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Effect of 10-minute oropharyngeal exercise on the apnoea-hypopnoea index

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Previously reported oropharyngeal exercises are long and difficult to perform. Therefore, we created a 10-min daily oropharyngeal exercise program and conducted a study to confirm its effectiveness. Twenty-five participants whose apnoea–hypopnoea index (AHI) values were greater than 5 were enrolled. All of the participants performed 10 min of exercise per day for 12 weeks and were evaluated for AHI values, tongue pressure, lip closure pressure, snoring, and Mallampati scores before and after the exercise. Twenty-two participants (88% of all participants) completed the oropharyngeal exercise. Another patient was unable to attend the last evaluation session due to illness. The AHI value improved significantly from an average of 20.9 to 16.9 times/hour in patients with a pre-exercise AHI of 5 to 30 (P = 0.0317). The AHI improvement group included younger participants than did the AHI deterioration group (P = 0.354), the lip closure pressures tended to increase from a median of 17.6 N to 21.3 N with oropharyngeal exercises (P = 0.0677). This novel oropharyngeal exercise may be appropriate for younger SAS patients with an AHI less than 30.

Keywords Oropharyngeal exercise, Obstructive sleep apnoea syndrome

The prevalence of obstructive sleep apnoea syndrome (OSAS) is high, and OSAS is thought to have an impact on prognosis as an independent risk factor for the eventual development of cerebrovascular and cardiovascular disorders. OSAS is classified as mild ($5 \le apnoea-hypopnea$ index [AHI, the number of apnoea and hypopneas per hour] < 15), moderate ($15 \le AHI < 30$), or severe ($30 \le AHI$) according to the AHI calculated by polysomnography (PSG). In Japan, an AHI ≥ 20 diagnosed by PSG is an indication for continuous positive airway pressure (CPAP) therapy, and patients with mild or moderate disease who have an AHI value of < 20 are eligible for an oropharyngeal appliance. However, the continuation rate of CPAP was only 50% at one year, and many patients with severe OSAS cannot continue CPAP¹⁻³. In addition, the use of oropharyngeal appliances (OAs) has improved by more than $50\%^4$ and is a highly adherent treatment⁵. However, the effectiveness of OA is limited. On the other hand, several outstanding reviews on oral exercise have been reported⁶⁻⁸. Studies have shown that oropharyngeal exercises improve the AHI⁹. However, it is difficult to continue oral exercises for 30 min a day for 3 months, and only 79% of patients are able to perform more than 85% of the exercises. Therefore, we have set our exercise duration to 10 min as a time to reduce drop-outs and allow the exercise to continue. In this study, we shortened the exercise to 10 min per day and evaluated the effectiveness of the novel exercise in improving the AHI value in OSAS patients.

Methods

Participants

This study is a prospective intervention study and is performed in Tokyo, Japan. Twenty-five participants whose AHI value was \geq 5 were enrolled. Adult Japanese males aged between 18 and 65 years were included. All of them were drivers employed at Nippon Kotsu Co., Ltd.

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Sample size

The results of a randomized controlled trial of oral exercises versus a control treatment for sleep apnoea revealed that the mean difference in AHI between the pre- and postexercise periods was 8.5 events/hour, and the standard deviation was 10.3 events/hour with respect to the amount of change from baseline in the AHI⁹. Because of the small variability in the AHI reported in previous studies at our institution to assess the effect of tongue strength training on the same race as this study¹⁰, we estimated the mean difference in the postexercise–preexercise (AHI) score to be -5.0 events/hour and the standard deviation to be 8 events/hour for the current case group before and after the exercises. For the analysis of the primary endpoint, the number of subjects required for the null hypothesis that there is no difference in the mean difference in the AHI between the pre- and the postexercise periods would be 23 if paired t tests were conducted with a two-sided significance level of 5% and a power of 80%. As we estimated that there would be approximately 2 dropouts, the target number of subjects for this study was set at 25.

Inclusion and exclusion criteria

The inclusion criteria were as follows: individuals with an AHI value of \geq 5 on the simple SAS monitor, individuals who were 18 years or older at the time consent was obtained, individuals with written consent for this study obtained from the subject him/herself, individuals who had a smartphone, and individuals who were able to participate in the postexercise test. Here, the Japanese guidelines define an AHI of 5 to less than 15 as mild disease, 15 to 30 as moderate disease and 30 or more as severe disease. The exclusion criteria were as follows: individuals with tongue abnormalities that would make oropharyngeal exercises difficult; individuals who were undergoing oropharyngeal interventions, such as weight loss, OA, and CPAP treatment, for OSAS; and individuals who would not be able to safely participate in this clinical trial (e.g., those with angina pectoris or acute myocardial infarction within 3 months of onset or those with heart failure with a NYHA cardiac function classification of degree II or higher).

