

# Classification of adherence of CPAP users: a four-group comparison based on utilization rate and mean usage time on usage days

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## Abstract

[Aim] The definition of good adherence to continuous positive airway pressure (CPAP) therapy for obstructive sleep apnea syndrome (OSA) is a utilization rate of  $\geq 70\%$  and a mean usage time on usage days of  $\geq 4$  hours, and users who deviate from this definition are regarded as having poor adherence. Personalized guidance is required to improve the adherence of users with poor adherence. Hence, a more detailed classification is needed rather than simply classifying users as having poor and good adherence. Thus, this study aimed to clarify the significance of classification of adherence into four groups based on the two indices of utilization rate (%) and mean usage time (hours).

[Method] This study examined CPAP users at the CPAP specialist outpatient department from October to November 2016. In total, 535 patients were included, and information on CPAP adherence, physical data at initial consultation, and data on motivation for consultation were collected. The survey period was set as 2 months. The CPAP users were divided into four groups, and a 4-group comparison was conducted on factors that affect adherence, using the  $\chi^2$  test, the Kruskal-Wallis test, and the pairwise method. The utilization rate was set as the vertical axis and the mean usage time on usage days was set as the horizontal axis to create a scatter plot. The four segments were created by intersecting the axes with the values of “70%” and “4 hours”, with the top right set as the good adherence group “ $\geq 70\%/\geq 4$  hours”; moving counterclockwise, the next segments were set as the insufficient adherence time group “ $\geq 70\% < 4$  hours,” poor adherence group “ $\leq 70\% < 4$  hours,” and insufficient adherence days group “ $< 70\%, \geq 4$  hours.”

[Results] The good adherence group (n=393) accounted for 70% of users; the remaining 30%, conventionally classified together as users with poor adherence, were distributed into insufficient adherence time group (n=31), poor adherence group (n=49), and insufficient adherence days group (n=62). No significant differences in sex or residual AHI were observed, but significant difference was observed in age, usage history, and BMI between the good adherence group and poor adherence group. The percentage of patients with hypertension was significantly different between the good adherence group and insufficient adherence days group. There was a significant difference in the percentage of patients who sought consultation due to subjective symptoms between the insufficient adherence days group and insufficient adherence time group. The percentage of patients who sought consultation due to a recommendation by a company medical checkup showed a significant difference between the good adherence group and insufficient adherence days group.

[Conclusion] These results suggest that adherence can be divided into four groups based on utilization rate and mean usage time on usage days, and that these classifications may be helpful for constructing a guidance management system that emphasizes personalized guidance systems.

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## KEY WORDS

CPAP; adherence; utilization rate; mean usage times; Sleep Apnea Syndrome

### Introduction

Continuous positive airway pressure (CPAP) therapy was first reported in 1981 as an alternative therapy to tracheostomy for obstructive sleep apnea syndrome (OSA)<sup>1)</sup>. Research outcomes have been accumulated as evidence during the intervening period of almost 40 years, and CPAP is currently widely used as first-line therapy for OSA in Western countries and in Japan<sup>2-5)</sup>.

In 1998, public insurance was applied to CPAP in Japan; monthly consultations are generally mandated for CPAP users, and medical practitioners are obligated to provide guidance and management<sup>6)</sup>. Two major changes have been observed in the intervening 20 years since that time.

The first is the improvement in the CPAP machine and interface. The first CPAP machines were ventilators that forced breathing, and required the user to wear a helmet-like mask. However, now the machines are quieter, smaller, lighter, and more automated, and have improved into advanced precision medical equipment<sup>7-8)</sup>. Comfort, sealing, and design were also pursued for the interface<sup>9)</sup>. These changes have resulted in a comfortable breathing experience. The machines are now also equipped with memory functions that not only record the usage days and usage hours, but also sense and record the user's apnea hypopnea index (AHI) and mask leaks, which enables detailed evaluation of the adherence of each individual user<sup>10)</sup>. Furthermore, development of self-powered CPAP machines that can be used during disasters, coupled with development of information and communication technology, have now enabled machines that support remote monitoring, with potential further advances in the future<sup>11)</sup>.

One other change is the discovery that CPAP is effective for a variety of people. The first patients were only those with subjective symptoms of OSA. However, as research progressed, it was found that unlike Westerners, Japanese people were prone to the sleep apnea syndrome (SAS), even when they were not obese. This was due to the maxillofacial shape unique to Asians<sup>12)</sup>. Moreover, SAS was revealed to not

only affect the symptoms of daytime sleeping, but also lifestyle diseases, such as hypertension<sup>13)</sup>, cardiovascular disease<sup>14-15)</sup> and diabetes<sup>16)</sup>. Therefore, a joint research team comprising the Japanese Circulation Society and 7 other societies created guidelines for the diagnosis and treatment of SAS<sup>17)</sup>. As a result, the participants and related diseases were diversified to include elderly patients, women, non-obese patients, and patients with a history of cardiovascular disease.

