

The relationship between continuous positive airway pressure adherence and health literacy in patients with sleep apnea syndrome: A prospective cohort study
(睡眠時無呼吸症候群における持続陽圧換気療法のアドヒアランスとヘルスリテラシーの関係についての前向きコホート研究)

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■ABSTRACT

Objective: We aimed to assess differences in health literacy between patients adherent and non-adherent to continuous positive airway pressure (CPAP) therapy.

Methods: We included patients newly diagnosed with sleep apnea syndrome who had started CPAP therapy between February 2019 and October 2020 with ≥ 6 follow-up months or who self-interrupted CPAP therapy < 6 months. We recorded the CPAP wearing time after 3 and 6 months. Patients were divided into the CPAP adherent (using CPAP for ≥ 4 hours per night) and non-adherent (self-interrupted CPAP therapy/using CPAP for < 4 hours per night) groups. We compared the European Health Literacy Survey Questionnaire 47 (HLS-EU-Q47) median score between CPAP adherent and non-adherent groups after 3 months and 6 months.

Results: At 3 months, there were 10 and 27 patients in the CPAP adherent and non-adherent groups, respectively. After 6 months, there were 15 and 22 patients in the CPAP adherent and non-adherent groups, respectively. There were no significant differences in the HLS-EU-Q47 median score after 3 and 6 months between CPAP adherent and non-adherent groups. Among the 27 patients in the CPAP non-adherent group after 3 months, only 6 patients became CPAP adherent after 6 months. There was a significant difference in the HLS-EU-Q47 median score between the patients who became adherent to CPAP and who remained non-adherent to CPAP after 6 months.

Conclusion: There were no significant differences in health literacy after 3 and 6 months; however, previously non-adherent patients who subsequently became adherent tended to have higher health literacy.

Keywords: Adherence; CPAP; Health literacy; HLS-EU-Q47; SAS

■INTRODUCTION

Sleep apnea syndrome is a sleep-related respiratory disorder characterized by repeat apnea, hypoxia, and respiratory effort-related arousal during sleep (1). The standard therapy for sleep apnea syndrome is continuous positive airway pressure (CPAP) therapy, which has been shown to improve daytime sleepiness, quality of life (QOL) (2, 3), impaired glucose tolerance, hypertension, and cardiovascular events (4–7). However, CPAP adherence can be problematic since some patients self-interrupt CPAP usage or use it for a shorter-than-expected duration (8, 9).

It has been suggested that only 30–80% of patients are CPAP adherent (10). Factors associated with CPAP non-adherence include mild severity of sleep apnea syndrome, mild subjective symptoms, depression, claustrophobia, and poor upper airway patency (11).

On the other hand, poor medication adherence and poor control of chronic diseases, including diabetes mellitus, are associated with poor health literacy (12–15). Health literacy is defined as an individual's capacity to obtain, process, and understand basic health information and services required for making appropriate health decisions (16). There has been increasing attention on health literacy in the field of chronic disease management, with a report indicating that it is an important factor (17).

Health literacy can be categorized into three domains: health care, disease prevention, and health promotion. Some tools have been developed to comprehensively measure these domains of health literacy (18). This includes the European Health Literacy Survey

Questionnaire 47 (HLS-EU-Q47) (19), which was used in this study. We hypothesized that CPAP adherence is associated with health literacy and, therefore, aimed to examine the relationship between CPAP adherence and health literacy.

■METHODS

This prospective cohort study was conducted according to the Strengthening the Reporting of Observational studies in Epidemiology guidelines.

Participants

We included patients who visited the sleep apnea specialist outpatient department of Chiba University Hospital between February 2019 and October 2020. Five sleep specialist physicians were in charge of managing the patients. The patients had been newly diagnosed with sleep apnea syndrome and had started CPAP therapy, with ≥ 6 follow-up months or self-interruption of CPAP therapy < 6 months.

CPAP therapy indications were based on the Japanese insurance system; specifically, having problematic symptoms such as daytime sleepiness and ≥ 20 episodes of apnea, hypoxia, and respiratory effort-related arousal during sleep assessed by means of polysomnography (PSG; apnea-hypopnea index [AHI] ≥ 20) or having 40 episodes of apnea and hypoxia during sleep based on the out-of-center sleep test (AHI ≥ 40). We used WatchPAT[®]; Philips Respironics Inc., PA, USA

or SAS-2100®; Teijin Pharma Ltd., Tokyo, Japan for out-of-center sleep test.

