Effects of Augmented Continuous Positive Airway Pressure Education and Support on Compliance and Outcome in a Chinese Population*

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Objectives: **To study the effects of augmentation of continuous positive airway pressure (CPAP) education and support on compliance and outcome in patients with obstructive sleep apnea (OSA).**
Design: **A randomized, controlled, parallel study of basic vs augmented CPAP education and support.**
Setting: **A university teaching hospital.**
Patients: **A total of 108 OSA patients randomized into basic-support (BS) and augmented-support (AS) groups.**
Interventions: **Patients in the BS group (n = 54) were given educational brochures on OSA and CPAP, CPAP education by nurses, CPAP acclimatization, and were reviewed by physicians and nurses at weeks 4 and 12. Patients in the AS group (n = 54) received more education, including a videotape, telephone support by nurses, and early review at weeks 1 and 2.**
Measurements: **Objective CPAP compliance, Calgary sleep apnea quality of life index (SAQLI), and cognitive function after 1 month and 3 months; and Epworth sleepiness scale (ESS) after 3 months of CPAP treatment.**
Results: **At 4 weeks, CPAP usage was 5.3 ± 0.2 h/night (mean ± SEM) vs 5.5 ± 0.2 h/night in the BS and AS groups, respectively (p = 0.4). At 12 weeks, CPAP usage was 5.3 ± 0.3 h/night vs 5.3 ± 0.2 h/night in the two groups, respectively (p = 0.98). There was greater improvement of SAQLI at 4 weeks (p = 0.008) and at 12 weeks (p = 0.047) in the AS group. There was no significant difference between BS and AS groups in terms of improvement of ESS and cognitive function.**
Conclusion: **Augmentation of CPAP education and support does not increase CPAP compliance, but leads to a greater improvement of quality of life during the reinforced period.**
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Key words: compliance; continuous positive airway pressure education; obstructive sleep apnea; outcome

Abbreviations: AHI = apnea-hypopnea index; AS = augmented-support; BS = basic-support; CPAP = continuous positive airway pressure; ESS = Epworth sleepiness scale; OSA = obstructive sleep apnea; SAQLI = sleep apnea quality of life index

Obstructive sleep apnea (OSA) syndrome is a common disorder affecting 2 to 4% of middle-aged adults.[1] Excessive daytime sleepiness is a major consequence of OSA, due to sleep fragmentation triggered by repetitive episodes of partial or complete upper-airway obstruction.[2] Sleep fragmentation may also contribute to impaired cognition or altered mood,[3] and patients are prone to accidents at work or while driving,[4] with poor work and social functioning.[5]

Introduced by Sullivan et al[6] in 1981 as a pneumatic splint to prevent collapse of the upper airway, nasal continuous positive airway pressure (CPAP) has remained the standard treatment for OSA, and several randomized placebo-controlled trials have

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shown significant improvement of symptoms, quality of life, and daytime function in patients treated with nasal CPAP.[7–11] CPAP compliance, however, has been variable in different studies, ranging from 2.8 to 6.0 h/night in new CPAP users.[7–14] In a prospective study of 23 newly diagnosed OSA patients commencing CPAP treatment, we previously reported an objective CPAP compliance rate of 64% and 67% at 1 month and 3 months, respectively,[15] with acceptable compliance as defined by Kribbs et al[12] as CPAP use of at least 4 h/d for at least 70% of the nights per week.

In this study, we would like to explore if augmentation of CPAP education and support within our resources would enhance CPAP compliance and improve treatment outcomes such as sleepiness, quality of life, and cognitive function among our OSA patients.

Materials and Methods

We performed a prospective, randomized, controlled, parallel study of basic vs augmented CPAP education and support on newly diagnosed OSA patients commencing nasal CPAP treatment.

