8), $p < 0.01$, in favor of facial masks, based on 103 patients with ResMed devices]. After adjustment for type of mask and device, increasing age was also associated with higher leaks [0.2 liter/min for each additional year (95% CI: 0.1–0.3), $p = 0.02$, 103 patients with ResMed devices].

Other Parameters

As expected, V_T (ml/kg) was lowest in patients with obesity-hypoventilation, although V_T values were similar to other indications when calculated with ideal body weight (data not shown). Reported (spontaneous) RR was slightly above back-up RR in most patients. Patients with neuromuscular disorders had the highest percentage of respiratory cycles triggered by the ventilator, and tended to be 'captured' by the ventilator (i.e. passively ventilated). Software and ventilators used during the study period did not provide percentage of spontaneous expiratory cycling.

Discussion

This study gives an overview of ventilator settings and data recorded by ventilator software in stable patients treated by long-term home bi-level positive pressure ventilation for CHRF. The data presented (table 1) show minor differences between diagnostic categories in terms of ventilator settings: as expected, expiratory positive airway pressure (EPAP) values are slightly higher in patients with overlap syndrome or obesity hypoventilation because of the necessity of stabilizing the upper airways in the presence of obstructive sleep apneas and/or hypopneas. Inspiratory positive airway pressure (IPAP) values are lowest in patients with neuromuscular diseases, who most often do not have any associated pulmonary parenchymal disorder and thus have a normal or near normal compliance. Low IPAP values in CSAS were expected as well: higher values would increase alveolar ventilation and thus increase the risk of hypocapnia, inducing an increase in central events. Back-up RR is set just below spontaneous RR in most cases, as measured by the ventilator (table 2). The percentage of spontaneous inspirations is lowest in neuromuscular disorders: these patients tend to have their RR 'captured' by the ventilator. Compliance is on average quite satisfactory (only 10.6% of patients used their ventilator less than 3.5 h/day). The residual apnea index (AI) is very low, and most patients with a high residual AHI under NIV had either CSAS, or, to a lesser degree, neuromuscular disorders.

Compliance

Data recorded by ventilator software are extremely useful for assessing compliance and the pattern of ventilator use. The pattern of ventilation is an indirect indicator of tolerance to NIV and comfort: for instance, multiple interruptions during the night after short periods of

NIV or an erratic pattern of use over several days are suggestive of poor adaptation to NIV, and patient discomfort (fig. 1). Compliance was highest in patients with neuromuscular disorders (which possibly reflects a higher dependence on ventilatory support) and lowest in patients with CSAS although the small number of patients in each group does not allow definite conclusions to be drawn. A detailed report on compliance is important for (1) deciding to pursue or not ventilatory support (this was not a problem in this series); (2) discussing alternate patterns of daily use of NIV in case of poor tolerance during the night (i.e. daytime sessions) [13], and (3) understanding insufficient impact of NIV on ABG or clinical symptoms.

Leaks

The importance of leaks with respect to the efficacy of NIV and structure of sleep has been stressed in previous reports [8]. Unintentional leaks are a major contributors to intolerance to NIV, patient-ventilator asynchrony and suboptimal correction of ABGs and nocturnal hypoventilation. Thus estimation of leaks by the ventilator – if reliable – is a very useful contribution. Combined assessment of leaks with additional polygraphic modules provided by some manufacturers is possible and useful for determining to what extent leaks are implicated in recurrent or prolonged decreases in SpO_2 . Recently, Rabec et al. [9] showed that leaks assessed by built-in software of VPAP III (ResMed) ventilators were highly correlated with bench test measurements. These results cannot, however, be extrapolated to all home bi-level ventilators: a bench test performed with 7 home ventilators showed major discrepancies between devices as to the reliability of reported leaks [10]. One important caveat is that different ventilators estimate leaks differently. Intentional leak of the exhalation valve of the mask is sometimes included in the reported value, and sometimes not (ResMed software subtracts intentional leaks for ResMed masks). Also, leaks may be averaged over the whole respiratory cycle, or only during EPAP. For both devices tested in this study, leaks are measured continuously cycle by cycle. When the 'intentional leak' of the mask is not subtracted, the expected mask leak at the set pressure of the ventilator should theoretically be subtracted from the total value reported. Curves of intentional leaks as a function of pressure are available for all commercialized masks. However, to date, ventilator software does not provide the average pressure over the whole respiratory cycle, and thus estimating precisely the intentional leak of a given mask requires a complex computation which should take into account IPAP and EPAP values, I:E ratio and RR [9].

Also, increasing pressure support by 10 cm H₂O can lead to a doubling of intentional leaks [14]. For these reasons, upper limits of acceptable values provided by manufacturers are arbitrary and in fact depend on the characteristics of the interface and the pressures used [14].