We excluded patients who did not consent to study participation, did not answer the minimum number of required items on the HLS-EU-Q47, and those with the lowest or highest HLS-EU-Q47 score for all items.

Regarding sample size estimation, the Mann–Whitney U test was conducted using the HLS-EU-Q47 score, a confidence interval of 95%, and detection power of 0.8, with reference to a previous study on CPAP non-adherent patients (10, 20) as well as focus group discussions with experts and research teams. The required sample size was estimated as 52 patients.

CPAP adherence

We defined patients who were using CPAP for ≥ 4 hours per night as CPAP adherent (5, 6, 21). Contrastingly, we defined patients who self-interrupted CPAP therapy or used CPAP for < 4 hours per night as CPAP non-adherent. CPAP adherence was determined at 3 and 6 months after starting CPAP therapy, with the CPAP adherent and non-adherent groups being defined at each time as 3M adherent, 3M non-adherent, 6M adherent, and 6M non-adherent group. Moreover, the patients who were 3M non-adherent and improved to CPAP adherent at 6 months after starting CPAP therapy were defined as 3M non-adherent 6M adherent group. Those who were 3M non-adherent and still CPAP non-adherent at 6 months after starting CPAP therapy were defined as 3M non-adherent 6M non-adherent group.

In this study, we did not conduct any educational program for improving health literacy.

Data collection

The HLS-EU-Q47 was developed by the European Health Literacy Survey consortium and is comprised of 47 questions, including 16, 15, and 16 questions about health care literacy (HC-HL), disease prevention health literacy (DP-HL), and health promotion health literacy (HP-HL), respectively.

The Japanese version of the HLS-EU-Q47 was developed and validated as an appropriate tool to measure health literacy. All the questions had 5 answer options, which were “very easy,” “fairly easy,” “fairly difficult,” “very difficult,” and “do not know/not applicable.” They were scored as follows: 1 = “very difficult,” 2 = “fairly difficult,” 3 = “fairly easy,” 4 = “very difficult.” The question, “do not know/not applicable,” was considered as a missing value (22).

Based on previous literature, the minimum number of valid responses was 43 among 47 questions (23). All the patients completed the self-administered HLS-EU-Q47 at the first visit. Similar to the original scale, the scores were standardized on a metric between 0 and 50 based on the following formula (23):

$$(Mean - 1) \times \frac{50}{3}$$

We compared the HLS-EU-Q47 median score between the 3M adherent and 3M non-adherent, and between the 6M adherent and 6M non-adherent groups, respectively.

We also compared the components of health literacy, including HC-HL, DP-HL, and HP-HL. Moreover, we investigated possible confounding factors, including age; sex; height; weight; body mass index (BMI); smoking history; depressive mood; disinterest; claustrophobia; nose-related diseases; difficulty falling asleep; sufficient sleeping time; AHI; Epworth Sleepiness Scale (ESS). Sleep latency of ≥ 30 minutes was considered long sleep latency (24), while ≥ 6 sleeping hours was considered sufficient sleep time (24).

Additionally, we performed a sub-analysis by assessing the HLS-EU-Q47, HC-HL, DP-HL, and HP-HL median score between the 3M non-adherent 6M adherent group and 3M non-adherent 6M non-adherent group.

Statistical analysis

All statistical analyses were performed using SPSS Statistics for Windows 26.0 (IBM Corp., NY, USA). Statistical significance was set at $p < 0.05$. The Mann–Whitney U test (two-sided test) was used for between-group comparisons of the HLS-EU-Q47, HC-HL, DP-HL, and HP-HL median score after 3 and 6 months.

Moreover, Pearson’s chi-square test (two-sided test) and the Mann–Whitney U test (two-sided test) were used for between-group comparisons of age; sex; height; weight; BMI; smoking history; depressive mood; disinterest; claustrophobia; nose-related diseases; difficulty falling asleep; sufficient sleeping time; AHI; ESS. We used AHI regarding the severity of sleep apnea syndrome.

Ethical approvals

This study was approved by the ethics committee of Chiba University Hospital. Before providing informed consent, the patients received an explanation of the research. This study was registered at UMIN Clinical Trials Registry (UMIN-CRT) (UMIN000037793).

