An overnight comparison of two ventilators used in the treatment of chronic respiratory failure

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ABSTRACT: Differences between bilevel ventilators used for noninvasive intermittent positive pressure ventilation (NIPPV) have been demonstrated during bench testing. However, there are no clinical studies comparing these machines. The authors have previously shown that the Quantum pressure support ventilator and Sullivan variable positive airway pressure II ST differ in performance during bench testing. To examine the clinical significance of this, these two machines were compared in the overnight treatment of subjects with chronic respiratory failure.

Ten clinically-stable subjects with thoracic scoliosis were recruited. The subjects were already established on NIPPV, but none were using either of the ventilators to be tested. After familiarisation, the patients used the two ventilators in random order on consecutive nights. Peripheral oxygen saturation and transcutaneous carbon dioxide tension ($P_t\text{CO}_2$) were measured continuously, and sleep was recorded using polysomnography.

There were no significant differences in arterial oxygen saturation, $P_t\text{CO}_2$ or sleep duration and quality between the two nights.

Despite previously illustrated variation in laboratory performance, no differences were seen between the two ventilators when comparing overnight gas exchange and sleep *in vivo*. Further study is required to evaluate the significance of the differences found during bench testing in the clinical setting.

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Noninvasive positive pressure ventilation (NIPPV) is well established in the treatment of chronic respiratory failure. Regular nocturnal treatment improves overnight oxygen saturation and daytime arterial blood gases in obstructive and restrictive pulmonary disorders [1, 2]. There are beneficial effects on sleep duration and efficiency and improvements in quality of life [3, 4]. The outlook is particularly favourable in patients with chest wall or nonprogressive neuromuscular diseases, with almost 80% of these patients continuing to benefit from treatment after 5 yrs [5].

Despite the success of treatment, the optimal mode of ventilation is not known. Pressure preset ventilation is increasingly popular, but its superiority over volume preset ventilation is unproven. There are no differences between these two modes when comparing the improvements seen in gas exchange in patients with chronic [6, 7] or acute [8] respiratory failure. It has been argued that pressure preset ventilation has the advantage of leak compensation [9, 10], and some patients who fail on a volume preset device may benefit from changing the ventilator [11]. However, in a study of patients well treated on a volume preset ventilator, a proportion deteriorated when tried on pressure preset ventilation [12].

There are no clinical studies comparing pressure

preset ventilators, although laboratory comparisons of such devices have shown differences between the machines tested [13, 14]. The authors have previously shown that the Quantum pressure support ventilator (PSV) (Healthdyne/Respironics Inc., Murrysville, PA, USA) and Sullivan variable positive airway pressure (VPAP) II ST (Resmed Ltd, North Ryde, Australia) differ in performance during bench testing [15]. To examine the clinical significance of this these two machines were compared in the overnight treatment of stable subjects with chronic respiratory failure due to thoracic scoliosis.

Methods

Subjects were recruited from the population of patients attending the authors' unit with respiratory failure due to thoracic scoliosis. Those already established on home nocturnal NIPPV for ≥ 6 months were eligible. Subjects were excluded if they required supplemental oxygen, were already using either of the two ventilators to be studied or had any change of symptoms or drug therapy in the 4 weeks prior to the study. All subjects gave informed consent.

Two ventilators, Quantum PSV (Healthdyne/Respironics Inc.) and Sullivan VPAP II ST (Resmed

Ltd), were compared. They were used in the spontaneous/timed mode with the minimum expiratory pressure. During a period of familiarisation, the subjects selected all the other settings for each machine. A preference for peak inspiratory positive airway pressure (IPAP), risetime and respiratory rate were noted independently according to comfort. The subjects used their own mask and the same circuit incorporating a whisper swivel II expiratory valve (Respironics Inc.) with each ventilator.

On the first day of attendance, the inclusion and exclusion criteria were reviewed and baseline measurements were recorded. Spirometry was performed using a rolling seal spirometer (Vitalograph Ltd, Buckingham, UK) and total lung capacity (TLC) was estimated using body plethysmography (Masterlab, Jaeger, Germany). Gas transfer could not be measured due to low intrathoracic gas volumes. A penetrated posteroanterior chest radiograph was performed so that the Cobb angle could be calculated. Arterial blood gas (ABG) tensions were measured at rest, breathing room air.

Overnight studies were then performed on consecutive nights, using each of the two ventilators in random order. A period of familiarisation during the day preceded the night-time study. Peripheral oxygen saturation (Sp,O_2) using a finger probe (Datex Ohmeda, Helsinki, Finland) and transcutaneous carbon dioxide tensions (Pt,CO_2) using a heated skin electrode (TINA, Radiometer, Copenhagen, Denmark) were monitored during familiarisation to ensure that the ventilator settings were optimal.

