

# Randomised trial of CPAP vs bilevel support in the treatment of obesity hypoventilation syndrome without severe nocturnal desaturation

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► Additional details of the methods and further discussion of the results are published online only at <http://thorax.bmj.com/content/vol63/issue5>

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Received 14 March 2007  
Accepted 2 December 2007  
Published Online First  
18 January 2008

## ABSTRACT

**Background:** Untreated, obesity hypoventilation is associated with significant use of health care resources and high mortality. It remains unclear whether continuous positive airway pressure (CPAP) or bilevel ventilatory support (BVS) should be used as initial management. The aim of this study was to determine if one form of positive pressure is superior to the other in improving daytime respiratory failure.

**Methods:** A prospective randomised study was performed in patients with obesity hypoventilation referred with respiratory failure. After exclusion of patients with persisting severe nocturnal hypoxaemia ( $SpO_2 < 80\%$  for  $> 10$  min) or carbon dioxide retention ( $> 10$  mm Hg) despite optimal CPAP, the remaining patients were randomly assigned to receive either CPAP or BVS over a 3-month period. The primary outcome was change in daytime carbon dioxide level. Secondary outcome measures included daytime sleepiness, quality of life, compliance with treatment and psychomotor vigilance testing.

**Results:** Thirty-six patients were randomised to either home CPAP ( $n = 18$ ) or BVS ( $n = 18$ ). The two groups did not differ significantly at baseline with regard to physiological or clinical characteristics. Following 3 months of treatment, daytime carbon dioxide levels decreased in both groups (CPAP 6 (8) mm Hg; BVS 7 (7) mm Hg) with no between-group differences. There was no difference in compliance between the two treatment groups (5.8 (2.4) h/night CPAP vs 6.1 (2.1) h/night BVS). Although both groups reported an improvement in daytime sleepiness, subjective sleep quality and psychomotor vigilance performance were better with BVS.

**Conclusions:** Both CPAP and BVS appear to be equally effective in improving daytime hypercapnia in a subgroup of patients with obesity hypoventilation syndrome without severe nocturnal hypoxaemia.

**Trial registration number:** Australian Clinical Trials Registry ACTRN01205000096651.

Obstructive sleep apnoea (OSA) is a common disorder in the general middle-aged population,<sup>1</sup> with the prevalence rising rapidly as obesity increases.<sup>2</sup> Despite significant sleep breathing abnormalities, most patients with obstructive sleep apnoea and significant obesity are able to maintain normal daytime carbon dioxide levels. However, a small proportion of patients will develop hypercapnia in the absence of lung or neuromuscular disease and be diagnosed with obesity hypoventilation syndrome. Recent work suggests that around 1 in 10 patients presenting to a sleep laboratory are

hypercapnic, with the prevalence rising as body mass index (BMI) increases.<sup>3</sup> In a population of morbidly obese patients (BMI  $> 40$  kg/m<sup>2</sup>) recruited from an obesity clinic, 23% were found to be hypercapnic.<sup>4</sup> While the exact pathophysiological mechanisms linking severe obesity with the development of daytime respiratory failure remain unclear, there is increasing evidence that timely and appropriate treatment of these patients is crucial in reducing the significant morbidity and mortality associated with this disorder.<sup>5–6</sup>

