Original Article

Quality of Life and Adverse Side Effects of Continuous Positive Airway Pressure Therapy in Thai Patients with Obstructive Sleep Apnea

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Objective: To evaluate the quality of life (QOL) and adverse side effects of continuous positive airway pressure (CPAP) therapy in Thai patients with obstructive sleep apnea (OSA).

Material and Methods: The present study was conducted at Siriraj Hospital by reviewing medical records, symptoms questionnaire, functional outcomes of sleep questionnaire (FOSQ), and Epworth sleepiness scales (ESS) of adult OSA patients who were treated with CPAP between November 2010 and June 2017. Patients who failed to follow-up or had incomplete questionnaires were excluded.

Results: Data of 135 OSA patients, which included 99 males and 36 females with a mean age of 50.2±11.1, apnea-hypopnea index of 48.8±30.2 events per hour, and follow-up time of 50.6 months with a range of 13 to 79 months, were recruited. There were 57 patients or 42.2% using fixed-pressure CPAP and 78 patients or 57.8% using auto-adjusting CPAP. A statistically significant improvement in scores of all FOSQ subscales, global FOSQ, and ESS were found after CPAP therapy ($p<0.05$). Good treatment adherence through self-reported data was found in 123 patients or 91.1% at approximately three months and 97 patients or 71.9% after more than one year follow-up. The most common reported side effects of CPAP were mask discomfort at 60%, nose congestion at 47.4%, and dry mouth at 40%. However, these side effects were mostly mild to moderate and tolerable.

Conclusion: CPAP therapy can significantly improve QOL of Thai patients with OSA who continuously use it in both the short-term and long-term. However, side effects are common especially mask discomfort and nasal congestion in short-term.

Keywords: Obstructive sleep apnea; Quality of life; Continuous positive airway pressure; CPAP; Side effects; Thai

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OSA is a common disorder characterized by chronic repetitive cessations or decrements of airflow through the upper airway during sleep. It can potentially lead to adverse public health consequences such as excessive daytime sleepiness (EDS), impaired quality of life (QOL)[1-3], hypertension[4], motor vehicle accidents(5), cardiovascular diseases[6], stroke, depression, and sexual dysfunction[7]. Although factors such as severity of disease, underlying etiology, and requirement of patients need to be considered for treatment, continuous positive airway pressure (CPAP) is still accepted as the first line of defense and is currently the most common therapy[1,8]. It works by maintaining upper airway patency as a pneumatic splint.

Provided that all patients, especially severe cases[9], are treated with CPAP successfully, adverse consequences of OSA may be prevented or improved[10-15]. However, its limitations and complications lead to a poor long-term compliance rate with less than 50% commonly reported in literature[8,16,17]. In Thailand, reports of CPAP outcomes and side effects are still limited, and it is unclear if

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it differed from other centers[18,19]. The objectives of the present study were to evaluate the QOL of Thai patients with OSA before and after CPAP, as well as the side effects of this treatment.

Materials and Methods

The present study was a retrospective study conducted at the Department of Otorhinolaryngology and Siriraj Sleep Center, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand, after approval from the Siriraj Institutional Review Board (SIRB), COA no. Si 344/2014. Medical charts and related questionnaires of OSA patients with an AHI of five or more per hour aged 18 years or older treated with CPAP between November 2010 and June 2017 were reviewed. These included specific and structured form of self-reported questionnaires regarding the symptoms and potential side effects of CPAP, functional outcomes of the sleep questionnaire (FOSQ), and Epworth sleepiness scales (ESS). The severity of these symptoms and side effects were evaluated using ordinal scale with 0 for none, 1 for mild to moderate, and 2 for severe. All of which were obtained during regular visits, especially in the first three months and after one year. The sample size was calculated using the nQuery tool to be at least 128 plus around 5% to 10% for samples with insufficient data.