Oropharyngeal exercise

The participants performed oropharyngeal exercises to move their tongues, cheeks, and soft palates for a total of 10 min once a day for 12 weeks (Fig. 1). Due to their working schedule, they exercised during the morning (5:00am-9:00am) and late at night (10:00 pm-12:00am). The detailed instructions given to the participants were as follows: (1) Stick out the tongue, put it back into the mouth and slide the tongue back into the mouth as far as possible, as if stroking the tip of the tongue against the upper jaw. Move the tip of tongue to the back of the mouth as if it were touching the throat. Hold this position, and then return the tongue to its original position. Perform this tongue roll motion 20 times for a total of 60 s. (2) Open the mouth slightly, press the entire tongue firmly against the upper jaw, and hold it there for 3 s. As the tongue is brought back down, make a tongue-clicking sound. Perform this tongue lifting motion 20 times for a total of 60 s. (3) Open the mouth wide enough to see the uvula. Lift the soft palate to create a wide pharyngeal space. Hold the soft palate in the lifted position for 1 s. Perform this action of lifting the soft palate 30 times for a total of 90 s. (4) Open the mouth, press the tip of the tongue against the back of the lower teeth, and then press the entire tongue against the mandible. The tongue should then resemble concave cup. Perform this downward pressing of the tongue 20 times for a total of 60 s. (5) (6) Close the lips and rotate the tongue in a wide, smooth motion, as if pushing it firmly into the lips and cheeks. Perform this tongue rolling motion 15 times on each side for a total of 90 s. (7) Close the mouth, inhale for 5 s, and then compress the cheeks together. Hold this position for 5 s. Try to imagine that the cheeks are sucking in all the air from the mouth. Next, keep the mouth closed, and inflate the cheeks; hold this position for 10 s. Remember to inhale and exhale. Perform this cheek-inhalation motion three times. (8) Straighten the back, and look straight up at the ceiling. Rhythmically thrust the tongue forward five times as strenuously as possible, and then hold this position for three seconds as if licking the nose. Perform this tongue-thrusting action 6 times for a total of 60 s. (9) Collect saliva in the mouth to make it easier to swallow. Swallow the saliva while holding the tongue between the lips. The tip of the tongue should be visible through the lips. Perform this swallowing action 10 times for a total of 60 s. (10) Look up so that the face is as parallel to the ceiling as possible. Squeeze the lips as if kissing the ceiling, and keep the mouth pursed and tucked for 5 s. Perform this mouth-sucking motion 10 times for a total of 60 s.

A video application was used to assist the participants in performing the exercises and to ensure accuracy. Discontinuation or interruption of the exercises was confirmed online. Follow-up inspections were planned to take place at week 12.

Endpoint

The primary endpoint was the effect of oropharyngeal exercises on the AHI value at Week 12. The secondary endpoints were tongue pressure, lip closure pressure, snoring, and the Mallampati score. Oral findings were assessed by photographs.

Statistical analyses

The AHI was analysed for each SAS severity level. Matched t tests were performed for the AHI, tongue pressure, and lip closure pressure. Fisher's test was used to compare the two groups. All tests were two-sided, and *p* values ≤ 0.05 were considered to indicate statistical significance. All the statistical analyses were performed via EZR version 1.55 (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R (version 4.1.2; R Foundation for Statistical Computing, Vienna, Austria)¹¹.

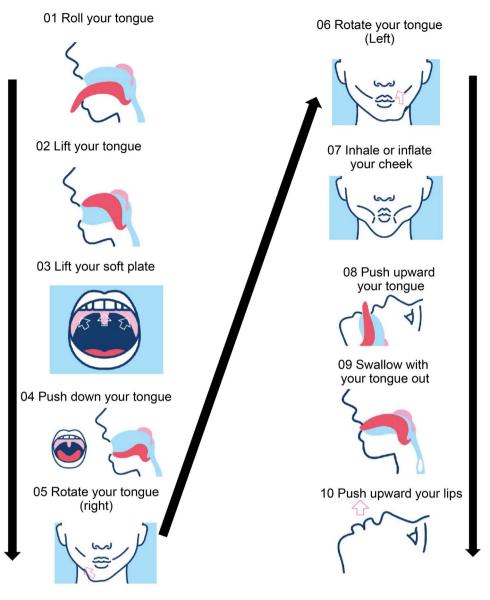


Fig. 1. Schema of oropharyngeal exercise.