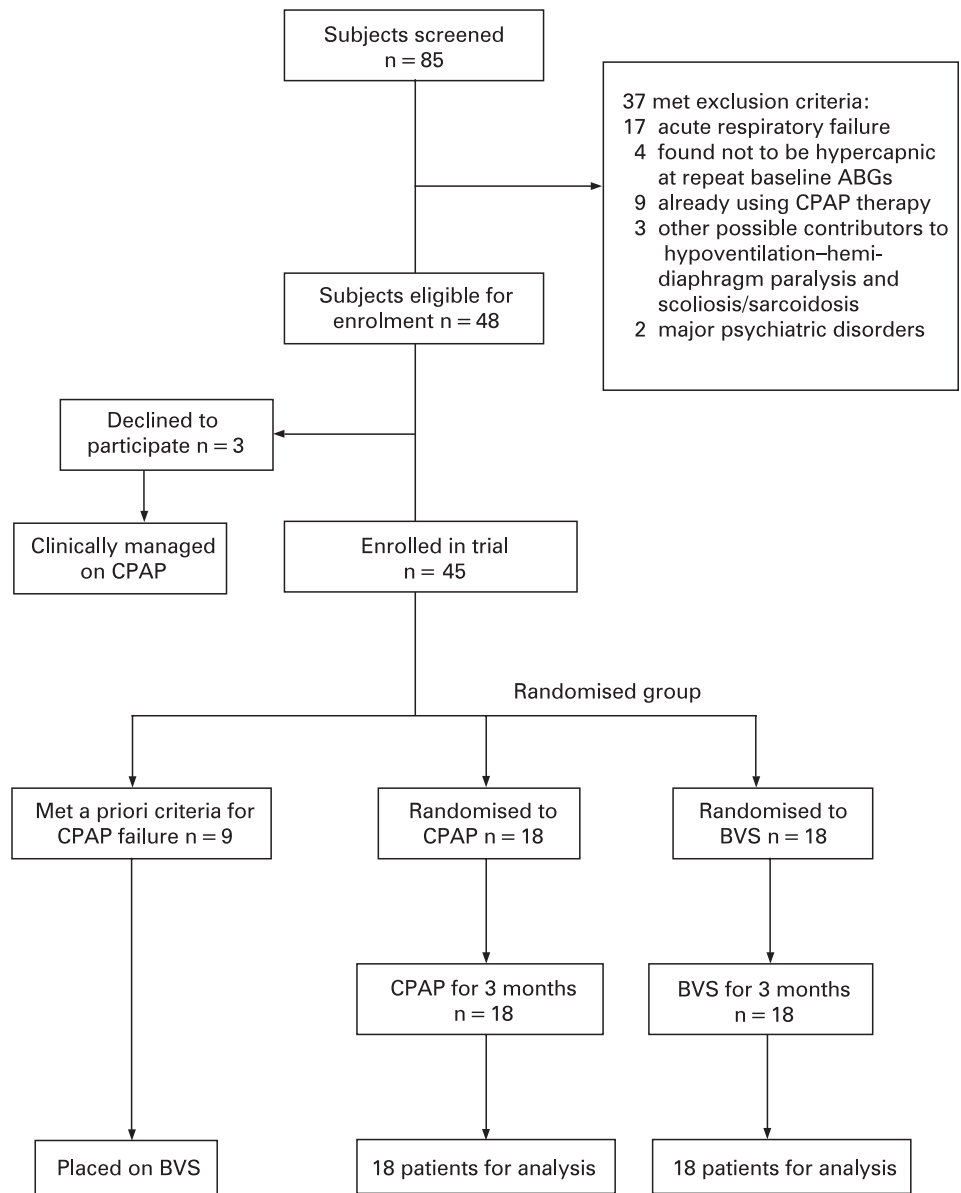
Both continuous positive airway pressure (CPAP) and bilevel ventilatory support (BVS) have been used clinically to manage patients with obesity hypoventilation syndrome.<sup>3–9</sup> Although many patients appear to respond to CPAP,<sup>10–11</sup> some do not<sup>12–13</sup> and occasionally even more severe sleep-disordered breathing can appear when obstructive events are abolished.<sup>14</sup> With recent clinical trends towards limited diagnostic monitoring and home treatment of obstructive sleep apnoea, it is possible that a significant number of patients with obesity hypoventilation syndrome may not be initially identified and consequently managed with CPAP alone. Understanding how such patients may respond to CPAP and how this compares with BVS is therefore an important clinical question. Furthermore, there has been limited investigation into changes in health-related quality of life (HRQL)<sup>11</sup> and cognitive function in this group of patients once treatment is started. The current trial was therefore undertaken to determine whether BVS is more effective than CPAP in reversing daytime respiratory failure in patients with obesity hypoventilation syndrome without persisting severe nocturnal hypoxaemia. In addition, we wished to compare compliance with treatment, HRQL and neurocognitive performance between the two treatments. Preliminary results of this study have been presented in abstract form.<sup>15</sup>

## METHODS

### Subjects

Patients with obesity and daytime hypercapnia were recruited from the Sleep Disorders Clinic and Sleep Investigation Unit at Royal Prince Alfred Hospital. Inclusion criteria included: (1) obesity with a BMI  $\geq 30$  kg/m<sup>2</sup>; (2) stable awake compensated respiratory failure with arterial carbon dioxide tension ( $PaCO_2$ )  $\geq 45$  mm Hg and pH  $\geq 7.34$ ; (3) the absence of any significant respiratory, neuromuscular or other disorder that could account for the hypercapnia; (4) ratio of forced

