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Research Article

Intensive Communication by Health Professionals Added to Web-Based Telemedicine Does Not Improve PAP Adherence in OSA Patients

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Abstract

Background: Although web-based telemedicine (WBT) in association with intensive communication by health professionals has been demonstrated to improve PAP adherence in OSA patients, there has been no study aimed at differentiating the impact of communication by health professionals on PAP adherence from that of WBT alone. The purpose of this study is to estimate the significance of communication by a health professional on PAP-associated variables under conditions in which OSA patients were treated with PAP equipped with a modem allowing intensive WBT monitoring.

Design: A single-center, randomized trial.

Patients: Newly-diagnosed adult patients (more than 20 years old) with moderate-to-severe OSA (n=70), who were fresh for PAP use.

Interventions: The patients were randomized into P1group (n=34) and P2group (n=36). The P1group measurements were focused on evaluating the supplementary effect of communication by a health professional as an adjunct to WBT monitoring on PAP-related variables. The P2 group was designed to measure the withdrawal effect of a health professional from WBT monitoring.

Observation periods: 6 months.

Primary outcome: PAP adherence based on an average of the total time of PAP use and an average percentage of days in which PAP is used over four hours at night.

Secondary outcomes: PAP-related physiological variables including air leakage and apnea-hypopnea index (AHI).

Results: WBT alone substantially improved PAP adherence. Neither the addition nor the withdrawal of communication by a health professional modified PAP adherence. Irrespective of the study protocols, air leakage was reduced in a time-dependent manner.

Conclusion: The crucial factor for improving PAP adherence is the introduction of web-based telemedicine, whereas the addition of a health professional's contribution might have little effect on PAP adherence so far as the web-based telemedicine monitoring is already or simultaneously applied.

Keywords: Obstructive sleep apnea (OSA); Positive-airway-pressure (PAP); Adherence; Web-based telemedicine; Health professional

Introduction

Obstructive sleep apnea (OSA) is characterized by recurrent collapse of the upper airway during sleep, leading to nocturnal hypoxemia, sleep fragmentation, and daytime hypersomnolence. OSA evokes overwhelming adverse consequences including stroke, heart failure, and other cardiovascular diseases, resulting in increased all-cause mortality [1-8]. A significant number of motor vehicle accidents have been attributed to OSA [9]. The most effective treatment for OSA patients is continuous positive airway pressure (PAP), leading to a reduction in mortality caused by cardiovascular disease and motor vehicle crashes [10-12]. Optimizing PAP adherence is an important aspect in the management of OSA patients. However, patient adherence to PAP therapy is poor; i.e., 20-30% of patients discontinue PAP therapy within four months or use it under less optimal conditions [13-16]. Adherence to PAP treatment is influenced by numerous factors including the following [17,18]: biomedical characteristics (severity of the disorder, adverse effects of PAP, therapeutic response), psychological aspects (anxiety, claustrophobia), social interactions (family support), technological factors (applied pressure, humidification, mask fitting), and economic considerations (cost, insurance coverage). Although it is impossible to solve a variety of the problems that collectively elicit non-adherence to PAP therapy, some of the problems are improved

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by an intensive support program that includes timely interventions by health professionals in combination with telephone calls and/or home visits [19-24]. Sparrow et al. [25] developed an automated telephone-linked communication (TLC) system and examined its effectiveness for improving the adherence to PAP therapy. Although the TLC system did not allow daily investigation of various PAP-related physiological variables such as air leakage and applied pressure, Sparrow et al. found that the TLC enhanced the adherence of OSA patients to PAP treatment, resulting in a reduction of sleep apnea and depressive symptoms. Using a current web-based telemedicine (WBT) system enabled us to closely monitor a variety of physiological variables during PAP treatment and to conduct rapid troubleshooting of problems that could occur daily, Fox et al. [18] certified that intensive contact by a research coordinator in association with WBT significantly improved PAP adherence in moderate-to-severe OSA patients. In addition to the benefits from the WBT system, however, Fox et al. identified an important disadvantage to this system; i.e., a significant increase in the coordinator time spent on patients compared to that of the PAP standard treatment without WBT. This finding indicates that PAP treatment using a WBT system combined with the involvement of health professionals would be notably expensive because the WBT system *per se* is expensive, and the active contribution of health professionals might increase the cost of this type of treatment. Because the WBT system permits comprehensive monitoring of objective physiological variables during PAP treatment, it is possible that the WBT system *per se* nearly optimizes PAP adherence without the aid of intensive communications by health professionals. Socio-economically, differentiating the effect on PAP treatment of a WBT system from that of other supporting procedures including active contribution by health professionals is fundamental in a variety of aspects. The purposes of this study were to determine the following issues during the PAP treatment undergone by patients with moderate to severe OSA: 1) the effect of a WBT system on PAP-associated objective physiological variables, including adherence to PAP therapy (the primary outcome) as well as air leakage and residual respiratory events (the secondary outcomes); 2) the supplementary effect of active intervention by a health professional appended to a WBT on the primary and secondary outcomes; 3) the integrated effect of a WBT and active intervention by a health professional on the primary and secondary outcomes; and 4) the withdrawal effect, on the primary and secondary outcomes, of active intervention by a health professional from the condition under which a WBT and health-professional intervention were simultaneously applied.

