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ORIGINAL RESEARCH ARTICLE

Long-term benefits of a new oral appliance on adult snoring: a trend analysis

Jui-Kun Chiang,[1] Yen-Chang Lin,[2] Hsiao-Chen Yu,[2] Chih-Ming Lu,[3]* Yee-Hsin Kao[4]*

[1]*Department of Family Medicine, Dalin Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation, Chiayi*
[2]*Nature Dental Clinic, Puli Township, Nantou*
[3]*Department of Urology, Dalin Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation, Chiayi*
[4]*Department of Family Medicine, Tainan Municipal Hospital (Managed by Show Chwan Medical Care Corporation), Tainan, Taiwan*

**These authors contributed equally*

ABSTRACT

Background: Snoring constitutes a worldwide public health concern that may be associated with daytime fatigue, endothelial dysfunction, vascular injury, stroke, cardiovascular diseases, and diabetes among female patients. This study explored the effects of the so-called Lin Oral Appliance (LOA) on Taiwanese adults' snoring rates.
Methods: A time series analysis was conducted to examine the associations between LOAs' tongue compressors of different lengths, and snoring rates were calculated using the SnoreClock app. The LOA comprises 2 components: custom-made dental braces and tongue compressors of adjustable lengths; different versions had different-length compressors.
Results: Our multiple linear regression time-series model revealed the effects of the LOA on snoring rates. The results indicated the following: i) LOA tongue compressor lengths of 1 and 2.5 cm (LOA-1 and LOA-2.5, respectively) were associated with reduced snoring rates; ii) sleep durations of 5.5-7.5 h and daytime sleepiness were associated with increased snoring rates; and iii) among participants with snoring rates above 10%, the snoring rates observed 1-7 days before a given day constituted a significant factor influencing snoring rates on the given day.
Conclusions: We discovered that the LOA could reduce snoring rates and that the 2.5-cm compressor length in the LOA produced the best results.

Key words: Oral appliance; snoring rates; trend analysis.

Correspondence: Yee-Hsin Kao, MD, Department of Family Medicine, Tainan Municipal Hospital (managed by Show Chwan Medical Care Corporation), 670 Chung Te Road, Tainan, 70173 Taiwan. E-mail: m2200767@gmail.com

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Conflict of interest: Yen-Chang Lin is the inventor and owner of the patent [patent number: I602555 (Taiwan), ZL 2013 1 0753192.9 (China)]. JK Chiang received grants from the Dalin Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation (DTCRD108(2)-E-09) and Buddhist Tzu Chi Medical Foundation (TCMF-A 111-11). The other authors declare no competing interests, and all authors confirm accuracy.

Availability of data and materials: The data that support the findings are available from the corresponding author on reasonable request.

Ethics approval and consent to participate: This was a time series analysis study, and the protocol was reviewed and approved by the Research Ethics Committee of the Buddhist Dalin Tzu Chi Hospital in Taiwan (No. B10703013).
All participants signed informed consent forms.

Introduction

Snoring is a prevalent condition that considerably affects public health. Not all individuals with snoring have clinically significant obstructive sleep apnea (OSA); nevertheless, snoring is the earliest and most common symptom of OSA, occurring in 70-95% of patients with OSA [1,2]. Additionally, the intensity of snoring increases with OSA severity [1], and snoring increases the risk of vascular diseases [3]. Increasing bodies of evidence indicate that snoring may be associated with excessive daytime sleepiness, xerostomia upon waking up, endothelial dysfunction, vascular injury, stroke, cardiovascular diseases, and diabetes among female individuals [4-9]. Snoring has been reported to affect more than 40% of the populations of some Asian countries, including Taiwan (59.1%) [10], Malaysia (47.3%) [11], and Turkey (40.7%) [12]. Variations in the prevalence of snoring can be attributed to ethnicity; for example, people of Chinese descent have a narrower cranial base (smaller thyromental distance) and a flatter midface structure (larger thyromental angle) than do people of other ethnicities after adjustment for body mass index (BMI) and neck circumference [13].

