

Performance of ventilators for noninvasive positive pressure ventilation in children

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Abstract

The aim of the study was to evaluate the performance characteristics of all the ventilators proposed for home noninvasive positive pressure ventilation in children in France.

Seventeen ventilators, (volume-targeted, n=1, pressure-targeted, n=12, and dual ventilators, n=4) were evaluated on a bench which simulated 6 different paediatric ventilatory patterns. For each ventilator, the quality of the inspiratory and expiratory trigger, and the ability to reach and maintain the preset pressures and volumes were evaluated with the 6 patient profiles.

The performance of the ventilators showed a great variability and depended on the type of trigger (flow or pressure), the type of circuit, and the patient profile. Differences between the preset and measured airway pressure and between the tidal volume measured by the ventilator and on the bench were observed. Leaks were associated with the inability to detect the patient's inspiratory effort or autotriggering. No single ventilator was able to adequately ventilate the 6 paediatric profiles. Only few ventilators were able to ventilate the profiles simulating the youngest patients.

A systematic paediatric bench evaluation is recommended for every ventilator proposed for home ventilation in order to detect any dysfunction and to guide the choice of the appropriate ventilator for a specific patient.

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Introduction

Noninvasive positive pressure ventilation (NPPV) is increasingly used at home in children [1]. NPPV may improve respiratory failure in children with neuromuscular disease [2, 3], upper airway obstruction and sleep apnea [4], and lung diseases such as cystic fibrosis [5]. These diseases concern both infants as well as older children, which implies that the ventilator is able to adapt to a large range of patient demands. Children with respiratory failure, and especially the youngest ones, may develop “extreme” breathing patterns, which may represent a “challenge” for a ventilator [6]. Indeed, home ventilators may not be able to adequately synchronise with the patient respiratory effort [7, 8], leak compensation may be insufficient, and the triggers of assist modes and alarms are not always adapted for young children. This is explained by the fact that most ventilators have not been specifically developed for paediatric patients. However, in practice, the clinician has to deal with the available devices.

Although some studies have tested or compared home ventilators in young patients with cystic fibrosis [7, 8] or upper airway obstruction [6], no study has evaluated different types of ventilators in children with various causes of chronic respiratory insufficiency. In France, 17 ventilators are proposed for home ventilation in children. The choice of the most appropriate ventilator for a specific patient is thus a real challenge for the clinician. Indeed, the testing of several ventilators in every single patient is unrealisable in practice.

The aim of the present study was to evaluate the performance of the 17 ventilators available for home ventilation in France with the most common “paediatric profiles”, namely neuromuscular disease, upper airway obstruction, and cystic

fibrosis. Therefore, we used a bench lung model that simulated the mechanical respiratory characteristics and the pattern of breathing of six “typical” paediatric patient profiles.

Material and methods

Patients profiles

In our clinical practice, about one third of the children treated with NPPV at home have neuromuscular diseases, one third has upper airway obstruction, and the last third have lung diseases or other causes of chronic hypercapnic respiratory insufficiency [1]. We selected thus from our NPPV cohort, 6 patient profiles who represent approximately 90% of the patient profiles (Table 1).

During routine initiation of NPPV and follow up, breathing pattern in baseline condition, respiratory mechanics and respiratory output were recorded using a pneumotachograph (Fleisch # 3, Lausanne, Switzerland) and a catheter mounted pressure transducer system with two integral transducers (Gaeltec, Dunvegan, Isle of Skye, UK). Breathing pattern in baseline condition, i.e., when the patient was not connected to a ventilator and was spontaneously breathing, was inferred by measuring the patient flow rate. The tidal volume (V_T) and the inspiratory time (T_{insp}) were directly deduced from this flow tracing (Table 1).

The patient's respiratory mechanics was inferred when the patient was connected to the ventilator by measuring transdiaphragmatic pressure (P_{di}) and esophageal pressure (P_{es}) as previously described [5]. Briefly, dynamic lung compliance (C_{Ldyn}) was calculated as the ratio of V_T to the P_{es} difference between the beginning and the end of inspiration during quiet breathing. Individual values

indicated in Table 1 were averaged on the basis of 10-20 consecutive cycles during air breathing.

Airway and lung resistance (R) were calculated according to the formula based on the technique of Mead and Whittenberger: $R = [(P_{es_0} - P_{es}) - (V/C_{Ldyn})] / V'$ where P_{es_0} is the P_{es} value at the start of inspiratory flow, V is the instantaneous volume, C_{Ldyn} is calculated for the same breath, and V' is the instantaneous airflow [9]. Mean values over the inspiration were used as estimates of inspiratory airway and lung resistance (Table 1).

The analysis of the patient's profile was approved by the hospital ethics committee and patients and parents gave their informed consent.

Testing of the ventilators

Seventeen ventilators were tested (Table 2). Twelve ventilators were pressure targeted ventilators, one ventilator was a volume targeted ventilator, and 4 ventilators had the 2 modes. Every ventilator was tested with the 6 different patient profiles with the recommended circuits. When assist-control ventilation (ACV) and pressure support ventilation (PSV) were available, both modes were tested.

