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ORIGINAL ARTICLE

Evaluation of auto bi-level algorithm to treat pressure intolerance in obstructive sleep apnea

Nigel Ball · Nancy Gordon · Eileen Casal · James Parish

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Abstract
Purpose The objective of this study was to evaluate whether a new auto-adjusting bi-level algorithm was comparable to a standard method for prescribing bi-level therapy.
Methods This study was a prospective randomized, double-blinded crossover evaluation of the equivalency of the auto-adjusting bi-level mode (VAuto™) compared to standard bi-level mode, using a pre-determined difference in Apnea–Hypopnea Index (AHI) of five events per hour. Data were obtained during sleep studies performed on two separate nights. Twenty-two subjects met the entry criteria and were enrolled in the study at four investigational sites in the USA.
Results Mean AHI for the auto-adjusting bi-level mode was 6.2±5.4 events per hour and for the standard bi-level mode 8.3±5.8 events per hour. The AHI for the two modes were clinically equivalent. The difference in median pressure between these two modes was −3.8 cm H_2O±3.6 (p= 0.0008) in favor of the auto-adjusting bi-level mode. In addition, the maximum pressure was significantly higher in the auto-adjusting bi-level mode (16.0 cm H_2O vs. 14.1 cm H_2O, p=0.02).
Conclusions Our results demonstrated that the auto-adjusting bi-level mode normalized AHI comparable to the standard bi-level mode. The results of this study have several significant implications for the clinical management of sleep apnea. Obstructive sleep apnea (OSA) is a common condition and is associated with untoward complications. Non-compliance with positive airway pressure (PAP) limits the efficacy of the PAP therapy. The auto-adjusting bi-level mode provides a potentially reliable alternative for sleep clinicians faced with prescribing bi-level PAP for non-compliant patients. This study documents that this type of auto-adjusting device provides effective treatment of OSA.

Keywords Sleep apnea · Obstructive sleep apnea · Bi-level positive airway pressure · Auto bi-level positive airway pressure

N. Ball
Swedish Medical Center,
550 17th Avenue, Suite A20,
Seattle, WA 98122, USA

N. Gordon
Gordon and Associates,
1400 Shattuck Ave Ste 5,
Berkeley, CA 94709, USA

E. Casal
ResMed Corp,
9001 Spectrum Center Blvd.,
San Diego, CA 92123, USA

J. Parish (✉)
Mayo Clinic,
13400 Shea Boulevard,
Scottsdale, AZ 85259, USA
e-mail: parish.james@mayo.edu

Introduction

Obstructive sleep apnea (OSA), a common sleep disorder characterized by recurrent episodes of airway occlusion during sleep, is associated with many serious health conditions including cardiovascular disease, hypertension, diabetes, daytime sleepiness, and poor quality of life [1–5]. Commonly accepted as the most effective treatment for OSA, continuous positive airway pressure (CPAP) therapy has been shown to reduce symptoms of daytime sleepiness,

blood pressure, and to improve quality of life and cardiovascular outcomes [6–9].

Despite the effectiveness of CPAP, non-compliance is a primary barrier to relief of symptoms associated with OSA. Rates of nightly use are suboptimal in a large percentage (29–83%) of patients, using a typical adherence standard of greater than 4 h of use per night [9, 10]. Non-compliant CPAP users fail to use positive airway pressure for various reasons, one of which is pressure intolerance.

Typically, CPAP is titrated to the critical opening pressure required to assure patency of the upper airway during the entire respiratory cycle. However, it is likely that this critical opening pressure changes during the respiratory cycle. With CPAP, the same therapeutic pressure is used during inspiration and exhalation. This results in many patients feeling uncomfortably high resistance to breathing during expiration, particularly at high CPAP pressures. This discomfort can lead to poor sleep quality with residual sleepiness the following day, discontinuation of the device during the night, and general anxiety due to difficulties experienced during breathing while using the device. Overall these issues may contribute to lower CPAP compliance, although many other variables including social, cognitive, and psychological factors also play a role in CPAP compliance [10–12]. Furthermore, the effective PAP pressure changes with sleep stage and body position during sleep, being higher during REM sleep and in the supine position compared to NREM sleep and the non-supine position. With CPAP, the constant pressure may result in a pressure that is not optimal during large segments of the night, which may also contribute to lower adherence to therapy.

