

# Compliance After Re-Prescription for Positive Airway Pressure in Obstructive Sleep Apnea Patients Who Failed Positive Airway Pressure Therapy

Jeonghyun Lee, MD, JunYeong Jeong, MD, Jaeha Lee, MD, Jae Yong Lee, MD, PhD, and Ji Ho Choi, MD, PhD

Department of Otorhinolaryngology-Head and Neck Surgery, Soonchunhyang University College of Medicine, Bucheon Hospital, Bucheon, Republic of Korea

**Background and Objectives:** Little is known about studies evaluating positive airway pressure (PAP) compliance after re-prescription. Therefore, the aim of this study was to investigate PAP compliance after re-prescription in obstructive sleep apnea (OSA) patients who failed initial PAP therapy.

**Methods:** We retrospectively reviewed OSA patients who had received a re-prescription for PAP from March 2020 to June 2021. We compared the compliance rate between initial prescription and re-prescription for PAP and investigated the reasons for PAP failure after the first prescription.

**Results:** A total of 10 consecutive OSA patients (mean age=45.6±13.7 years and male:female=8:2) who received a re-prescription for PAP were included. Of them, 8 patients (80%) met the compliance criteria (i.e., Korean National Health Insurance criteria) for PAP after re-prescription. The compliance rate increased from 36.3±18.2% (initial prescription) to 61.3±28.8% (re-prescription); this was not of statistical significance ( $p=0.074$ ). PAP/mask-related discomfort was the most common reason for PAP failure, followed by nasal obstruction, unintentional mask removal, and pressure-related discomfort.

**Conclusion:** Even if initial PAP therapy fails, the proportion of patients who meet the compliance criteria may be improved through various forms of clinical aid and support after re-prescription of PAP.

**Keywords:** Obstructive sleep apnea; Positive airway pressure; Re-prescription; Compliance.

## INTRODUCTION

Obstructive sleep apnea (OSA) is a disease characterized in that the closure of the upper airway repetitively occurs during sleep, causing respiratory disturbance such as hypopnea or apnea, as a result of which frequent interruptions of sleep and hypoxia are accompanied [1]. This can be diagnosed when the apnea-hypopnea index (AHI) is five or higher on polysomnography, and symptoms or complications are accompanied,

or when the AHI is 15 even if there are no symptoms [2]. OSA shows a prevalence of 4% to 5% in male and 3% to 4% in female, and the prevalence is known to increase in elderly and obese people [3]. Possible symptoms of OSA include decreased concentration and memory decline, morning headache, and fatigue and excessive daytime drowsiness coming even after sufficient sleep [4]. OSA may cause serious complications such as cardiovascular diseases, diabetes, hypertension, and cerebral stroke, and, since its correlation with degenerative brain diseases or malignant tumors has been established recently, the importance of accurate diagnosis and appropriate treatment for this disease is being further emphasized [5-7].

To improve OSA, an appropriate treatment method has to be selected in general taking into account the anatomic features, the polysomnography result, and the risk factors of the patient [8]. The predominantly conducted treatment methods include positive airway pressure (PAP), oral appliance, and surgical operations, and weight control or positional ther-

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**Address for correspondence:** Ji Ho Choi, MD, PhD, Department of Otorhinolaryngology-Head and Neck Surgery, Soonchunhyang University College of Medicine, Bucheon Hospital, 170 Jomaru-ro, Bucheon 14584, Republic of Korea

**Tel:** +82-32-621-5015, **Fax:** +82-32-621-5016

**E-mail:** [handsomemd@hanmail.net](mailto:handsomemd@hanmail.net)

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apy may be additionally applied [4,8]. Among such treatment methods, PAP plays a central role in the treatment of OSA because it has been already proven to improve objective indicators such as AHI and subjective symptoms such as daytime sleepiness through several studies [9].