Materials and Methods

Study oversight

We conducted a single-center, randomized trial in patients with moderate-to-severe OSA regarding a WBT system with and without active intervention by a health professional. The authors confirmed that all ongoing and related trials for this intervention were registered (Registration: Japan Primary Registries Network (JPRN), UMIN000013644 (UMIN Clinical Trials Registry), http://www.umin.ac.jp/ctr/). The study was directed toward differentiating the impact of communication by a health professional on a variety of PAP-related variables from the impact of WBT alone. All of the participants provided written informed consent for their data to be used for the clinical trial and agreed to the inclusion of their data in the database that would be used for this analysis. The study was approved by the Human Ethics Committee of the Tokyo Women's Medical University (No: 2044).

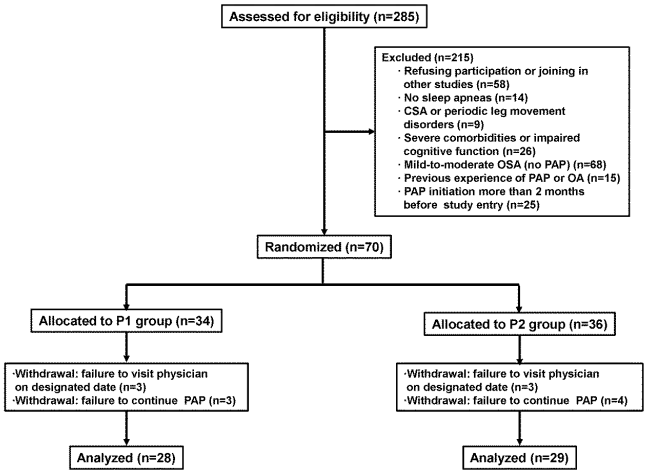

Figure 1: CONSORT flow diagram of patient recruitment and exclusion.

Study population (Figure 1)

Eligible participants were selected from the adult patients of more than 20 years old, who were referred to our Comprehensive Medical Center of Sleep Disorders with complaints related to sleep-disordered breathing. Each subject was required to complete questionnaires regarding age, height, body weight, lifetime cigarette consumption, drinking, snoring, nocturnal urination, breathing pattern (i.e., through the nose or the mouth), types of dreams, depressive feelings, restless leg symptoms, gastroesophageal reflux, nasal congestion, and medical histories regarding comorbidities and medications. The subjects completed the Epworth Sleepiness Scale (ESS) and the Athens Insomnia Scale (AIS). The subject underwent full overnight polysomnography (PSG) (EEG-9200 Neurofax, Nihon Kohden, Tokyo, Japan) at the sleep laboratory of the center. The sleep stages and disturbed respiratory events were scored by a trained sleep technician referring to the recommendations proposed by the American Academy of Sleep Medicine [26]. The patients who were confirmed to have moderate-to-severe OSA with an AHI of more than 20events/hr by the PSG examination were initiated with nasal or oronasal PAP therapy (S9™, ResMed, Sydney, Australia/Teijin Co., Tokyo, Japan). Consulting with the manuals established in our sleep center, titration of the applied pressure for the PAP device, fitting of a nasal or oronasal mask, and instructions on the operating procedure for the machine were performed at the sleep laboratory of the center during an overnight observation by a trained sleep technician and a PAP practitioner.