**Figure 1** Flow diagram outlining screening and recruitment of patients. CPAP, continuous positive airway pressure; BVS, bilevel ventilatory support; ABG, arterial blood gas.



expiratory volume in 1 s/forced vital capacity (FEV<sub>1</sub>/FVC)  $\geq 70\%$ ; (5) no major psychiatric illness that would affect the patient's ability to participate in the study; and (6) not currently being treated with positive pressure therapy. Based on clinical consensus and safety concerns, a priori criteria were set so that patients who displayed significant and prolonged desaturation or significant carbon dioxide retention during an initial CPAP trial were excluded from the study. These criteria were: (1) oxygen saturation remaining below 80% continuously ( $>10$  min) in the absence of frank apnoea; (2) an acute rise in transcutaneous carbon dioxide pressure (TcCO<sub>2</sub>) (TCM3, Radiometer, Copenhagen, Denmark) during episodes of rapid eye movement (REM) sleep  $\geq 10$  mm Hg; or (3) an increase in afternoon to morning PaCO<sub>2</sub> of  $\geq 10$  mm Hg in those patients with an awake PaCO<sub>2</sub>  $>55$  mm Hg. Figure 1 outlines patient screening and recruitment for the study.

**Study design**

Following routine baseline sleep studies, spirometry and arterial blood gas measurements, a CPAP titration was performed.

Those patients meeting the above criteria for significant and prolonged desaturation or significant carbon dioxide retention during the initial titration night at best CPAP pressures were excluded from randomisation. The remaining patients were then randomly allocated to either longer-term CPAP or BVS using opaque sealed envelopes.

Baseline evaluation performed prior to the CPAP titration night included anthropometric measurements and quality of life and sleep questionnaires, cognitive tests and psychomotor vigilance testing performed according to standard methods. Full details of these measurements and titration of positive pressure therapy are outlined in the online supplement. Patients were discharged home on positive pressure therapy for a 3-month period.

At follow-up, baseline measurements were repeated and a CPAP titration was again performed to determine the patient's current response to treatment. The results of this study, along with arterial blood gas tensions and compliance with treatment, were then used to determine the patient's longer term home treatment.

**Table 1** Baseline characteristics of study patients

	CPAP (N = 18)	BVS (N = 18)	p Value
Age (years)	52 (17)	47 (13)	0.29
Sex (M:F)	14:4	9:9	0.09
BMI (kg/m <sup>2</sup> )	52 (7)	54 (9)	0.49
Awake SpO <sub>2</sub> (%)	90 (86–92)	87 (84–93)	0.86
Baseline PaCO <sub>2</sub> (mm Hg)	52 (49–55)	49 (47–57)	0.36
Bicarbonate (mmol/l)	30 (29–33)	30 (29–32)	0.56
FEV <sub>1</sub> /FVC ratio (%)	81 (6)	81 (7)	0.72
Neck circumference (cm)	50 (4)	51 (5)	0.53
Waist:hip ratio	0.99 (0.09)	0.97 (0.13)	0.51

Data presented as mean (SD) or median (interquartile range) as appropriate.

BMI, body mass index; BVS, bilevel ventilatory support; CPAP, continuous positive airway pressure; SpO<sub>2</sub>, oxygen saturation; PaCO<sub>2</sub>, arterial carbon dioxide tension; FEV<sub>1</sub>, forced expiratory volume in 1 s; FVC, forced vital capacity.

### Analysis of data

The primary objective was to determine if there was a difference in change in daytime carbon dioxide levels between two different forms of positive pressure therapy—CPAP and BVS—after a 3-month period of treatment. The secondary objectives included compliance with treatment, changes in quality of life and neurocognitive function.

An a priori power calculation suggested that a sample size of 13 in each group would be needed to detect a difference in the mean change in arterial carbon dioxide of 7 mm Hg with a power of 80% and a p value of <0.05. Comparison between normally distributed parametric data was made using paired *t* tests for within-group analysis. The Mann-Whitney *U* test was used for non-parametric data or non-normally distributed variables as indicated. The level of significance was taken as *p*<0.05. Analyses were performed using a commercially available statistical software package (SPSS Version 14.0; SPSS, Chicago, Illinois, USA).