The setting of the ventilator (targeted pressure/volume, positive end-expiratory pressure (PEEP)) was different for each patient profile (Table 1). The 2 first patients were patients with neuromuscular disease, a 4-yr old boy with spinal muscular atrophy and a 17-yr old boy with Duchenne muscular dystrophy. Because both ACV and PSV may be used in these patients, ventilators able to deliver one or both modes were tested. For patient 3 with cystic fibrosis, ventilators able to deliver PSV and/or ACV were tested. For these first three patients, PSV or ACV with zero end-expiratory pressure of zero (ZEEP) was chosen because of the absence or a low (< 2 cm H_2O)

level of intrinsic PEEP [5, 10]. Patient 4 was an infant with laryngomalacia in whom only ventilators able to deliver PS with PEEP were tested. PSV ventilators with PEEP were tested in patient 5 having obstructive sleep apnea due to vocal cord paralysis. All the PSV ventilators able to deliver ZEEP were tested in patient 6 with central apnea.

All ventilators were studied at their most sensitive inspiratory trigger that did not induce auto-triggering. When possible, the highest inspiratory flow was used. In the majority of the ventilators, the expiratory trigger was set automatically. In 4 ventilators (GK 425ST, KNIGHTSTAR 330, VIVO 40, VPAP 3STA), it was possible to modify the sensitivity of the expiratory trigger. In this case, we used the most sensitive level that did not induce a T_{insp} inferior to the spontaneous T_{insp} . When available on the same ventilator, pressure and flow-triggering were tested. In case of an optional integrated humidification system, the ventilator was tested with and without the humidification system. For all the ventilators, the most recent model (year 2006) was used.

Experimental bench study

Each tested ventilator was connected via its standard circuit to the first chamber of a two-chamber Michigan test lung MII Vent Aid TTL; Michigan Instrument, Grand Rapids, MI) (Figure 1). The second chamber of the test lung (driving chamber) was connected to a flow-rate generator that could produce various wave forms previously stored in a microcomputer. The two chambers were physically connected to each other by a small metal component that allowed the driving chamber to lift the testing chamber. The flow rate generator, developed by the laboratory as previously described, was built by associating pressurised air, flow rate

measurement and a servo valve driven by a microcomputer [11]. This allows a continuous adjustment of the servo valve in order to produce for each patient profile the desired flow, as indicated in the paragraph “patient profiles”. Moreover, in order to simulate the mechanical characteristics of respiratory system of each patient, the compliance of the testing chamber was adjusted and a resistance was added between the testing chamber and the tested ventilator. The compliance of the testing chambers (compliance of the respiratory system C_{rs}) was set according to the formula $1/C_{rs} = 1/C_w + 1/CL$, where C_w was the chest wall compliance theoretical value which represents about 4% of the patient’s predicted value of vital capacity per cm H₂O and CL was the lung compliance corresponding to the patient’s CL_{dyn} . The resistance was a parabolic airway resistor (Pneuflo® Airway resistor Rp5, Rp20, Rp50 or Rp200; Michigan Instrument, Grand Rapids, MI). For each profile, the resulting breathing effort generated in the bench test was characterised by the inspiratory airway occlusion pressure at 0.1 second ($P_{0.1}$), and by the volume ($V_{0.1}$) and the flow ($V'_{0.1}$) at 0.1 second after initiation of a spontaneous breath (Table 1). $P_{0.1}$ was inferred when the tested ventilator and its circuit (Figure 1) were replaced by a rigid stopper, while $V_{0.1}$ and $V'_{0.1}$ were inferred when the lung test was opened to the atmosphere. A leak valve was added to simulate leaks that could occur through a mask during NPPV, which allowed the testing of an increasing leak.

Airway pressure (P_{aw}) and flow were measured at the end of the ventilator circuit using respectively a pressure differential transducer (Validyne DP 45 \pm 56 cm H₂O, Northridge, CA) and a pneumotachograph (Fleish n°2, Lausanne, Switzerland) associated with a pressure differential transducer (Validyne DP 45 \pm 3.5 cm H₂O). The leak flow was also measured with a second pneumotachograph. Calibration of pressure and flow was performed before each test. Signals were digitised at 200 Hz

by an analogic/digital system (MP100, Biopac Systems, Goleta, CA) and recorded on a microcomputer for further analysis.

As classically done, the following parameters were computed from each pressure and/or flow trace: PEEP, pressure support for PSV, measured tidal volume (V_{Tm}) and the tidal volume indicated by the ventilator (V_{Tv}). The sensitivity of the inspiratory trigger was evaluated on the trigger time delay (ΔT : time between the onset of inspiratory effort to the point of minimum airway pressure), and the trigger pressure (ΔP : pressure swing between the baseline pressure and the minimum airway pressure) [7]. The sensitivity of the expiratory trigger was evaluated as the difference between the patient's inspiratory time during spontaneous breathing (T_{insp}) and the inspiratory time during NPPV (T_I). The pressurisation slope was calculated from the time of the minimum airway pressure up to this time +150 ms. Each parameter was averaged on the base of 30 respiratory cycles.