Exclusion criteria (Figure 1)

The following subjects were excluded from participating; 1) subjects who refused to participate in the study or those who were in concurrent studies at the center, 2) subjects who had no abnormal respiration during sleep (an overall apnea-hypopnea index (AHI) < 5 events/hr), 3) subjects with central sleep apneas (CSA) (an overall AHI ≥ 5 events/hr in which CSA-type apneas and hypopnea as predominated) or with periodic leg movement disorders, 4) subjects with any pathological condition, including malignancy in any organ,

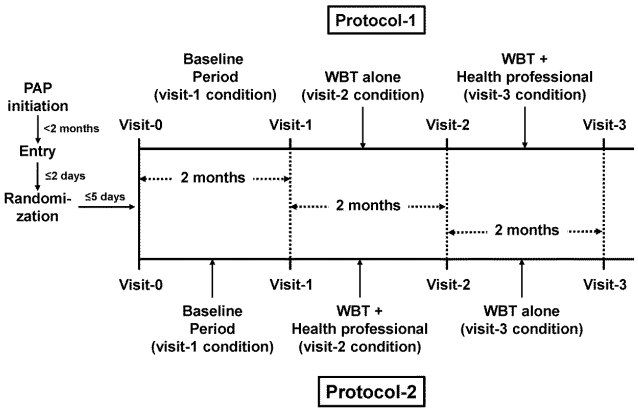

Figure 2: Study protocols.
The patients' enrollment was accomplished within two months after PAP initiation. The patients' randomization was completed within two days after enrollment. Each patient was scheduled to visit outpatient clinic within five days after randomization (i.e., the first visit defined as visit-0 in each study protocol). In protocol-1, the two months between visit-0 and visit-1 denote the baseline period without any intervention (the visit-1 condition). The next two months, between visit-1 and visit-2, indicate the period in which web-based telemedicine (WBT) alone is introduced (the visit-2 condition), whereas the last two months between visit-2 and visit-3 correspond to the period in which active communication by a health professional is appended to WBT monitoring (the visit-3 condition). In protocol-2, the two months between visit-0 and visit-1 denote the baseline period with no intervention (the visit-1 condition). The next two months between visit-1 and visit-2 denote the period in which both WBT monitoring and active communication by a health professional are simultaneously introduced (the visit-2 condition). The last two months between visit-2 and visit-3 denote the period in which communication by a health professional is removed from the therapeutic process (the visit-3 condition).

severe heart failure, heart attack or stroke, renal failure requiring dialysis, or impaired cognitive function, 5) subjects with mild-to-moderate OSA ($5 \leq AHI < 20$ events/hr), to whom PAP was not introduced, 6) subjects who had had previous treatment with PAP or an oral appliance (OA), and 7) subjects to whom PAP was launched over two months prior to study entry.

We excluded patients who were in concurrent clinical trials at our sleep center to avoid an excessive burden on an individual patient, in accordance with the ethics policy of our university. We did not enroll the patients in whom the time of study entry was more than two months apart from the time of PAP initiation. This was because adherence to PAP therapy had been shown to be predominantly decided within a couple of months after PAP initiation [13-16].

Determination of the total number of patients enrolled

We adopted the two-arm design for examining the effect of web-based telemedicine (WBT) with and without active intervention by a health professional on PAP-associated objective variables at three different occasions (Figure 2). Considering the statistical analysis on the variables used for evaluating the PAP adherence (the primary outcome, see below), we planned to enroll the number of patients sufficient for detecting a change of 30 min for the total time of PAP use/night and a change of 5 points concerning the %days of 4-hr PAP use defined as the average percentage of days in which PAP was used over four hours/night during a certain observation period. We preliminarily investigated the PAP adherence in ten patients continuing PAP therapy for more than two months, resulting in an average total time of PAP use of 266 ± 63 min/night (mean ± SD), and the %days of 4-hr PAP use was 59.2 ± 10.5 %. Using a statistical-power analysis based on Design of Experiments (JMP Start Statistics, SAS Institute Inc., Cary, NC, USA), the mean and SD values of the total time of PAP use predicted that, under a statistical condition with a significant level (α) at 0.05 and a statistical power ($1-\beta$) at 0.8, the data harvested from 22 patients at each time point were necessary for detecting a 30-min difference in the values of the total time of PAP use measured at three different occasions. Similarly, we noticed that the data for 22 patients at each time point could detect a 5-point difference in the % days of 4-hr PAP use under a condition with α at 0.05 and ($1-\beta$) at 0.8. Based on these pilot observations, we considered that at least 22 participants should be recruited for each arm of the study protocols. Assuming that the withdrawal rate from the study was 20%, we finally decided to recruit at least 30 participants for each of the study protocols (i.e., 60 participants in total).