Bi-level PAP therapy is an alternative mode of treatment that may be indicated for patients who are non-compliant or who report dissatisfaction with PAP due to intolerance of the fixed pressure of CPAP [13, 14]. Bi-level PAP delivers two pressures, higher for inspiration and lower for expiration, respectively. PAP delivered in a bi-level mode may provide the patient more comfortable breathing during the expiratory phase of the respiratory cycle. Although data are limited that bi-level PAP improves compliance to CPAP in routine use, bi-level PAP may be useful to "rescue" patients who have difficulty exhaling against the fixed pressure of CPAP [15, 16].

Auto-adjusting CPAP (APAP or AutoPAP) devices adjust PAP automatically based on continuous measurements of airway flow and pressure, and provide lower pressures as needed, for example during NREM sleep and in non-supine sleep. Our hypothesis is that it may be advantageous to combine the advantages of bi-level PAP (different pressures within the respiratory cycle) and auto-adjusting PAP (different pressures within NREM–REM sleep cycles and the night) to provide greater flexibility in PAP pressure changes for bi-level therapy and, overall, a more optimal pressure profile.

The objective of this study was to evaluate whether a new auto-adjusting bi-level algorithm (VAuto™, ResMed Corp, San Diego, CA, USA) was comparable to a standard method for prescribing bi-level therapy, because this auto-adjusting bi-level algorithm might allow patients to be sent home with bi-level PAP without requiring an additional in-lab bi-level study. The Apnea–Hypopnea Index (AHI) and various sleep and respiratory characteristics were compared between the two modes, as well as leak values and patient tolerance. Subject and clinician preference was also assessed.

Materials and methods

Subjects

The study population consisted of 22 subjects referred to four US clinical sites. The study was conducted under the Investigational Device Exemption requirements. Investigational Review Board approval was obtained prior to the enrollment commencement. Study enrollment commenced in February, 2007, and closed in November, 2007.

Eligible subjects were 18 years of age or older and with a prior diagnosis of OSA. OSA was defined as an AHI $\geq$15 events per hour without symptoms, or an AHI $\geq$5 events per hour with symptoms and a Central Apnea Index <5 events per hour. Documented completion of a diagnostic study (either a full-night diagnostic and titration, or a split-night study including titration), using CPAP, within 1 year of study entry was required. CPAP prescription pressures between 8 and 20 cm H_2O were allowed. Subjects must have subsequently failed CPAP use due to pressure intolerance, and be naïve to bi-level therapy. All subjects gave written informed consent prior to participation in the study.

Subjects were not eligible if they had recent sinus surgery, required the use of supplemental oxygen, had any in-hospital surgeries within 2 weeks of study entry, had seasonal allergies which could interfere with therapy, had an allergy to the mask or other equipment used in the study, had a history of clinically significant epistaxis within 6 months of study entry, were pregnant at the time of study entry, or had any co-morbidities which, in the opinion of the investigator, could interfere with participation in the study.

Study design

This study was a prospective randomized, double-blinded crossover evaluation of the equivalency of the auto-

adjusting bi-level mode compared to standard bi-level mode, using a pre-determined difference in AHI of five events per hour. Data were obtained during sleep studies performed on two separate nights. Subject tolerance of each mode was assessed by a questionnaire completed the morning after each study night.