PAP is a treatment method that uses the principle of preventing airway obstruction by continuously maintaining the air pressure in the upper airway where stenosis takes place, and the public health insurance benefits have been enforced for it in Korea since July 2018 [10]. At present, the PAP prescription criteria of the Korean National Health Insurance (KNHI) reinforced in December 2020 require that, in the case of adults (13 years of age or older), the patient has to fall under one of the following in type 1 polysomnography: 1) the AHI is 15 or higher; 2) the AHI is 10 or higher and the patient is suffering from at least one among insomnia, daytime sleepiness, impaired cognitive functions, and mood disorder; or 3) the AHI is five or higher and the patient has at least one among hypertension, an ischemic heart disease, a history of stroke, and oxygen saturation less than 85%. The general compliance criterion related to the use of PAP is that the number of using PAP for 4 hours or more a day has to be 70% of the total number of days of use, and the domestic compliance criteria for PAP benefits have been arranged similarly reflecting such a criterion [10].

Although many domestic studies investigated the PAP compliance rate up to now since the start of the KNHI benefits for PAP, no study investigated the compliance rate after PAP was prescribed again for the OSA patients who failed in PAP therapy because they failed to pass the compliance criteria (benefit extension criteria of the KNHI). Accordingly, in the present study, we intend to compare the compliance rate after the initial PAP prescription and the compliance rate after the PAP re-prescription targeting the patients who have gotten PAP re-prescription among the OSA patients who have failed in the PAP therapy after the start of the domestic application of the benefits for PAP and investigate the percentage of patients who have passed the compliance criterion (benefit extension criterion of the KNHI) after the PAP re-prescription.

## METHODS

### Subjects

The present medical record retrospective analysis research was carried out after the approval by the Institutional Review Board (SCHBC 2022-06-027) of Soonchunhyang University Bucheon Hospital. The research was carried out for the patients who got PAP re-prescription from March 2020 to June 2021 after they failed to pass the PAP compliance criteria of the KNHI among the adult patients who were diagnosed with

OSA through a history taking (main symptoms, past medical history, comorbidities, etc.), physical examination (tonsil size, palate-tongue position, overall endoscopy of the upper airway, etc.), imaging studies, and polysomnography. Cases, where the data could not be used because, for example, the data in the medical records including polysomnography and results related to PAP usage disappeared or were lost were excluded from the analysis.

### Polysomnography

Various vital signs such as electrooculogram, electroencephalogram, chin and leg electromyograms, respiratory air-flow and effort, oxygen saturation, electrocardiogram, snoring, and sleep posture were monitored during sleep using standard (level 1) polysomnography equipment (Embla N7000/Embletta MPR, Medicare-Embla, Reykjavik, Iceland) to evaluate respiratory disturbances such as apnea and hypopnea. In addition, sleep scoring data such as total recording time (TRT), total sleep time (TST), sleep efficiency, non-rapid eye movement (non-REM) sleep (stages N1 to 3), REM sleep (stage R), and respiratory events such as AHI, respiratory disturbance index (RDI), minimum oxygen saturation, and snoring were checked through the analysis of the various vital signs mentioned above. All the raw data of the polysomnography were interpreted based on the scoring manual of the American Academy of Sleep Medicine (AASM) [11].

### PAP compliance criteria (domestic PAP benefit extension criteria) and related information

PAP therapy for domestic OSA patients has been started to be covered by the KNHI benefits since July 2018 [10]. The PAP benefit compliance criteria of the KNHI are divided into primary (initial) and secondary (latter) compliance criteria. The primary compliance criterion is that the number of days using PAP for 4 hours or more a day must be more than 70% (21 days) of 30 consecutive days of the usage period within the compliance period (maximum 90 days) and, if the PAP use record of the patient fulfills such a criterion, the KNHI benefits for PAP will be extended (after that, the KNHI benefits will be extended if the secondary compliance criterion is fulfilled, and the secondary compliance criterion is that the average use time a day has to be 2 hours or more during the immediately previous prescription period [maximum 3 months]). If the PAP use record of the patient fails to fulfill the compliance criteria for the benefits, the KNHI benefits will not be extended and the re-prescription will be limited for 6 months thereafter. In the present study, the compliance rates (the percentage of the number of days using PAP for 4 hours or more a day to the use period of 30 consecutive days, number of days of using PAP for 4 hours or more a day/30

days $\times$ 100) were compared by applying the KNHI (primary) PAP benefit compliance criterion to the PAP use record of the patients during the initial PAP prescription and re-prescription compliance periods. In addition, the reasons why some patients failed to fulfill the KNHI (primary) benefit compliance criterion were investigated by analyzing the medical records at the time of initial PAP prescription.