Enrollment and randomization of patients

The enrollment of participants was started on February 1, 2011 and ended on April 30, 2014 when the total number of participants registered for the study certainly exceeded the pre-scheduled number of 60. During these 3 years, a total of 285 patients were assessed for eligibility and 70 patients who were fresh for PAP use and not against the exclusion criteria were recruited for the analysis. Stratifying the patients according to age, gender, the ESS score before introducing PAP, and the AHI before PAP use, we randomized them into P1 and P2 groups (1:1 ratio) using a randomized block design to ensure balance of the confounding factors between the two groups. The enrollment and subsequent randomization of patients was executed by a research coordinator, who was independent of our sleep center. At a time point of entry, the research coordinator acquired, from the patients, the agreement for participating in the present clinical trial in a written informed consent form and explained them concerning the purpose and details of the study protocols. The research coordinator finished the patient randomization within two days after enrollment. Thus, the assignment of each patient to the P1 or P2 group was blinded to all of the persons who were involved in the study after randomization, including the patients and the assessors. The research coordinator guided the patients to securely grasp the time schedule when they should visit the outpatient clinic. The first visit to the outpatient clinic was set up within five days after randomization (visit-0 in each study protocol, Figure 2). Furthermore, the research coordinator notified the assessors of what should be done for the patient on an appointed date of each study protocol.

The P1 group (n=34; men: 29, women: 5) was assigned to follow protocol-1, whereas the P2 group (n=36; men: 30, women: 6) was assigned to complete protocol-2 (Figure 2). Although 13 participants (6 in the P1 group and 7 in the P2 group) dropped out from the study protocols during the observation periods, the remaining 57 participants accomplished the whole study processes. The first reason for the withdrawal was that the participant failed to visit the outpatient clinic on a designated date (3 in each group). The second reason was that the participant discontinued the PAP at a certain time during the observation period (3 in the P1 group and 4 in the P2 group). Finally, the number of participants who completed the study protocol allowing estimation of the primary and secondary outcomes

Table 1: The questionnaire (Q-1) asking three subjective variables in association with PAP treatment including OSA-related symptoms, feelings regarding PAP, and anxieties related to PAP.

Categories	Questions	Scores										
OSA-related symptoms	Is daytime sleepiness better?	0	1	2	3	4	5	6	7	8	9	10
	Is nighttime sleep better?	0	1	2	3	4	5	6	7	8	9	10
Feelings regarding PAP	Do you feel effective about PAP?	0	1	2	3	4	5	6	7	8	9	10
	Do you want to continue PAP?	0	1	2	3	4	5	6	7	8	9	10
Anxieties related to PAP	Do you feel burden on PAP?	0	1	2	3	4	5	6	7	8	9	10
	Do you forget to use PAP?	0	1	2	3	4	5	6	7	8	9	10
	Do you feel frustrated on PAP therapy?	0	1	2	3	4	5	6	7	8	9	10
	Do you feel uneasy about PAP operation?	0	1	2	3	4	5	6	7	8	9	10

Every participant was required to assess a score ranging from zero to ten for each question at three outpatient clinic visits (visit-1, visit-2, and visit-3). A higher score represented a more favorable response regarding OSA-related symptoms and feelings regarding PAP, while a higher score indicated a more unfavorable response regarding anxieties related to PAP.

summed to 28 patients (men: 24, women: 4) in the P1 group or 29 patients (men: 24, women: 5) in the P2 group (Figure 1).