We evaluated the performance of an auto-adjusting bi-level algorithm against a conventional method of selecting bi-level pressures using a standard bi-level algorithm, both on the ResMed VPAP™ devices (Fig. 1). The auto-adjusting bi-level mode is designed to auto-adjust the bi-level pressures in 20 min or less. The conventional method of selecting bi-level pressures used the patient's optimal CPAP pressure setting, derived from their original prescription. The inspiratory positive airway pressure (IPAP) was set equal to that on the CPAP prescription and the expiratory positive airway pressure (EPAP) was set at 4 cm H_2O less than the IPAP. This setting provided enough pressure relief during exhalation and without significantly increasing the ventilation impact [17]. By demonstrating that the auto-adjusting bi-level mode was equivalent in efficacy to a conventional method, we postulated that clinicians would have another clinically precise option for addressing pressure intolerance. This might also reduce the need to perform an additional bi-level titration study with polysomnography in a sleep lab.

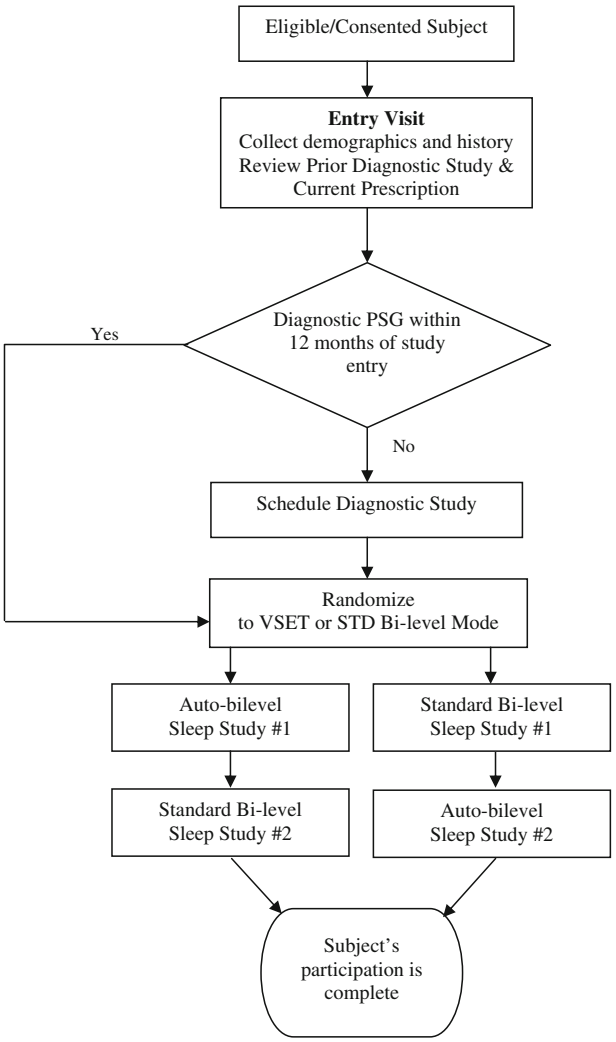

Fig. 1 Evaluation on auto bi-level algorithm to treat pressure intolerance in obstructive sleep apnea

Additional objectives were (1) to assess the median pressure relative to Apnea/Hypopnea Index values between the two modes; (2) to assess leak values relative to median pressure between the two modes; (3) to determine the proportion of subjects who were able to tolerate the auto-adjusting bi-level mode compared to the standard bi-level mode during PSG; and (4) compare subject/clinician preference between the two modes.

Subjects underwent two full-night attended PSG studies in American Academy of Sleep Medicine (AASM)-accredited Sleep Centers. One night was spent on the auto-adjusting bi-level mode and one night was spent on the standard bi-level mode. A computer-generated randomization schedule was used to assign each subject to the first mode of use, either auto-adjusting bi-level mode or standard bi-level mode. Prior to beginning the study, the subject was allowed a short acclimatization period to adjust to the device and mode. The same type of mask was used by the subject for both studies. Heated humidification was used during both studies, if required by the subject.