In order to facilitate the interpretation of the results and guide the reader, the performances of the ventilators are presented qualitatively as follows. The inspiratory trigger was considered "appropriate" if $\Delta T \leq 100$ ms and $\Delta P \leq -1$ cmH₂O [12], "acceptable" if $\Delta T \leq 150$ ms and $\Delta P \leq -1.5$ cmH₂O or if $\Delta T \geq 100$ ms or $\Delta P \leq -1$ cmH₂O, and "inappropriate" if the ventilator did not detect the inspiratory effort or in case of autotriggering. The coping of the ventilator with leaks was ranked as follows: (1) relatively insensitive to a leak (no triggering or auto-triggering for a leak ≥ 40 l/mn), (2) moderately sensitive to a leak (no triggering or auto-triggering for a leak >10 and < 40 l/mn), (3) very sensitive to a leak (no triggering or auto-triggering for a leak ≤ 10 l/mn). The results of the performance of each ventilator are also given qualitatively as follows: "appropriate": for ACV, $V_{Tm} < \text{required } V_T \pm 10\%$, and for PSV, measured PS (PS_m) $< \text{required PS} \pm 10\%$, and pressurisation slope ≥ 60 cm

H₂O/s, “acceptable”: for ACV, $V_{Tm} < \text{required } V_T \pm 15 \%$, and for PSV: $PSm < \text{required } PS \pm 15 \%$, and pressurisation slope $\geq 40 \text{ cm H}_2\text{O/s}$, “inappropriate”: does not detect the inspiratory effort or autotriggering or, for ACV: $V_{Tm} \geq V_T \pm 15 \%$, or for PSV, $PSm \geq \text{required } PS \pm 15 \%$, and pressurisation slope $< 40 \text{ cm H}_2\text{O}$.

Results

Except for 3 cases; SMARTAIR in the patient with cystic fibrosis (profile # 3), VIVO 40 in the patient with vocal cord paralysis (profile # 5), and VS ULTRA double circuit pressure trigger in the patient with central apnea (profile #6), we found very close results with and without humidification system. The results given are thus the average obtained with and without humidification system.

The complete data concerning the performance of each ventilator with the 6 different patient profiles are given in the online supplement (Online Tables 1 to 6). For the patient with spinal muscular atrophy, all the 7 ventilators that had a compatible mode had inappropriate triggers (Table 3). For the adolescent with Duchenne muscular dystrophy, only 2 ventilators (the EOLE 3 with a flow trigger and the LEGENDAIR) had an appropriate inspiratory trigger in the ACV mode. However, the EOLE was very sensitive and the LEGENDAIR moderately sensitive to leaks. Of the 5 other ventilators that had a compatible mode, all had an inappropriate trigger. For the patient with cystic fibrosis, only 4 ventilators had an appropriate trigger (the EOLE 3 with a flow trigger, the LEGENDAIR with both modes, the SMARTAIR with a simple circuit, the VS ULTRA in the PSV mode with a pressure trigger and a double circuit, and in the ACV mode with a simple circuit). The VS ULTRA in the PSV mode

with a simple circuit and in the ACV mode with a double circuit and a pressure trigger had an acceptable trigger. But the ELYSEE 150, the NEFTIS, and the VS INTEGRA had all inappropriate triggers. None of the 16 PSV ventilators was able to detect the inspiratory effort of the infant with laryngomalacia. For the patient with vocal cord paralysis, 4 ventilators (the iSLEEP 22, the KNIGHTSTAR 330, the VS INTEGRA with a simple circuit and the VS SERENA) had an appropriate trigger. However, these ventilators were either moderately sensitive (the iSLEEP 22 and the VS SERENA) or very sensitive (the KNIGHTSTAR 330 and the VS INTEGRA with a simple circuit) to leaks. Eight ventilators had an acceptable trigger with this patient profile (the GK 425ST, the HARMONY 2, the LEGENDAIR, the NEFTIS 2, the SYNCHRONY, the SYNCHRONY 2, the VPAP 3STA, and the VS ULTRA with a simple circuit or a double circuit with a pressure trigger). Only 4 ventilators had an inappropriate trigger (the ELYSEE 150, the SMARTAIR, the VIVO 40, and the VPAP 3STA). Four ventilators were relatively insensitive to leaks (the GK 425ST, the HARMONY 2, the SYNCHRONY, and the SYNCHRONY 2), 3 were moderately sensitive to leaks (the iSLEEP 22, the VPAP 3STA, and the VS SERENA), the 5 others being very sensitive to leaks. None of the 6 ventilators that had a compatible mode had an appropriate trigger for the patient with central apnea. Three ventilators had an acceptable trigger (the LEGENDAIR, the SMARTAIR with a simple circuit, and the VS ULTRA), but none of these ventilators coped adequately with leaks. The ELYSEE 150, the NEFTIS 2, and the VS INTEGRA had inappropriate triggers.

