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(Citation)
Progress in Rehabilitation Medicine,9:20240010

(Issue Date)
2024

(Resource Type)
journal article

(Version)
Version of Record

(URL)
https://hdl.handle.net/20.500.14094/0100490889

doi: 10.2490/prm.20240010 Progress in Rehabilitation Medicine 2024; Vol. 9, 20240010

ORIGINAL ARTICLE

Effects of Tongue Strength Training on Patients with Mild to Moderate Sleep-disordered Breathing: A Randomized Controlled Trial

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Objectives: Several studies have reported that oropharyngeal myofunctional therapy (OMT) reduces the severity of obstructive sleep apnea (OSA). However, because OMT protocols are often complicated, they take time and effort to implement. The aim of this study was to determine the therapeutic effect of 8 weeks of simple tongue strength training with a training device. **Methods**: Twenty patients with mild to moderate sleep-disordered breathing were randomized to the control group (n=10) or intervention group (n=10). The patients in the intervention group completed 8 weeks of daily tongue strength training using a training device. After 8 weeks, we evaluated each patient for sleep-disordered breathing by portable monitoring. We also evaluated each patient's body mass index (BMI), neck circumference, Epworth Sleepiness Scale (ESS) score, and tongue pressure. **Results:** No significant difference was found in the change in apnea hypopnea index (AHI) from baseline to 8 weeks between the control and intervention groups (P=0.44). However, the changes in neck circumference (P=0.02) and maximum tongue pressure (P=0.03) from baseline to 8 weeks were significantly different between the two groups. No significant difference was found for changes in BMI and ESS scores from baseline to 8 weeks between the two groups. **Conclusions**: Tongue strength training in patients with sleep-disordered breathing did not significantly improve AHI as measured by portable monitoring, although significant changes were observed for increased tongue pressure and reduced neck circumference.

Key Words: apnea hypopnea index (AHI); obstructive sleep apnea; sleep-disordered breathing; tongue pressure; tongue strength training

INTRODUCTION

Sleep-disordered breathing, also called sleep-related breathing disorder, is classified into 19 types according to the International Classification of Sleep Disorders.[1)] Obstructive sleep apnea (OSA) is the most common sleep-related breathing disorder. OSA is characterized by repetitive upper airway collapse during sleep with consequent oxygen desaturation, frequent arousals, and sleep fragmentation. OSA contributes to reduced quality of life, impaired work performance, and increased risk of motor vehicle crashes. Although several treatments exist, they are often either poorly tolerated or only partially alleviate abnormalities.[2)] Currently, most OSA patients are prescribed continuous positive airway pressure (CPAP), which is effective, but the acceptance rate is less than 50%.[3,4)] Oral appliances (OAs) have a higher adherence rate than CPAP.[5)] A meta-analysis of 15 randomized controlled trials including 491 patients assigned to OA treatment and 481 patients assigned to CPAP treatment assessed the effects of these devices on apnea hypopnea index (AHI);

Received: August 9, 2023, Accepted: March 13, 2024, Published online: March 23, 2024
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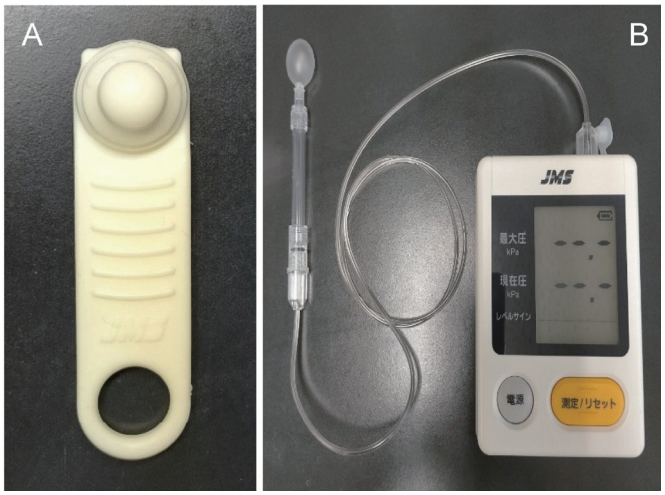