The American Academy of Sleep Medicine and American Academy of Dental Sleep Medicine recommend administering oral appliances (OAs) not only to adult patients who require treatment for primary snoring, but also to patients with OSA who are intolerant of continuous positive airway pressure therapy or prefer alternate therapy [14]. A study reported that OAs i) have a 50% success rate in reducing the apnea/hypopnea index to <10, and ii) reduce snoring by 45% [15]. Currently, OAs are commonly used to treat snoring and other types of sleep-disordered breathing [16]. Although various types of OAs are available on the market, an effective OA must be custom made and adjustable and should be provided by a qualified dentist [14].

OAs can be classified into two categories: mandibular advancement devices (MADs) and tongue-repositioning or tongue-retaining devices for stabilization [17]. The possible mechanism through which MADs reduce snoring and OSA involves mandibular protrusion and induction of changes in the anterior position of the tongue, soft palate, lateral pharyngeal walls, and mandible, resulting in improved anatomical airway patency [18] and decreased upper airway collapsibility due to the neuromuscular activation of the upper airway dilator muscles [19]. Additionally, MADs engender decreased lower arch crowding, overbite, and mandibular intermolar width over time [20]. Tongue-retaining devices apply suction to retain an individual's tongue while they sleep [21]. We previously presented a new patented MAD with a tongue compressor, called Lin Oral Appliance (Airflow-Interference-type Nasal-Congestion-Relieving and Snore-Ceasing Oral Appliance, LOA; Taiwan Patent No. I602555; China Patent No. ZL 2013 1 0753192.9) [22]. We used a smartphone snoring app (SnoreClock) to detect snoring during ordinary sleep over approximately 5 weeks. The aim of current study was to examine the efficacy of the LOA in reducing snoring and performed a time-series analysis to analyze the time-dependent effect of the device on snoring among Taiwanese adults.

Methods

Study participants

We recruited 24 individuals with snoring (International Classification of Diseases, Tenth Revision, Clinical Modification Code R06.83) who were administered the LOA at a dental clinic between August 1 and December 31, 2019, to participate in this study. Those who had snoring problems and were willing to participate in the study were included, and those who were aged <20 years were excluded from the study. Participation was voluntary, and all participants signed informed consent forms before enrollment. The included participants were required to install the paid SnoreClock app on their smartphones. Additionally, they received training for ameliorating snoring through remedial interventions, such as oropharyngeal exercises. The Ieto's study reported that oropharyngeal exercises included four components, were effective in reducing snoring [23]. In the current study, the participants were instructed to push forcefully the dorsal part of their tongue against the hard palate and close their mouths for 10 min before sleep. The advantage was to train the muscle strength of the oropharyngeal cavity. The study protocol was reviewed and approved by the Research Ethics Committee of the Buddhist Dalin Tzu Chi Hospital in Taiwan (No. B10703013).

LOA device

The LOA is composed of medical-grade ethylene/vinyl acetate, and the cost of each LOA unit is NT$ 10,000 (approximately US$ 361). The LOA comprises two components: custom-made dental braces and tongue compressors of varying adjustable lengths. The LOA braces are fixed on the entire dental arch of the upper jaw. The tongue compressor is applied behind the center of the upper jaw; one of its edges is anchored between the first and second molars on the left side of the mandible, and the other edge is anchored between the first and second molars on the right side of the mandible. The compressor exerts force at the center of the tongue, and it allows airflow to the back of the throat, thus avoiding obstructions from the back of the mouth and tongue and expanding the mouth space during breathing. Moreover, the length of the compressor ranges from 0.5 to 3.5 cm and can be adjusted accordingly (Figure 1). The LOA reduces snoring through three possible mechanisms. First, it maintains a patent upper airway and expands the orolaryngopharyngeal volume by compressing the tongue and pushing it forward (through the tongue compressor), if necessary, during sleep. Second, the tension in the oropharynx may be increased through the support of the tongue compressors. Third, the tongue compressor stabilizes the deeper fascia that runs along the tongue to the caudal part of the respiratory muscles during breathing movements during sleep, which simultaneously reduces snoring.