The quality of the expiratory triggers is represented online in Table 7. The major observation is that the performance of the expiratory triggers varies according to the ventilator but also the patient profile. Only the KNIGHTSTAR 330 and the LEGENDAIR were able to detect the expiratory effort of patient 4, who was the infant

with laryngomalacia. The expiratory trigger of the ELYSEE was good in patient 2 (Duchenne muscular dystrophy) but much less in patient 3 (cystic fibrosis) and patient 5 (vocal cord paralysis).

Concerning the performance of the ventilators, for patient 1 with spinal muscular atrophy, only the ELYSEE 150 in the ACV mode with a simple circuit had an appropriate performance. The performance of the NEFTIS 2 and the VS ULTRA with a double circuit and a flow trigger were acceptable. Four ventilators had an inappropriate performance (the EOLE 3, the LEGENDAIR, the SMARTAIR, and the VS INTEGRA). The ELYSEE 150, the LEGENDAIR in the ACV mode, and the VS ULTRA in the PSV mode with a simple circuit or a double circuit with a flow trigger had an appropriate performance. The performance of the VS ULTRA in the ACV mode with a double circuit and a flow trigger was acceptable, whereas the performance of the NEFTIS 2, the SMARTAIR and the VS INTEGRA was inappropriate. For the patient with cystic fibrosis, only 3 ventilators had an appropriate performance (the EOLE 3, the NEFTIS 2, and the VS ULTRA with the 2 modes with a simple circuit or a double circuit with a flow trigger). The KNIGHTSTAR 330 was the only ventilator having an acceptable performance in the infant with laryngomalacia. For the patient with vocal cord paralysis, 2 ventilators had a acceptable performance (the VPAP 3STA and the VS ULTRA with a simple circuit or with a double circuit and a pressure trigger), all the other devices having a compatible mode had inappropriate performances. For the patient with central apnea, the ELYSEE 150 with a double circuit and the VS ULTRA with a double circuit and a flow trigger had appropriate performances, whereas the 4 other ventilators that had a compatible mode had inappropriate performances.

Discussion

The current study is the first to provide a strictly protocolised bench test evaluation of the performance of a broad range of home ventilators, all not primarily developed for children, for 6 different paediatric patient profiles. The major findings of the study can be summarised as follows: 1) no ventilator is perfect and able to adequately ventilate the 6 different patient profiles, 2) the performance of the ventilators was very heterogeneous and depended on the type trigger and circuit, and most importantly, on the characteristics of the patient, 3) the sensitivity of the inspiratory triggers of most of the ventilators was insufficient for infants.

Paediatric specificities

The present study confirms the limitations of the currently available ventilators for home ventilation in children. Numerous ventilators were not able to adequately respond to the patient's demands. Several paediatric specificities may explain these difficulties. First, the patient's inspiratory effort may be too low, or lower than those of adults, which reduces the ability of the ventilator to detect the onset of the inspiration. For the 6 patient profiles, $P_{0.1}$ in the lung model ranged between 0.4 cm H₂O and 4.3 cm H₂O. These values are in agreement with the values reported in the literature for adults [13]. A recent study observed that the inspiratory effort, evaluated by $P_{0.1}$, was higher in children with neuromuscular disease than in healthy controls [14]. However, when we compared for each patient his $P_{0.1}$ value with the number of ventilators detecting the patient's inspiratory effort, we observed that the patients who had the lowest $P_{0.1}$ were also those in whom the majority of the ventilators were not able to

detect the patient's inspiratory effort. Indeed, only 39% of the ventilators were able to detect the inspiratory effort of patient 1 (Online Table 1), who has a $P_{0.1}$ of 0.94 cm H₂O and only 9% of the ventilators were able to detect the inspiratory effort of patient 4 (Online Table 4), who has a $P_{0.1}$ of 0.4 cm H₂O. This suggests that the inspiratory effort generated by the youngest children may be too small to be detected by the majority of the ventilators. Moreover these two patients had also the smallest $V_{0.1}$ and $V'_{0.1}$ during spontaneous breathing (with a $V_{0.1}$ of 5.8 ml and 1.3 ml, and a $V'_{0.1}$ of 17ml/s and 17 ml/s, for patient 1 and 4, respectively). This implies that a ventilator with a trigger based upon a flow signal should be able to detect a flow and/or a volume inferior to these values in order to generate an adequate ΔT . In practice, the use of a high back up rate, i.e. equivalent or 2 or 3 breaths below the patient's spontaneous breathing rate, may overcome problems associated with an inadequate inspiratory trigger. Such a setting is recommended for patients with neuromuscular disease [15].

The patient with central apnea should theoretically be ventilated with a controlled mode. But, these patients may have some spontaneous breaths. Thus, in order to increase the comfort of NPPV and favour the synchronisation of the patient with the ventilator, a spontaneous mode with a back up rate slightly below the spontaneous breathing rate of the patient may be used, allowing the evaluation of the inspiratory trigger in this patient.