Fig. 1. (A) Pecopanda® tongue pressure training device. (B) Tongue pressure measurement device.

the findings revealed that OAs produced a significant mean reduction in AHI. However, the mean reduction in AHI in the CPAP group was 6.24 events/h [95% confidence interval (CI) 4.34–8.14] greater than that in the OA group. In 2015, a meta-analysis of 34 randomized clinical trials found that OAs were associated with a mean reduction in AHI of 13.6 events/h (95% CI 12.0–15.3).[6] Furthermore, both CPAP and OA are symptomatic treatments, thereby compensating for underlying issues. OSA symptoms will relapse when the patient stops using the devices. Therefore, there is clear need for new OSA treatments that cure the causes of the disorder.[7] Furthermore, there remains need for improvements in patient adherence to existing treatments and the development of new treatments (or combinations of treatments).[2]

Orofacial myofunctional therapy (OMT) has been recently introduced as a treatment option for OSA and consists of isotonic and isometric exercises targeted to oral and oropharyngeal structures. These exercises are designed to improve muscle tone, endurance, and coordinated movements of pharyngeal and peri-pharyngeal muscles.[8] Several studies have reported that OMT lowered the AHI in OSA patients.[7,9] In addition, Suzuki et al.[7] reported that OMT significantly reduced the severity of OSA and significantly increased tongue pressure. Dysfunctional upper airway dilating muscles will also predispose patients to OSA.[10] The largest airway dilator muscle is the genioglossus, which constitutes most of the tongue.[2]

In Japan, it has been reported that tongue pressure increases after 4 or 8 weeks of tongue pressure training using the Pecopanda® (JMS, Hiroshima, Japan) (**Fig. 1A**).[11,12] This silicone rubber training device is used for rehabilitation of deteriorated oral and swallowing functions. The convex part of the device is crushed by the tongue in the oral cavity, and when the tongue is relaxed, the dented part is restored to its original shape by the elasticity of the rubber. Therefore, we conducted this study based on the hypothesis that the use of a simple tongue strength training device (Pecopanda®) would reduce the severity of sleep-disordered breathing.

MATERIALS AND METHODS

Patients and Study Design

We recruited patients at Kobe University Hospital in Japan from April 1, 2021, and we continued follow up until August 23, 2022. We enrolled the following patients: aged 20 years or older with mild to moderate sleep-disordered breathing (AHI 15 to less than 30 events/h) on portable monitoring and had not received any treatment for sleep-disordered breathing. Written informed consent was provided by the patients. Portable monitoring had to be performed 90 days before enrollment. The following exclusion criteria were used: cardiac disease requiring hospitalization; dementia; neuromuscular diseases requiring hospitalization; dysmotility of the tongue; ulcers in the oral cavity; and other reasons judged by the physicians.

Twenty patients with mild to moderate sleep-disordered breathing were randomized to the control group (n=10) or the intervention group (n=10). The patients in the intervention group received 8 weeks of daily tongue strength training by using a tongue pressure training device (Pecopanda®). Briefly, the patients crushed the convex part of the device by bringing the tongue close to the oral floor five times for about 1 s and ten times for about 2 s. This procedure was repeated consecutively three times and was performed in the morning, at noon, and in the evening. Four types of the devices were available, with different forces required from the tongue to crush them (10, 15, 20, or 30 kPa). To obtain the appropriate strength, we selected a tongue pressure training device with a strength that was at least 85% of the patient's tongue pressure. If there was no tongue-pressure training device that had a strength greater than 85% of the tongue pressure, the device that required the most force (30 kPa) was selected.