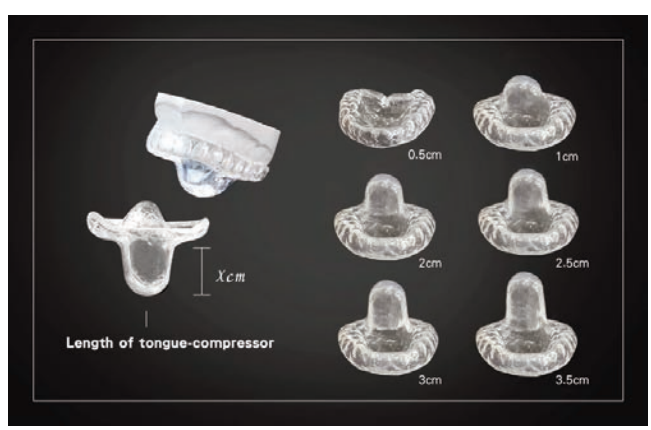

Figure 1. Different versions of the Lin oral appliances.

Snoring detection

Snoring apps are typically user friendly, and they record sound information while the user sleeps. They also provide convenient and personalized sleep care [24]. They predict snoring with 93-96% accuracy, but their performance varies considerably between smartphone models [25]. In the current study, snoring rates were detected by smartphones that had been installed with the paid app SnoreClock. The app provides information on the following variables: sleep duration, snoring duration, snoring loudness (in dB), maximum snoring loudness (in dB), and snoring duration rate (%). We then carefully listened to the recordings; any equivocal sounds were confirmed by an ear, nose, and throat (ENT) specialist: this is referred to as the "manual method" hereafter. The snoring epoch is composed of several snoring signals interrupted by pauses (<10 s). Therefore, the duration of snoring was represented by the sum of total snoring epochs. Moreover, the sensitivity, specificity, positive predictive value, and negative predictive value of the app were calculated. A strong correlation was observed between the results obtained through a manual measurement of snoring and SnoreClock, which were reviewed by an ENT specialist. The correlation between SnoreClock and the manual method for detecting snoring was 0.907 ($p<0.001$). The results indicated that SnoreClock is a highly accurate app for detecting snoring, with a mean accuracy rate of 94.6% in our previous study [26]. This app was used to collect time-series data regarding snoring rates in this study. Snoring rate was used as a measure and was derived by dividing the snoring duration by the total sleep time. The recording time - defined as the time interval from the pressing of the start button to the pressing of the stop button on the SnoreClock app - was used as a proxy for the total sleep time. Generalized additive models (GAMs) were used to detect nonlinear effects of continuous covariates.

Statistical analysis

Because the data on snoring rates were not normally distributed, the outcome (snoring rates) was log transformed. Time-series analysis was conducted on the snoring rates to identify significant time-dependent factors influencing snoring. To explore the potential 1-7-day lag effects and autocorrelation, the day lags for snoring rates were created. The 1-7-day lags for past snoring rates were also included during the stepwise variable selection.

All the relevant significant and nonsignificant covariates from the univariate analysis was included in the variable list to be selected. The linear regression time-series model provided direct predictions of responses and an easily interpretable goodness-of-fit measure (R^2) for assessing the quality of prediction [27]. Data analysis was performed using R 4.1.2 software (R Foundation for Statistical Computing, Vienna, Austria). A two-sided $p\leq0.05$ was considered statistically significant.