The concept of adherence in CPAP research also changed with the aforementioned changes. In the beginning, when CPAP was first listed under public insurance, deciding whether to continue or discontinue CPAP was an important issue, and emphasis was placed on not discontinuing the therapy. Therefore, continuation factors and discontinuation predictors were investigated by comparing the continuation group to the discontinuation group<sup>18-20)</sup>. Discontinuation factors were not identified as a result of this research, but it was found that a variety of factors exerted a complex effect that resulted in discontinuation, and measures were adopted to prevent discontinuation, including machine development and innovations for early education<sup>21-22)</sup>. Additionally, with the recent improvements in CPAP machines, attention is now more focused on the quality of adherence of users who continue to use the machines, rather than on whether or not users stopped using the CPAP machines.

CPAP adherence is defined as "compliance to a utilization rate of  $\geq 70\%$  and a mean usage time on usage days of  $\geq 4$  hours"<sup>23-24)</sup>. The quality of adherence is evaluated as "good" for people who use the machine in accordance with the definition and as "poor" for people who do not use the machine in accordance with the definition. It is necessary to provide guidance and management to people with "poor" adherence to change their behavior to "good" adherence, to achieve the goals of CPAP therapy.

The current guidance and management have been made into a flowchart for each problem item, with each problematic event dealt with according to the problem, such as mask fitting and mask changes implemented for

mask problems, a combination of otorhinolaryngological therapy and humidifiers used to address nasal/oral symptoms, and adjusting the CPAP pressure if patient does not actually experience a therapeutic effect<sup>25-26)</sup>. However, it is difficult to say that these measures address the diversity of the lifestyle background, directivity, and related diseases of CPAP users.

This can be explained by the results of a previous qualitative study<sup>27)</sup> that clarified the behavior of CPAP usage in non-obese patients. The study showed that adherence in non-obese patients was higher than in obese patients and, interestingly, they performed CPAP with a focus on time and days. Therefore, to increase the adherence to CPAP, which should be used every day, it is necessary to consider the factors of time and days.

This means that the same intervention method for a certain problematic event is not necessarily optimal for improving CPAP adherence. In other words, it is vital to convert to guidance and management that intervenes with problems depending on the characteristics of the CPAP users and adherence quality, rather than intervention focused on the problematic event itself.

Therefore, this study aimed to evaluate the four classifications of adherence quality, rather than the current two, and to discover whether lifestyle background, directivity, and related disease characteristics of CPAP users were specific to each classification.

## **Method**

### **1. Participants**

The study examined CPAP users seen at the CPAP specialist outpatient department from October to November 2016. For patients who visited the department several times during the survey period, the initial data during the period were adopted, and 535 patients were included in the study as patients for whom information on CPAP adherence, physical data at initial consultation, and data on motivation for consultation could be collected. The medical institution for the surveyed patients was a hospital that had focused on the correlation between SAS and lifestyle diseases from an early stage in Japan and had a specialist CPAP outpatient department. Fall was selected as the survey period, as fall has relatively little

impact on the condition.

### **2. Method of classifying adherence quality into four groups**

The method of classifying adherence quality into four groups was based on the four classification criteria proposed by Sakurai<sup>28)</sup>. In 2003, Sakurai proposed a method of setting the “rate of effective use (%)” as the vertical axis, and the “total rate of use (%)” as the horizontal axis and classifying adherence into four groups based on where each value intersected at 70%, in an attempt to classify the characteristics of adherence. It is thought that this method based on four classifications did not become widespread due to the cumbersome calculations caused by the limited functions of the CPAP machines at the time. However, usage time can now be easily calculated with recent CPAP machines and it is also possible to find the average usage time only on the day of use. This is thought to have led to the expansion of the ability of self-management by removing the complexity of calculations. Therefore, in this study we used the method of classification of adherence into four groups using the two axes of “utilization rate” and “mean usage time”, which can now be easily calculated by the CPAP machines.

The specific method used to classify adherence into four groups was based on the definition of adherence of a “utilization rate of  $\geq 70\%$  and a mean usage time on usage days of  $\geq 4$  hours”. The “utilization rate” was set as the vertical axis, and the “mean usage time on usage days” was set as the horizontal axis, and these are the adherence indices. Four segments were created by intersecting the two axes at the reference values of “70%” and “4 hours”. The top right of the four segments was named Group I, and moving counterclockwise, the next segments were named Groups II, III, and IV, reflecting the following qualities of adherence for the four groups. The criteria and names are as set out below.

