Original Article

Custom-Made Oral Appliances for the Treatment of Obstructive Sleep Apnea: Outcomes in Thai Patients

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Objective: To evaluate the outcomes of custom-made oral appliances (OAs) for the treatment of obstructive sleep apnea (OSA) in Thai patients.

Materials and Methods: A retrospective review of polysomnography (PSG) results and relevant information, including patient characteristics, visual analog scale (VAS) of sleep-associated symptoms, and Epworth Sleepiness Scale (ESS) of patients treated with an OA between January 2010 and January 2018 was done at Siriraj Hospital, Thailand. Inclusion criteria were OSA patients aged 18 years or older who underwent diagnostic and therapeutic PSG with a custom-made OA. Exclusion criteria were patients who were lost to follow-up or had incomplete PSG data.

Results: Sixty-seven OSA patients were recruited. The median apnea-hypopnea index (AHI) was significantly decreased from 16.5 (11.5, 27.8) to 5.1 (2.8, 11.3) events per hour ($p<0.001$) and the median minimal oxygen saturation increased from 82.0 (77.0, 86.0) to 87.0 (80.0, 90.0) with OA treatment ($p<0.001$). ESS scores decreased from 9 (6, 13) to 7 (4, 9) ($p<0.001$) and the VAS of snoring loudness and frequency as rated by family members or bed partners decreased from 6 (4, 7.5) to 3.3 (2, 5) and from 5.5 (3.2, 7.6) to 3.4 (2, 5.3), respectively ($p<0.001$). Forty-one patients (61%) had a 50% reduction of AHI, and an AHI of less than 15 events per hour after treatment, which were considered good responses. Common adverse effects of the treatment included temporomandibular joint discomfort, dry mouth, excessive salivation, gingival pain, and toothache, but these occurred to only a mild-to-moderate degree and were tolerable.

Conclusion: Custom-made OA is an effective alternative treatment for OSA in selected Thai patients, particularly for those with a mild-to-moderate degree.

Keywords: Custom-made oral appliance, Obstructive sleep apnea, OA, OSA, Thai

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Obstructive sleep apnea (OSA) is a highly prevalent able disease characterized by recurrent episodes of upper airway obstruction resulting in frequent arousals and transient oxygen desaturations during sleep. Common presentations of this condition include snoring, witnessed apnea, and excessive daytime sleepiness (EDS) and if left untreated, several negative consequences may occur, such as an impaired quality of life[1], neurocognitive impairment[2], hypertension[3], cardiovascular disease, and metabolic dysregulation[4,5]. In general, the prevalence of OSA defined as an apnea-hypopnea index (AHI) of five or more events per hour has been reported to be approximately 22% in men and 17% in women[6,7]. In Thailand, the prevalence was reported to be 15.4% in men and 6.3% in women[8].

Although, the first-line treatment of OSA is currently continuous positive airway pressure (CPAP) therapy, several patients often have difficulty adhering to or even refuse this therapeutic method[9,10]. For those who cannot accept CPAP, an oral appliance (OA) that improves the airway patency of patients during sleep by protruding the mandible and accompanying tongue tissues[11] is a potentially viable effective alternative. Among the several types of OA available, the American Academy of Dental Sleep Medicine (AADSM) currently recommends that the first-line

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treatment in patients with mild-to-moderate OSA who prefer an OA and patients with severe OSA who are intolerant to CPAP therapy should be a custom-made mandibular advancement device (MAD)[12,13]. Although, there are plenty of studies showing the effectiveness of MADs[12-15], the craniofacial structure in Mongoloid and Caucasoid are different and this may affect the result of treatment[16]. Consequently, the objective of the present study was to evaluate the efficacy of custom-made MADs for OSA treatment in Thai patients.

Materials and Methods

The present study was approved by Siriraj Institutional Review Board (SIRB) and conducted at the snoring clinic in the Department of Otorhinolaryngology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. Data from polysomnography (PSG) tests and the responses to relevant questionnaires of OSA patients treated between January 2010 and January 2018 were collected and reviewed.