■RESULTS

During the study period, 48 patients started CPAP therapy for the first time and were followed up for ≥ 6 months or self-interrupted CPAP therapy < 6 months. We excluded 2 patients who did not consent to study participation, 6 patients who did not answer the minimum number of the HLS-EU-Q47 items, and 3 patients who received the lowest or highest score for all the HLS-EU-Q47 items (Figure 1).

【Figure 1 here】

Among the 37 patients, 10 (27.0%) and 27 (73.0%) patients were in the 3M adherent and non-adherent groups, respectively. Moreover, 6 (22.2%) patients self-interrupted CPAP therapy and 21 (77.8%) patients used CPAP for < 4 hours per night. Additionally, 15 (40.5%) and 22 (59.5%) patients were in the 6M adherent and non-adherent groups, respectively. Further, 6 (27.3%) patients self-interrupted CPAP therapy and 16 (72.7%) patients used CPAP for < 4 hours per night. There were no significant differences between 3M adherent and non-adherent groups, 6M adherent and non-adherent groups respectively, in age; sex; height; weight; BMI; smoking history; depressive mood; disinterest; claustrophobia; nose-related diseases; difficulty falling asleep; sufficient sleeping time; AHI; ESS (Table 1).

【Table 1 here】

There was no significant difference in the HLS-EU-Q47 median score between the 3M adherent and non-adherent groups (32.7 vs. 34.4, respectively; $p = 0.85$). Moreover, there were no significant between-group differences in the median score for HC-HL (31.3 vs. 36.5; $p = 0.88$), DP-HL (33.3 vs. 36.7; $p = 0.94$), and HP-HL (29.2 vs. 31.3; $p = 0.93$) (Table 2).

【Table 2 here】

Similar to the 3M groups, there was no significant difference in the HLS-EU-Q47 median score between the 6M adherent and non-adherent groups (37.2 vs. 33.2, respectively; $p = 0.18$). Moreover, there were no significant between-group differences in the median score for HC-HL (37.0 vs. 36.5; $p = 0.30$), DP-HL (42.2 vs. 33.9; $p = 0.28$), and HP-HL (31.3 vs. 30.7; $p = 0.20$) (Table 3).

【Table 3 here】

Among the 27 patients in the 3M non-adherent group, 6 patients were the 3M non-adherent 6M adherent group and 21 patients were the 3M non-adherent 6M non-adherent group. There was a significant difference in the HLS-EU-Q47 median score between the 3M non-adherent 6M adherent and 3M non-adherent 6M non-adherent group (46.8 vs. 33.0, respectively; $p = 0.031$). Moreover, there were significant between-group differences in the median score for HC-HL (44.4 vs. 36.5; $p = 0.004$) and HP-HL (45.8 vs. 30.2; $p = 0.031$). There

was no significant between-group difference in the median score for DP-HL (49.5 vs. 33.3; $p = 0.075$) (Table 4).

【Table 4 here】

Among the 27 patients in the 3M non-adherent group, there were no significant differences between the 3M non-adherent 6M adherent and 3M non-adherent 6M non-adherent groups in age; sex; height; weight; BMI; smoking history; presence of depressive mood, disinterest, claustrophobia, nose-related diseases, difficulty falling asleep, sufficient sleeping time; AHI; ESS (Table 5).

【Table 5 here】

■DISCUSSION

We observed no significant between-group differences in health literacy after 3 and 6 months. Additionally, among the patients who were CPAP non-adherent after 3 months, those who became CPAP adherent after 6 months showed a tendency of having higher health literacy.

Patients with high health literacy are less likely to self-interrupt drug therapy (12) and may have better control over chronic diseases, including diabetes mellitus (13–15). Individuals with higher health literacy are considered to have a better understanding of the disease and treatment significance, as well as higher motivation for health improvement. Our findings demonstrated the possibility of an association between high health literacy and CPAP adherence

improvement. Patients with high health literacy showed a tendency toward adherence, even if not ideally employing CPAP in the short term, but gradually acquiring the ability to use it appropriately.

Regarding the lack of association between short-term CPAP adherence and health literacy, CPAP adherence is influenced by not only health literacy, but also other components, such as using individualized optimal CPAP mask and pressure settings (25), and subjective symptom improvement (26). If the patients have optimal CPAP mask and pressure settings, and feel improvement of subjective symptoms in the short term, they might adhere to CPAP usage despite low health literacy. If not, the ability to understand importance of CPAP usage might be associated with health literacy. Therefore, CPAP adherence improvement can be associated with high health literacy.