Patients

From our respiratory and sleep clinic, we recruited 108 consecutive, symptomatic patients with newly diagnosed OSA. Significant OSA was defined as apnea-hypopnea index (AHI) ≥ 10 events/h of sleep as shown by overnight polysomnography (Sleep Lab 1000p; Aequitron Medical; Minnetonka, MN) plus self-reported sleepiness. Overnight polysomnography recorded EEG, electro-oculogram, submental electromyogram, bilateral anterior tibial electromyogram, ECG, chest and abdominal wall movement by inductance plethysmography, and airflow measured by a nasal pressure transducer (PTAF; Pro-Tech; Woodinville, WA), and backed up by oronasal airflow measured with a thermistor and finger pulse oximetry. Sleep stages were scored according to standard criteria by Rechtshaffen and Kales.[16] Apnea was defined as cessation of airflow for > 10 s, and hypopnea was defined as a reduction of airflow $\geq 50\%$ for > 10 s plus an oxygen desaturation of $> 4\%$ or an arousal. The subjects were randomized into two arms, with group 1 receiving basic CPAP education and support and group 2 receiving augmented education and support. Our study was approved by the Ethics Committee of the Chinese University of Hong Kong, and appropriate informed consent was obtained from the subjects.

Study Protocols

Basic Support: Following confirmation of significant OSA from the overnight diagnostic sleep study, each patient was interviewed by the physician on duty and offered a trial of nasal CPAP treatment. Each patient was given a 10-min CPAP education program by a respiratory nurse who explained the basic operation and care of the CPAP device and mask. An brochure on OSA and CPAP treatment in Chinese was given to each patient during the education session. The nurse chose a comfortable CPAP mask from a wide range of selections for the patient, who was then given a short trial of CPAP therapy with the AutoSet (Resmed; Sydney, Australia) CPAP device for approximately 30 min of acclimatization in the afternoon. Attended CPAP titration was performed with the AutoSet auto-titrating device on the second night of the study in our hospital, with full polysomnography. Throughout the night and the next morning, the nurses on duty would deal with any discomfort related to the CPAP treatment. The CPAP pressure for each patient was set at the minimum pressure needed to abolish snoring, obstructive respiratory events, and airflow limitation for 95% of the night, as determined by the overnight AutoSet CPAP titration study. Several studies have shown that automatic CPAP titration is as effective as manual titration in correcting the obstructive respiratory events, arousal frequency, and improving oxygenation.[17–20] All the patients were prescribed the Aria CPAP device (Respironics; Murrysville, PA), which automatically turned on when the patients breathed into the mask and shut off when the mask was removed. The Aria CPAP contains a microprocessor with dual time meters recording both machine run time and time spent at effective pressure (measured by a mask pressure transducer recorder). The patients subsequently were followed up by physicians and nurses at the CPAP clinic at 1 month and 3 months to deal with any problem with the CPAP device or mask fit, and CPAP pressure was adjusted if necessary.

Augmented Support: In addition to the basic-support (BS) group, patients in the augmented-support (AS) group were given extra education on OSA and CPAP by physicians via a locally produced 15-min videotape. Our respiratory nurses would also reinforce knowledge about OSA and provide solutions for potential problems with the use of CPAP during an additional 15-min education session. The patients were reviewed early by physicians at week 1 and week 2. The respiratory nurses also followed up these patients by phone on day 1 and day 2, and at weeks 1, 2, 3, 4, 8, and 12 to help sort out any technical problem and encourage the use of CPAP.

Outcome Measurements

Prior to commencement of nasal CPAP, all patients had to go through several measurements. These included assessment of subjective sleepiness with the Epworth sleepiness scale (ESS), quality of life with the Calgary sleep apnea quality of life index (SAQLI), and psychometric tests.

The ESS[21] is a questionnaire specific to symptoms of daytime sleepiness, and patients are asked to score the likelihood of falling asleep in eight different situations with different levels of stimulation, adding up to a total score of 0 to 24. The ESS has been shown to have significant correlation with the Multiple Sleep Latency Test, an objective measure of sleepiness.[22]

The Calgary SAQLI has 35 questions organized into four domains: daily functioning, social interactions, emotional functioning, and symptoms, with a fifth domain, treatment-related symptoms, to record the possible negative impacts of treatment. The SAQLI has a high degree of internal consistency, face validity as judged by content experts and patients, and construct validity as shown by its positive correlations with the Short Form-36 Health Survey questionnaire and the improvement in scores in patients successfully completing a 4-week trial of CPAP. It contains items shown to be important to patients with sleep apnea, and it is designed as a measure of outcome in sleep apnea clinical trials.[23] Scoring of the SAQLI was based on the manual by Flemons and Reimer.[24]