During the acclimatization period for the auto-adjusting bi-level night, the pressure support was set to 4 cm H_2O. The exhalation and trigger settings were adjusted for comfort: on the auto-adjusting bi-level mode there are three expiratory transition settings (slow, medium, or fast) and three levels of breath trigger sensitivity (low, medium, or high). In the standard bi-level mode, the IPAP and EPAP were set using a conventional prescription for bi-level therapy, determined from the past CPAP titration study. The inspiratory positive airway pressure was set equal to that on the CPAP prescription and the expiratory positive airway pressure was set at 4 cm H_2O less than the IPAP. The trigger setting adjusted for comfort. The study began at the conclusion of the acclimatization period. This was an observational sleep study; no adjustments were made to the flow generator in either mode during the sleep study, except for leaks, which were to be adjusted using standard company leak guidelines for values greater than 0.4 L/s. At the conclusion of the auto-adjusting bi-level study, a standard bi-level mode prescription (IPAP and EPAP) was calculated by dividing the pressure support by 2 and adding this value to the 95th percentile pressure for the IPAP and subtracting it for the EPAP.

Full PSG was performed using the clinical sites' polysomnography equipment. Channels monitored and

recorded with surface electrodes included electroencephalogram, electrooculogram, and submental electromyogram. Arterial oxygen saturation was recorded by digital pulse oximetry. Chest and abdominal effort were recorded using inductance plethysmography. Airflow was recorded via nasal cannula with a pressure transducer and a thermocouple. Apnea was defined as complete cessation of airflow for at least 10 s; hypopnea was defined as a 50% or greater decrease in airflow for at least 10 s and accompanied by at least a 3% drop in oxygen saturation.

The PSG studies were scored locally by RSPGT technologists and reviewed by an investigator board-certified in Sleep Medicine. American Academy of Sleep Medicine sleep scoring criteria was used for scoring the diagnostic PSG [18, 19]. Time in bed, sleep efficiency, awakening index, total sleep time, sleep staging, Central Apnea Index, Obstructive Apnea Index (AI), Obstructive Hypopnea Index, Apnea–hypopnea index, O_2 desaturation time, and Arousal Index were determined from the polysomnography. In addition, respiratory characteristics such as median tidal volume, maximum tidal volume, median respiratory rate and maximum respiratory rate, and median leak and pressure values were also collected via the flow generator.

Both subjects and sleep scoring technologists were blinded to device mode. A separate, non-blinded sleep technologist was assigned to the subject during the study nights. This technologist monitored patient comfort, conducted the polysomnography study, made adjustments to the interface, e.g., to address significant leak, but did not adjust flow generator settings. Sleep data were collected and scored by sleep technicians and reviewed by one of the investigators.

A subject was considered evaluable and part of the final dataset for endpoint analysis if both study nights were attempted, and at least one study night was successful, defined as therapy optimized at the end of the study. The time interval between the randomized sleep studies was up to 2 weeks. All subjects were required to complete all studies within a 4-week window from the time of consent.

Questionnaires

Subjects completed a questionnaire after each sleep study to assess and compare comfort during sleep with the device. Subject preference between the modes and the clinician experience, specifically the sleep technologists' rating of each mode's ease-of-use, were each assessed by using a six-point Likert Scale In both cases answers were recorded from 1 to 6, with 1 being the least favorable answer and 6 being the most favorable.

Responses for all of the questionnaires were divided into two groups, based on whether the rating was below or above the midpoint of possible ratings: ratings 1–3 were counted as "negative," while ratings 4–6 were considered "positive."

Statistical analysis

Subjects were randomized to either the standard bi-level or auto-adjusting bi-level mode first, based on a randomization schedule generated by the study's statistician. All variables were analyzed using descriptive statistics (frequency, mean±standard deviation). In order to test identity of two means Student's t test was applied in case of normal distribution, otherwise Wilcoxon signed-rank test was used. For discriminating between normal and non-normal distributed variables Shapiro–Wilk test was applied. We considered $p<0.05$ to be statistically significant. Statistical analysis was performed with SAS 8.2 (SAS Inc., Cary, NC, USA).