Patients in the intervention group used a diary to record their adherence to training. Adequate adherence was defined by the completion of at least 50% of the indicated training. Once every 4 weeks, the patients visited Kobe University Hospital for doctors to check diaries and provide guidance

to ensure that oral exercises were being performed properly. Subjective daytime sleepiness was measured by using the Epworth Sleepiness Scale (ESS), which evaluates the propensity to sleep from none (0) to intense (3) in eight different situations. A total score greater than 10 indicates excessive daytime sleepiness.[13] The following patient information was recorded at baseline and after weeks 4 and 8: body mass index (BMI), neck circumference, ESS score, and tongue pressure. Neck circumference was measured at the level of the cricothyroid membrane. Tongue pressure was measured with a tongue pressure measurement device (JMS) (**Fig. 1B**). Measurements obtained with the JMS device are comparable with those obtained with the Iowa Oral Performance Instrument®, which is used internationally for tongue pressure measurement.[14] We recorded the value on the maximum pressure display of the digital tongue depressor as the maximum tongue pressure value. After weeks 4 and 8, we evaluated each patient's AHI and lowest oxygen saturation of the peripheral artery (SpO_2) with a portable long-term recordable pulse oximeter (SAS2200; Nihon Kohden, Tokyo, Japan). Apnea was defined as a reduction in the amplitude of airflow by more than 90% from the pre-event baseline for no less than 10 s. Hypopnea was defined as a reduction in amplitude of the airflow by more than 30% from the pre-event baseline for no less than 10 s in association with a decrease of 3% or more in SpO_2. AHI was calculated as the total number of apnea events per hour plus hypopnea events per hour in nocturnal recording periods.

We did not have access to information that could identify individual participants during or after data collection. This study was approved by the ethics committee of Kobe University (A200011) on December 21, 2020. The study was conducted in accordance with the Declaration of Helsinki and is registered in the University Medical Hospital Information Network in Japan (UMIN 000041489, https://center6.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000047368). The date of registration was November 30, 2020.

Outcomes

The primary outcome was change in AHI from baseline to that after 8 weeks of tongue strength training (difference between intervention and control groups). Secondary outcomes were changes in the lowest SpO_2 during sleep, ESS score, neck circumference, and maximum tongue pressure after 8 weeks.

Sample Size and Statistical Analyses

The primary hypothesis of this study was to determine the superiority of the tongue training device group over the non-intervention group in patients with sleep-disordered breathing. A previous study[9] of patients with moderate sleep apnea syndrome used upper airway muscle exercise therapy in a manner that was different from that used in the present study. The results of the study showed little change in AHI from baseline (22.4 ± 5.4 events/h; mean ± standard deviation) to that at 3 months (25.9 ± 8.5 events/h) in the control group, whereas 3 months of exercise therapy significantly improved the AHI by approximately 8.7 events/h the intervention group (from 22.4 ± 4.8 to 13.7 ± 8.5 events/h).[9] Assuming that the mean difference in ΔAHI between the intervention and control groups before and after treatment is 8 events/h with a standard deviation of 6 events/h, the number of study subjects required per group under a two-sided 5% level of significance and 80% power in a *t*-test was 9 cases per group. Considering the possibility of exclusion and dropout, we set the number of subjects to 10 in each group, for a total of 20 subjects.

Baseline characteristics of patients were compared between groups using the Student's *t*-test for normally distributed continuous variables, whereas the Mann–Whitney U test was used for continuous variables with non-normal distributions. Categorical data was compared using Fisher's exact tests. A paired *t*-test was used to analyze within-group changes between the different time points. AHI, lowest SpO_2, ESS score, neck circumference, and tongue pressure were evaluated by repeated measures analysis of variance. All tests were two-sided, and $P \leq 0.05$ was considered significant. All statistical analyses were performed using EZR version 1.55 (Saitama Medical Center, Jichi Medical University, Omiya, Japan) as a graphical user interface for R (version 4.1.2; R Foundation for Statistical Computing, Vienna, Austria).[15] No multiplicity adjustment was considered for the non-primary outcome variables, and the secondary outcome results must be interpreted cautiously.