Cognitive function tests, including trail-making, digit-symbol, digit-span, and Stroop color testing, were performed to provide objective evidence for improvement in daytime function on CPAP treatment, as reported by Engleman et al.[7–10] The trail-making test estimated the minimum time required to connect a

structured number sequence; the lower the score, the better the performance. The digit-symbol and digit-span tests involved the immediate memory and recall of number sequences, while the Stroop color test evaluated the correct matching of colors and their corresponding characters. For the Stroop color, digit-symbol, and digit-span tests, a higher score indicated superior performance.

With the exception of the ESS, which was repeated at 3 months, all other baseline measurements were repeated at 1 month and 3 months. During the CPAP clinic follow-up, our patients were asked to report subjectively the amount of time they used the CPAP device per day and any problem associated with the use of CPAP.

The objective CPAP compliance was measured at 1 month and 3 months, with the Aria CPAP data downloaded into a personal computer using the Respironics Encore software (Respironics). The time spent at effective pressure was recorded as the objective compliance.

Statistical Analysis

Data were analyzed on an intention-to-treat basis. For comparison between basic and augmented education groups at each time point, an unpaired *t* test was used for normally distributed variables, and the Mann-Whitney test was used for nonnormally distributed variables. The improvement of variables from baseline was tested by paired *t* test.

Results

One hundred eight patients (11 female patients) entered the study and underwent baseline assessment. The mean age was 45 ± 11 years (mean ± SD); body mass index, 30 ± 8 kg/m^2; and AHI, 48 ± 24. There were slight but significant differences between the two groups in ESS and trail B. Otherwise, there was no statistically significant difference in other baseline outcome measures (Table 1). All the patients returned for follow-up, but there was a technical problem with the Aria/Encore software, resulting in missing CPAP compliance data for 11 of the 108 patients (2 in the BS group and 9 in the AS group) at 3 months. Except for 17 socially disadvantaged patients (7 BS patients and 10 AS patients) who were eligible for government support, all of the others had to purchase or rent their CPAP units through a local distributor. Other results are reported as mean ± SEM.

CPAP Levels

The CPAP levels at baseline were 9.5 ± 0.2 cm H_2O and 11.1 ± 0.3 cm H_2O for the BS and AS groups, respectively. At 4 weeks, an equal number of patients in each group (9 of 54 patients; 16.7%) required adjustment of pressures, and the adjusted pressures became 9.3 ± 0.2 cm H_2O and 10.9 ± 0.3 cm H_2O for the BS and AS groups, respectively. At 12 weeks, 5 of 54 patients (9.3%) and 6 of 54 patients (11.1%) in the BS and AS groups required adjustment, and the adjusted pressures became 9.2 ± 0.3 cm H_2O and 10.4 ± 0.3 cm H_2O, respectively.

Compliance

There was no significant difference between the two groups in terms of objective CPAP usage and compliance rates. At 4 weeks, the CPAP usage was 5.3 ± 0.2 h/night vs 5.5 ± 0.2 h/night ($p = 0.4$), while at 12 weeks, the CPAP usage was 5.3 ± 0.3 h/night vs 5.3 ± 0.2 h/night ($p = 0.98$) in the BS and AS groups, respectively. The compliance rates were 71% at both 4 weeks and 12 weeks in the BS group, while those of the AS group were 79% and 74%, respectively. At both 4 weeks and 12 weeks, patients in both groups overestimated the actual amount of time they used CPAP, with the self-reported compliance much higher than the objective compliance in both groups ($p < 0.001$; Table 2).