Group I: Utilization rate  $\geq 70\%$ , mean usage time  $\geq 4$  hours: good adherence group

Group II: Utilization rate  $\geq 70\%$ , mean usage time  $< 4$  hours: insufficient adherence time group

Group III: Utilization rate  $< 70\%$ , mean usage time  $< 4$  hours: poor adherence group

Group IV: Utilization rate  $< 70\%$ , mean usage time  $\geq 4$

hours: insufficient adherence days group

### 3. Factors related to adherence and data collection methods

#### 1) Data related to adherence

Data used as indicators of adherence were based on functions that calculate the CPAP internal memory data, calculated by the CPAP machines. We collected the usage time on usage days collected with the CPAP internal memory, averaged by the number of days the machine was used. Data since the previous consultation were recorded in the internal memory brought in by the CPAP users, and the data that form the CPAP sleep index were downloaded to electronic medical records from the CPAP internal memory with a dedicated analysis software.

The “utilization rate” was used to calculate the ratio of usage days from the sum of the number of usage days and the number of non-usage days recorded in the CPAP internal memory. The “mean usage time on usage days” was calculated by averaging the usage time on the days that CPAP was used.

#### 2) Data showing the characteristics

Data on characteristics were extracted from the results of previous studies<sup>18-20)</sup>, and data were collected from the medical records into the following characteristics.

(1) Medical data: Consultation interval for CPAP outpatient, Number of CPAP usage days and non-usage days, CPAP usage time per day, residual AHI, and CPAP usage history (months of usage)

(2) Physical data: sex, age, and body mass index (BMI) indicating the degree of obesity at introduction of CPAP

(3) Medical history:

(4) Motivation for consultation: Based on the data collected on the first visit, the following six categories were made.

- Sought consultation due to subjective symptoms
- Recommended by family
- Recommended by a cardiologist
- Recommended by medical personnel other than cardiologists
- Recommended by an acquaintance
- Recommended by company medical checkup

### 4. Analysis method

A scatter plot was used to confirm whether CPAP

users could be classified into four groups based on CPAP adherence indices, and a 4-group comparison was conducted for adherence, medical, and physical data, medical history, and motivation for consultation. IBM SPSS Statistics 24 (IBM Corp., Armonk, NY) was used for all statistical analyses. Data were displayed as mean  $\pm$  standard deviation; because it is not normally distributed, the Kruskal-Wallis test was used for analysis of continuous variables, and pairwise comparison was conducted as multiple comparisons for instances where significant differences were observed. Pearson's  $\chi^2$  test was used for analysis of categorical variables, and Fisher's exact test was used when the expected frequency was less than 5 cells and more than 20% of all cells. Level of significance was set at  $p < 0.05$ .

### 5. Ethical considerations

This research was a retrospective study, with clinical sleep information and other information obtained from medical records. Therefore, the director of the hospital ensured that the opt-out study was made public and the opportunity for refusal was granted, and considerations were made to ensure individuals could not be identified. This study was approved by the medical ethics review board of University A (Approval Number: 710-1), and was implemented after obtaining approval from the ethics review board of the medical institution that cooperated with the research.

## Results

### 1. Outline of participants

Among the 535 participants, 413 (77.2%) and 122 (22.8%) were men and women, respectively, with a mean age of  $63.3 \pm 13.4$  years (mean  $\pm$  standard deviation); the mean number of years of CPAP use was  $4.0 \pm 3.2$  years (Table 1).

The CPAP outpatient consultation interval was one, two, and three months for 207, 190, and 138 participants, respectively. There was no significant differences in the consultation interval between the groups (Table 2).

### 2. CPAP users scatter plot based on “utilization rate” and “mean usage time on usage days”

The “utilization rate” was set as the vertical axis, and the “mean usage time on usage days” was set as the horizontal axis. The four segments were created by intersecting the axes with the values of “70%” and

Table 1. Participant characteristics (n =535)

Characteristics		N (%)	Mean ± SD
Sex	Male	413 (77.2)	
	Female	122 (22.8)	
Age (years)			63.3 ± 13.4
BMI before starting CPAP (kg/m <sup>2</sup> )			26.9 ± 4.9
Number of years using CPAP (years)			4.0 ± 3.2
CPAP utilization rate (%)			83.7 ± 23.1
Mean CPAP usage time/day (hours)			5.6 ± 1.6
Consultation interval	1 month	207 (38.7)	
	2 month	190 (35.5)	
	3 month	138 (25.8)	