These limitations of the ventilators observed in the present study with simulated paediatric patterns were not completely unexpected since few devices have been specifically developed for children. Also, the majority of the manufacturers (12 out of 17) do not implicitly recommend to ventilate the youngest children with their ventilator ("adult + child", "not for newborn", "> 30 kg"). The quality of the

inspiratory triggers may also limit the performance of ventilators. Nevertheless due to the lack of information disclosed by the manufacturers concerning the principle and the algorithms used for the inspiratory trigger, it is difficult to understand why a ventilator seems to have a better trigger than another. With a classical pressure trigger a closed system is mandatory in order to facilitate the generation of a differential pressure. For example in the case of the “EOLE 3 pressure trigger” we did not observe a large decrease of the P_{aw} during the patient’s inspiratory effort while a inspiratory flow signal is detected. This confirms an open system which is one explanation of the lack of detection of the inspiratory effort observed with this ventilator. With a trigger based upon flow signal the system should be open. One of the major problems of such a trigger is the take up of the leak. Nevertheless our results do not suggest that a simple circuit + leak allowed a better or a worse inspiratory trigger than a ventilation without leak (with a simple or double circuit). In case of a flow trigger, the ventilator should be able to detect very low flows especially in young children who have the smallest V_T . Significant differences with regard to the expiratory triggers were also observed. These results are in agreement with our clinical results which showed that the sensitivity of the expiratory triggers may be insufficient for infants requiring NPPV for severe upper airway obstruction [6].

Characteristics of the ventilators

Ventilators become more sophisticated and tend to integrate continuously new options and measures. A large number of ventilators are able to deliver different ventilatory modes, such as PSV, with or without PEEP, as well as ACV. Different circuits (simple, double or leak circuit) and triggers (pressure or flow triggers) may be

available on the same ventilator. The present study clearly shows that the performance of a ventilator may vary according to the ventilatory mode or the type of trigger and circuit. Indeed, the quality of the inspiratory trigger varied among the different ventilators and also for a specific ventilator, according to the patient profile. As example, the ΔT of the NEFTIS was shorter with patient 6 (0.15 s) who had a high inspiratory effort than with patient 1 who had a low inspiratory effort (0.28 s) (Online Tables 1 and 6). It is important that the clinician who will choose the device is aware of these differences; which are rarely specified by the manufacturer.

Some ventilators, such as the LEGENDAIR, had a low pressurisation slope and stability index, which signifies that the ventilator is not able to reach the preset pressure within a minimal time frame. Most ventilators “measure” physiological variables such as V_T or P_{aw} . Significant differences were observed for almost all the ventilators between the results shown on the ventilator and the values measures on the bench. This may be explained by the fact that most of these variables are estimated by a software incorporated inside the ventilator. Because NPPV is a “leak” ventilation, the V_{TV} represents the volume of air generated by the device. On the bench, the V_{Tm} was measured by a pneumotachograph inserted between the circuit and the interface. This measure was thus closer to the patient and reflects thus more accurately the V_T received by the patient in case of a calibrated leak ventilation. But differences between the V_T set on the ventilator, the V_T measured by the ventilator and by a pneumotachograph have also been observed previously with other ventilatory modes [16]. Of note, less discrepancy was observed for P_{aw} .

The ability of a ventilator to compensate for additional leaks is important in case of NPPV. The effect of an additional leak in the inspiratory circuit was thus tested for every ventilator. Most of the ventilators were not able to cope with

additional leaks, which resulted in autotriggering or the inability to detect the patient's inspiratory effort.

Advantages and limitations of the study

We compared the responses of several devices to identical mechanical properties of the respiratory system and patterns of inspiratory flow contour, which was not possible in a clinical study given the variability of these respiratory parameters. In addition, given the number of ventilator available to test, one could not reasonably ask to children to perform this study.

One limitation of the bench is that the resistance added by the test system may be more representative of upper airway obstruction, as encountered in the patients with laryngomalacia and vocal cord paralysis, than small airway disease, such as encountered in the patient with cystic fibrosis.

One other limitation of our study was that our 6 patients were recorded during wakefulness and not during sleep. Sleep may be associated with both upper airway and inspiratory effort instability. Thus, the mechanical output during spontaneous respiratory drive, i.e. the inspiratory flow or airway depression that the ventilator has to detect in order to synchronise the ventilator assistance to the patient inspiratory effort, may be less easy to detect during sleep. We refrained recording the patients during sleep, although NPPV is generally performed during sleep, considering that NPPV is initially started and adapted during wakefulness, before being tested during sleep. In addition, we used “typical” patient profiles but in clinical practice, the addition of several factors favouring nocturnal hypoventilation is a common situation, such as the association of obesity and upper airway obstruction in patients with

Duchenne muscular dystrophy. We were not able to integrate such mixed pathologies in the present bench model. Neither were we able to include dynamic modifications like upper airway obstruction and decrease of respiratory drive during sleep as well as. If we are confident that the ventilators which were not able to detect the simulated respiratory efforts would not be able to detect the respiratory efforts in real life condition, we cannot ascertain that the ventilators considered as appropriate by our bench study were effectively appropriate in real life condition. Therefore, our study only allows to “preselect” ventilator devices which can be reasonably tested in a paediatric patient, and cannot exclude a clinical evaluation before considering that a ventilator is really appropriate for a child.