In this study, leaks were on average low. Use of facial masks (73% of our patients) was associated with significantly lower leaks while increasing age was associated with higher leaks. The association with age may be related either to age-related alterations in skin and subcutaneous tissues or to a higher incidence of mask malposition in older patients. Interestingly, neither pressure settings, time to peak, nor back-up rate were significantly related to leaks.

Reporting leaks under NIV has immediate clinical implications. Detection of high leaks in our patients at home led to adjustment or change of the interface, teaching of patient and/or home care provider, and, sometimes, adjustment of ventilator settings. Evaluating the benefit of the adjustments made is also facilitated by the longitudinal monitoring of this parameter. The only major caveat is to ensure that leaks are reliably assessed by the device used by the patient [9, 10].

V_T and V_E

Our results are in agreement with previous reports and recommended values in this setting. However, estimations of V_T and V_E are subject to major differences according to the devices tested, pressure settings and leaks [9, 10, 15]. V_T tends to be underestimated by several home devices; bias seems to increase with higher pressure support values, and may be affected by leaks [10, 15]. For the VPAP III ResMed device, Rabec et al. [9] found that the correlation between V_E measured on a bench test and by ventilator software was highly significant, with a very low bias, but with wide limits of agreement (−1.8 to 1.9 liters/min). It thus seems that the clinician should not rely solely on either V_T or V_E readings to adjust ventilator settings, especially when higher insufflation pressures are used, or important leaks are detected. Further independent testing is required for this parameter.

RR and Percentage of Spontaneous Inspirations

Spontaneous RR of the patient and percentage of cycles triggered by the patient retrieved from ventilator software must also be interpreted with caution. Indeed, a low percentage of spontaneous inspiratory triggering may occur when the patient has a back-up RR above his spontaneous RR: the patient is then ‘captured’ by the ventilator RR. However, in the presence of leaks, or con-

ditions in which inspiratory efforts may not be perceived by the ventilator (patients with severe neuromuscular disease, intrinsic positive end-expiratory pressure in severe COPD, upper-airway closure), a low percentage of spontaneous inspiratory triggering may in fact reflect the inability of the ventilator to perceive the patient’s RR (ineffective triggering, i.e. unrewarded inspiratory efforts), leading to patient-ventilator asynchrony. Furthermore, whether it is preferable to ventilate patients with a high or a low rate of spontaneous triggering is still a matter of debate [16, 17]. The present study shows a trend for a higher percentage of patients ‘captured’ by their ventilator in neuromuscular disorders: these patients were historically ventilated in a ‘controlled’ mode. Practically, a high percentage of cycles triggered by the patient decreases the likelihood of important patient-ventilator asynchrony.

Apnea-Hypopnea Index

There is a confusion related to the validity of the AHI index in patients under positive-pressure ventilation. The first problem is the lack of a standardized definition for hypopneas under positive-pressure ventilation. The second difficulty is that manufacturers do not provide clear definitions of the events reported by their software and their mode of detection. Definitions of respiratory events occurring under NIV have recently been proposed as a framework for monitoring and future studies [18]. The third limitation is the lack of independent validation of these signals, and of the ability of software to detect and differentiate central from obstructive events. In the present study, the highest values detected under NIV occurred in the CSAS group, followed by patients with neuromuscular disorders: absolute values should, however, be interpreted with caution, and confirmed by polygraphy or polysomnography.

Study Limitations

ABG contemporary to downloaded ventilator reports were not available for all patients since the present study is based on home visits by registered nurses, and ABG were not performed in this setting. Thus one could question the adequacy of the ventilator settings in these patients. However, clinical stability over a long period (patients had been under NIV for an average of 4.1 ± 2.6 years), absence of clinical signs of cardiac or respiratory failure and acceptable pulse oximetry tracings indicate that this population reflects what can be expected in patients on long-term NIV for CHRF.

Conclusions

Recent home ventilators with built-in software provide substantial information for monitoring home NIV, such as compliance, pattern of ventilator use, and estimation of leaks, all of which have a direct impact on patient management. Interpretation of leaks must, however, take into account the way in which data are estimated and reported (i.e. with or without intentional leaks included), and the fact that significant discrepancies exist between devices as to the reliability of this parameter. Other parameters, such as estimated V_T and V_E , could theoretically be useful for adjusting pressure support: however, available literature suggests a tendency for devices to underestimate V_T , to exhibit an increasing bias with higher pressures, and wide limits of agreement. The clinician should thus not rely only on these data for adjusting ven-

tilator settings. Items such as percentage of spontaneous versus triggered inspirations or expirations warrant further clinical validation. Globally, certain items provided by ventilator software are a useful adjunct to recommended tools for basic monitoring of NIV, such as ABGs, nocturnal pulse oximetry, and when available, nocturnal capnography. However, in the presence of unexplained desaturations and/or discomfort, respiratory polygraphy or polysomnography remain the gold standard for assessing the quality of nocturnal ventilation.

Financial Disclosure and Conflicts of Interest

The authors have no conflict of interest as concerns the present study.

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