SD standard deviation, BMI body mass index, CPAP continuous positive airway pressure

Table 2. The consultation interval for CPAP users (n =535)

Group	n	the consultation interval			p-value
		1 month n=207	2 month n=190	3 month n=138	
I Good adherence group	393	147 (37.4)	137 (34.9)	109 (27.7)	0.871
II Insufficient adherence time group	31	13 (41.9)	13 (41.9)	5 (16.1)	
III Poor adherence group	49	23 (46.9)	17 (34.7)	9 (18.4)	
IV Insufficient adherence days group	62	24 (38.7)	23 (37.1)	15 (24.2)	

Kruskal-Wallis test

“4 hours”, and the degree of variation among the participants is shown in a scatter plot. The breakdown of the groups is as follows: 73.5% (n=393) of the participants were in the good adherence group (top right) ; 5.8% (n=31) were in the insufficient adherence time group (top left) ; 9.1% (n=49) were in the poor adherence group (bottom left) , and 11.6% (n=62) were in the insufficient adherence days group (bottom right) (Figure 1) .

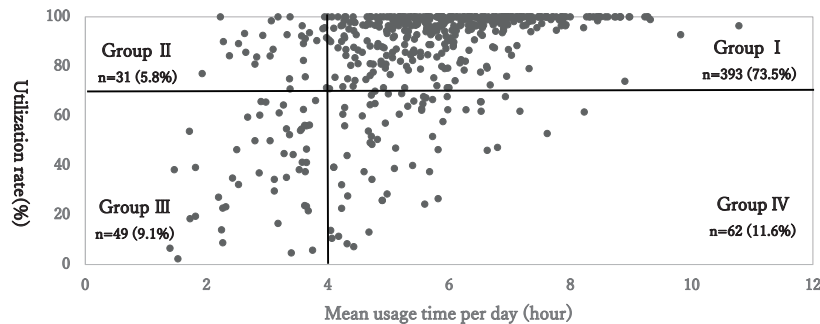


Figure 1 "Scatterplot of adherence of CPAP users"

Breakdown when the top right of the four segments is set as the good adherence group, and moving counterclockwise, the next segments are set as the insufficient adherence time group, poor adherence group and insufficient adherence days group

- Group I : Good adherence group (n=393)
- Group II : Insufficient adherence time group (n=31)
- Group III : Poor adherence group (n=49)
- Group IV : Insufficient adherence days group (n=62)

### 3. Comparison of related factors among the four groups.

1) Medical data: residual AHI, CPAP usage history (months of usage)

The mean value of residual AHI, which indicates the incidence of apnea-hypopnea while using CPAP, was at most 5 times per hour, which is the medical outcome, for all groups. The results of the Kruskal-Wallis test revealed no significant differences among the groups (p=0.157) .

A significant difference existed in the CPAP months of usage, which represents CPAP history (p=0.001) , and the results of multiple comparisons revealed that the poor adherence group had significantly less usage history than the good adherence group (Table 4) .

2) Physical data: Sex, age, and BMI at introduction of CPAP

When a  $\chi^2$  test for independence was conducted to determine the association between sex and each group, the result was p=0.785, indicating no significant association (Table 3) .

A significant difference was observed among the four groups (p<0.001) in the comparison of the mean ages using the Kruskal-Wallis test, and the results of multiple comparisons indicated that the good adherence group

Table 3. Comparison among 4 groups in sex

		Group I Good adherence group	Group II Insufficient adherence time group	Group III Poor adherence group	Group IV Insufficient adherence days group	$\chi^2$ value	p-value
Male	n=413 n (%)	299 (72.4)	25 (6.1)	39 (9.4)	50 (12.1)	1.066	0.785
Female	n=122 n (%)	94 (77.1)	6 (4.9)	10 (8.2)	12 (9.8)		