Nevertheless, systematic comparison of bench data with *in vivo* data is lacking. However, for most of the typical situations, the *in vitro* results are in agreement with the *in vivo* patient tracings. Indeed, the lack of detection of the patient’s inspiratory and expiratory effort by the majority of the bilevel devices in infants and young children has been previously observed by our group [6]. The insufficient sensitivity of the inspiratory trigger of the EOLE 3XLS has also been observed in young patients with cystic fibrosis [7]. Moreover, the majority of the problems encountered during the bench testing with the different ventilators have been observed on patients [6].

Practical recommendations

Our results underline the necessity of a systematic bench evaluation of all ventilators proposed for NPPV in children. This evaluation should ideally include the assessment of the quality of the inspiratory (pressure and/or flow) trigger, the ability

of the ventilator to reach and maintain the preset volume or pressure, as well as the coping with leaks. However, for some patients, such as patients with neuromuscular disease or central apnea, effort independent modes are recommended, precluding the evaluation of the inspiratory trigger. This bench evaluation should be followed by a clinical evaluation in the patients for whom the ventilator has shown good or acceptable performances, as defined by specific criteria (for example as those proposed in the present work).

The choice of a ventilator for a specific patient depends on the patient's characteristics (underlying disease, age and weight), the ventilatory mode that will be used, and the performance of the ventilator. Other ventilator characteristics, not evaluated in the present work, such as the accuracy of the alarms, the possibility of humidification or additional oxygen therapy, have also to be taken in account. Finally, the ergonomics, such as transportability and internal battery are important in clinical use. But ultimate efficacy must be checked in each individual case by daytime performance and comfort, associated with overnight control.

Conclusion

This bench study, which evaluated for the first time 17 home ventilators with the 6 most common paediatric profiles, shows that the performance of the ventilators varied not only according to ventilator characteristics (type of circuit and type of trigger) but most importantly also according to the patient profile, including his age and weight as well as his underlying disease. Even if different modes and different ventilators may be used in a specific patient, we recommend a systematic bench

evaluation, coupled to a clinical *in vivo* evaluation for all the ventilators proposed for home NPPV in children.

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Table 1: Patient profiles and ventilatory modes used for the bench lung model study.

Patient*	Pathology	Age (year)	Weight (kg)	V _T (ml)	T _{insp} (s)	CL _{dyn} (L/cm H ₂ O)	R(cmH ₂ O/L.s) /Rp	P _{0.1} (cm H ₂ O)	V _{0.1} (ml)	V' _{0.1} (ml/s)	Tested ventilatory mode
1	spinal muscular amyotrophy	4	13	150	1.3	0.038	52/50	0.94	5.8	71	PSV10 ZEEP ACV250 ZEEP
2	Duchenne muscular dystrophy	19	70	293	0.9	0.024	17/20	2.8	9.5	142	PSV16 ZEEP ACV500 ZEEP
3	cystic fibrosis	14	27	188	1.1	0.019	57/50	2.5	11.0	135	PSV16 ZEEP ACV500 ZEEP
4	laryngomalacia	0.25	4	18	1.0	0.024	200#	0.4	1.3	17	PSV14 PEEP8
5	vocal cord paralysis	4	12	250	1.3	0.064	6/5	1.4	14.7	180	PSV14 PEEP8
6	central apnea	13	42	296	1.1	0.153	7/5	4.3	19.7	273	PSV12 ZEEP

Abbreviations: V_T: tidal volume, T_{insp}: inspiratory time, CL_{dyn}: dynamic lung compliance, Rp: resistance of the respiratory system, # the measure of the Rp was not possible in this patient, PSV: pressure support ventilation, ZEEP: zero positive end-expiratory pressure, PEEP: positive end-expiratory pressure, ACV: assist control ventilation, P_{0.1}: inspiratory airway occlusion pressure at 0.1 sec after the initiation of spontaneous breath, V_{0.1}: inspired volume at 0.1 sec after initiation of spontaneous breath, V'_{0.1}: flow at 0.1 sec after initiation of spontaneous breath. P_{0.1}, V_{0.1} and V'_{0.1} are measured on the bench test.

* The respiratory mechanics were measured during wakefulness.