Sleepiness

There was significant improvement of ESS in both the BS group and the AS group at 12 weeks, with the

Table 1—*Patient Characteristics at Baseline

Characteristics	BS Group (n = 54)	AS Group (n = 54)	p Value
AHI, events/h	52 ± 3	45 ± 4	NS
BMI, kg/m^2	28.4 ± 0.6	30.2 ± 0.9	NS
ESS	11.6 ± 0.7	13.9 ± 0.6	0.02
SAQLI	40 ± 4.3	47 ± 4.5	NS
Trail A	42 ± 3	36 ± 2	NS
Trail B	79 ± 7	61 ± 3	0.03
Digit span	19 ± 1.7	20 ± 1.6	NS
Digit symbol	71 ± 3	75 ± 3	NS
Color A	44 ± 2	45 ± 2	NS
Color B	7.7 ± 0.5	8.7 ± 0.5	NS

*All values are given as mean ± SEM; BMI = body mass index; NS = not significant.

Table 2—*Subjective and Objective Compliance at 4 Weeks and 12 Weeks

Compliance, h/Night	BS Group (n = 54)	AS Group (n = 54)	p Value
Self-reported at wk 4	6.4 ± 0.2	6.6 ± 0.2	0.5
Self-reported at wk 12	6.5 ± 0.2	6.3 ± 0.2	0.6
Objective at wk 4	5.3 ± 0.2	5.5 ± 0.2	0.4
Objective at wk 12	5.3 ± 0.3	5.3 ± 0.2	0.98
Compliance rate at 4 wk, %†	71 ± 4	79 ± 4	0.15
Compliance rate at 12 wk, %†	71 ± 4	74 ± 4	0.6

*All values are given as mean = SEM; self-reported vs objective compliance, $p < 0.001$.

†Compliance rate defined as at least 4 h of CPAP use per night for ≥ 70% of the nights per week.

mean baseline ESS falling by 7.4 ± 0.8 and 8.1 ± 0.8, respectively, with $p < 0.001$ in both groups. However, there was no significant difference for the degree of improvement between the two groups, with $p = 0.6$ (Fig 1 and Table 3).

Quality of Life

There was significant improvement of the Calgary SAQLI within both groups, with $p = 0.01$ and $p = 0.001$ at 4 weeks and 12 weeks, respectively, for the BS group, and $p < 0.01$ at both 4 weeks and 12 weeks for the AS group. There was no significant difference between the two groups with regard to daily functioning, social interaction, and emotional functioning. There was greater improvement of symptoms at 12 weeks in the AS group ($p = 0.03$), while there was no significant difference at 4 weeks. In terms of treatment-related symptoms from the CPAP treatment, there were no significant differences between the two groups. Overall, there was greater improvement of quality of life in the AS group at 4 weeks and 12 weeks, with $p = 0.008$ and $p = 0.047$, respectively (Table 4).

Cognitive Function

There was greater improvement in digit span in the AS group at 4 weeks, with $p = 0.049$. However, this effect became insignificant at 12 weeks. None of the other cognitive function outcome variables showed any significant difference between the two groups at week 4 and week 12 (Table 3).

Table 3—*Improvement of Cognitive Function and ESS From Baseline on CPAP

Variables	BS Group (n = 54)	AS Group (n = 54)	p Value
Δ from baseline at wk 4			
Trail A	5 ± 2	3 ± 2	0.4
Trail B	16 ± 4	10 ± 3	0.3
Digit span	1 ± 2	6 ± 3	0.049
Digit symbol	4 ± 2	0 ± 2	0.2
Color A	6 ± 2	5 ± 2	0.8
Color B	2 ± 1	2 ± 1	0.9
Δ from baseline at wk 12			
Trail A	7 ± 2	5 ± 1	0.5
Trail B	18 ± 4.5	13 ± 3	0.3
Digit span	0.2 ± 1.1	0.8 ± 0.4	0.6
Digit symbol	2.7 ± 2.5	4.8 ± 1.5	0.5
Color A	8 ± 2.4	9.1 ± 1.5	0.7
Color B	1.9 ± 0.9	1.7 ± 0.3	0.8
ESS	7.4 ± 0.8	8.1 ± 0.8	0.6

*All values are given as mean ± SEM.