$\chi^2$  test



Table 4. CPAP user background

	Group I Good adherence group n=393	Group II Insufficient adherence time group n=31	Group III Poor adherence group n=49	Group IV Insufficient adherence days group n=62
Medical data				
Residual AHI (times/hour)				
Mean ± SD	2.7 ± 2.6	3.2 ± 2.4	3.3 ± 3.0	2.4 ± 1.9
95% CI	[2.4, 3.0]	[2.3, 4.1]	[2.4, 4.1]	[1.9, 2.8]
Months using CPAP (months)				
		**		
Mean ± SD	50.7 ± 39.3	40.3 ± 42.7	29.8 ± 27.0	44.3 ± 34.9
95% CI	[46.8, 54.6]	[24.7, 56.0]	[22.0, 37.6]	[35.5, 53.2]
Physical data				
Age (years)				
		***		
Mean ± SD	65.6 ± 13.0	59.5 ± 11.9	53.6 ± 11.9	57.9 ± 12.4
95% CI	[64.4, 66.9]	[55.1, 63.9]	[50.2, 57.1]	[54.8, 61.1]
BMI before starting CPAP (kg/m <sup>2</sup> )				
		**		
Mean ± SD	26.7 ± 4.9	25.9 ± 3.6	29.5 ± 6.1	27.0 ± 4.4
95% CI	[26.2, 27.2]	[24.6, 27.2]	[27.7, 31.2]	[25.9, 29.2]

Kruskal-Wallis test, Multiple comparison (Pairwise method), AHI apnea hypopnea index, SD standard deviation, CI confidence interval, CPAP continuous positive airway pressure, BMI body mass index, \*p<0.05 \*\*p<0.01 \*\*\*p<0.001

was significantly older than the poor adherence and the insufficient adherence days groups (p<0001). Given that a significant difference was observed with the insufficient adherence time group (p<0.05), the good adherence group was significantly older.

A significant difference existed in the mean BMI at introduction of CPAP (p=0.012), and the results of multiple comparisons indicated that the poor adherence group tended to be more obese than the good adherence group (Table 4).

### 3) Medical history

For medical history, Pearson's  $\chi^2$  test was performed for each of the six diseases. Fisher's exact test was performed only for "depression" because it had an expected frequency of less than 5 cells and more than 20% of all cells. As a result, no significant differences were observed among the groups in terms of diabetes, cardiovascular disease, stroke, depression, or dyslipidemia, with the exception of hypertension (p=0.020). The residual analysis showed that the percentage of patients with hypertension was high and low in the good adherence group and insufficient adherence days group, respectively (Table 5).

### 4) Motivation for consultation

The Pearson's  $\chi^2$  test or Fisher's exact test was performed for each of the six categories of motivation for consultation, as described above. No significant differences existed among the groups

Table 5. Comparison of medical history between the four groups

	Group I Good adherence group n=393 n (%)	Group II Insufficient adherence time group n=31 n (%)	Group III Poor adherence group n=49 n (%)	Group IV Insufficient adherence days group n=62 n (%)	$\chi^2$ value	p-value
Medical history						
Hypertension	249 (63.4)	15 (48.4)	32 (65.3)	28 (45.2)		
	Adjusted standardized residual	2.2	-1.4	0.7	-2.6	9.829 0.020
Diabetes	121 (30.8)	7 (22.6)	20 (40.8)	17 (27.4)		
	Adjusted standardized residual	0	-1	1.6	-0.6	3.614 0.306
Heart disease	179 (45.5)	11 (35.5)	14 (28.6)	29 (46.8)		
	Adjusted standardized residual	1.5	-0.9	-2.2	0.5	6.192 0.103
Cerebrovascular	59 (15.0)	4 (12.9)	7 (14.3)	5 (8.1)		
	Adjusted standardized residual	1.1	-2	0.1	-1.4	2.181 0.536
Depression	18 (4.6)	3 (9.7)	5 (10.2)	0		
	Adjusted standardized residual	-0.5	1.3	1.8	-1.9	— 0.050†
Dyslipidemia	138 (35.1)	12 (38.7)	15 (30.6)	22 (35.5)		
	Adjusted standardized residual	0.1	0.5	-0.7	0.1	0.611 0.894

$\chi^2$  test, †Fisher's exact test,

Table 6. Comparison of the motivation for consultation between the four groups

	Group I Good adherence group n=393 n (%)	Group II Insufficient adherence time group n=31 n (%)	Group III Poor adherence group n=49 n (%)	Group IV Insufficient adherence days group n=62 n (%)	$\chi^2$ value	p-value
Motivation for consultation						
Sought consultation due to subjective symptoms	57 (14.5)	11 (35.5)	7 (14.3)	4 (6.5)		
	Adjusted standardized residual	-0.3	3.3	-0.1	-2	14.008 0.003
Recommended by family	55 (14.0)	3 (9.7)	8 (16.3)	9 (14.5)		
	Adjusted standardized residual	0	-0.7	0.5	0.1	0.714 0.87
Recommended by a cardiologist	174 (44.3)	11 (35.5)	15 (30.6)	29 (48.8)		
	Adjusted standardized residual	1.1	-0.8	-1.8	0.7	4.400 0.221
Recommended by medical personnel other than a cardiologists	84 (21.4)	5 (16.1)	14 (28.6)	12 (19.4)		
	Adjusted standardized residual	-0.1	-0.7	1.3	-0.4	2.155 0.541
Recommended by an acquaintance	12 (3.1)	1 (3.2)	1 (2.0)	0		
	Adjusted standardized residual	1.1	0.2	-0.3	-1.4	— 0.055†
Recommended by company medical checkup	11 (2.8)	0	4 (8.2)	8 (12.9)		
	Adjusted standardized residual	-2.8	-1.2	1.4	3.6	— 0.002†