Ethical issues

This prospective interventional study was approved by the institutional review board (reference number: A230003). Informed consent was obtained from all participants included in the study. All procedures performed were in accordance with the ethical standards of the institutional and national research committees and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This interventional study was registered in the UMIN clinical trial registration system (registration number, UMIN000052129, date of first trial registration is 23/11/2023, https://center6.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000059498).

Results

Participant characteristics

The participants' characteristics are summarized in Table 1. This study was performed from December 2023 to February 2024. One participant had a complicated cervical hernia and was unable to complete oropharyngeal exercise. Three participants, including this patient, did not perform the exercises sufficiently well; however, 22 participants completed the oropharyngeal exercise (88% of participants). In addition, one patient was unable to attend the last evaluation session due to illness.

The effect of oropharyngeal exercise on outcomes

The analysis was performed with 21 participants, excluding 3 participants with insufficient (subjects who performed insufficient exercises only performed less than 70% of the total) oropharyngeal exercise and 1 participant who was not able to undergo the final analyses. The AHI value did not improve significantly in the

	N=25
Age, years, median	49(29-61)
BMI, kg/m*m, median	24.51 (17.72-33.95)
AHI, /hour	24 (13-66)
Mild $(5 \le AHI < 15)$	3
Moderate ($15 \le AHI < 30$)	17
Severe $(30 \le AHI)$	5

 Table 1. Participants' characteristics. (), range; BMI, body mass index; AHI, apnea-hypopnea index.

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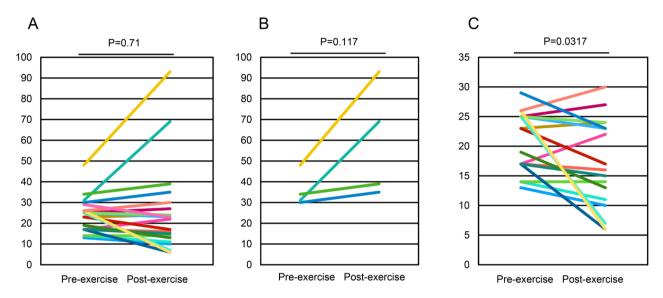


Fig. 2. The effect of oropharyngeal exercise on the apnoea-hypopnea index (AHI). AHI in (A) all participants (N=21), (B) participants whose preexercise AHI was \geq 30 (N=4), and (C) participants whose preexercise AHI was \geq 5 to <30 (N=17).

	AHI improved	AHI did not improve	
	(N=12)	(N=5)	P value
Age, years, median	42.5 (29-60)	55 (49-61)	0.0498
BMI, kg/m*m, median	24.23 (17.96-33.95)	19.96 (17.72–24.8)	0.113
Mallampati improved (Yes/No)	8/4	3/2	1
Tongue pressure improved (Yes/No)	10/2	4/1	1
Lip closure pressure improved (Yes/No)	4/8	2/3	1
Snore improved (Yes/No)	7/5	2/3	0.62

Table 2. Characteristics of participants with an apnea–hypopnea index of less than 30. (), range; AHI, apnea–hypopnea index; BMI, body mass index.

21 participants or participants with a pre-exercise AHI value of 30 or greater; however, this value improved significantly from an average of 20.9 times/hour to 16.9 times/hour in patients with a preexercise AHI value of 5 to 30, who were not generally indicated for CPAP (P=0.0317) (Fig. 2A-C). The standard deviation of the postexercise AHI value was 22.

The characteristics and results of the participants with an AHI of 5 to 30 are summarized in Tables 2, and 3, respectively. The group with improved AHI values was significantly younger than the group without improvement (P = 0.0498).

Although the tongue pressure and snoring did not improve significantly (P=0.354 and 0.146, respectively), the lip closure pressure tended to increase from a median of 17.6 N to 21.3 N with oropharyngeal exercise (P=0.0677) (Fig. 3A-C). For 77.2% of the 22 participants, improvements in Mallampati scores were observed.

	Pre-exercise	Post-exercise			
	(N=17)	(N=17)	P value		
AHI, times/hour, median	23 (13–29)	16 (6-30)	0.0498		
Tongue pressure, kPa, median	44.1 (24.2-62.3)	45.4 (32.1-54.5)	0.354		
Snoring, times/hour, median	100.8 (4.9–296.6)	78.7 (9.9-421.8)	0.146		
Lip closure pressure, N, median	17.6 (11.3–31)	21.3 (10.9–31.7)	0.0677		
Mallampati score					
Ι	1	5			
II	0	1			
III	2	6			
IV	14	5			

Table 3. Results of participants with an apnea-hypopnea index of less than 30. (), range; AHI, apnea-hypopnea index.