### RESULTS

Of the 85 subjects initially screened, 37 were excluded from the study. Reasons for exclusion are given in fig 1, with acute respiratory failure the major reason. Three further patients were invited to participate in the study but declined: two felt they would not be able to return for follow-up and one did not want to participate. This left 45 patients available for enrolment. Nine patients met the a priori criteria for outright initial CPAP failure and were treated with BVS on clinical grounds. The

remaining 36 patients underwent randomisation, with 18 being allocated to CPAP and 18 to BVS.

### Baseline anthropometric and sleep variables

Baseline characteristics of the two randomised groups did not differ, although fewer women were randomised to the CPAP group (table 1). Likewise, there were no significant differences between groups with regard to sleep architecture, oxygenation or total respiratory disturbance index (table 2).

### Initial response to CPAP

The initial response to CPAP titration is outlined in table 3. In 7 of the 18 patients randomised to CPAP the initial response to CPAP was categorised as acceptable, while in the remaining 11 patients the response was incomplete with the respiratory disturbance index remaining >10 events/h or sustained oxygen desaturation >80% and <88% on best pressure. In the group randomised to BVS, the initial response to CPAP was acceptable in 11 patients. Mean home bilevel pressures used for the BVS group were 16 (2) cm H<sub>2</sub>O inspiratory positive airway pressure and 10 (2) cm H<sub>2</sub>O expiratory positive airway pressure, with all patients using a spontaneous mode of support. A full-face mask was used for home use in 13 patients (5 allocated to BVS and 8 on CPAP) while 23 patients used a nasal mask (13 on BVS and 10 using CPAP). In 7 patients (3 in the CPAP group and 4 in the BVS group) initial daytime and/or nocturnal oxygen (flow 1–2 l/min) was required to prevent SaO<sub>2</sub> falling below 88%.

**Table 2** Baseline sleep and gas exchange data in all patient groups

	CPAP	BVS	p Value
Minimum SpO <sub>2</sub> (%)	55 (14)	53 (20)	0.75
%TST <90 (%)	74 (52–99)	90 (57–100)	0.47
%TST <80 (%)	19 (7–53)	33 (14–72)	0.28
TST (min)	251 (108–333)	328 (259–345)	0.11
Sleep efficiency (%)	69 (42–87)	78 (65–84)	0.38
% NREM	88 (7)	87 (8)	0.67
% REM	12 (7)	13 (8)	0.67
NREM RDI (events/h)	93 (59–112)	70 (19–97)	0.14
REM RDI (events/h)	61 (57–91)	48 (30–68)	0.13
% hypopnoeas of TRDI	79 (25–87)	77 (45–92)	0.69
ESS	15 (8–17)	14 (12–19)	0.59

Data presented as mean (SD) or median (interquartile range) as appropriate.

BVS, bilevel ventilatory support; CPAP, continuous positive airway pressure; SpO<sub>2</sub>, oxygen saturation; TST, total sleep time; NREM, non-rapid eye movement sleep; REM, rapid eye movement sleep; ESS, Epworth Sleepiness Scale; RDI, respiratory disturbance index; TRDI, total respiratory disturbance index.

**Table 3** Effect of initial CPAP therapy on overnight sleep parameters in patients allocated to longer term CPAP or BVS therapy

	CPAP group	BVS group	p Value
Effective CPAP level (cm H <sub>2</sub> O)	14 (3)	13 (2)	0.65
Min SpO <sub>2</sub> (%)	70 (12)	74 (10)	0.27
%TST <90 (%)	39 (16–80)	57 (14–86)	0.66
AHI (events/h)	22 (29)	13 (12)	0.22
Sleep efficiency (%)	73 (18)	80 (12)	0.18
% REM	23 (12)	22 (12)	0.75
Change TccO <sub>2</sub> NREM-REM (mm Hg)	5 (3)*	4 (2)†	0.25

Data presented as mean (SD) or median (interquartile range) as appropriate.

BVS, bilevel ventilatory support; CPAP, continuous positive airway pressure; SpO<sub>2</sub>, oxygen saturation; TST, total sleep time; AHI, apnoea-hypopnoea index; NREM, non-rapid eye movement sleep; REM, rapid eye movement sleep; TccO<sub>2</sub>, transcutaneous carbon dioxide pressure.

\*n = 13; †n = 15.