$\chi^2$  test, †Fisher's exact test

for recommendation from family, medical staff, or acquaintances, but significant differences existed for "sought consultation due to subjective symptoms" (p=0.003) and "company medical checkup" (p=0.001). The residual analysis showed that the percentage of patients

in the “sought consultation due to subjective symptoms” category was high and low in the insufficient adherence time group and insufficient adherence days group, respectively. Whereas the percentage of patients in the “recommended by company medical checkup” category was high and low in the insufficient adherence days group and good adherence group, respectively (Table 6).

## **Discussion**

### **1. Significance of successfully classifying CPAP adherence into four groups**

Here we discuss the significance of grouping adherence into four groups based on this overall distribution.

#### **1) Relationship with the distribution population**

The good adherence group located in the top right has a “utilization rate of  $\geq 70\%$  and a mean usage time on usage days of  $\geq 4$  hours”, which is defined as adherence, and therefore corresponds to the conventional “good adherence group”. Given that this group accounts for 73.5% of the whole, the CPAP adherence in Japan is consistent with that reported in the findings of reports indicating that 70% of users are in the good adherence group, whereas 30% are in the poor adherence group<sup>29)</sup>, which demonstrates the validity of this study.

A certain percentage of CPAP users were distributed in the “insufficient adherence time group”, “poor adherence group”, and “insufficient adherence days group”, positioned in the top left, bottom left, and bottom right sides, respectively, which are conventionally all grouped together as the “poor adherence group”. The percentage of patients in each group is shown. Although there was no report in which the patients were divided into four groups as described here, the results reported for the two groups of good adherence and poor adherence were consistent with the result of this study which is 7:3. Therefore, the general population can be divided into these four groups. Moreover, the distribution of patients in these four groups may be representative of the general population. However, further studies are needed to confirm this.

#### **2) Significance of a lack of significant difference in residual AHI among the four groups**

Previous studies often compared the values of AHI

at diagnosis of SAS before introduction of CPAP. However, no consensus was reached, as some studies revealed that the more severe the AHI value before CPAP was introduced, the better was the adherence to CPAP<sup>19)</sup>. In contrast, other studies revealed no significant differences in AHI at diagnosis of SAS in the continuation and discontinuation groups<sup>18)</sup>. Recently, the number of SAS patients who are non-obese and lack subjective symptoms has increased. Therefore, this study focused on residual AHI to objectively evaluate the effect of CPAP, rather than AHI at diagnosis of SAS before CPAP was introduced. Residual AHI represents the number of times apnea hypopnea occurs while using CPAP; if residual AHI is high, then the doctor determines that effective CPAP is not being used, and then changes the CPAP setting pressure.

The results of this study indicated that all groups cleared the target of 5 or less times per hour, with no significant difference among the groups. This means that adherence is not affected by how skillfully the doctor correctly sets the CPAP pressure nor by achieving the medical outcome. In other words, even if the CPAP pressure set by a doctor is optimal, it does not always lead to patients consistently using CPAP. This suggests that it is not possible to improve adherence by simply achieving the medical outcome of residual AHI, instead, it is essential to consider certain patient characteristics.

### **2. Utilization in clinical practice**

Here we discuss how grouping into four groups can be used effectively in actual clinical practice.

#### **1) Focusing on sex and age**

Previous studies reported that CPAP continuation rate was slightly lower in women<sup>30)</sup>, but the prevalence of OSA in Japan is reportedly 6-7 times higher in men than in women<sup>31)</sup>, and the small cohort of female participants mean that there are few previous studies that compared sex differences for adherence, and there is no fixed opinion on this matter. There were no significant sex-related differences among the groups in this study. With the recent improvements in the mask interface, it is presumed that there is now a reduced tendency for the masks to leave indentations and the design of the mask has also improved, which may have led to improved adherence in women.