AHI equivalency was analyzed by means of the paired t test, using the clinically relevant margin of five events per hour ($\mu=5$). A p value of 0.05 or less, where $\mu=5$, was sufficient to conclude that the auto-adjusting bi-level mode is not different by the clinically relevant margin.

Results

Fifty-three subjects were screened for study entry at four investigational sites in the USA. Twenty-two subjects met the entry criteria and were enrolled in the study. Seventeen of the 22 enrolled subjects had evaluable results (both study nights attempted, and at least one study night successful); five subjects were not evaluable. Two of the non-evaluable subjects failed to attempt the second sleep study night, and three completed both studies but therapy was not optimized in either study. Both subjects who withdrew after the first sleep study had been randomized to auto-adjusting bi-level therapy first and did not attempt the second study PSG using the standard bi-level mode. One subject was lost to follow-up; the other chose to withdraw due to pressure intolerance.

Prior to the statistical analysis of the results, an analysis was conducted to determine if mode order (whether a subject was randomized to auto-adjusting bi-level mode first or standard bi-level first) had an effect on the primary endpoints. A potential mode-order effect was assessed using a two-way analysis of variance, with mode-assignment order as a between-subjects factor. There was no order effect found for either AHI or subject tolerance.

Of the 22 subjects enrolled in the study, 68% (15/22) were male. Mean age of the subjects was 56.3 years, (range 38 to 70 years). Average BMI was 37.0 kg/m^2; ranging

Table 1 Subject demographics and clinical characteristics

Demographics	
Gender	Percent % (*n*/*N*)
Males	68% (15/22)
Females	32% (7/22)
Age (years)	
Range (min, max)	38–70
Mean (*N*)±SD	56.3 (22)±9.3
Age: frequency grouping	Percent % (*n*/*N*)
35–44	13% (3/22)
45–54	32% (7/22)
55–64	32% (7/22)
65+	23% (5/22)
BMI (kg/m^2)	
Range (min, max)	24.8–53.6
Mean (*N*)±SD	37.0 (22)±7.8
Race	Percent % (*n*/*N*)
White	86% (19/22)
African–American/Black	14% (3/22)
Clinical characteristics	
Diagnostic PSG	
AHI (events per hour)	
Range (min, max)	7.4–132
Mean (*N*)±SD	53.4 (22)±30.1
Sleep history	
RLS	14% (3/22)
CSA	5% (1/22)
Mixed apnea	27% (6/22)
Excessive daytime sleepiness	64% (14/22)
Snoring	91% (20/22)
Awaken with shortness of breath at night	27% (6/22)
Stop breathing during the night	77% (17/22)
Awaken un-refreshed in the morning	68% (15/22)
Medical history (subjects may have more than one type of condition)	Percent % (*n*/*N*)
Type I diabetes	9% (2/22)
Type II diabetes	27% (6/22)
Hypertension	59% (13/22)
Medication	Percent % (*n*/*N*)
Anti-depressants	45% (10/22)

from 24.8 to 53.6 kg/m^2. Mean AHI from the diagnostic study was 53.4 events per hour (range 7.4 to 132). See Table 1.

Sleep-related conditions affecting more than half of subjects included snoring (91%, 20/22), cessation of breathing during the night (77%, 17/22), awakening un-refreshed (68%, 15/22), and excessive daytime sleepiness (64%, 14/22). Mixed apnea and shortness of breath were both reported by 27% of subjects (6/22). Three subjects had a history of restless leg syndrome, and one had complex sleep apnea. There were no reports of narcolepsy. See Table 1.

Non-sleep-related conditions affecting more than five subjects included hypertension (59%, 13/22) and type 2 diabetes (27%, 6/22). Type 1 diabetes and asthma were reported for two subjects. Ten subjects had seasonal and/or drug allergies. There were no subjects with a reported history of cardiovascular disease, pulmonary disease, or neuromuscular disease.