Discussion

Nasal CPAP has remained the standard treatment for OSA since it was first introduced almost 2 decades ago.[6] Several randomized, placebo-controlled trials have shown significant improvement of symptoms, quality of life, and daytime function in patients treated with nasal CPAP.[7–11] However, nasal CPAP is a rather obtrusive and cumbersome therapy, and compliance has been variable in different studies, ranging from 2.8 to 6.0 h/night in new CPAP users.[7–14]

Several studies have been published examining ways to facilitate CPAP compliance. Fletcher and Luckett,[14] in a prospective, randomized crossover

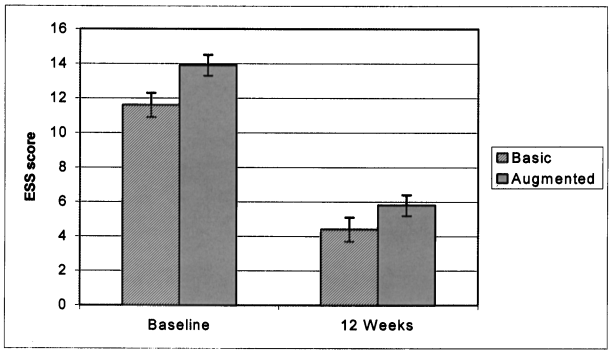

Figure 1. ESS scores given as mean ± SEM at baseline and 12 weeks. ESS scores fell by 7.4 ± 0.8 and 8.1 ± 0.8, respectively, from baseline values in the BS and AS groups, with $p < 0.001$ in both groups. However, there was no difference for the degree of improvement between groups ($p = 0.6$).

Table 4—*Improvement of Calgary SAQLI at 4 Weeks and 12 Weeks

Variables	BS Group (n = 54)	AS Group (n = 54)	p Value
Δ from baseline at 4 wk			
Domain 1	4.9 ± 1.1	7.6 ± 1.3	0.056
Domain 2	2.5 ± 0.6	4.5 ± 1.1	0.249
Domain 3	3.7 ± 0.9	5.6 ± 1.0	0.104
Domain 4	3.0 ± 0.5	5.1 ± 0.9	0.103
Domain 5	6.8 ± 1.1	4.4 ± 0.7	0.133
Total	7.3 ± 2.8	18.4 ± 3.5	0.008
Δ from baseline at 12 wk			
Domain 1	4.3 ± 0.8	8.5 ± 1.9	0.106
Domain 2	2.1 ± 0.7	5.9 ± 1.4	0.226
Domain 3	3.1 ± 0.7	6.2 ± 1.6	0.125
Domain 4	3.3 ± 0.7	5.3 ± 1.0	0.03
Domain 5	3.6 ± 0.6	4.0 ± 1.1	0.947
Total	9.1 ± 2.5	21.9 ± 5.2	0.047

*Results given as mean ± SEM. Domain 1 = daily functioning; Domain 2 = social interaction; Domain 3 = emotional functioning; Domain 4 = symptoms; Domain 5 = treatment-related symptoms. Calculation of SAQLI was based on the 1996 Calgary SAQLI manual by Flemons and Reimer.[24] Total SAQLI score = Domains 1 + 2 + 3 + 4 − 5.

study, examined the effect of weekly (thrice) and then monthly (twice) positive reinforcement via telephone support on hourly compliance of 10 new CPAP users for 3 months vs no reinforcement for 3 months. Their study suggested that positive reinforcement by telephone did not favorably alter compliance. However, as half of their patients had already received telephone support during the reinforced period, it was difficult to determine the effects of reinforcement, as there was likely a carrying-over effect of such support in the nonreinforced period. In a randomized controlled trial involving 33 subjects of two interventions to improve compliance, Chervin et al[25] showed that telephone support or educational literature might improve self-reported CPAP usage, but their result fell short of statistical significance ($p = 0.059$). In a retrospective and nonrandomized study of 73 patients in an outpatient clinic, Likar et al[26] showed that group education sessions could improve compliance with CPAP therapy. More recently, in a prospective study of 80 consecutive new patients with OSA, randomized to receive usual support or additional nursing input (including CPAP education at home and involving their partners, a 3-night trial of CPAP titration in a sleep center, followed by additional home visits), Hoy et al[27] reported that there was greater improvement of objective CPAP compliance, OSA symptoms, mood, and reaction time in the intensively supported group at 6 months. However, such an intensive approach, which involves 2 extra nights of CPAP titration and additional nursing staff to provide home visits, is rather costly and may not be feasible or cost-effective in most sleep disorder centers with preexisting long queues for sleep studies.