In the analysis of the HLS-EU-Q47 items, there were no significant differences between adherent and non-adherent groups in the HC-HL, DP-HL, and HP-HC median score after 3 and 6 months. However, there were significant differences in the HC-HL and HP-HL median score between the 3M non-adherent 6M adherent and 3M non-adherent 6M non-adherent group. HC-HL evaluates the acquisition, understanding, evaluation, and utilization of information in healthcare, which includes the ability to understand and follow the doctor's instructions (23). Therefore, patients with a high HC-HL score may show improved CPAP adherence. HP-HL evaluates the acquisition, understanding, evaluation, and utilization of information in health promotion. Namely, HP-HL includes the ability to understand and utilize information that facilitates health promotion, including the ability to make decisions to improve health condition (23). Therefore,

patients with a high HP-HL score may show improved CPAP adherence. DP-HL evaluates the acquisition, understanding, evaluation, and utilization of information in disease prevention, which includes the ability to understand and utilize information that facilitates disease prevention, including vaccination and medical examinations (23); therefore, DP-HL may not be as effective as HC-HL and HP-HL in evaluating CPAP adherence in patients diagnosed with sleep apnea syndrome.

Regarding the clinical application of our findings, it may be possible to predict self-interruption and inadequate CPAP usage through pre-CPAP evaluation of health literacy. Additionally, health literacy can be improved by education (27), which may facilitate the ideal use of CPAP.

This study has several limitations. First, we included a small number of patients since the epidemic of the 2019 coronavirus disease (COVID-19) decreased the number of outpatients and PSG patients requiring hospitalization. In this study, there was no significant difference between the 6M adherent and non-adherent groups; however, the 6M adherent group tended to have higher HLS-EU-Q47 median score than the 6M non-adherent group. Therefore, a significant difference may appear with the inclusion of more cases. Additionally, patients who could not be followed up for 6 months, for reasons such as being transferred to another hospital, were not included. Most of these patients were stable; therefore, they were requested to be transferred to a neighboring hospital. These patients, who were likely to be in the CPAP adherent group if they continued to be followed up, were not included in the study. Second, this was a single-center study

in a university hospital; therefore, this study may not be representative of all patients with sleep apnea syndrome. A previous study reported that the average HLS-EU-Q47 score in Japan was 25.3 (22), which is lower than the HLS-EU-Q47 median score in this study. Although few studies in Japan have investigated differences in CPAP adherence and health literacy between visiting hospitals, patients who visit university hospitals may have higher health literacy than those in other hospitals, assuming that one can willingly visit any hospital in Japan. Third, in this study, mask selection and pressure settings for CPAP therapy were at the discretion of each doctor. It was unrealistic to control this given the involvement of the patients' preference. Fourth, not all the patients in this study underwent PSG. Given the Japanese medical insurance system and the prevalence of COVID-19, CPAP may be introduced without PSG when the out-of-center sleep test meets the CPAP introduction criteria. Therefore, in this study, for patients who did not undergo PSG, the results of the out-of-center sleep test were used as the AHI.

■CONCLUSION

There were no significant differences between adherent and non-adherent groups in health literacy after 3 and 6 months; however, among the patients who were CPAP non-adherent after 3 months, those who became CPAP adherent after 6 months tended to have higher health literacy than those who did not.

Conflict of Interest: There are no conflicts of interest to declare for either the lead author or co-authors.

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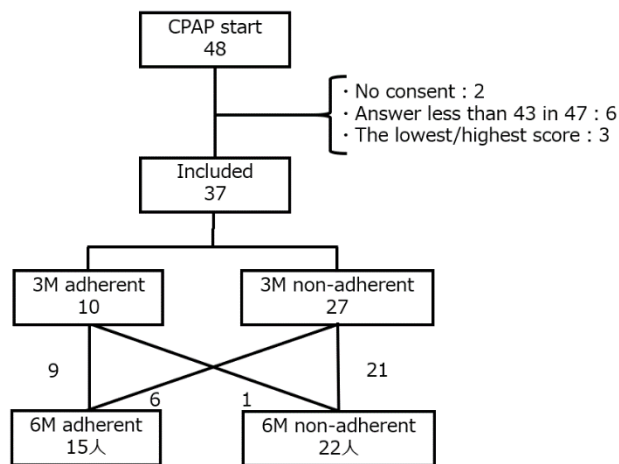
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Figure 1: Study flowchart.