Table 2: Ventilators tested

Ventilator	Manufacturer	Modes	Circuit	Trigger	ZEEP	CPAP	Humidifier	Remarks
ELYSEE150	ResMed SA, Saint Priest, France	P / V	S / D	nc tt	yes	no	no	adult + child
EOLE3	ResMed SA, Saint Priest, France	V	S / D	flow or pressure	yes	no	no	not for newborns
GK425ST	Tyco Healthcare, Elancourt, France	P	S + leak	nc tt	no	yes	yes	> 30 kg
HARMONY2	Respironics France, Carquefou, France	P	S + leak	nc tt	no	yes	yes	
iSLEEP22	ResMed SA, Saint Priest, France	B	S + leak	nc tt	no	yes	yes	
KNIGHSTAR330	Tyco Healthcare, Elancourt, France	B	S + leak	nc tt	no	yes	no	> 30 kg
LEGENDAIR	Airox, Pau, France	P / V	S	nc tt	yes	no	no	adult + child
NEFTIS2	TAEMA, Anthony, France	P / V	S	nc tt	yes	no	no	invasive + NPPV adult + child
SMARTAIR+	Airox, Pau, France	P	S / S + leak	nc tt	yes	no	no	invasive + NPPV
SYNCHRONY	Respironics France, Carquefou, France	P	S + leak	nc tt	no	yes	no	
SYNCHRONY2	Respironics France, Carquefou, France	P	S + leak	nc tt	no	yes	yes	> 30 kg
VIVO40	Breas Medical, Saint Priest, France	P	S + leak	nc tt	no	yes	yes	adult + child
VPAP3ST	ResMed SA, Saint Priest, France	P	S + leak	nc tt	no	yes	yes	
VPAP3STA	ResMed SA, Saint Priest, France	P	S + leak	nc tt	no	yes	yes	
VS INTEGRA	ResMed SA, Saint Priest, France	P	S / S + leak	nc tt	no:S+leak yes:S	no	no	adult + child
VS SERENA	ResMed SA, Saint Priest, France	P	S + leak	nc tt	no	no	no	adult + child
VS ULTRA	ResMed SA, Saint Priest, France	P / V	S / D / S + leak	flow or pressure	no:S+leak yes:S D	no	no	adult + child

Abbreviations: ZEEP: zero end-expiratory pressure, CPAP: continuous positive airway pressure, P: pressure targeted mode, V: volume targeted mode, B: bilevel positive pressure ventilation, S: simple circuit with expiratory valve, D: double circuit, S +leak; simple circuit with leak, nctt: no choice of trigger type, NPPV: noninvasive positive pressure ventilation.

Table 3: Trigger performances of the ventilators according to the 6 patient profiles.

	spinal muscular amyotrophy (PSV + ACV)	Duchenne muscular dystrophy (PSV + ACV)	cystic fibrosis (PSV + ACV)	laryngomalacia (PSV + PEEP)	vocal cord paralysis (PSV + PEEP)	central apnea (PSV + ZEEP)
ELYSEE 150	inappropriate	inappropriate	inappropriate	inappropriate	inappropriate	inappropriate
EOLE 3	inappropriate	acceptable ACV-a (3)	appropriate ACV-a (3)	no compatible mode	no compatible mode	no compatible mode
GK 425ST	no compatible mode	no compatible mode	no compatible mode	inappropriate	acceptable (1)	no compatible mode
HARMONY2	no compatible mode	no compatible mode	no compatible mode	inappropriate	acceptable (1)	no compatible mode
iSLEEP 22	no compatible mode	no compatible mode	no compatible mode	inappropriate	appropriate (2)	no compatible mode
KNIGHTSTAR 330	no compatible mode	no compatible mode	no compatible mode	inappropriate	appropriate (3)	no compatible mode
LEGENDAIR	inappropriate	acceptable ACV (2)	appropriate PSV (1) ACV (3)	inappropriate	acceptable (3)	acceptable (3)
NEFTIS 2	inappropriate	inappropriate	inappropriate	inappropriate	acceptable (3)	inappropriate
SMARTAIR	inappropriate	inappropriate	appropriate b (1)	inappropriate	inappropriate	acceptable b (3)
SYNCHRONY	no compatible mode	no compatible mode	no compatible mode	inappropriate	acceptable (1)	no compatible mode
SYNCHRONY 2	no compatible mode	no compatible mode	no compatible mode	inappropriate	acceptable (1)	no compatible mode
VIVO40	no compatible mode	no compatible mode	no compatible mode	inappropriate	inappropriate	no compatible mode
VPAP 3ST	no compatible mode	no compatible mode	no compatible mode	inappropriate	inappropriate	no compatible mode
VPAP 3STA	no compatible mode	no compatible mode	no compatible mode	inappropriate	acceptable (2)	no compatible mode
VS INTEGRA	inappropriate	inappropriate	inappropriate	inappropriate	appropriate b (3)	inappropriate
VS SERENA	no compatible mode	no compatible mode	no compatible mode	inappropriate	appropriate (2)	no compatible mode
VS ULTRA	inappropriate	inappropriate	acceptable PSV-b ACV-c (3) appropriate PSV-c ACV-b (3)	inappropriate	acceptable b-c (3)	acceptable c (2)

Abbreviations: PSV: pressure support ventilation ACV: assist control ventilation, PEEP : positive end-expiratory pressure, ZEEP : zero end-expiratory pressure.