### Education of and supports for patients related to PAP therapy

When the patients accepted PAP therapy, education and support related to PAP therapy were carried out separately from the education about OSA. First, detailed explanation and education about the treatment principle and effect of PAP, equipment configuration (main body of PAP device including a humidifier, a connecting tube, and a mask), related functions and usage, cleaning and managing method, and possible side effects and solutions were carried out, and much effort was made particularly to let the patients wear masks suitable for them. Short-term monitoring within 4 to 5 weeks was performed after the PAP prescription and, if any side effect or problem was found, a remedy was arranged as soon as possible and, if examination by another department is required, the problem was solved by requesting consultation with the related department. The contents of the education and support for the patients who got initial PAP prescription and re-prescription were similar, but in the case of re-prescription, the importance of the PAP therapy was further emphasized and motivation for the use of PAP was further reinforced at the same time. To be more specific, more emphasis was placed

on the possibility of various symptoms and complications that could occur when no treatment was given, and the importance of the economic benefits resulting from the application of the KNHI was emphasized as a means of motivation for the use of PAP in addition to the importance of maintenance of health.

### Statistical analysis

To compare the number of days using PAP more than 4 hours a day during the use period of 30 consecutive days within the compliance period and the compliance rates between initial prescription and re-prescription, Wilcoxon Signed Rank Test was used. SPSS Statistics version 27.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis, and the outcome was considered statistically significant when the p-value was less than 0.05.

## RESULTS

A total of 10 OSA patients who got PAP re-prescription were included as the subjects. The ages of the subjects (mean $\pm$ standard deviation) were 45.6 $\pm$ 13.7 years, the male-to-female ratio was 8 to 2, and the mean body mass index was 29.3 $\pm$ 4.7 kg/m<sup>2</sup>. The main symptoms of the subjects were snoring, sleep apnea, and daytime sleepiness, most of the cases had no comorbidities, and hypertension (20%), arrhythmia (10%), and diabetes (10%) were investigated as comorbidities. The most common tonsil size grade was grade 1 (70%) and was followed by grade 2 (20%) and then grade 3 (10%), and the palate-tongue position (modified Mallampatti grade) of the subjects

**Table 1.** Clinical data of obstructive sleep apnea patients with re-prescription for positive airway pressure

	Age	Sex	BMI	Chief complaint	Comorbidity	Tonsil size grade	Modified Mallampatti grade
1	28	M	22.5	Snoring, sleep apnea	None	Grade 1	Grade 3
2	70	F	33.6	Sleep apnea, excessive daytime sleepiness	Hypertension, arrhythmia	Grade 1	Grade 3
3	34	M	24.9	Snoring, sleep apnea	None	Grade 1	Grade 3
4	38	M	31.1	Excessive daytime sleepiness, sleep apnea	None	Grade 3	Grade 3
5	42	M	35.4	Snoring, sleep apnea	None	Grade 2	Grade 3
6	45	F	23.6	Excessive daytime sleepiness, sleep apnea	None	Grade 1	Grade 3
7	61	M	26.9	Snoring, sleep apnea	None	Grade 1	Grade 3
8	61	M	30.3	Sleep apnea, excessive daytime sleepiness	Diabetes mellitus	Grade 1	Grade 3
9	38	M	34.8	Sleep apnea, excessive daytime sleepiness	Hypertension	Grade 2	Grade 3
10	39	M	30.3	Snoring, sleep apnea	None	Grade 1	Grade 3

M, male; F, female; BMI, body mass index

were all grade 3. The clinical data of the subjects are summarized in Table 1.

As a result of analyzing the polysomnographic data of the subjects, the TRT (mean±standard deviation) was 444.5±29.8 minutes; TST was 368.8±65.8 minutes; sleep efficiency was 83.9±17.3%; stage N1 was 33.5±28.7%; stage N2 was 46.1±20.1%; stage N3 was 2.4±4.5%; stage R was 18.0±9.2%; AHI was 41.9±31.2, RDI was 47.1±28.9; minimum oxygen saturation was 79.3±11.7%; and snoring (duration) was investigated to be 47.0±21.7%. The polysomnography data of the subjects are presented in Table 2.