Results

The total data comprised 1,846 recordings from 24 participants. We constructed variables for the 1–7-day lags and added the corresponding data to the original data set. Because recording was interrupted during some days, the corresponding missing data were deleted. Finally, 1,525 recording files from 21 male and 3 female participants (mean recording days: 63.5±76.5) were included for analysis. The mean age of the participants was 40.0±9.5 years; Table 1 presents the demographic characteristics of the participants. Snoring rates were detected using the SnoreClock app. Table 1 also presents the different versions of the LOA used in the study. The tongue compressor lengths ranged from 0.5 to 3.5 cm (Figure 1). Among the participants wearing the LOA, those for whom the tongue compressor length was set to 1 cm (LOA-1) provided the highest number of recordings (469, 30.8%), followed by those for whom the tongue compressor length was set to 2 cm (LOA-2; 450, 29.5%) and those for whom the tongue compressor length was set to 3 cm (LOA-3; 238, 15.6%). Because the data on snoring rates were not normally distributed, they were log transformed, and any zero values were adjusted to 0.000001 before log transformation. This log transformation was monotonic; that is, higher snoring rates had higher logit-transformed values. The mean snoring rate was 19.0±18.6%, and the mean logit of snoring rates was −3.6±5.44. Dripping and nausea were the most frequent complaints by the participants while wearing the LOA, but most of the participants could usually tolerate these discomforts within 2 weeks of daily use of the device.

Our univariate linear regression demonstrated that the compressor lengths were negatively associated with snoring rates and the corresponding logit values (Table 2). We also created a plot of the effect of sleep durations on snoring rates derived after smoothing (Figure 2). Sleep durations between 5.5 and 7.5 h were associated with a higher risk of snoring rates.

We performed a multivariate analysis to identify major predictors of the logit values of snoring rates by fitting multiple linear regression time-series models by using stepwise variable selection (*i.e.*, by iterating between the forward and backward steps). The results are presented in Table 3. According to these results, first, participants with sleep durations between 5.5 and 7.5 h had higher snoring rates. Second, those who experienced daytime sleepiness had higher logit values of snoring rates compared with

Table 1. Demographic characteristics of participants

Variables	Value*
n (male/female)	24 (21/3)
Age, years	40.0±9.5
BMI	25.0±3.5
Hypertension, yes	4(16.7%)
Diabetes, yes	1(4.2%)
Education level	
Graduate school	10(41.7%)
College	8(33.3%)
Others	6(25.0%)
Number of recording files	1525
Recording number	63.5±76.5
Snoring rate, %	19.0±18.6
Logit of snoring rates	-3.6±5.44
Sleep duration, hours	6.7±1.2
Daytime sleepiness, yes vs no	38(2.5%)
LOA-x[#] (cm) use, n (%)	
LOA-0[§]	111(7.3%)
LOA-0.5	141(9.2%)
LOA-1	469(30.8%)
LOA-1.5	14(0.9%)
LOA-2	450(29.5%)
LOA-2.5	45(3.1%)
LOA-3	238(15.6%)
LOA-3.5	54(3.5%)
Oropharyngeal exercises, yes vs no	229(15.0%)

*Mean ± SD or n (%); BMI, body mass index; LOA, Lin oral appliance; [#]LOA-x, different lengths of tongue compressor of the LOA, and the length included 0.5 cm, 1.0 cm, 1.5 cm, 2.0 cm, 2.5 cm, 3.0 cm, and 3.5 cm; [§]LOA-0, participants not using the LOA.

those who did not. Third, different tongue compressor lengths exerted different effects on the logit value of snoring rates, with the 2.5-cm length having the strongest effect. Fourth, among participants with snoring rates of >10%, higher logit values of snoring rates at the 1-, 3-, 5-, 6-, and 7-day lags - which indicated the degree of the inherited autocorrelation - were associated with higher logit values of snoring rates observed for a given day. In the time-series effect in snoring, 1 day before the given day had the most effect, and followed by 3 days and 5 days before the given day (the estimate = 2.108, 1.673, and 1.319, respectively).

The R^2 value of the final multiple linear regression model was 0.316 (Table 3). The Pearson correlation between the observed and the predicted snoring rates was as high as 0.562 ($0.562^2 \approx 0.316$). Therefore, snoring rates could be predicted using this well-fitted regression model. The current model could be used to calculate the predicted snoring rate based on the patient's condition; some examples are provided in the supplementary file. For example, for a patient with a 6-h sleep duration, daytime sleepiness, LOA-1, an 8% t-1 snoring rate (49th day), a 7% t-3 snoring rate (47th day), an 8% t-5 snoring rate (45th day), a 20% t-6 snoring rate (44th day), and a 25% t-7 snoring rate (43rd day), our final model predicted that the snoring rate on the 50th day was 3.8%.