RESULTS

Flow Chart and Diagnosis

Figure 2 shows the CONSORT flow diagram for the study. Twenty patients were prospectively enrolled from April 1, 2021, and were followed up until August 23, 2022. Two patients in the intervention group dropped out (one withdrew consent, and the other was unable to perform portable monitoring at week 8). **Table 1** shows the demographic and clinical characteristics of patients assigned to the control or intervention group. Patient baseline BMI was significantly

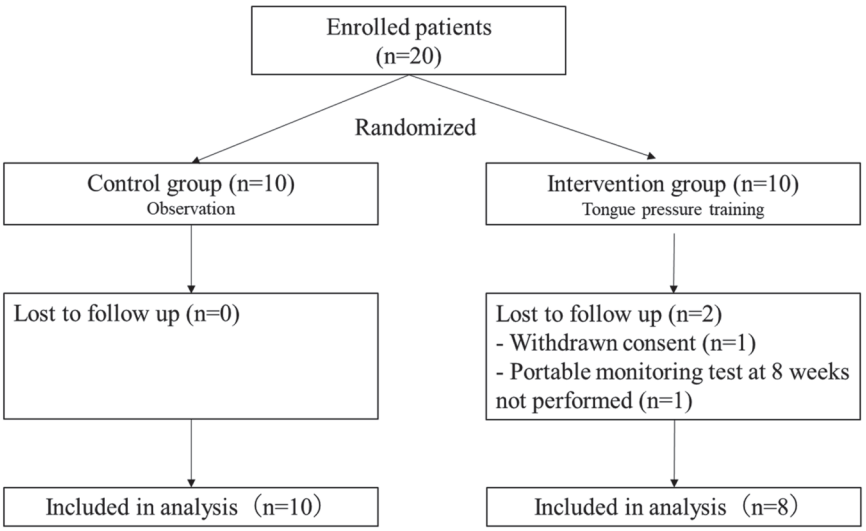

Fig. 2. CONSORT flow diagram of patient recruitment.

Table 1. Characteristics of patients

Characteristic	Control n=10	Intervention n=10	P value
Age, years	65.5 ± 10.1	55.5 ± 14.2	0.09
Sex (male), %	70	70	1.0
BMI, kg/m^2	21.7 ± 2.8	28.1 ± 7.0	0.03
Hypertension, yes	3	4	1.0
Diabetes, yes	0	1	0.44
Dyslipidemia, yes	1	4	0.30
Cardiovascular diseases, yes	2	1	1.0
Cerebrovascular diseases yes	2	1	1.0
Current or former smoker, yes	4	5	1.0
Drinking, yes	4	4	1.0
AHI, events/h	19.6 ± 5.2	19.9 ± 3.1	0.87
Lowest SpO_2, %	78 ± 5	79 ± 7	0.76
ESS score	5 ± 4	6 ± 4	0.73
Neck circumference, cm	35.5 ± 2.8	38.6 ± 4.6	0.09
Tongue pressure, kPa	35.8 ± 7.5	37.4 ± 5.2	0.58

Data given as mean ± standard deviation or number.

higher (P=0.03) in the intervention group. Otherwise, there was no significant difference between the two groups in patient baseline characteristics.