Study protocols (Figure 2)

The observation period was six months, during which the participants returned to the outpatient clinic to visit a sleep physician four times at regular intervals of two months. The P1 group was assigned to follow protocol-1, in which the first two months between the first visit (visit-0) and the second visit (visit-1) were taken as the baseline period (the visit-1 condition), in which PAP therapy was continued as usual without other active intervention. On the second visit (visit-1), a modem (NemLink®, Teijin Co., Tokyo, Japan), programmed to automatically transmit physiological information to a web-based database by a wireless telephone network (DoCoMo FOMA, NTT, Tokyo, Japan), was installed in the PAP device. This modem-attached PAP device was defined as a web-based telemedicine (WBT) system and was used for monitoring daily PAP adherence, applied PAP pressure, air leakage through the mask, and residual respiratory events. During the two months between visit-1 and visit-2 (the visit-2 condition), the participants were no longer contacted by the health professional. The investigation during these two months allowed us to estimate the effects of the WBT alone on the physiological variables. During the final two months between visit-2 and visit-3 (the visit-3 condition), the participants received active communication from a health professional once a week. The investigation during these two months was used to evaluate the supplementary effects of the active intervention by a health professional added to the WBT on the PAP-related variables.

The P2 group was assigned to complete protocol-2, in which the second two months and the third two months defined in protocol-1 were reversed; i.e., after the first two months (the baseline period), at visit-1, the participants were provided the modem-attached PAP device and the health professional contacted the participants once a week until the next visit (visit-2). This period (the visit-2 condition) allowed us to examine the integrated effects of the WBT and the intensive communication by the health professional on the objective variables related to the PAP treatment. During the subsequent two months, between visit-2 and visit-3 (the visit-3 condition), we investigated the effects of withdrawing the intensive communication with the health professional from the WBT system on PAP treatment.

Communication with patients

To minimize the variability in communication with participants, only the three assessors (K.Y.: the sleep physician, F.I.: the health professional, and Y.I.: the chief sleep technician) came into contact with the participant on a designated date during an observation period. The chief sleep technician (Y.I.) talked to the participant only at the time when a modem, transmitting information to a web-based database by a wireless telephone network, was installed in the PAP device. At this moment, he simply instructed the participant on the operating procedure for the modem without mentioning any matters in connection with the PAP adherence of this participant.

At each outpatient clinic visit (visit-0, visit-1, visit-2, and visit-3), the sleep physician (K.Y.) saw the participant and reviewed the information collected via a semiconductor chip which was routinely used for monitoring the PAP treatment of a given patient. The sleep physician did not look into the information obtained via the web-based telemedicine system. In addition, he was prohibited to touch on any issues relevant to the PAP adherence while giving a medical advice to the participant.

At outpatient clinic visits (visit-1, visit-2, and visit-3), the participant was required to complete the two questionnaires (Q-1 and Q-2). The Q-1 was an inquiry regarding three subjective variables including OSA-related symptoms, feelings regarding the efficacy of the PAP treatment, and anxieties related to the PAP treatment (Table 1). The participant was asked to assess a score ranging from zero to ten for each question, with a higher score representing a more favorable response regarding OSA-related symptoms as well as feelings concerning the efficacy of the PAP treatment. However, a higher score indicated a more unfavorable response related to anxieties resulting from the PAP treatment. The Q-2 comprised nine queries regarding the following discomforts resulting from PAP therapy; difficulty in exhalation, air leakage through the mask, dry mouth, nasal pain, involuntary removal of the device, vestige of compression by the mask, noise during the operation of the machine, difficulty in turning the body during sleep, and compression by the head gear. The Q-2 score ranged from zero to nine, with a higher score indicating greater discomfort resulting from PAP therapy. These data were reviewed by the health professional (F.I.) who was a respiratory nurse. Similar to the sleep physician, the health professional did not look over the information obtained via the web-based telemedicine

Table 2: Basic characteristics of OSA patients in P1 and P2 groups.

	P1 group (n=34)	P2 group (n=36)
Age (years)	60.8 (12.1)	62.5 (10.2)
Males : Females	29 : 5	30 : 6
Height (cm)	170.3 (6.1)	166.7 (7.0)
Body weight (kg)	78.0 (12.1)	70.7 (17.6)
Body mass index (BMI, kg/m^2)	26.9 (3.9)	25.2 (4.8)
ESS before PAP	6.9 (4.6)	8.3 (4.5)
Frequency of nocturnal urination before PAP (numbers/night)	1.3 (1.4)	1.4 (1.2)
AHI before PAP (events/hr)	41.2 (18.6)	44.6 (20.8)
AHI after PAP (events/hr)	1.5 (0.3)*	2.1 (1.7)*
Minimum SO_2 before PAP (%)	74.7 (8.6)	74.3 (9.8)
Minimum SO_2 after PAP (%)	91.6 (3.7)*	90.2 (3.1)*
Time lag between PAP initiation and study entry (months)	1.2 (0.4)	1.1 (0.5)