Despite supplementing the education session with a 15-min videotape, a longer CPAP education session by nurses, telephone support in the first 3 months, and early follow-up, CPAP compliance was not significantly increased among our new CPAP users in the AS group. As there was no significant difference between the two groups in terms of CPAP usage, it was not surprising that, apart from a greater improvement of digit span of marginal statistical significance ($p = 0.049$) at 4 weeks in the AS group, there was no significant difference in improvement of other cognitive function outcome variables at 4 weeks, and subsequent reassessment of cognitive function and ESS at 12 weeks.

The AS group reported greater improvement of quality of life at 4 weeks and 12 weeks ($p = 0.008$ and $p = 0.047$, respectively), and this was likely related to the psychological support and attention given to the patients by our nurses via telephone daily for the first 2 days, weekly for the first 4 weeks, and monthly for the subsequent 2 months, together with the weekly review by physicians in the first 2 weeks immediately after commencement of CPAP therapy.

The lack of significant improvement in CPAP compliance in the AS group might be due to the fact that our BS program was highly adequate and the additional measures did not confer any extra benefit. Indeed, overall, 71% of our patients in the BS group used their CPAP for at least 4 h/d, and at least 70% of the nights per week at 4 weeks and 12 weeks. The compliance rate was slightly lower than the 79% reported by Pepin et al[28] in a prospective, multicentre, European study, but much higher than that of 46% reported by Kribbs et al[12] in an American population. Our BS program consisted of educational brochures on OSA and CPAP, practical CPAP education, and acclimatization sessions conducted by our nurses, plus early CPAP clinic review at 4 weeks; these are all essential elements ensuring good CPAP compliance. The mean CPAP usage in the BS group of this study was more than the 3.9 h/night reported by Hoy et al[27] in their control group at 6 months. Apart from different patient populations, the major difference between their protocol and ours is the inclusion of educational brochures in our study. In addition, most of our patients had to purchase or rent the CPAP units themselves, and this factor may have increased the motivation of our patients. Our compliance results support the findings by Kribbs et al,[12] that the degree of compliance established within the first month of treatment with CPAP reliably predicts compliance at 3 months. Moreover, self-reported compliance, which was overestimated by our patients as in other studies,[12,13,29] should not be considered a reliable means to establish compliance.

There were several limitations in our study. Despite the randomization process, there were some differences in the baseline ESS score and trail B between the two groups. Hence, analysis was based on comparison of changes from baseline for the variables between the two groups. Apart from the CPAP usage measured by the Respironics Aria and Encore software and cognitive function tests, all other outcome variables such as ESS and SAQLI were subjective rather than objective measurements. There was also a technical failure with the Aria/Encore software, resulting in missing CPAP compliance data for two patients in the BS group and nine patients in the AS group at 12 weeks. Until there is breakthrough in the treatment of sleep-disordered breathing, CPAP remains a life-long therapy for most patients with OSA, but the results reported in this study were only up to 3 months of therapy. However, there is evidence from a large follow-up study that the average nightly CPAP use within the first 3 months is strongly predictive of long-term

use.[30] As an additional criticism of this study, automatic CPAP titration may not be regarded as standard practice by every sleep laboratory. However, the significant improvement of ESS at 12 weeks and SAQLI at 4 weeks and 12 weeks in both groups reassured us that the attended automatic CPAP titration had been effective. Automatic CPAP titration does not reduce the use[19] or acceptance[20] of CPAP compared with manual titration. The subsequent reduction in CPAP requirement in our patients has also been observed even with manual titration by Jokic et al[31] within 2 weeks of starting CPAP treatment, and this was likely to be due to resolution of upper-airway edema.[32]

In summary, this randomized controlled study shows that augmentation of CPAP education and support does not improve CPAP usage at 1 month and 3 months following commencement of CPAP treatment, but leads to a greater improvement of quality of life during the reinforced period. Nevertheless good basic education and support are essential in ensuring good CPAP compliance, and this is reflected by the high level of CPAP compliance in our patient population.

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