We excluded two patients from our analysis after they dropped out of the study. No change in BMI was observed in either group throughout the study period. In the control group, the mean AHI was 19.6 ± 5.2 events/h at baseline and 18.6 ±7.6 events/h after 8 weeks. In the intervention group, the mean AHI was 19.9 ± 3.5 events/h at baseline and 15.0 ± 3.9 events/h after 8 weeks. In the control group, the mean lowest SpO_2 was 78% ± 5% at baseline and 75% ± 8% after 8 weeks; in the intervention group, the mean lowest SpO_2 was 78% ± 5% at baseline and 79% ± 7% after 8 weeks. The mean ESS score of the control group was 5 ± 4 at baseline and 5 ± 3 after 8 weeks, whereas that of the intervention group was 5 ± 4 at baseline and 3 ± 2 after 8 weeks. The mean neck circumference in the control group was 35.5 ± 2.8 cm at baseline and 36.0 ± 2.2 cm after 8 weeks; in the

Table 2. Changes in AHI, lowest SpO_2, ESS score, neck circumference, and tongue pressure from baseline to 8 weeks, and evaluation by repeated measures analysis of variance

Group	Timeline	AHI (events/h)	Lowest SpO_2 (%)	ESS score	Neck circumference (cm)	Tongue pressure (kPa)
Control (n=10)	Baseline	19.6 ± 5.2	78 ± 5	5 ± 4	35.5 ± 2.8	35.8 ± 7.5
	8 weeks	18.6 ± 7.6	75 ± 8	5 ± 3	35.6 ± 2.2	33.6 ± 7.3
Intervention (n=8)	Baseline	19.9 ± 3.5	79 ± 7	5.1 ± 3.9	39.6 ± 4.0	37.5 ± 5.5
	8 weeks	15.0 ± 3.9	76 ± 7	3.1 ± 1.8	38.9 ± 3.5	45.6 ± 5.7
Between-group difference[a]	P value	0.44	0.82	0.62	0.02	0.03

Data given as mean ± standard deviation.
[a] Assessment of difference between groups for changes from baseline to 8 weeks.

intervention group, the mean neck circumference was 39.6 ± 4.0 cm at baseline and 38.9 ± 3.5 cm after 8 weeks. The mean tongue pressure in the control group was 35.8 ±7.5 kPa at baseline and 33.6 ± 7.3 kPa after 8 weeks; in the intervention group, the mean tongue pressure was 37.8 ± 5.5 kPa at baseline and 45.6 ± 5.7 kPa after 8 weeks. Changes in the AHI, lowest SpO_2, ESS score, neck circumference, and tongue pressure from baseline to week 8 were evaluated by repeated measures analysis of variance to compare the control and intervention groups. No significant difference was found for the primary outcome; that is, there was no significant change in AHI between the control and intervention groups (**Table 2**). Regarding the secondary outcomes, there was no significant change in the lowest SpO_2 or ESS score between the control and intervention groups (**Table 2**). However, the changes in neck circumference and maximum tongue pressure from baseline to week 8 were significantly different between the control and intervention groups (P=0.02 and 0.03, respectively) (**Table 2**).

Safety

An adverse event occurred in one patient in the intervention group. On the 8th day, the patient developed an intraoral mucosal epithelial abrasion (WHO classification of oral adverse events: scale 2), and the tongue strength training was suspended. The patient resumed training on the 27th day after the intraoral mucosal epithelial detachment was judged to have improved.

DISCUSSION

This study did not indicate that tongue strength training improved the severity of mild to moderate sleep-disordered breathing. Guimarães et al.[9] observed a significant reduction in AHI among patients who were randomized into an oropharyngeal exercise group. Suzuki et al.[7] reported that 6 months of OMT among middle-aged and elderly OSA patients treated with CPAP led to a significant decrease in AHI from 34.7 to 29.0 events/h (P=0.03), and tongue pressure increased significantly from 35.9 to 45.6 kPa (P<0.01). Diaféria et al.[16] also reported that a significant reduction in AHI was observed in the OMT group when compared with a placebo group. We consider that the oral myofunctional therapy used in these previous studies was somewhat complex and cumbersome, whereas the OMT used in our study was simple, involving only tongue strength training using instruments, allowing patients to continue the therapy for a long period. However, tongue strength training alone did not significantly reduce the severity of sleep-disordered breathing.