Following the adherence of patients who started CPAP after 3 and 6 months. No consent: The patients who did not consent to study participation. Answer less than 43 in 47: The patients who did not answer the minimum number of items on the HLS-EU-Q47. The lowest/highest score: The patients who received the lowest or highest score for all the HLS-EU-Q47 items.

CPAP: continuous positive airway pressure, HLS-EU-Q47: European Health Literacy Survey Questionnaire 47, 3M adherent/3M non-adherent: CPAP adherent/non-adherent after 3 months, 6M adherent/non-adherent: CPAP adherent/non-adherent after 6 months.

Table 1: Comparison of clinical characteristics between patients in the

	3M adherent (n=10)	3M non-adherent (n=27)	P-value	6M adherent (n=15)	6M non-adherent (n=22)	P-value
Age, yr *	58.0 (41.0-72.0)	54.0 (49.0-65.0)	0.78	54.0 (42.0-72.0)	55.5 (48.5-65.3)	0.66
Sex, Male (%)	6 (60.0)	20 (74.1)	0.41	9 (60.0)	17 (77.9)	0.27
Height, cm *	167.0 (160.0-170.5)	167.0 (163.0-173.0)	0.39	169.0 (162.0-172.0)	166.5 (162.0-172.3)	0.94
Weight, kg †	83.0 (67.1-105.5)	80.0 (68.7-98.0)	0.88	79.0 (61.0-100.0)	81.5 (70.4-98.0)	0.70
BMI, kg/m ² †	28.7 (24.9-39.6)	28.2 (25.0-32.7)	0.91	28.4 (24.7-30.1)	29.0 (26.4-34.2)	0.42
Smoking history, No (%)	7 (70.0)	13 (48.1)	0.24	10 (66.7)	10 (45.6)	0.21
Depressive mood, No (%)	4 (40.0)	10 (37.0)	0.87	6 (40.0)	6 (30.0)	0.83
Disinterest, No (%)	2 (20.0)	6 (22.2)	0.88	3 (20.0)	5 (22.7)	0.85
Claustrophobia, No (%)	2 (20.0)	1 (3.7)	0.27	2 (13.3)	1 (4.5)	0.35
Nose related diseases, No (%)	5 (50.0)	10 (37.0)	0.48	8 (53.3)	7 (31.8)	0.21
Difficulty falling asleep, No (%)	4 (44.4) †	10 (40.0) ‡	0.82	5 (33.3)	9 (47.4) ‡‡	0.42
Sufficient sleep time, No (%)	7 (77.8) †	17 (68.0) ‡	0.58	10 (66.7)	14 (73.7) ‡‡	0.67
AHI †	46.1 (30.5-53.7)	44.1 (37.1-52.9)	0.93	49.4 (37.1-61.7)	42.0 (31.4-49.7)	0.25
ESS †	6.0 (2.5-10.0) †	6.0 (4.5-10.0) ‡	0.73	7.0 (4.8-11.3) †	5.5 (4.0-8.8) ‡	0.29

3M adherent and 3M non-adherent groups.

* : Median (1st and 3rd quartiles)

†: 1 patient did not answer

‡ : 2 patients did not answer

‡‡: 3 patients did not answer

3M adherent/3M non-adherent: CPAP adherent/non-adherent after 3 months. 6M adherent/6M

non-adherent: CPAP adherent/non-adherent after 6 months. CPAP: continuous positive airway

pressure, BMI: body mass index, AHI: apnea-hypopnea index, ESS: Epworth Sleepiness Scale.

Table 2: Comparison of the HLS-EU-Q47 score between the 3M adherent and 3M non-adherent groups.

	3M adherent (n=10)	3M non-adherent (n=27)	P-value
HLS-EU-Q47 *	32.7 (28.5-42.8)	34.4 (28.4-41.8)	0.85
HC-HL *	31.3 (24.0-43.5)	36.5 (26.7-42.7)	0.88
DP-HL *	33.3 (28.1-48.9)	36.7 (28.9-45.6)	0.94
HP-HL *	29.2 (24.0-47.9)	31.3 (22.9-39.6)	0.93

* : Median (1st and 3rd quartiles)

3M adherent/3M non-adherent: CPAP adherent/non-adherent after 3 months. CPAP: continuous positive airway pressure, HLS-EU-Q47: European Health Literacy Survey Questionnaire 47, HC-HL: health care health literacy, DP-HL: disease prevention health literacy, HP-HL: health promotion health literacy.