Values are means and (SD). ESS: Epworth Sleepiness Scale. PAP: treatment by continuous positive airway pressure. AHI and minimum SO_2: values before and after initiation of PAP. No significant difference in any parameter between P1 and P2 groups. *: different from the values before initiation of PAP. Six patients in P1 group and seven patients in P2 group were dropped out during the observation period.

system. The health professional regularly spoke by telephone with each participant for least 30 min once a week during a designated period of two months regarding any problem and discomfort caused by the PAP therapy. Giving consideration to the subjective symptoms and feelings indicated in the two questionnaires of Q-1 and Q-2, the health professional encouraged the participant and actively advised him or her on the way how to alleviate the difficulty evoked from PAP use.

Outcome measures

The primary outcome was PAP adherence, which was assessed based on an average of the total time of PAP use at night (min/night) and an average percentage of days in which PAP was used over four hours (% days of 4-hr PAP use) during one observation cycle of each study protocol [18,27,28]. Furthermore, we evaluated whether the two PAP-associated variables, including air leakage and AHI, were varied in parallel with the change in PAP adherence (the secondary outcomes).

Statistical analysis

The calculations were performed using IBM SPSS Statistics software (Version 21.0, SPSS, Inc., an IBM company, NY, USA). Unless otherwise specified, the values were expressed as the means ± the standard deviations (SD). The statistical comparisons between the basic data obtained for the P1 and P2 groups were performed with the non-parametric Mann-Whitney U-test. The differences between the three repeated measures obtained in the visit-1, visit-2, and visit-3 conditions were analyzed by repeated measure ANOVA with Mauchly and Greenhouse-Geisser tests, followed by *post-hoc* multiple comparisons with Tukey and Games-Howell tests. A p-value lower than 0.05 was considered statistically significant.

Results

Basic characteristics of participants (Table 2)

The age distribution of the P1 group ranged from 34 to 78 years old, whereas that of the P2 group ranged from 34 to 80 years old, with no difference between the two groups. There were no significant differences in the other parameters between the groups, including the anthropometric parameters, the ESS, the numbers of nocturnal urination, the severity of OSA before the initiation of PAP (AHI and minimum SO_2), and the time lag between the PAP initiation and the study entry.

Table 3: Transitional changes in PAP-related physiologic variables in P1 and P2 groups.

	Visit-1 condition	Visit-2 condition	Visit-3 condition
P1 group			
Total time of PAP use during sleep (min/night)	256.6 (60.8)	290.1 (60.9)*	292.7 (66.2)*
% days of PAP use over 4 hrs (%)	58.0 (9.4)	67.0 (10.8)*	66.2 (11.4)*
Air leak (L/min)	15.1 (14.0)	15.5 (14.0)	10.3 (6.7)†
AHI (events/hr)	1.2 (0.9)	1.1 (0.7)	1.1 (0.8)
P2 group			
Total time of PAP use during sleep (min/night)	236.4 (65.8)	274.6 (64.2)*	270.1 (64.8)*
% days of PAP use over 4 hrs (%)	60.2 (10.9)	66.9 (9.8)*	67.1 (11.4)*
Air leak (L/min)	20.5 (10.7)	17.9 (8.7)*	16.1 (9.0)*,†
AHI (events/hr)	1.5 (1.6)	1.3 (1.6)	1.1 (1.2)*

P1 group: n=28 (men: 24, women: 4), P2 group: n=29 (men: 24, women: 5). Values are means and (SD).
*: different from the values under visit-1 condition. †: different from the values under visit-2 condition.

PAP adherence (Table 3)

In protocol-1, the total time of PAP use increased from 256.6 min (visit-1 condition) to 290.1 min after the WBT was introduced (visit-2 condition) (difference: 33.5, 95% confidence interval (CI): 13.1 to 53.9, p=0.038) (Figure 3). The active communication by a health professional appended to the WBT (visit-3 condition) did not further increase the total time of PAP use (difference: 2.6, CI: -17.8 to 23.0, p=0.92). The identical tendency was observed for the % days of 4-hr PAP use; i.e., it increased from 58.0% in the visit-1condition to 67.0% in the visit-2 condition (difference: 9.0, CI: 5.4 to 12.6, p=0.015), and no further increase was observed in the visit-3 condition (difference: -0.8, CI: -4.8 to 3.2, p=0.87) (Figure 3).