appropriate: $\Delta T \leq 100$ ms and $\Delta P \leq -1$ cmH₂O

acceptable: $\Delta T \leq 150$ ms and $\Delta P \leq -1.5$ cmH₂O or if $\Delta T \geq 100$ ms or $\Delta P \leq -1$ cmH₂O

inappropriate: the ventilator does not detect the inspiratory effort or in case of autotriggering

- (1) relatively insensitive to a leak: no triggering or auto-triggering for a leak ≥ 40 l/mn
 - (2) moderately sensitive to a leak: no triggering or auto-triggering for a leak >10 and < 40 l/mn
 - (3) very sensitive to a leak: no triggering or auto-triggering for a leak ≤ 10 l/mn
- a flow trigger
 - b simple circuit
 - c double circuit pressure trigger

Table 4: Performance of the ventilators according to the 6 patient profiles.

	spinal muscular amyotrophy (PSV + ACV)	Duchenne muscular dystrophy (PSV + ACV)	cystic fibrosis (PSV + ACV)	laryngomalacia (PSV + PEEP)	vocal cord paralysis (PSV + PEEP)	central apnea (PSV + ZEEP)
ELYSEE 150	appropriate ACV-b	appropriate	acceptable ACV-f	inappropriate	inappropriate	appropriate f
EOLE 3	inappropriate	inappropriate	appropriate ACV-a (1)	no compatible mode	no compatible mode	no compatible mode
GK 425ST	no compatible mode	no compatible mode	no compatible mode	inappropriate	inappropriate	no compatible mode
HARMONY2	no compatible mode	no compatible mode	no compatible mode	inappropriate	inappropriate	no compatible mode
iSLEEP22	no compatible mode	no compatible mode	no compatible mode	inappropriate	inappropriate	no compatible mode
KNIGHTSTAR 330	no compatible mode	no compatible mode	no compatible mode	acceptable	inappropriate	no compatible mode
LEGENDAIR	inappropriate	appropriate ACV	inappropriate	inappropriate	inappropriate	inappropriate
NEFTIS 2	acceptable	inappropriate	appropriate	inappropriate	inappropriate	inappropriate
SMARTAIR	inappropriate	inappropriate	inappropriate	inappropriate	inappropriate	inappropriate
SYNCHRONY	no compatible mode	no compatible mode	no compatible mode	inappropriate	inappropriate	no compatible mode
SYNCHRONY 2	no compatible mode	no compatible mode	no compatible mode	inappropriate	inappropriate	no compatible mode
VIVO 40	no compatible mode	no compatible mode	no compatible mode	inappropriate	inappropriate	no compatible mode
VPAP 3ST	no compatible mode	no compatible mode	no compatible mode	inappropriate	inappropriate	no compatible mode
VPAP 3STA	no compatible mode	no compatible mode	no compatible mode	inappropriate	acceptable	no compatible mode
VS INTEGRA	inappropriate	inappropriate	inappropriate	inappropriate	inappropriate	inappropriate
VS SERENA	no compatible mode	no compatible mode	no compatible mode	inappropriate	inappropriate	no compatible mode
VS ULTRA	acceptable d *	appropriate PSV-b-d* acceptable ACV-d*	appropriate PSV ACV-b-c acceptable ACV-d*	inappropriate	acceptable b-c	appropriate c

Abbreviations: PSV: pressure support ventilation ACV: assist control ventilation, PEEP : positive end-expiratory pressure, ZEEP : zero end-expiratory pressure.

appropriate: for ACV, measured tidal volume (V_{Tm}) < required $V_T \pm 10\%$, and for PSV, measured PS (PSm) < required PS $\pm 10\%$, and pressurisation slope ≥ 60 cm H₂O/s

acceptable: for ACV, V_{Tm} < required $V_T \pm 15\%$, and for PSV: PSm < required PS $\pm 15\%$, and pressurisation slope ≥ 40 cm H₂O/s

inappropriate: does not detect the inspiratory effort or autotriggering or, for ACV: $V_{Tm} \geq V_T \pm 15\%$, or for PSV, $PSm \geq$ required PS $\pm 15\%$, and pressurisation slope < 40 cm H₂O

b simple circuit

c double circuit pressure trigger

d double circuit flow trigger

f double circuit

* ZEEP = 1.4 cm H₂O

Legend on figure 1

Lung bench model used for the study.

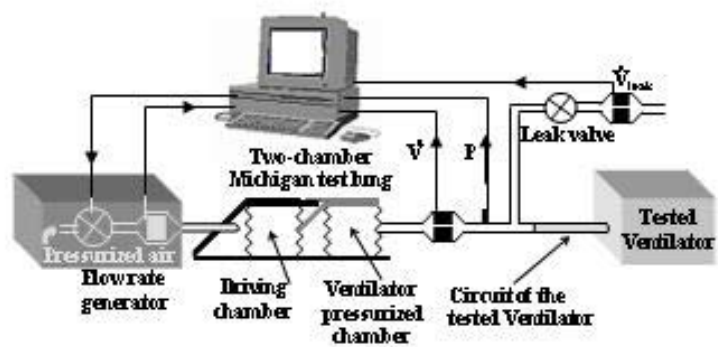


Figure 1