In previous studies that observed a reduction in the severity of OSA with OMT interventions, the AHI after intervention with OMT was compared with the preintervention AHI. These studies reported that AHI decreased by 5.7–8.7 events/h after the intervention.[7,9] In our study, the mean AHI in the control group did not show a significant decrease (from 19.6 ± 5.2 events/h at baseline to 18.6 ± 7.6 events/h after 8 weeks; P=0.627). However, patients randomized to the intervention group tended to have a decreased mean AHI (from 20.0 ± 3.5 events/h at baseline to 15.0 ± 3.9 events/h after 8 weeks; P=0.07); the magnitude of the decrease in AHI was 5.0 events/h. Based on the results of a previous study, we calculated that a mean difference in ΔAHI of 8 events/h with a standard deviation of 6 events/h would require 9 cases per group. In the current study, the ΔAHI was 5 events/h, with a standard deviation of 6 events/h, so the number of study subjects required per group was 23 cases. Therefore, the number of cases recruited in this study was insufficient because the ΔAHI was smaller than expected. This means that the observed decrease in AHI in the intervention group may not have been significant because of inadequate sample size.

Furthermore, with two out of ten cases in the intervention group dropping out, our estimate of the number of dropouts was inadequate.

Neck circumference decreased significantly in the intervention group in the current study. Increased neck circumference is a known risk factor for OSA.[17] Considering that the AHI tended to decrease in the intervention group, it is suggested that there may be an effect of tongue pressure training in reducing the severity of sleep-disordered breathing. In addition, we cannot rule out the possibility that tongue pressure training led to neck circumference exercise and caused a drop in neck circumference fat.

The ability to strengthen the genioglossus muscle is common between our study and previous studies in which OMT was able to reduce the severity of OSA.[7,9] In contrast with these previous studies, the tensor and levator veli palatini muscles and the palatopharyngeal and palatoglossus muscles, which elevate the soft palate, did not strengthen in our study. Therefore, the therapy used in our intervention may not have been able to significantly improve the severity of sleep-disordered breathing. Had our study included exercises targeting soft palate elevation, rather than just strengthening tongue pressure alone, the results might have been different.

Our study has some limitations. First, despite randomization, there was a significant difference in BMI between the intervention and control groups. Therefore, we considered matching by propensity score. However, matching by propensity score with the recommended caliper width of 0.2 was not feasible because of the limited number of cases. Furthermore, although we used an inverse probability weighting estimator because of the limited number of cases, it did not provide sufficient correction between groups. Second, this study used a type 4 portable long-term recording pulse oximeter rather than polysomnography to assess sleep-disordered breathing. This type 4 portable monitor tends to underestimate portable monitor (PM)-AHI because the PM-AHI index is defined as the number of apnea and hypopneas divided by the total measured time, which is longer than the total sleep time, and the PM-AHI does not include hypopnea associated with arousal.[18] Therefore, it is possible that the assessment of AHI was not sufficiently accurate. Third, given that the two patients who dropped out were excluded from analysis in this study, it may be possible that the treatment effect was larger than that in the intention-to-treat (ITT) analysis. Because one patient withdrew consent and the other was unable to assess sleep-disordered breathing by portable monitoring at week 8, we could not measure the primary endpoint (AHI). However, in this study, the number of patients who participated according to the treatment protocol was small, the causes for dropout were random, and it was expected that there was no difference between the ITT analysis and the on-treatment-analysis with respect to the primary endpoint. Therefore, we excluded the two dropouts from our analysis. Fourth, in this study, we assessed changes in the genioglossus by the measurement of tongue pressure. While we did not use ultrasound imaging to determine genioglossus size and contraction rates, the use of ultrasound imaging may have been useful for assessment of the genioglossus.

CONCLUSION

Eight weeks of tongue strength training in patients with sleep-disordered breathing led to a significant increase in tongue pressure but the reduction in AHI as measured by portable monitoring was not significant.

ACKNOWLEDGMENTS

The authors thank the study participants for their contribution to this research.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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