Mean AHI for the standard bi-level mode was 8.3±5.8 events per hour. AHI for the auto-adjusting bi-level mode was lower with a mean of 6.2±5.4 events per hour. The mean difference (AHI_{auto} minus $AHI_{standard}$) was −2.3±6.0 events per hour with a 95% CI of −5.5 to 0.9 events per hour. Therefore, the AHI for the two modes were clinically equivalent, as indicated by the upper confidence limit of the difference (UCL=0.9) being below the preset acceptable limit of five events per hour. This equivalency was statistically significant (p=0.0002). These data are presented in Table 2.

Secondary endpoints analyzed included median pressure requirements and median leak from the flow generator, sleep fragmentation from the PSG equipment, and subject preference assessed by a subject survey. The median pressure in the auto-adjusting bi-level mode was 9.8 cm H_2O±2.9 and the median pressure in the standard bi-level mode was 13.8 cm H_2O±2.8. The difference in pressure between these two modes was −3.8 cm H_2O±3.6 (95% CI −5.7 to −1.9, p=0.0008). In addition, the maximum pressure was statistically significantly higher in the auto-adjusting bi-level mode (16.0 cm H_2O vs. 14.1 cm H_2O, p= 0.02). Data for the median pressure and median leak for both the auto-adjusting bi-level and standard modes are presented in Table 3.

Table 2 Respiratory event data: Apnea/Hypoxia Index (AHI; events per hour)

Endpoint	Auto-adjusting bi-level PAP *N* Mean±SD	Standard bi-level PAP *N* Mean±SD	Difference *N* Mean±SD (95% CI)	μ (Acceptable difference)	p value	Equivalent?
AHI	17 6.2±5.4	16 8.3±5.8	16 −2.3±6.0 (−5.5–0.9)	+5	0.0002	Yes

Table 3 Median pressure and median leak: flow generator

	Auto-adjusting bi-level PAP (N=17)	Standard bi-level PAP (N=16)	Difference (auto-adjusting–standard bi-level PAP) (N=16)
Median pressure (cm H_2O)	9.8±2.9	13.8±2.8	−3.8[a]±3.6
95th % pressure (cm H_2O)	13.5±3.1	14.1±2.4	−0.4±3.2
Maximum pressure (cm H_2O)	16.0±3.1	14.1±2.5	1.9[b]±2.9
Median leak (liters/min)	4.9±7.4	5.0±1.8	0.2±8.8
95th % leak (liters/min)	17.3±18.6	22.1±22.0	−4.3±23.3
Maximum leak (liters/min)	74.9±55.6	58.8±21.5	16.7±51.3

[a] Median pressure: auto-adjusting bi-level mode is statistically lower than standard bi-level, p=0.0008

[b] Maximum pressure: standard bi-level mode is statistically lower than auto-adjusting bi-level PAP, p=0.02

Polysomnography data are presented in Table 4 (Sleep characteristics, Respiratory characteristics during PSG). No statistical differences were found in the sleep characteristics (Table 4 (Sleep characteristics)), except for obstructive apnea index which was significantly lower in auto-adjusting bi-level mode than standard bi-level, $p<0.05$. There were no statistical differences for respiratory characteristics except for 95th percentile tidal volume where the standard bi-level mode is statistically higher than auto-adjusting bi-level, t test p=0.03 and signed-rank test p=0.02.

Tolerance to the pressure during the entire night as assessed by the clinician is presented in Table 5. The subjects appeared to tolerate the pressure well in 94% of cases while on either auto-adjusting bi-level or standard bi-level.

Subject assessments are presented in Table 6 (Patient survey). Auto-adjusting bi-level received a higher proportion of positive responses (at least 10% difference) for satisfaction with the treatment, ease of falling asleep and ability to stay asleep. Standard bi-level mode was ranked higher for satisfaction with mask seal.