There are conflicting reports about age, with some

reports indicating that the younger the patient, the poorer the adherence due to a lack of a sense of danger and sense of urgency regarding complications, thus, the older the patient, the better the adherence<sup>20)</sup>, while other reports claim that elderly patients have poor adherence due to a lack of subjective symptoms<sup>32)</sup>. However, the results of this study indicate that the good adherence group was significantly older than the other groups, hence the older the patient the better the adherence, and the younger the patient the poorer the adherence. This result is thought to be because older patients are more likely to adhere to healthy behaviors based on experience than younger patients, as described in previous studies<sup>20)</sup>. The recent improvements in CPAP machines, which make it easier for elderly patients to operate the machine, have also promoted greater CPAP adherence among the elderly. Additionally, CPAP masks such as a nasal mask or nasal pillow mask are being developed that differ from the conventional full-face mask and have a design that minimizes the skin contact area<sup>9)</sup>.

Therefore, improvements in devices such as CPAP devices and masks target the needs of all generations and sex. In the future it will be necessary to examine intervention methods that closely match the needs of CPAP users for guidance and management.

## 2) Focusing on CPAP usage history and BMI at introduction of CPAP

The good adherence group had significantly longer CPAP usage than the poor adherence group. This is consistent with the finding that generally most people who stop using CPAP do so within the first year<sup>33)</sup>. This is the reason why early education at introduction of CPAP is considered to be important, and the reason that facilities provide guidance and management intervention selectively for patients who have poor adherence immediately after introduction of CPAP. Here, we would like to draw attention to the fact that in this study no significant difference existed between the insufficient adherence time and insufficient adherence days groups. In other words, this means that a certain number of CPAP users continue using CPAP for any number of years without adequate adherence, namely insufficient time and insufficient number of days. In a busy clinical practice, the CPAP usage history of the insufficient adherence time and insufficient

adherence days groups is shorter, and the guidance and management tend to be a lower priority than the poor adherence group, who are more likely to discontinue use. However, using ineffective CPAP is futile, so it is essential to proactively and effectively intervene in the insufficient adherence time group and insufficient adherence days group.

A significant difference was observed in BMI at introduction of CPAP between the good adherence group and the poor adherence group. Many existing studies report that BMI does not affect adherence<sup>34)</sup>. However, these are research reports from a time when many of the patients were obese with a mean BMI of around 30 kg/m<sup>2</sup>. This does not suit the current scenario where CPAP users are diverse, including non-obese patients. The results of the present study indicated that the more obese the participant the poorer the adherence, and the less obese the participant the better the adherence. As medical staff, we present the goal of “if you lose weight you can stop using CPAP” to obese patients, but we do not present the goal of losing weight to non-obese patients. Despite not presenting a goal, non-obese patients have better adherence than obese patients. This means that to impart a sense of crisis in obese people in the poor adherence group, it may not be correct to simply imply the goal of “if you lose weight you can stop using CPAP”.

Based on the above findings, dividing the participants into four groups makes it possible to subcategorize the priority of guidance and management and revise the wording used for these patients.

## 3) Use of medical history

Previous studies, such as the one conducted by Noguchi reported that patients with a history of cardiovascular diseases tended to frequently use CPAP<sup>35)</sup>, so it was assumed that patients with a history of cardiovascular disease had good adherence, but in this study, no significant difference was observed for cardiovascular diseases. Only hypertension was significantly different between the groups, and the good adherence group had more participants with a history of hypertension than the insufficient adherence days group. This finding suggests that awareness of hypertension may slightly increase adherence. However, the participants reported their medical history through a multiple-choice questionnaire, and it is possible that a



person with hypertension may have multiple diseases. Therefore, further studies are necessary to confirm the significance of hypertension.

#### 4) Use of motivation for consultation

Previously, many SAS patients sought consultation with the main complaint of daytime somnolence, but the results of this study clarified that CPAP users' motivation for consultation has diversified, with SAS being indicated by medical personnel as a result of cardiovascular and ischemic cerebrovascular diseases.

Furthermore, patients with subjective symptoms, such as daytime somnolence and headache, generally have better adherence<sup>32)</sup>. However, the results of this study revealed that many participants in the insufficient adherence time group had subjective symptoms. In other words, despite subjective symptoms and clinical advice, the use of CPAP has not been effective. This finding matches reports that daytime somnolence does not correlate with adherence<sup>33)</sup>. Further, even if the daily usage time is short in the insufficient adherence time group, this practice has become a habit, so it is considered difficult to shift these people to the good adherence group. Therefore, if patients in the insufficient adherence time group also have subjective symptoms, then it is easier to motivate these patients, and this should be the group that is easiest to instruct.