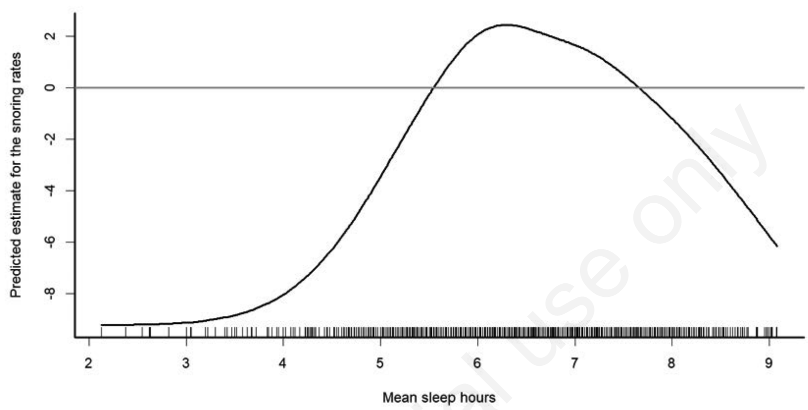

Figure 2. Predicted estimate of sleep duration for the snoring rates.

Table 2. Univariate linear regression for the original snoring rates and the logit values of snoring rates (number of recording files=1525).

	Snoring rates, %		Logit of snoring rates	
Variable	Estimate	p	Estimate	p
Age	-0.04	0.363	-0.002	0.848
Male vs female	-0.44	0.730	-0.09	0.818
Daytime sleepiness, yes *vs* no	-3.34	0.247	1.75	0.050
BMI	0.67	<0.001	-0.05	0.277
Sleep duration, hour	0.42	0.277	-0.52	<0.001
LOA length, cm	-7.61	<0.001	-1.55	<0.001

BMI, body mass index; LOA, Lin oral appliance.

Table 3. Predictors of snoring rates by the fitted multiple linear regression time-series model.

Covariates	Estimate	Std. error	t value	p
Intercept	-8.038	0.256	-31.433	<0.001
LOA 1 cm	-0.630	0.264	-2.387	0.017
LOA 2.5 cm	-5.037	0.672	-7.500	<0.001
Daytime sleepiness, yes vs no	2.516	0.751	3.351	0.001
Recording duration, 5.5-7.5 hours	0.696	0.244	2.853	0.004
Snoring rate (*t*-1)*, >10%	2.108	0.297	7.091	<0.001
Snoring rate (*t*-3), >10%	1.673	0.304	5.510	<0.001
Snoring rate (*t*-5), >10%	1.319	0.311	4.247	<0.001
Snoring rate (*t*-6), >10%	0.987	0.321	3.078	0.002
Snoring rate (*t*-7), >10%	1.238	0.309	4.006	<0.001

LOA, Lin oral appliance; Multiple R^2 = 0.316; note that *t* was the number of days since the beginning; *(*t*-n) denotes "n days before the given day of the observed response", where "n" specifies the number of lagged days.

Discussion

Our data revealed that the LOA can reduce snoring rates, especially when the length of the tongue compressor was set to 2.5 cm. Major factors associated with higher snoring rates comprised a sleep duration between 5.5 and 7.5 h and daytime sleepiness. Additionally, time-series analysis revealed the time-dependent effects of the device on snoring. Among participants with a snoring rate above 10%, the snoring rate observed for a given day was associated with the snoring rates observed for previous days, and the snoring rate observed 1 day before the given day was the most significant factor influencing snoring.