During each night of the study a number of measurements were made. Standard electroencephalogram, electro-oculogram and submental electro-myogram were recorded onto a data-logging system (Alice 3, Healthdyne/Respironics Inc.). The recordings were used to stage sleep by two experienced polysomnographers who were blinded as to which ventilator was used on which night. Sp,O_2 and Pt,CO_2 were recorded continuously onto a second data-logging system (CARDAS, Oxcams Medical Sciences Ltd, Oxford, UK). The Pt,CO_2 signal was calibrated against an ABG specimen on each night.

Statistics

Data are presented as mean $\pm$ SD. Paired t-tests were used to compare parameters and a p-value of <0.05 was considered significant.

Results

Ten subjects (three females) were recruited. One had an idiopathic adolescent scoliosis, but all the others had a congenital scoliosis. The spinal deformity was severe with a Cobb angle 101 ± 20.4 degrees, forced expiratory volume in one second 0.7 ± 0.3 L (24% predicted), forced vital capacity 1.1 ± 0.3 L (27% pred), TLC 2.5 ± 0.56 L (39% pred). Subjects were well established on mask ventilation (mean 54.7, range 11–120 months) and ABG tensions confirmed that

they were adequately treated; oxygen tension in arterial blood 10.4 ± 0.8 kPa, carbon dioxide tension in arterial blood 6.0 ± 0.4 kPa.

The settings on the two test ventilators were compared. There was no difference in: the preset IPAP (Quantum 21.0 ± 3.5 cmH₂O and VPAP 20.8 ± 3.6 cmH₂O, $p=0.69$); the preset risetime (Quantum 0.5 ± 0.4 s and VPAP 0.3 ± 0.0 s, $p=0.14$); and the preset respiratory rate (Quantum 15.4 ± 1.2 breaths per minute (bpm) and VPAP 15.0 ± 1.5 bpm). Three subjects volunteered an overall preference for the Quantum and five favoured the VPAP.

Sleep data

For three of the nights, from two subjects (nos. 7 and 10), it was not possible to score sleep due to the poor quality of the record. From the complete data (eight subjects), no differences were seen between the nights with each ventilator for total sleep time, sleep latency, sleep efficiency (total sleep time/time from first sleep page to last sleep page) or arousals (table 1). Similarly, there were no significant differences in the durations of light (stage 1 and 2) and deep (stage 3 and 4) nonrapid eye movement or rapid eye movement sleep (fig. 1). A number of subjects commented that they found it more difficult to sleep than normal due to the monitoring equipment used.

Table 1. – Comparative sleep data

	Quantum	VPAP	p-value
Total sleep time min	303.2 $\pm$ 79.4	314.4 $\pm$ 54.2	0.72
Sleep latency min	20.1 $\pm$ 14.4	21.8 $\pm$ 13.5	0.21
Sleep efficiency %	73.1 $\pm$ 17.4	79.8 $\pm$ 10.1	0.23
Arousal index h ⁻¹	7.7 $\pm$ 4.7	8.0 $\pm$ 5.3	0.85

Data are presented as mean $\pm$ SD. VPAP: variable positive airway pressure II ST; Quantum: Quantum pressure support ventilator. Manufacturer's details are as follows: Quantum (Healthdyne/Respironics Inc., Murrysville, PA, USA), VPAP (Resmed Ltd, North Ryde, Australia).

Fig. 1. – Duration of sleep (total, light, deep and nonrapid eye movement (REM)) in subjects using the Quantum pressure support ventilator (□) and the Sullivan variable positive airway pressure II ST (▨). #: $p=0.72$; *: $p=0.6$; +: $p=0.38$; §: $p=0.73$.

Table 2. – Comparative oximetry and transcutaneous carbon dioxide tension ($P_t\text{CO}_2$) data

	Quantum	VPAP	p-value
Mean Sp_tO_2 %	92.5±2.6	92.8±2.1	0.46
Minimum Sp_tO_2 %	81.5±15.3	87.5±1.9	0.24
$\text{Sp}_t\text{O}_2 < 90\%$ min	69.4±122.1	56.0±103.8	0.33
$\text{Sp}_t\text{O}_2 < 90\%$ no.	23.9±31.3	22.3±26.2	0.89
4% desaturations no.	8.8±5.0	9.8±6.6	0.42
Mean $P_t\text{CO}_2$ kPa	7.3±1.3	7.1±1.2	0.52

Data are presented as mean±SD. VPAP: variable positive airway pressure II ST; Quantum: Quantum pressure support ventilator; Sp_tO_2 : peripheral oxygen saturation; $P_t\text{CO}_2$: transcutaneous carbon dioxide tension. Manufacturer's details are as follows: Quantum (Healthdyne/Respironics Inc., Murraysville, PA, USA), VPAP (Resmed Ltd, North Ryde, Australia).