Continuous positive airway pressure

All patients were treated with either auto-titrating CPAP (APAP) or manual-titrating (fixed pressure) CPAP machines according to their preference and affordability. CPAP education and opportunities in the first to third week of home trial period was provided to all patients. Various interfaces, including a nasal mask, nasal pillow, or full-face mask were properly fitted and selected by patients. Pressure settings were derived from split-night polysomnography (PSG), full-night CPAP titration PSG, or home APAP titration using the ninetieth to ninety-fifth percentile pressure. Treatment compliance or adherence along with treatment related complications was monitored using data recorded by the machines and patients' self-reports.

Good CPAP compliance[20] was defined as minimum usage of 4 hours or more per day and at least 5 days per week or approximately 70%. However, they were self-report compliance, thus, they may have been overestimated.

Functional outcomes of sleep questionnaire

The FOSQ is a 30-item self-administered disease-specific QOL questionnaire to assess the impact of sleep on five domains of daily activities. These consist of general productivity with eight items, vigilance with seven items, social outcomes with two items, activity level with nine items, and sexual relationships with four items. The score of each question ranges from one to four with a score of 0 coded as not available (N/A) or missing response and not included in the calculation. Lower scores translated into worse QOL. The mean of each subscale and a global score ranged from 1 to 4 and 5 to 20, respectively. The authors used the validated Thai version of the FOSQ[21] in the present study with permission because it is one of the most widely used tools for assessing sleep-related QOL.

Epworth sleepiness scales

The ESS is an eight-item self-administered questionnaire to assess the chance of dozing or degree of daytime sleepiness in common situations. The score of each item ranges from 0 to 3 and thus the total score ranged from 0 to 24. Low ESS scores represent less daytime sleepiness. In the present study, the authors used the validated Thai version of the ESS with permission from the patients[18].

Statistical analysis

Continuous data, such as scores of the questionnaires were presented as mean ± standard deviation (SD) and categorical data presented as numbers and percentages. To assess changes in related scores before and after treatment, paired t-tests, and analysis of variance (ANOVA) were used accordingly. Statistical analysis was performed using the PASW Statistics, version 18.0 (SPSS Inc., Chicago, IL, USA). The accepted significance level was p-value less than 0.05 in 2-tailed tests.

Results

The data of 135 patients, including 99 males and 36 females, treated using CPAP and with a mean follow-up time of 50.6 months and a range of 13 to 79 months, were recruited in the present study. The details of patients' demographic data are presented in Table 1. Seventy-eight patients (57.8%) used APAP and 57 patients (42.2%) used fixed-pressure CPAP. One hundred fifteen patients also used nasal masks. The averages device adherent time were 5.86 and 5.80 hours per night at post-treatment follow-up in the first three months and after more than one year, respectively. Good treatment adherence was found in 123 patients or 91.1% at three months and 97

Table 1. Demographic data of the recruited OSA patients (n=135)

Characteristics	Data
Male; n (%)	99 (73.3)
Age (years); mean±SD	50.2±11.1
BMI (kg/m^2); mean±SD	29.0±5.5
Underlying diseases; n (%)	
Hypertension	36 (36.7)
Cardiovascular diseases	2 (2.0)
Cerebrovascular diseases	1 (1.0)
Rhinitis/sinusitis	13 (13.3)
Diabetes	13 (13.3)
Dyslipidemia	30 (30.6)
Psychiatric diseases	2 (2.0)
Pulmonary diseases/asthma	1 (1.0)
AHI (events/hour); mean±SD	48.8±30.2
ESS scores; mean±SD	10.4±5.3
Severity; n (%)	
Mild OSA	18 (13.3)
Moderate OSA	28 (20.7)
Severe OSA	89 (65.8)

BMI=body mass index; AHI=apnea-hypopnea index; ESS=Epworth sleepiness scales; OSA=obstructive sleep apnea; SD=standard deviation

patients (71.9%) at more than one year follow-up. There were statistically significant improvements in the FOSQ and ESS scores after CPAP therapy as shown in Table 2. However, there was no statistically significant change in the FOSQ scores of patients before and after CPAP treatment between those who utilized APAP and CPAP (Table 3) as well as between those who had good compliance and those who had poor compliance (Table 4). Most therapeutic side effects from self-reported ranged from none or mild to moderate and this decreased over time. Further details are shown in Table 5.