Table 4 Sleep fragmentation: PSG

	Auto-adjusting bi-level PAP (N=17)	Standard bi-level PAP (N=16)	Difference (auto-adjusting–standard bi-level PAP) (N=16)
Sleep characteristics (PSG)			
Time in bed (minutes)	450.5±97.1	470.5±38.8	−15.0±60.3
Central Apnea Index (CAI; events per hour)	0.4±0.9	1.1±2.2	−0.7±1.4
Apnea Index (AI; events per hour)	2.1±2.3	4.0±3.6	−1.9*±2.5
Hypopnea Index (HI; events per hour)	3.9±3.9	3.7±3.2	0.0±4.0
O_2 desaturation time (<90%; % time)	0.9±1.4 (N=16)	2.1±5.3	−1.2±5.0
Arousal Index (ARI; events per hour)	13.2±10.1	13.3±6.5	0.6±8.0
Sleep efficiency (SE; %)	81.8±8.8	82.3±11.9	−0.4±8.4
Awakening Index (AWI; minutes)	5.1±3.3	5.1±4.2	0.3±2.8
Total sleep time (TST; minutes)	371.3±91.3	382.7±67.7	−7.1±55.2
Time: stage 2 (minutes)	235.1±54.3	247.3±43.4	−9.8±36.6
Time: REM (minutes)	72.8±35.0	76.8±36.2	−4.3±29.1
Time: stage 3–4 (minutes)	9.1±25.5	8.4±23.9	0.1±3.9
Respiratory characteristics during PSG			
Median tidal volume (ml)	391.2±98.8	371.9±87.5	12.5±69.5
95th percentile tidal volume (ml)	641.2±172.5	684.4±188.6	−65.6*±109.1
Maximum tidal volume (ml)	1,182.4±422.4	1,050.0±326.6	112.5±460.6
Median resp rate (BPM)	14.7±1.9	15.3±2.5	−0.5±2.0
95th percentile resp rate (BPM)	17.9±2.5	19.0±2.9	−0.9±2.5
Maximum resp rate (BPM)	26.0±8.0	26.9±5.9	−2.7±5.5

Data is presented as mean±SD. The differences were analyzed by paired t test

*$p<0.05$

Table 5 Sleep quality data: subject tolerance to pressure

Clinician survey: did patient tolerate pressure(s) well for the entire night?		
Device Mode	Yes Percent (*n*/*N*)	No Percent (*n*/*N*)
Auto-adjusting bi-level PAP	94% (16/17)	6% (1/17)
Standard bi-level PAP	94% (16/17)	6% (1/17)

Clinician survey results are provided in Table 6 (Clinician survey). There are no significant differences between modes.

Discussion

We assessed whether a new auto-adjusting bi-level algorithm would result in an AHI reduction at least equivalent to that provided by a conventional method for prescribing bi-level therapy. Our results demonstrated that the auto-adjusting bi-level mode normalized AHI comparable to the standard bi-level mode. Both the AHI and AI were lower with the new mode. This is an important finding because the new auto-adjusting bi-level algorithm provides the opportunity for a patient to be sent home with bi-level PAP therapy without requiring an additional in-lab bi-level titration study.

The median pressure for the auto-adjusting bi-level mode was significantly lower, while the maximum pressure was significantly higher. The patient survey data indicate that the auto-adjusting bi-level mode potentially offers a more comfortable, or at least tolerable, night of sleep than the standard mode. Using an auto-adjusting device designed to address intra-night variations in pressure requirements provides valuable confidence that the algorithm will reliably respond throughout the night and self-adjust to address the respiratory events. This may be contrasted with current devices providing only fixed or intra-breath accommodation.