As a result of analyzing the PAP usage data of the subjects, the number of days using PAP for 4 hours or more a day (mean±standard deviation) during the use period of 30 consecutive days in the initial prescription compliance period was 10.9±5.5 and the compliance rate was 36.3±18.2%. The number of days using PAP for 4 hours or more a day during the use period of 30 consecutive days in the re-prescription compliance period was 18.4±8.7, and the compliance rate was 61.3±28.8%. Among 10 OSA patients who got PAP re-prescription, the

number of patients who fulfilled the KNHI PAP benefit compliance criterion was 8, and the percentage was investigated to be 80%. As a result of comparing the number of days using PAP more than 4 hours a day (10.9±5.5 vs. 18.4±8.7) and the compliance rates (36.3±18.2% vs. 61.3±28.8%) during the use period of 30 consecutive days in the compliance period between initial prescription and re-prescription, although both of them showed an increase, there was no statistical significance ( $p=0.074$ ). The PAP use data of the subjects are shown in Table 3.

As a result of investigating the reasons why some patients failed to fulfill the KNHI PAP benefit compliance criterion during the initial PAP prescription period, the most common reason was 'inconvenience or stuffiness of using a PAP device/mask', the second reason was 'nose-related symptoms such as nasal congestion' and the next reasons for compliance failure were 'unintentional removal of the mask while sleeping' and 'pressure-related problems' (Table 4).

All 10 patients used a nasal-type mask and an automatic PAP device during the initial prescription and re-prescription

**Table 2.** Polysomnographic data of obstructive sleep apnea patients with re-prescription for positive airway pressure

	TRT (min)	TST (min)	SE (%)	Stage N1 (%)	Stage N2 (%)	Stage N3 (%)	Stage R (%)	AHI (event/hr)	RDI (event/hr)	MinO <sub>2</sub> (%)	Snoring (%)
1	430.6	414.4	96.2	12.8	57.5	2.2	27.5	8.1	20.0	92.0	58.1
2	429.5	375.5	87.4	12.1	58.7	4.1	25.1	44.6	46.3	73.0	35.7
3	423.9	410.7	96.9	5.2	68.2	0	26.6	11.5	14.6	87.0	39.8
4	426.5	404.5	94.8	38.8	39.1	0.2	21.9	67.2	67.6	49.0	30.2
5	418.0	324.0	77.5	20.7	49.7	14.6	15.0	41.5	48.1	82.0	85.7
6	433.5	398.0	91.8	5.1	72.4	2.9	19.6	10.1	17.9	85.0	73.2
7	456.5	420.5	92.1	36.2	47.3	0.4	16.1	12.7	21.3	82.0	32.9
8	452.9	377.2	83.3	41.9	35.1	0	23.0	55.7	60.0	80.0	64.5
9	453.2	362.0	79.9	88.5	6.2	0	5.3	99.3	100.8	81.0	25.1
10	520.0	201.0	38.7	73.6	26.4	0	0	68.4	74.6	82.0	24.9

TRT, total recording time; TST, total sleep time; SE, sleep efficiency; N, non-rapid eye movement; R, rapid eye movement; AHI, apnea-hypopnea index; RDI, respiratory disturbance index; MinO<sub>2</sub>, minimum oxygen saturation

**Table 3.** Compliance data of obstructive sleep apnea patients with re-prescription for positive airway pressure

	Initial prescription			Re-prescription		
	Used days ≥4 hrs	Total days	% Used days ≥4 hrs	Used days ≥4 hrs	Total days	% Used days ≥4 hrs
1	9	30	30	24	30	80
2	8	30	27	21	30	70
3	8	30	27	21	30	70
4	14	30	46	21	30	70
5	0	30	0	2	30	7
6	9	30	30	21	30	70
7	19	30	63	3	30	10
8	18	30	60	28	30	93
9	13	30	43	21	30	70
10	11	30	37	22	30	73