Oximetry and transcutaneous carbon dioxide tension

For five nights, from three subjects (nos. 4, 5 and 7), the $P_t\text{CO}_2$ record could not be used because of the poor quality of the signal. Comparing the complete data, there were no significant differences in $P_t\text{CO}_2$ (seven subjects) or Sp_tO_2 (10 subjects) between the two nights (table 2).

Discussion

The authors have previously shown that the Quantum and VPAP differ in performance during bench tests in a number of respects [15]. Both ventilators compensate well when a leak is introduced into the circuit, with any fall in the resulting tidal volumes (V_T) being <10%. Inspiratory time with the VPAP, however, is prolonged by the presence of a leak. This leads to an increase in the V_T , but theoretically could lead to incoordination and difficulty with expiration at rapid respiratory rates. The trigger for the VPAP is more sensitive than that of the Quantum, and thus, less patient work is expended in triggering the ventilator. In addition, there were unexpected effects on V_T when the ventilators were triggered by simulated patient effort. V_T with the Quantum fell due to premature expiratory cycling. In contrast, simulated patient effort was "rewarded" by the VPAP with an increase in the resulting V_T during some tests.

Therefore, there are a number of differences between the machines that could particularly influence the interaction between the patient and the ventilator. Despite the differences seen during bench testing, there were no differences in the overnight treatment of stable patients with chronic respiratory failure due to thoracic scoliosis.

This may be because there is a real difference between the two machines that was not detected due to insufficient patient numbers. The total number of subjects included in the present study was small. However, the results are closely matched and there is no suggestion of a trend toward one or other of the ventilators from the data. If a large number of subjects are required to demonstrate a statistically significant

difference, then the clinical significance is likely to be small.

The relevance of bench tests to the clinical situation is uncertain. Bench testing is sensitive to small differences between devices. All published studies have shown statistically significant results [9, 13–15], while several clinical studies comparing machines and modes of ventilation have shown no differences in outcome [6–8, 16, 17]. The differences measured on bench tests may not be clinically relevant or patients may be able to compensate for them. LOFASO *et al.* [13] showed differences between two ventilators in trigger sensitivity, initial flow rate and imposed work on bench tests. When the same two devices were compared in a clinical trial with intubated patients, the subjects increased their work of breathing to maintain equivalent ventilation and gas exchange when using the ventilator shown to be inferior in the bench tests. The clinical outcome may be affected if a higher work of breathing is imposed in the long-term, particularly in subjects liable to fatigue, but this has not so far been demonstrated.

Some subjects deteriorate despite regular NIPPV and subsequently improve when the ventilator is changed [11]. The precise reason for this improvement is not known, but may relate to differences in the ventilators that are apparent on bench testing [9]. It is probable that differences in devices illustrated in the laboratory have some clinical relevance, but the outcome will vary according to the precise clinical situation.

NIPPV is particularly well established in the treatment of subjects with chest wall disorders [2] and the long-term prognosis is good [5, 18]. The outcome of regular NIPPV in obstructive lung disease has improved in recent years, but remains less favourable [1, 5]. NIPPV improves outcome in acute respiratory failure [19, 20] and acute exacerbations of chronic obstructive pulmonary disease [21, 22]. However, 15–31 per cent of patients still require intubation [19–22] and mortality varies between 6–38% [19–22]. Subjects were taken from a group that respond well to treatment and were clinically stable. Small variations in ventilator performance might not be detectable over a single night of treatment. A longer period of time may be required to translate small differences in work of breathing and ventilation into worsening gas exchange and sleep disturbance. It is also probable that differences would be more apparent in patient groups that were more difficult to treat, such as those with obstructive lung disease or acute respiratory failure.

In conclusion, there is a paucity of data on which to inform decisions regarding selection of ventilators for noninvasive intermittent positive pressure ventilation. Bench tests have illustrated differences between devices [9, 13–15], but the clinical significance of these findings remains uncertain. In comparing pressure and volume preset ventilation, differences in clinical outcome may only become apparent during long-term treatment [11, 12]. There are no long-term studies comparing bilevel positive pressure ventilators. The present authors did not illustrate any difference between the two machines tested. This may have

been due to insufficient patient numbers, too short a treatment period or a patient group that was relatively easy to ventilate. This was in effect a pilot study. The ideal design for a future study would be a randomised controlled clinical trial comparing the outcome of two or more devices used during the initial treatment period in subjects presenting for the first time with respiratory failure.

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