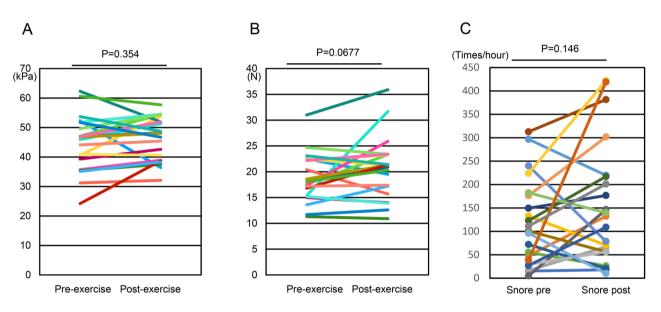


Fig. 3. The effects of oropharyngeal exercise on several parameters in participants (N=21). Tongue pressure (A) did not improve significantly (P=0.354). The lip closure pressure (B) tended to increase (P=0.0677). Snoring (C) did not improve significantly (P=0.146).

Discussion

On the basis of login information, as many as 88% of the 25 participants in this study were able to complete the exercise. Furthermore, the AHI value improved significantly from an average of 20.9 times/hour to 16.9 times/ hour in patients with a pre-exercise AHI of 5 to 30 (P=0.0317) and Mallampati data were improved in 77.2% of the 22 participants suggested that this novel shot exercise was effective enough to improve OSA. The exercises were easy to perform while looking at one's phone and were effective for mild-to-moderate OSA, although they were not as effective for severe OSA. As this exercise program was found to be more effective in younger people, it may need to be improved to increase its effectiveness in older people.

A meta-analysis of 9 studies (3 studies comparing oropharyngeal exercise with sham therapy) revealed that oral exercise decreases the AHI value but that snoring does not seem to change¹². Puhan MA conducted a study in which participants were randomized to oropharyngeal exercises using brass musical instruments or waiting lists¹³. Although exercises were performed for at least 20 min at least 5 days a week for 4 months, this unique method allowed all exercise groups to be analysed in the final analysis. Ieto V et al. conducted a study in which participants were randomized to receive treatment with nasal dilator strips plus respiratory exercises or oropharyngeal exercises¹⁴. The oropharyngeal exercise consisted of 8 min sessions conducted 3 times a day for 3 months. The completion rate of exercise was reported to be more than 75%. Villa MP et al. performed a study of oropharyngeal exercise, which consisted of exercising 3 times daily for 2 months¹⁵. In this study, 42 children and 14 children out of 16 children in the exercise group completed the exercise (87.5%). Diaféria G et al. conducted a study in which the participants were divided into a placebo group, an oropharyngeal exercise group, a CPAP group, and a combined group¹⁶. The exercise consisted of 20 min sessions conducted 3 times per day for 3 months. The completion rate of exercise was only 63% in the exercise therapy group and 65% in the combined therapy group. Goswami U et al. performed a study in which participants were randomized to sham therapy

or smartphone-based oropharyngeal exercise, which consisted of 15 min of gameplay per day for 12 weeks¹⁷. Similar to that in the present study, which involved smartphones, the rate of exercise completion was only 50%.

The limitation of this study is that the AHI value did not improve significantly in the 21 participants or participants with a pre-exercise AHI value of 30 or greater (P=0.71 or 0.117, respectively). We did not decide on the sample size by chance, but on the basis of prior statistical judgement. We believe that this occurred because the improvement in the AHI was lower than expected, the standard deviation was greater than expected, or there was a lack of improvement in severe disease. Another limitation is that nose findings were not examined.

Conclusion

The novel 10-min oropharyngeal exercise shows good continuity rate and may be appropriate for patients with mild-to-moderate OSA. Including the concept of monitoring patients in remote environments for the application of this model of exercise routines, with the support of videos and monitoring by application, would be an important opportunity to reach more patients in countries with deep territories.

Date availability

If someone wants to request the data from this study, TN, a Corresponding Author, will respond and send the data.

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Author contributions

T.N. wrote the main manuscript text and M.H. prepared figures. T.N., M.H., and S.I. planned study. Y.H., A.H., and K.K. supervised the study. Y.H., M.T., and K.M. managed and collected data. All authors reviewed and approved the manuscript.

Declarations

Competing interests

The authors declare no competing interests.

Additional information

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