**Impact of 3 months of positive pressure**

Follow-up data were available for all 36 patients randomised to treatment. At review, both groups had experienced a reduction in weight of around 5 kg, improvement in daytime PaCO<sub>2</sub> and a reduction in bicarbonate. However, there was no difference between treatments for any of these parameters (table 4). The mean number of hours of nightly positive pressure use was not affected by the type of treatment to which the patient was allocated, with both groups using treatment more than 5.5 h/night.

Subjective daytime sleepiness improved with treatment, with no difference between groups (table 2). However, only those patients randomised to BVS experienced a significant improvement in subjective sleep quality (table 4). Within-group improvements in the 36-item Short Form Health Survey (SF-36) dimensions of Physical functioning, Role-physical, Vitality and Social functioning were seen in the BVS group, while only Vitality improved in the CPAP group (table 5). No differences in treatment effect were seen between the two groups in any dimension of the SF-36 questionnaire (table 5). Similarly, no differences in treatment effect were found in the four performance tasks measured (Trails B, digit span forward, digit span backwards and digit symbol substitution). Of the three metrics analysed in the psychomotor vigilance test, only the mean of the slowest 10% of reaction times showed a significant difference between treatments, favouring BVS (p = 0.03).

**Longer term management**

Following 3 months of treatment, 30 patients were found to have a good response to nocturnal CPAP and were recommended to continue with this treatment long term. Four

patients in the CPAP group and two in the BVS group continued to show oxygen desaturation in REM sleep despite control of upper airway obstruction and were recommended BVS as long-term therapy.

**DISCUSSION**

This study compared the impact of CPAP and BVS on clinical outcomes in a subset of patients with obesity hypoventilation syndrome without severe CPAP resistant nocturnal hypoxaemia. While both CPAP and BVS have been used to treat obesity hypoventilation syndrome previously, this is the first study to compare the two modalities in a randomised fashion. Using daytime PaCO<sub>2</sub> as the primary outcome measure, we found no significant treatment effect differences between the two forms of positive pressure therapy, with both groups experiencing a significant fall in PaCO<sub>2</sub> with a mean difference of 1 mm Hg between groups. Likewise, no significant treatment effect differences could be found between groups with respect to weight loss, compliance with therapy or daytime sleepiness, with both groups experiencing similar improvements with treatment. The BVS treated group reported better subjective sleep quality and performed slightly better on a psychomotor vigilance task than the CPAP group. However, the clinical significance of these small differences is unclear. Both groups experienced significant improvements in the Vitality dimension of the SF-36, while the BVS group also had significant within-group improvements in three other dimensions. However, no between-group differences were seen.

There are limited data on the clinical outcomes following the introduction of positive airway pressure therapy in patients with obesity hypoventilation. Currently, around 11% of

**Table 4** Change in daytime gas exchange, weight and subjective sleep quality following 3 months of positive pressure in the three treatment groups

Outcome	Change in CPAP group Mean (SD)	Change in BVS group Mean (SD)	Mean difference between treatments (95% CI)	p Value†
Paco <sub>2</sub> (mm Hg)	-5.8 (8.4)*	-6.9 (6.7)*	1.04 (-4.5 to 6.6)	0.7
Awake Spo <sub>2</sub> (%)	6 (3)*	8 (5)*	1.9 (-5.2 to 1.3)	0.24
Bicarbonate (mmol/l)	-2.3 (8.5)*	-2.5 (2.5)*	0.2 (-4.2 to 4.6)	0.93
Weight loss (kg)	-4.9 (7.8)*	-5.6 (9.4)*	0.7 (-5.2 to 6.5)	0.82
Mean nightly therapy use (h)	5.8 (2.4)	6.1 (2.1)	0.33 (-1.8 to 1.2)	0.66
ESS	-6 (8)*	-9 (5)**	2.89 (-1.78 to 7.56)	0.21
PSQI	-1.93 (3.5)	-5.6 (3.9)**	3.67 (0.82 to 6.5)	0.013

BVS, bilevel ventilatory support; CPAP, continuous positive airway pressure; Paco<sub>2</sub>, arterial carbon dioxide tension; Spo<sub>2</sub>, oxygen saturation; ESS, Epworth Sleepiness Scale; PSQI, Pittsburgh Sleep Quality Index.

\*p < 0.05, \*\*p < 0.001, within group changes from baseline.

†p Value denotes mean difference between CPAP and BVS treatment groups using unpaired t tests.