A noteworthy methodology in the current study is the repeated measurements of snoring rates for 24 participants. The mean number of recordings was 63.5±76.5, and the mean snoring rate was 19.0±18.6%. Measuring periodic snoring (threshold ≥15%) at home is a simple and useful method for predicting the probability of OSA [28]. The participants could immediately contact the dentist via phone communication apps to adjust their LOA devices according to their tolerance and symptom severity, because the snoring rates could change from day to day. Accordingly, repeated measurements could demonstrate the trend of treatment effects and help detect daily variations in snoring rates. However, sleeping position was not considered during the recording process in the current study; a wrong negative result may occur in position-dependent OSA, which was avoided by using repeated measurements.

OAs, designed for treating snoring and other sleep-disordered breathing conditions, are portable, noninvasive, well tolerated, and commonly used currently [16,29]. A previous study classified OAs into two categories: i) MASs, and ii) tongue-repositioning or tongue-retaining devices [17]. In the current study, we applied a novel LOA to effectively reduce snoring. The LOA includes tongue compressors of various lengths. For the participants in this study, the tongue compressor length in the LOA was initially set to 0.5 cm (LOA-0.5). Subsequently, the tongue compressor length could be adjusted at 0.5-cm intervals according to the preference and tolerance levels of the participants. We observed that the various tongue compressor lengths were associated with different snoring rates. The tongue compressor length of 2.5 cm was found to exhibit the highest effectiveness in reducing snoring rates compared with the other lengths (LOA-3.0 and LOA-3.5). A possible explanation is that some participants, especially male participants, with severe snoring may have used longer tongue compressor length settings (such as LOA-3.0 or LOA-3.5). Once the LOA decreased snoring, the 1-day lag effect was associated with a decrease in snoring rate the following day. Additionally, the 7-day lag effect was similar. A possible explanation for the 1-day lag effect is that the condition of the previous day may have influenced the next day's condition. Moreover, a possible explanation for the similar 7-day lag effect is that lifestyle patterns may have been unchanged throughout the week.

Previous studies have reported that sleep duration and snoring are associated with a higher risk of cardiovascular disease, metabolic disorders, and esophageal cancer [30-32]. Short sleep (<6 h) and long sleep (>9 h) durations have been associated with high risks of cardiovascular disease and all-cause mortality [33,34]. However, few studies have investigated the association between sleep duration and snoring. Our data indicated that participants with a sleep duration of 5.5-7.5 h tended to have higher snoring rates. A possible explanation is the "diluted" effect for patients with longer sleeps hours. Moreover, patients with shorter sleep hours might have more effective sleep quality with less snoring. Further investigation with larger samples is warranted to clarify this phenomenon.

In the present study, daytime sleepiness (which was self-reported through a "yes" or "no" answer) was positively associated with snoring, consistent with findings in the literature [4]. Previous studies have identified other potential risk factors for snoring, including obesity (BMI >30), alcohol consumption, cigarette smoking, age >40 years, male sex, use of sleep medication, neck circumference >40 cm, family history of snoring, and daytime sleepiness [4,35-37].

Limitations

The present study has some limitations. First, the recording duration on the SnoreClock app was used as a proxy for sleep duration. Therefore, some extra waking time may have been included in the total sleep time, and the snoring rates might have been underestimated. Nevertheless, the corresponding bias could be limited if the participants usually fell asleep quickly. Second, the number of participants using the LOA-3 (n=2) and LOA-3.5 (n=1) settings was small. Finally, the side effects of LOA use were not explored in this study. Future studies should identify the associations between snoring and health-related consequences of LOA use.

Conclusions

This study revealed that the LOA can reduce snoring rates, especially when the tongue compressor length in the LOA was set to 2.5 cm. We also observed that factors influencing snoring rates were a sleeping duration between 5.5 and 7.5 h, daytime sleepiness, and time-series effects. Among participants with a snoring rate above 10%, the snoring rate observed on the given day was associated with the snoring rates observed for previous days, with the rate observed 1 day before the given day exerting the highest effect.

Abbreviations

AHI: apnea/hypopnea index;
CPAP: continuous positive airway pressure;
GAM: generalized additive models;
LOA: Lin oral appliance;
MAS: mandibular advancement splints;
OA: oral appliance;
OSA: obstructive sleep apnea;
SLE: significance levels for entry;
SLS: significance levels for stay.

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