The results of this study have several significant implications for the clinical management of sleep apnea. OSA is a common condition and is associated with untoward complications. Non-compliance with CPAP limits the efficacy of the CPAP therapy. The auto-adjusting bi-level mode provides a potentially reliable alternative for sleep clinicians faced with prescribing bi-level PAP for non-compliant patients. Data are limited that bi-level PAP improves patient adherence compared with fixed CPAP in patients receiving initial therapy [15, 16]; however, bi-level therapy may provide the clinician with an option for patients not adherent with CPAP due to pressure intolerance. One preliminary, non-randomized observational study showed that auto CPAP may be useful in improving adherence in patients intolerant of conventional CPAP [20]. Vennelle et al. demonstrated in a recent trial of variable pressure positive airway pressure that there is a significant order effect in a randomized controlled trial that needs to be taken into account in future trials comparing novel PAP devices [21]. However, our study found no order effect for either AHI or subject tolerance. Further trials would be necessary to investigate the potential role of auto-

Table 6 Questionnaires

Percent answering questions positively[a]	Auto-adjusting bi-level PAP	Standard bi-level PAP
Patient survey		
How refreshed did you feel after waking in the morning?	94% (15/16)	88% (14/16)
How easy was it for you to fall asleep?	69% (11/16)	59% (10/17)
How difficult was it to stay asleep during the night?	81% (13/16)	71% (12/17)
How often did you wake up feeling breathless?	100% (16/16)	100% (16/16)
How satisfied were you with the mask seal?	75% (12/16)	94% (16/17)
How satisfied were you with the treatment?	88% (14/16)	76% (13/17)
Clinician survey		
How easy was the flow generator to set up?	100% (17/17)	88% (15/17)
How easy was it to download the data from the flow generator?	100% (16/16)	100% (15/15)
How easy was the PSG signal from the flow generator to interpret during the study?	100% (17/17)	94% (15/16)
Did the patient appear to tolerate the pressure(s) well? (percent of respondents answering "Yes")	94% (16/17)	94% (16/17)

[a] Positive=4 or better on 1–6 Likert scale

adjusting bi-level PAP in improving adherence with other types of positive airway pressure therapy. However, this study documents that this type of auto-adjusting device provides effective treatment of OSA. Use of the auto-adjusting bi-level mode eliminates heuristic decision loops, without loss of efficacy. The auto-adjusting mode may also be suitable in the sleep lab when there is understaffing or inexperience with bi-level titration. This study shows that an additional PSG study in the sleep lab is not needed to achieve adequate efficacy.

Algorithms which modify the expiratory release pressure (expiratory pressure relief) are often included by major PAP manufacturers and have been proposed to improve compliance in pressure-sensitive patients. One study of flexible expiratory pressure relief mode versus standard CPAP showed no difference in efficacy or compliance, but larger studies are needed [22].

The study questionnaire results suggest that subjects tolerated the PAP therapy delivered by the auto-adjusting bi-level mode. Clinicians observed that nearly all (94%) subjects rated the pressure of either of the two modes well. While more auto-adjusting bi-level patients reported feeling refreshed in the morning and found it easier to fall asleep, and they reported being more satisfied with the treatment mode (88%) than standard bi-level mode (76%), these findings were not significant with the current sample size.

There are limitations to this study that warrant future investigation. The efficacy of the auto-adjusting bi-level mode was only tested in an acute environment—the sleep lab—rather than at home. In addition, this multicenter study, designed to test for equivalency, had an appropriate but small sample size of evaluable patients. Thus the potential benefits suggested by the improved performance could not be fully established. Further study of the efficacy and cost effectiveness of this new algorithm designed to address PAP pressure intolerance is warranted to understand detailed and especially long-term compliance benefits.

These results suggest that using the auto-adjusting bi-level mode is a promising option when transitioning non-compliant obstructive sleep apnea patients to a bi-level PAP prescription. These data indicate that this new algorithm, without an additional titration study in the sleep lab, provides results at least as good as those of a conventional method for standard bi-level PAP. The impact on long-term compliance remains to be determined.

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