Table 3: Comparison of the HLS-EU-Q47 score between the 6M adherent and 6M non-adherent groups.

	6M adherent (n=15)	6M non-adherent (n=22)	P-value
HLS-EU-Q47 *	37.2 (28.5-49.2)	33.2 (28.1-39.6)	0.18
HC-HL *	37.0 (24.7-45.0)	36.5 (26.0-39.0)	0.30
DP-HL *	42.2 (28.5-50.0)	33.9 (28.9-43.5)	0.28
HP-HL *	31.3 (25.0-49.0)	30.7 (22.4-36.6)	0.20

* : Median (1st and 3rd quartiles)

6M adherent/6M non-adherent: CPAP adherent/non-adherent after 6 months.

CPAP: continuous positive airway pressure, HLS-EU-Q47: European Health Literacy Survey

Questionnaire 47, HC-HL: health care health literacy, DP-HL: disease prevention health

literacy, HP-HL: health promotion health literacy.

Table 4: Comparison of the HLS-EU-Q47 score between the 3M non-adherent 6M adherent and 3M non-adherent 6M non-adherent groups.

	3M non-adherent 6M adherent (n=6)	3M non-adherent 6M non-adherent (n=15)	P-value
HLS-EU-Q47 *	46.8 (33.4-49.6)	33.0 (27.8-38.9)	0.031 §
HC-HL *	44.4 (34.4-45.2)	36.5 (25.3-38.0)	0.004 §
DP-HL *	49.5 (32.2-50.0)	33.3 (28.9-42.9)	0.075
HP-HL *	45.8 (28.9-50.0)	30.2 (21.9-36.7)	0.031 §

* : Median (1st and 3rd quartiles) §: P <0.05

3M non-adherent 6M adherent: CPAP non-adherent after 3 months becoming CPAP adherent

after 6 months, 3M non-adherent 6M non-adherent: CPAP non-adherent after 3 months

remaining CPAP non-adherent after 6 months. CPAP: continuous positive airway pressure,

HLS-EU-Q47: European Health Literacy Survey Questionnaire 47, HC-HL: health care health

literacy, DP-HL: disease prevention health literacy, HP-HL: health promotion health literacy.

Table 5: Comparison of clinical characteristics between patients in the 3M non-adherent 6M adherent and 3M non-adherent 6M non-adherent groups.

	3M non-adherent 6M adherent (n=6)	3M non-adherent 6M non-adherent (n=15)	P-value
Age, yr *	58.5 (49.5-71.5)	54.0 (48.0-64.5)	0.30
Sex, Male (%)	4 (66.7)	16 (76.2)	0.64
Height, cm *	171.0 (162.0-181.0)	166.0 (161.0-173.0)	0.42
Weight, kg *	80.5 (60.0-111.3)	80.0 (69.9-96.0)	1.00
BMI, kg/m ² *	27.2 (24.1-33.8)	28.2 (26.2-33.3)	0.52
Smoking history, No (%)	4 (66.7)	9 (42.9)	0.30
Depressive mood, No (%)	2 (33.3)	8 (38.1)	0.83
Disinterest, No (%)	1 (16.7)	1 (4.8)	0.71
Claustrophobia, No (%)	0 (0.0)	1 (4.5)	0.59
Nose related diseases, No (%)	4 (66.7)	6 (28.6)	0.09
Difficulty falling asleep, No (%)	1 (16.7)	9 (43.4) [‡]	0.18
Sufficient sleep time, No (%)	3 (50.0)	14 (73.7) [‡]	0.28
AHI *	55.2 (44.4-71.3)	42.0 (30.6-48.1)	0.10
ESS *	9.0 (4.5-15.0)	6.0 (4.0-9.0) [‡]	0.37

* : Median (1st and 3rd quartiles)

‡: 2 patients did not answer

3M non-adherent 6M adherent: CPAP non-adherent after 3 months becoming CPAP adherent

after 6 months, 3M non-adherent 6M non-adherent: CPAP non-adherent after 3 months

remaining CPAP non-adherent after 6 months. CPAP: continuous positive airway pressure,

BMI: body mass index, AHI: apnea-hypopnea index, ESS: Epworth Sleepiness Scale.