**Table 5** Changes in quality of life and neurocognitive testing following 3 months of positive pressure treatment

Outcome	Change with CPAP Median (IQR)	Change with BVS Median (IQR)	p Value between- group differences
SF-36			
Physical functioning	8 (−5–30)	24 (0–35)	0.2
Role-physical	18 (0–50)	31 (0–50)	0.32
Bodily pain	8 (−10–26)	11 (0–21)	0.51
General health	10 (−5–27)	9 (0–16)	0.99
Vitality	14 (−5–35)	26 (12–45)	0.2
Social functioning	8 (−25–25)	23 (0–50)	0.12
Role-emotional	4 (0–33)	17 (0–67)	0.5
Mental health	13 (0–28)	7 (−8–24)	0.75
Physical combined score	7 (−6–28)	20 (9–34)	0.22
Mental combined score	12 (8–19)	21 (6–33)	0.28
Psychomotor vigilance test			
Lapses	0.6 (0–0.5)	−2 (−4–0)	0.07
Median (ms)	9 (−16–27)	−21 (−29–0)	0.07
Mean of slowest 10% reaction times (1/rt)	0.07 (−0.2–0.2)	0.32 (0.05–0.5)	0.03
Trails B (s)	−21 (−34–0.5)	−2 (−20–17)	0.1
DSF	−0.3 (−1–0)	0.35 (−1–2)	0.16
DSB	0.08 (0–1)	0.5 (−1–2)	0.25
DSS	4 (0–8)	2 (0–6)	0.57

CPAP, continuous positive airway pressure; BVS, bilevel ventilatory support; DSF, digit span forward; DSB, digit span backwards; DSS, digit symbol substitution.

patients with obstructive sleep apnoea presenting to sleep laboratories are likely to be hypercapnic.<sup>3</sup> However, with the increasing prevalence of obesity in the general population, it is likely that these numbers will increase. With a move towards limited diagnostic monitoring and automated titration of obstructive sleep apnoea, it is possible that some patients with obesity hypoventilation syndrome, particularly those with less severe nocturnal hypoventilation and without overt signs of cardiorespiratory failure, may be treated initially with CPAP alone. Laboratory titration algorithms for PAP therapy in obesity hypoventilation syndrome have fairly uniformly suggested commencing in CPAP mode, with a switch to BVS if persistent desaturation below 88–90% occurs in the absence of apnoeic events.<sup>9 13 16</sup> In most centres the titration and decision about ongoing therapy is based on a split night or single night titration. This study was undertaken to understand better the short-term consequences of maintaining patients with obesity hypoventilation syndrome on CPAP, especially if a complete response to CPAP was not achieved during the initial titration study.

To our knowledge this is the first study to randomly assign patients with obesity hypoventilation syndrome to either CPAP or BVS to determine if there is a difference in the longer term in daytime hypercapnia or clinical outcomes between these two therapies, albeit in a specific subgroup of patients. One previous randomised crossover trial has investigated the impact of 6 weeks BVS in a spontaneous/timed mode (BVS-S/T) to BVS-S/T with average volume assured pressure support (AVAPS) in 10 patients with obesity hypoventilation syndrome failing initial CPAP therapy.<sup>17</sup> Both forms of BVS were found to improve oxygenation, sleep quality and HRQL, with AVAPS providing a more efficient reduction in overnight TccO<sub>2</sub> than standard BVS-S/T. However, the lower carbon dioxide level during sleep did not translate into further clinical benefits with regard to sleep quality or HRQL. Interestingly, during both forms of BVS, desaturation index, arousal and hypopnoeas

remained raised and were not different from that seen during the CPAP night. Therefore, despite significant residual sleep breathing events on BVS, substantial clinical improvements in these patients were achieved. It could be argued that using a BVS mode with a back-up rate may have yielded more significant differences between CPAP and BVS therapy in our study. However, using BVS in a S/T mode does not guarantee complete resolution of respiratory events or normalisation of sleep quality, with patient-ventilatory asynchrony or periodic breathing reported to occur frequently in stable patients with obesity hypoventilation syndrome using this mode.<sup>18</sup> The longer term consequences of an incomplete response to either CPAP or BVS, especially during the initial titration night, warrant further investigation.