In protocol-2, the total time of PAP use increased from 236.4

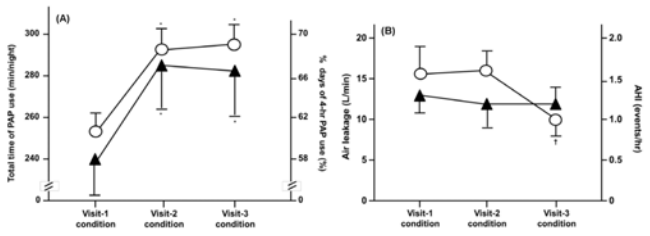

Figure 3: The adherence to the PAP therapy, air leakage, and AHI in patients following protocol-1
(A): The changes in the total time of PAP use during sleep (circles) and the percentage of days in which PAP is used over four hours (% days of 4-hr PAP use, triangles). (B): The transitional changes in air leakage from the mask (circles) and the AHI (triangle). The values are expressed as the means ± the standard errors. *: significantly different from the values obtained at the baseline period (the visit-1 condition). †: significantly differing from the values obtained in the visit-2 condition.

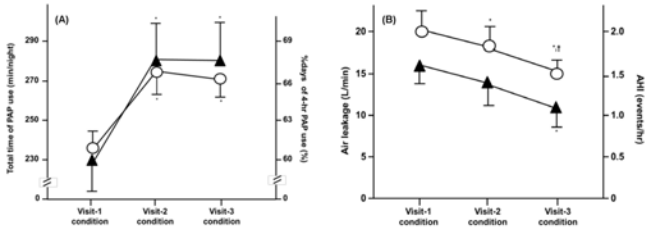

Figure 4: The adherence to the PAP therapy, air leakage, and AHI in patients following protocol-2
(A): The changes in the total time of PAP use during sleep (circles) and the percentage of days in which PAP is used over four hours (% days of 4-hr PAP use, triangles). (B): The transitional changes in the air leakage (circles) and the AHI (triangles). The values are expressed as the means ± the standard errors. *: significantly different from the values obtained in the baseline period (visit-1 condition). †: significantly differing from the values obtained in the visit-2 condition.

min in the visit-1 condition to 274.6 min in the visit-2 condition (the active communication by a health professional overlaid on the WBT) (difference: 38.2, CI: 15.2 to 61.1, p=0.016), and there was no difference between the visit-2 condition and the visit-3 condition (the withdrawal of health-professional assistance) (difference: -4.5, CI: -27.5 to 18.5, p=0.91) (Figure 4). Qualitatively, a consistent trend was investigated for the % days of 4-hr PAP use; i.e., an increase from 60.2% in the visit-1 condition to 66.9% in the visit-2 condition (difference: 6.7, CI: 2.1 to 11.3, p=0.049), and no further change was observed in the visit-3 condition (difference: 0.2, CI: -3.9 to 4.3, p=0.96) (Figure 4).

Air leakage and AHI (Table 3)

In protocol-1, air leakage was significantly reduced from the visit-2 condition to the visit-3 condition (difference: -5.2, CI: -8.7 to -1.7, p=0.046), whereas the AHI did not change throughout the observation period from visit-1 to visit-3 (difference between visit-1 and visit-2: -0.1, CI: -0.5 to 0.3, p=0.90; difference between visit-2 and visit-3: 0.0, CI: -0.4 to 0.4, p=0.98; difference between visit-1 and visit-3: -0.1, CI: -0.5 to 0.3, p=0.89) (Figure 3).

In protocol-2, air leakage was gradually reduced from the visit-1 condition to the visit-2 condition (difference: -2.6, CI: -5.0 to -0.2, p=0.012) and from the visit-2 condition to the visit-3 condition (difference: -1.8, CI: -3.3 to -0.27, p=0.017) (Figure 4). Although the AHI qualitatively revealed the identical trend as that of the incidence of air leakage, a statistically significant decrease in the AHI was only observed in the visit-3 condition (vs. visit-1 condition, difference: -0.4, CI: -0.8 to -0.04, p=0.043) (Figure 4).

Discussion

Effects of web-based telemedicine alone on PAP-related variables

In protocol-1, we found that the introduction of a modem-equipped PAP device substantially increased the total time of PAP use and the % days of 4-hr PAP use with little change in air leakage or the AHI (Figure 3). These facts clearly indicate that web-based telemedicine alone, with no additional intervention, could enhance the adherence to PAP therapy in patients with moderate to severe OSA.