The study also revealed that there tended to be more participants who sought consultation after a company medical checkup in the insufficient adherence days group, where the participants infrequently use the CPAP machine, despite using it for a longer period of time per night. Sleep management is mandated in company medical checkups in industries that employ drivers, and these people's lifestyle background and sleep environment can be affected by shift work and difficulties securing a power source for CPAP machines. Thus, it is essential to provide intervention that suits the lifestyle of these CPAP users, including use of self-powered CPAP machines.

No previous studies investigated the motivation for consultation, but given that significant differences were observed in certain areas in each group, in the future, it may be possible to discover characteristics of CPAP users from motivation for consultation as a factor that affects adherence.

#### 5) Use of four grouping

Previous guidance and management methods provided guidance to ensure good acceptance of the therapy, including providing knowledge and education on the necessity of CPAP, mask fitting, and using appropriate pressure setting, prioritizing these interventions in the early stage of CPAP introduction, and then, if problems occur, taking measures to resolve those problems. Emphasis was placed on seeking behavioral changes in users with poor adherence. However, just as CPAP machines have progressed to better suit the natural sleep of users, as medical personnel, we also must adapt to better suit the lifestyle of diversified CPAP users. When doing so, using the more subdivided grouping of "good adherence group", "insufficient adherence time group", "poor adherence group", and "insufficient adherence days group" will make it easier to intervene based on determining the priority and importance of intervention, rather than simply finding the poor adherence group by simply grouping adherence into the two conventional groups, "good adherence group" and "poor adherence group". Ascertaining the characteristics of each group will lead to personalized care.

### 3. Limitations and issues with this study

Since this study was carried out at a single center, regional effects may have been overlooked. Therefore, it is necessary to expand the study population to include the whole country.

Moreover, since BMI was analyzed before CPAP introduction but not after CPAP introduction, the basis for weight management guidance may be insufficient.

Since the information was obtained from medical records and there was no unified category for medical history and motive for medical examinations, it is possible that there may be bias due to differences in the individual abilities of doctors and nurses.

### Conclusion

In this study, we found that CPAP users can be grouped into four groups, with differences in age, usage history, BMI, medical history, and motivation for consultation among these groups. This suggests that each group has different characteristics. This finding is considered useful for formulation of policies and construction of an educational system during clinical

practice for intervention, prioritizing consideration of the individuality of CPAP users when implementing guidance and management to maintain good adherence.

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## CPAP 使用者のアドヒアランスの性質分けの試み ～「使用率」と「使用日の平均使用時間」による 4 群比較～

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### 要 旨

[目的] 閉塞性睡眠時無呼吸の CPAP 療法のアドヒアランスの定義は「使用率 $\geq$  70% かつ使用日の平均使用時間 $\geq$  4 時間」であり, この定義から外れれば不良とみなされる。不良者には個別性重視の指導が必要であり, 良好か不良かの 2 群ではなく, より細分化する必要があると考えた。そこで「使用率」と「平均使用時間」の 2 つの指標から, アドヒアランスを 4 群に性質分けすることの意義を明らかにする。

[方法] 2016 年 10 月～11 月に CPAP 外来を受診した患者 535 人を対象とし, CPAP 使用状況や身体データ等のデータを収集した。「使用率」を縦軸, 「使用日の平均使用時間」を横軸とし, 散布図を作成した。「70%」と「4 時間」の値で 2 軸を交差させ, 対象者を 4 群化し, 右上を良好群「 $\geq$  70%/ $\geq$  4 時間」とし, 反時計回りに, 時間不足群「 $\geq$  70%/ $<$  4 時間」, 不良群「 $<$  70%/ $<$  4 時間」, 日数不足群「 $<$  70%/ $\geq$  4 時間」とした。 $\chi^2$  検定, Kruskal-Wallis 検定を使用し, アドヒアランスの影響要因について 4 群比較を行った。

[結果] 良好群 (n = 393) が全体の 7 割を占め, 従来は不良群として一括りにされていた残りの 3 割は, 時間不足群 (n = 31), 不良群 (n = 49), 日数不足群 (n = 62) に分配された。性別や残存 AHI に有意差は認めず, 年齢や使用歴, BMI は, 良好群と不良群に有意差を認め, 高血圧の割合は, 良好群と日数不足群に有意差を認めた。日数不足群と時間不足群では, 自覚症状の有無の割合, 良好群と時間不足群では, 企業健診で指摘された割合に有意差を認めた。

[結論] 「使用率」と「使用日の平均使用時間」からアドヒアランスの 4 群化は可能であり, 個別性を重視する指導管理システム構築の一助になりうることが示唆された。