In this study, patients reported severely impaired health status before treatment. Significant within-group improvements in Vitality scores occurred with both forms of short-term PAP therapy. Significant within-group improvements in other health dimensions were seen only in patients randomised to BVS (Physical functioning, Role-physical and Social functioning). However, significant between-group differences following treatment could not be demonstrated, probably due to the wide variability in responses and small study numbers. For many individuals, irrespective of the treatment used, quality of life scores following treatment still remained significantly below that reported in a previous study of patients with obesity hypoventilation syndrome following 3–6 months of CPAP therapy.<sup>11</sup> As the patients reported here were massively obese with a mean BMI of around 52 kg/m<sup>2</sup>, this failure to normalise SF-36 dimension scores is not surprising and almost certainly is due to the presence of other co-morbid conditions.<sup>5</sup> Use of a more disease-specific instrument may have identified more subtle differences between the two treatment groups not identified in a general tool like the SF-36. Future studies should address more fully quality of life issues in this population and the impact of different PAP therapies on health outcomes.

Compliance is obviously an important component of treatment success, and this in turn relies on patients' tolerance of the treatment and the benefits they feel they derive from it. It has previously been argued that BVS may be more comfortable than CPAP because the patient exhales against a lower mask pressure,<sup>19</sup> and this would result in greater adherence with treatment. However, this has not been shown in obstructive sleep apnoea,<sup>20</sup> and the current study has likewise failed to show any difference in nocturnal use of treatment between the two therapies, with a mean nightly use of around 6 h for both groups. This suggests that, in patients with obesity hypoventilation syndrome with predominantly upper airway obstruction, the type of PAP therapy is not a major factor associated with treatment compliance.

We arbitrarily reviewed patients after 3 months of treatment based on clinical practice.<sup>21</sup> However, more recent data suggest that a 4-week period may be sufficient to achieve the full benefits of therapy with regard to changes in blood gases,<sup>7, 16</sup> irrespective of the type of PAP therapy used.<sup>16</sup> Three months of treatment appeared to be a sufficient time period to allow improvements in nocturnal breathing such that a significant proportion of initial CPAP "incomplete responders" could be maintained on CPAP as long-term therapy. Other authors have also reported that a substantial minority of patients who initially require BVS could be maintained out of respiratory failure by the long-term use of CPAP therapy.<sup>7, 22</sup> However, for other measures such as quality of life and neurocognitive function, it is possible that longer periods of time may be needed to achieve improvements and future research would need to address this issue.

A major limitation of this study is that the results are applicable only to a subset of patients with obesity hypoventilation syndrome—that is, those without severe persisting hypoventilation during initial CPAP titration. This limits the applicability of the findings to the entirety of subjects with obesity hypoventilation syndrome. However, at the time of commencing this study there were safety concerns about continuing CPAP when severe sustained nocturnal hypoventilation persisted. Earlier data had indicated that untreated hypercapnia was associated with a fourfold increase in mortality among the severely obese.<sup>6</sup> We therefore believed it would be inappropriate to continue CPAP in those patients who continued to experience sustained severe oxygen desaturation or large rises in carbon dioxide despite control of upper airway dysfunction. However, the findings of this preliminary study have shown that the short-term use of CPAP in patients with obesity hypoventilation syndrome, even in those in whom nocturnal gas exchange and breathing abnormalities are not completely corrected during the first night of therapy, does not result in clinically significant differences in outcome compared with those placed on BVS. The patients currently reported had a high incidence of concomitant obstructive sleep apnoea in addition to their sleep hypoventilation. While this seems to be the case for the majority of patients with obesity hypoventilation syndrome,<sup>23, 24</sup> the results of this study cannot be extended to patients with obesity hypoventilation syndrome presenting with purely sleep hypoventilation. Therefore, until results from larger randomised clinical trials in patients with obesity hypoventilation syndrome with more severe sustained nocturnal hypoventilation are available, initial intervention with BVS with the possibility of transfer back to CPAP in the longer term would appear to be a reasonable and safe approach to treatment in this patient group.<sup>25</sup> In addition, the sample size used in this study would be insufficient to detect differences in carbon

dioxide changes occurring between the two groups. However, there are currently no data to determine what is a clinically important change in daytime carbon dioxide in this population. Future studies would need larger sample sizes to examine more subtle differences between treatments and to follow subjects over longer time periods to determine the impact on HRQL and hospital admissions. Further discussion and outlining of study limitations are included in the online supplement.