Protocol-2 demonstrated that, irrespective of the communication by a health professional, PAP therapy using a modem-equipped device significantly enhanced PAP adherence in association with decreased air leakage (Figure 4), confirming the findings from protocol-1. We, therefore, considered that the web-based telemedicine alone would certainly have an improving effect of PAP adherence.

Effects of intervention by a health professional on PAP-related variables

Although the addition of the active communication of a health professional appended to the web-based telemedicine (protocol-1) significantly inhibited air leakage from the mask, it did not improve PAP adherence (Figure 3). The elimination of the contribution of a health-professional from the therapeutic process (protocol-2) did not worsen PAP adherence, air leakage, and the AHI (Figure 4). Contrary to our expectations, air leakage was further improved under conditions in which the contribution of a health professional was removed. We hypothesized that this contradicting phenomenon might be explained by a time-dependent increase of experience in fitting the mask. The time-dependent improvement of air leakage in either of the study protocols suggests that, in addition to the introduction of web-based telemedicine and/or the health-professional aid, the time-dependent practice in PAP use should be taken into account while interpreting the results of PAP adherence. The trends of PAP adherence, however, did not qualitatively parallel those of air leakage in respective study protocols (Figures 3,4). This fact may preclude the time-dependent increase of experience in PAP use from playing a major role in improving the PAP adherence. Therefore, we concluded that the improvement of PAP adherence would be predominantly achieved by supervising patients by web-based telemedicine and neither by active intervention from a health professional nor by time-dependent augmentation of practice in PAP use.

The comparison with the findings reported by other investigators

The findings obtained in the present study are qualitatively in agreement with those of most previous studies [18-25,27,28], while they are inconsistent with a study reported by Taylor et al. [29]. Analyzing the adherence to PAP therapy in OSA patients who were randomized to a telemedicine (intervention) arm or a traditional-care arm, Taylor et al. demonstrated that the PAP adherence did not differ between the two arms. The detection power concerning the PAP adherence, however, might be lower in the intervention group based on the self-reported data than that analyzed from the detailed physiological information. On the use of an automated telephone-linked communication system, through which patients were compelled to report their perceptions and experiences with OSA as well as the PAP usage time, Sparrow et al. [25] found that the application of a telephone-linked communication system during PAP treatment significantly improved self-reported PAP adherence. Fox et al. [18] found that the combination of web-connected telemedicine system and intervention by a research coordinator increased the adherence to PAP therapy. However, these authors did not analyze which factor would be the most crucial to improving PAP adherence. To address this issue, we designated the observation protocols to allow systematic evaluations regarding the importance of web-based telemedicine in combination with the additive or withdrawing effect of active communication by a health professional for PAP adherence. The results conclusively suggest that the web-based telemedicine

system *per se* is the most important component for motivating OSA patients to continue with PAP use. The patients might perceive that they are continuously watched by members of the healthcare team via the web-based telemedicine system. This perception might serve as one of the significant factors for augmenting the adherence to PAP therapy.

Study limitations

First, we should acknowledge that this study was undertaken in a single sleep center and multicenter studies are needed to certify the general applicability of the findings from this study.

Second, the present study did not support the beneficial contribution of health professional aids to PAP adherence. However, we should pay heed to the fact that the findings investigated in the present study do not signify that the active intervention from a health profession is truly insignificant for ameliorating PAP adherence. This is because our study protocols were lacking in an intervention arm that allowed direct estimation of the health professionals' contribution to PAP adherence in the absence of web-based telemedicine monitoring.

Third, we did not analyze, on PAP adherence, the negative effect of psychological factors that had been recognized as playing an important role in determining PAP adherence [30,31]. However, this is beyond the scope of the present study because we focused our mind on PAP adherence influenced mainly by technological factors. Further studies are indispensable for elucidating the interplay between web-based telemedicine monitoring and mentality-related PAP adherence.

Conclusion

We found that adherence to PAP therapy in patients with moderate to severe OSA would be substantially ameliorated by web-based telemedicine for monitoring a variety of PAP-related physiological variables. The addition of active communication by health professionals might have little effect on improving PAP adherence under a condition in which the web-based telemedicine monitoring is already or simultaneously applied.

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