Discussion

Although previous studies show that CPAP therapy can significantly improve both generic and disease-specific QOL in OSA patients with only mild to moderate side effects[22], data in Thailand is still limited[3]. The results of the present study in 135 Thai patients with OSA revealed that there was significant improvement in all subscales of the FOSQ and ESS scores in the short-term and long-term after being treated with CPAP, provided that patients continued using the device and did not stop the follow-ups. When comparing patients treated with APAP and CPAP, there was no statistically significant difference in QOL. These findings were in accordance with the results of previous studies[23-29]. Unlike other findings, the present study showed no significant difference between individuals who had good and poor CPAP compliance[30,31]. This might be due to incomplete data from CPAP monitoring as some machines did not have memory cards or did not provide correct data, thus, the compliance of patients who used them was obtained from the questionnaires instead(32). However, it is possible that patients still had good QOL despite using CPAP less than four hours per night[33].

Regarding side effects of CPAP, mask discomfort, mouth dryness, and nasal congestion were the most common findings reported across the study period, which corresponded with the previous studies[22,34]. Most CPAP-related side effects reported by patients were in the mild to moderate category and tolerable. Interestingly, mask discomfort was reported in the short-term rather than long-term. This was due to

Table 2. Comparison of FOSQ and ESS scores pre- and post-treatment with CPAP in the three months and after more than 1 year of follow-up

	Pre-treatment (n=135); mean±SD	Post-treatment; mean±SD		p-value
		1st follow up (n=135)	2nd follow up (n=135)	
FOSQ				
General productivity	3.1±0.9	3.9±1.1	3.5±0.3	<0.001**
Social outcome	3.4±0.9	3.8±0.4	3.9±0.2	0.005*
Activity level	3.1±0.7	3.4±0.4	3.5±0.3	<0.001**
Vigilance	2.8±1.0	3.1±0.5	3.3±0.4	<0.001**
Sexual relationship	3.0±0.9	3.3±0.7	3.3±0.6	0.037*
FOSQ global scores	14.8±3.9	17.0±2.3	17.2±1.5	<0.001**
ESS scores	10.4±5.3	5.3±4.1	4.1±4.3	<0.001**

FOSQ=functional outcomes of sleep questionnaire; ESS=Epworth sleepiness scale; CPAP=continuous positive airway pressure; SD=standard deviation

1st follow up: at least three months after treatment initiation, 2nd follow up: at least twelve months after treatment initiation

* The mean difference was significant at the level of <0.05; ** At the level of <0.001

Table 3. The comparison of post-treatment FOSQ scores between CPAP and APAP

	1st follow up; mean±SD			2nd follow up; mean±SD		
	CPAP	APAP	p-value	CPAP	APAP	p-value
General productivity	3.8±0.3	3.7±0.4	0.57	3.7±0.3	3.7±0.3	0.29
Social outcome	3.9±0.3	3.9±0.3	0.66	3.9±0.4	3.8±0.3	0.74
Activity level	3.6±0.4	3.5±0.5	0.90	3.5±0.4	3.6±0.4	0.09
Vigilance	3.5±0.5	3.5±0.5	0.96	3.4±0.4	3.6±0.5	0.14
Sexual relationship	3.4±0.9	3.4±0.8	0.98	3.3±1.0	3.5±0.8	0.26
FOSQ global	18.1±1.7	18.1±1.9	0.99	17.6±1.7	18.3±1.9	0.13

FOSQ=functional outcomes of sleep questionnaire; CPAP=continuous positive airway pressure; APAP=auto-titrating CPAP; SD=standard deviation

1st follow up: at least three months after treatment initiation, 2nd follow up: at least twelve months after treatment initiation

The mean difference is significant at the level of <0.05

Table 4. The comparison of post-treatment FOSQ scores between good compliance group and poor compliance group