In conclusion, we have shown that both nocturnal CPAP and BVS are equally effective in improving gas exchange in selected patients with obesity hypoventilation syndrome without initial severe persisting nocturnal hypoxaemia, with no differences between treatments in weight loss, daytime sleepiness or compliance over a 3-month period. However, patients treated with BVS had significantly greater improvements in subjective sleep quality and reaction time compared with the CPAP group. The results of this study open the way for larger trials that include patients with more severe nocturnal hypoventilation in order to better define the role of CPAP and BVS in patients with obesity hypoventilation syndrome, not only in the initial management of the disorder but also in the longer term.

**Acknowledgements:** The authors thank the staff of the Sleep Disorders Unit for their care of the patients and each patient for their participation in this study. They also thank Dr Keith Wong for his statistical advice.

**Funding:** AJP was supported by a NHMRC (Australia) Health Professional Research Fellowship and RRG by a NHMRC (Australia) Practitioner Fellowship and the NHMRC CCRE for Respiratory and Sleep Medicine.

**Competing interests:** The positive pressure devices used in this study were supplied by Air Liquide, Alexandria, Australia and Mayo Healthcare, Rosebery Australia. These companies were not involved in the design, data collection or interpretation of the findings of this study. AJP has received travel support and lecture fees from Weinmann, Germany. RRG has received travel and equipment support from Respicronics, USA. These authors' sleep laboratory has also received an industry-sponsored project grant from ResMed, Australia.

**Ethics approval:** The study protocol was approved by the institutional review board of the Central Sydney Area Health Service (protocol no. X03-0022) and written informed consent was obtained from all patients prior to entry into the study.

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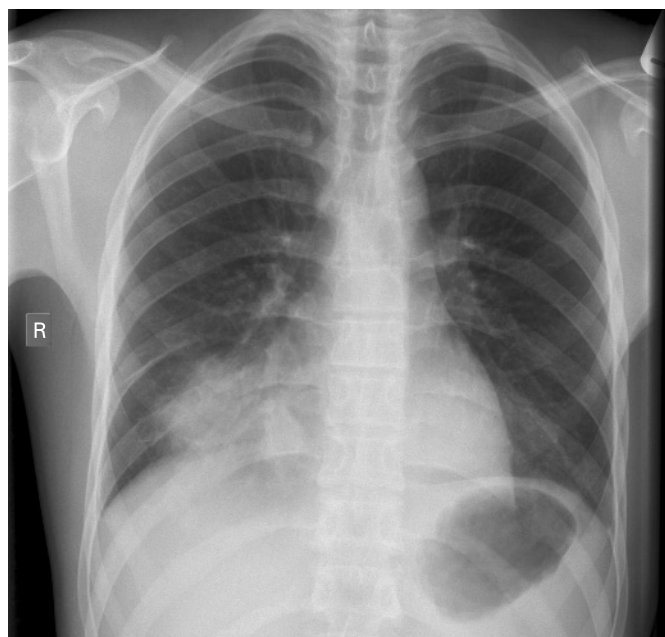
## Pulmonary puzzle

### Perils of fire eating

#### CLINICAL PRESENTATION

A 17-year-old man, a non-smoker, presented with a 4-day history of chest pain and dyspnoea. The symptoms had begun immediately after an episode of aspiration, which occurred whilst learning to be a fire eater. The patient was on holiday abroad at the time of the incident and attended the emergency department 3 days after returning home because his symptoms had persisted. There was no previous medical history.

Clinical examination revealed chest wall tenderness and crackles were heard in the right base. Room air blood gas analysis showed an arterial oxygen tension of 10.7 kPa, white blood cell count  $13.6 \times 10^9/l$ , C-reactive protein 131 mg/l and erythrocyte sedimentation rate 37 mm/h. A chest radiograph



**Figure 1** Chest radiograph showing an area of consolidation in the right middle lobe.



**Figure 2** Axial CT image demonstrating air space consolidation of the right middle and lower lobes bilaterally.

demonstrated a rounded density in the right middle lobe (fig 1). Treatment with oral prednisolone, co-amoxiclav and nebulised salbutamol was commenced. A high-resolution CT scan of the thorax showed an area of consolidation in the right middle lobe and ground-glass attenuation in the right middle and bilateral lower lobes (fig 2).

#### QUESTION

What is the diagnosis?

See page 439.

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**Competing interests:** None.

*Thorax* 2008;**63**:401. doi:10.1136/thx.2007.090001