**Table 4.** Reasons for PAP failure after initial prescription in obstructive sleep apnea patients with re-prescription

Reasons for positive airway pressure failure after initial prescription	
1	PAP/mask-related discomfort, unintentional mask removal, pressure-related discomfort
2	PAP/mask-related discomfort
3	PAP/mask-related discomfort, nasal obstruction
4	PAP/mask-related discomfort, nasal obstruction, unintentional mask removal, pressure-related discomfort
5	PAP/mask-related discomfort
6	PAP/mask-related discomfort, nasal obstruction
7	PAP/mask-related discomfort, nasal obstruction
8	PAP/mask-related discomfort
9	PAP/mask-related discomfort, nasal obstruction
10	PAP/mask-related discomfort, nasal obstruction

PAP, positive airway pressure

periods, and the pressures prescribed for 8 patients were the same in the initial prescription and re-prescription. However, the pressures in the re-prescription for two patients were adjusted since they felt discomfort with the pressures in the initial prescription.

## DISCUSSION

In the present study, we compared the compliance rate after PAP re-prescription with the compliance rate after the initial PAP prescription targeting the patients who wanted to use PAP again and got PAP re-prescription among the OSA patients who failed to succeed in PAP therapy after the PAP therapy started to be covered by the KNHI and checked the percentage of the patients who fulfilled the compliance criterion (benefit extension criterion of the KNHI) after the PAP re-prescription. As a result, it was found that both the number of days using PAP for 4 hours or more a day during the use period of 30 consecutive days in the compliance period and the compliance rate increased, but there was no statistical significance. The percentage of patients who passed the KNHI PAP benefit compliance criterion after PAP re-prescription was found to be 80%. The authors searched related literature, but could not find any study that evaluated the compliance rate after PAP re-prescription up to now. To the best of our knowledge, the present study has significance in that it is the first study in Korea that has investigated the compliance rate after PAP re-prescription.

Although the PAP therapy for OSA which is thought to be a chronic disease has a definite advantage in that it is very effective if it is well sustained, it also has a limitation in that it is not helpful at all if the patient does not use it for various rea-

sons. The percentage of patients who refuse to use PAP from a relatively early stage after PAP is recommended as a treatment method has been reported to be 4.5% at the least and 50% at the most [12-14]. In addition, when we look into the domestic and overseas studies that have investigated whether patients well comply with PAP therapy, the PAP compliance rate has been reported to be about 30% to 80% in general [15,16].

In Korea, investigations related to PAP compliance began to be reported in the mid-2000s. Choi et al. [17] investigated the PAP compliance rate at the time when at least 6 months elapsed after PAP prescription pressure inspection was carried out in person or through telephone interviews, as a result of which they reported that 26 patients, 43.4% of a total of 60 PAP therapy patients, continuously used PAP. In addition, the authors investigated the reasons why some of the patients failed to PAP therapy, and the most common reason was 'discomfort of wearing a mask (26.5%)'. The next common reasons were 'the sound is noisy (17.6%)', 'the problem was solved in another way (17.6%)', 'nose is stuffy and mouth is dry (11.8%)', 'it has no effect (11.8%)', and 'it is annoying to use it every day (8.8%)' in the order listed. Han et al. [18] also evaluated the PAP compliance rate (a case where the number of days using PAP for 4 hours or more a day was 5 days a week) through telephone interviews with a total of 106 PAP therapy patients, and the result showed that 44 patients (41.5%) fulfilled the compliance criterion. The most common reasons why some patients stopped PAP therapy were investigated to be 'PAP use is stuffy', 'wearing a PAP device/mask is inconvenient, annoying, and cumbersome', 'side effects of PAP (nasal discharge, cough, skin itching, or pleurisy)', 'symptom improvement resulting from weight loss', 'I want a surgery as the effect is insignificant', 'frequent business trip', 'the spouse feels inconvenient due to machine noise', 'mask is disgusting', and 'excessive drinking' in the order listed. In particular, 'use of a PAP device/mask is stuffy or inconvenient' and 'rhinitis symptom such as nasal congestion' are thought to be the parts that have to be most importantly checked in the patients who use PAP for the first time based on such a result.