	1st follow up; mean±SD			2nd follow up; mean±SD		
	Good compliance	Poor compliance	p-value	Good compliance	Poor compliance	p-value
General productivity	3.7±0.3	3.7±0.7	0.64	3.7±0.3	3.8±0.4	0.37
Social outcome	3.9±0.2	3.8±0.6	0.15	3.8±0.4	3.9±0.5	0.84
Activity level	3.5±0.4	3.5±0.6	0.78	3.5±0.4	3.6±0.4	0.67
Vigilance	3.5±0.5	3.4±0.7	0.84	3.5±0.5	3.5±0.5	0.49
Sexual relationship	3.4±0.8	3.3±1.0	0.67	3.3±0.9	3.6±0.6	0.10
FOSQ global	18.1±1.5	17.7±3.2	0.50	17.8±1.8	18.3±2.0	0.31

FOSQ=functional outcomes of sleep questionnaire; CPAP=continuous positive airway pressure

1st follow up=at least three months after treatment initiation, 2nd follow up=at least twelve months after treatment initiation

The mean difference is significant at the level of <0.05

Table 5. Side effects of CPAP use in the first three months and after one year follow-up (n=135)

Side effects	1st follow up; n (%)			2nd follow up; n (%)		
	None	Mild to moderate	Severe	None	Mild to moderate	Severe
Nose congestion	71 (52.6)	62 (45.9)	2 (1.5)	88 (65.2)	45 (33.3)	2 (1.5)
Rhinorrhea	89 (65.9)	46 (34.1)	0 (0.0)	105 (77.8)	29 (21.5)	1 (0.7)
Mask discomfort	54 (40.0)	77 (57.0)	4 (3.0)	89 (65.6)	46 (34.4)	0 (0.0)
Dry eye/air leak	81 (60.0)	53 (39.2)	1 (0.8)	96 (71.5)	36 (26.3)	3 (2.2)
Rash/skin irritation	88 (65.2)	47 (34.8)	0 (0.0)	116 (85.9)	19 (14.1)	0 (0.0)
Self-image	103 (76.3)	31 (22.9)	1 (0.8)	100 (74.1)	35 (25.9)	0 (0.0)
Dry mouth	81 (60.0)	54 (40.0)	0 (0.0)	67 (49.6)	65 (48.1)	3 (2.2)

CPAP=continuous positive airway pressure

1st follow up: at least three months after treatment initiation, 2nd follow up: at least twelve months after treatment initiation

patients' ability to adapt or become familiar with their masks. Even though chin straps, proper mask fitting, switching to full-face masks, humidifiers, and pressure reduction were frequently prescribed as a routine protocol to alleviate mouth dryness, it was still reported in the long-term. Therefore, better understanding of underlying etiologies and better solutions to prevent airway dryness from CPAP is required. Nasal congestion was also a common side effect in the present study. To reduce this problem, proper humidification, saline sprays, antihistamines, and nasal decongestants were prescribed. If it did not improve the condition, nasal surgery such as radiofrequency Inferior turbinate reduction or septoplasty, was performed as necessary.

There were limitations of the present study. First, there was no control group to compare changes of clinical findings. Second, the data was subjective or self-reported by patients, so there may have been biases in responses to the questionnaires. Third,

information regarding brands or models of CPAP machines and mask types in the present study was not recorded, so the authors were unable to analyze the impact of these factors. Finally, there was no data on the reasons of the patients failed follow up, so the authors could not conclude if it occurred due to CPAP side effects. Future research with prospective design that focuses on specific subgroups of OSA patients, a control group, and use of additional objective measurements is required.

Conclusion

The present study confirmed that CPAP therapy can improve QOL of Thai patients with OSA, and there are minor adverse side effects in both the short-term and long-term. Patients treated with CPAP therapy should have a comprehensive follow-up with physicians to solve relevant problems and improve therapeutic outcomes.

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Conflicts of interest

The authors declare no conflict of interest in this study.

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