When we looked into the domestic studies that objectively evaluated the PAP compliance rate before the enforcement of the KNHI benefits for PAP, the PAP compliance rate was relatively not high. Kim et al. [15] investigated the PAP compliance rate of 69 OSA patients, and the result showed that 28 patients (40.6%) did not purchase a PAP device after 1 month of the PAP compliance period and, among 41 patients (59.4%) who purchased a PAP device, 24 patients (34.7%) used a PAP device at least for 3 months. On the other hand, it is reported that the PAP compliance rate has improved after the enforcement of the KNHI benefits for PAP compared to before. After analyzing the PAP data of 187 OSA patients who got PAP

prescription, Park et al. [19] found that 125 patients (66.8%) fulfilled the general PAP compliance rate (a case where the number of days using PAP for 4 hours or more a day is 70% or more of the total number of days using PAP) during the adaptation period of 90 days. The KNHI benefits for PAP started to be applied to the use of PAP for the treatment of OSA patients in Korea in July 2018. Since a PAP device had to be purchased to be used before KNHI benefits were applied to PAP, there is a possibility that it dropped the accessibility to actual PAP therapy because the economic burden of the cost was high or it had an effect on the declination of PAP compliance. However, after the KNHI benefits for PAP were applied, as the KNHI benefits were enforced in the form of a rental and a certain amount (50% to 80% of the PAP device rent) was paid by the National Health Insurance Corporation, the economic burden of the cost was greatly reduced. Such an economical gain is thought to have affected the increase of the patients who have fulfilled the PAP compliance criteria.

The present study has several limitations in that it retrospectively analyzed medical records, it used the PAP compliance criteria as the KNHI PAP benefit criteria, it only checked the short-term compliance rate, and the number of cases is relatively small. In particular, although both the number of days using PAP for 4 hours or more a day during the use period of 30 consecutive days in the compliance period and the compliance rate increased compared to the initial prescription, there was no statistical significance, which is thought to be because the relatively small number of cases had an effect on the analysis of statistical significance. Therefore, further study is required to be conducted including more patients.

In conclusion, as a result of investigating the percentage of the OSA patients who fulfilled the compliance criterion after the PAP re-prescription among the patients who failed to fulfill the compliance criterion (benefit extension criterion of the KNHI) after the initial PAP prescription and got PAP re-prescription, the percentage of patients who fulfilled the compliance rate after PAP re-prescription was found to be 80%. Accordingly, even though a patient failed to fulfill the compliance criteria after the initial PAP prescription, it is thought that we should not give up and continue to emphasize the importance of PAP therapy, motivate the patient, identify and solve the problem related to PAP therapy failure, and educate and support patients for improving PAP compliance.

#### Availability of Data and Material

The datasets generated or analyzed during the study are available from the corresponding author on reasonable request.

#### Conflicts of Interest

The authors have no potential conflicts of interest to disclose.

#### Author Contributions

**Conceptualization:** Ji Ho Choi. **Data curation:** Jeonghyun Lee, JunYeong Jeong, Jaeha Lee. **Formal analysis:** Jeonghyun Lee, JunYeong Jeong, Ji Ho Choi. **Funding acquisition:** Ji Ho Choi. **Investigation:** Jeonghyun Lee, JunYeong Jeong, Jaeha Lee. **Methodology:** Jeonghyun Lee, Ji Ho Choi. **Supervision:** Ji Ho Choi. **Writing—original draft:** Jeonghyun Lee. **Writing—review & editing:** Jae Yong Lee, Ji Ho Choi.

#### ORCID iDs

Jeonghyun Lee	<a href="https://orcid.org/0000-0003-1641-5924">https://orcid.org/0000-0003-1641-5924</a>
JunYeong Jeong	<a href="https://orcid.org/0000-0002-6934-1650">https://orcid.org/0000-0002-6934-1650</a>
Jaeha Lee	<a href="https://orcid.org/0000-0002-5176-7602">https://orcid.org/0000-0002-5176-7602</a>
Jae Yong Lee	<a href="https://orcid.org/0000-0003-0608-9010">https://orcid.org/0000-0003-0608-9010</a>
Ji Ho Choi	<a href="https://orcid.org/0000-0002-5194-930X">https://orcid.org/0000-0002-5194-930X</a>

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