Subjects

Inclusion criteria were patients aged 18 years or older with an AHI of five or more events per hour diagnosed from PSG patients who were treated with a custom-made OA due to CPAP intolerance or CPAP denial and patients who had a follow-up PSG with this treatment. Exclusion criteria were patients who were lost to follow-up and who had incomplete PSG data, such as severe artifacts, or a very poor sleep efficiency of less than 25%.

Oral appliance

The custom-made OAs reported in the present study were adjustable duobloc MADs fitted by qualified dentists of Siriraj Hospital and Faculty of Dentistry, Mahidol University, Bangkok, Thailand. After referral from sleep specialists, all the study patients were evaluated by dentists to see if they had contraindications, such as insufficient teeth, severe active periodontal diseases, craniofacial abnormalities, mandibular injuries, or preexisting temporomandibular joint (TMJ) dysfunction. After their acceptance of OA therapy, the patients had a dental impression taken to make a model for MAD fabrication, followed up with device adjustment by the dentists and sleep specialists for clinical evaluation. Once satisfied with the MAD fitting and adjustment or titration, the patients were scheduled for a repeat PSG with MAD therapy.

Outcome measurement

Both subjective and objective outcomes were evaluated during regular clinical visits. All the study patients were routinely asked to administer pre- and post-treatment the Thai version of the Epworth Sleepiness Scale (ESS),which is an 8-item validated questionnaire to measure daytime sleepiness[17] by asking the patients to rate the likelihood of them falling asleep in different common situations, with the total possible score ranging from 0 to 24[18]. The visual analog scale (VAS) was used by both patients and their family members or bed partners to rate the snoring loudness and frequency, with the possible scores ranging from 0 (no snoring) to 10 (maximum snoring). Follow-up PSG results after MAD titration were reviewed, focusing on changes of the related parameters, such as AHI, oxygen desaturation index (ODI), minimum oxygen saturation (min O_2 sat), and sleep stages. The treatment was considered a success if the follow-up PSG showed a posttreatment AHI of less than 15 events per hour and a decrease from baseline of at least 50%. Cure was considered if the post-treatment AHI was less than five events per hour.

Statistical analysis

Descriptive data, such as demographic data and PSG parameters, were reported as the mean ± standard deviation (SD), median and interquartile range (IQR: P25, P75) or number and percentage. The Wilcoxon signed ranks test was used to compare the pretreatment and posttreatment results and a p-value of less than 0.05 was considered statistically significant. Data were analyzed by using PASW Statistics for Windows, version 18.0 (SPSS Inc., Chicago, IL, USA).

Results

During the study period, 90 patients were considered to meet the inclusion criteria. However, 23 patients were excluded due to loss to follow-up (n=7), very poor sleep efficiency (n=2), and missing VAS or ESS data (n=14). Consequently, 67 patients, 39 males (58.2%) and 28 females (41.8%), with the mean age of 51.8±9.4 years old, were included in the final analysis. The range of the follow-up time was three to seven years with a mean and median of 5.2 years and 5.0 years, respectively. According to the AHI, 30 patients were considered to have mild OSA, with an AHI of 5 to 14.99 events per hour, 25 patients moderate OSA with an AHI of 15 to 29.99 events per hour, and 12 patients severe OSA with an AHI of 30 or more events per hour.

Table 1. Objective outcomes after treatment with custom–made oral appliances

Parameters	Pretreatment; median (P25, P75)	Posttreatment; median (P25, P75)	Difference; median (P25, P75)	p-value
AHI (events/hour)	16.5 (11.5, 27.8)	5.1 (2.8, 11.3)	10.4 (5.1, 19.8)	<0.001
Minimum O_2 sat (%)	82.0 (77.0, 86.0)	87.0 (80.0, 90.0)	5.0 (1.0, 7.0)	<0.001
Time O_2 sat <90% (%)	1.2 (0.2, 3.7)	0.5 (0.1, 2.3)	0.2 (0.0, 2.1)	<0.001
3% O_2 desat (events/hour)	11.6 (7.0, 20.5)	5 (2.6, 9.6)	6.2 (2.5, 11.7)	<0.001
Mean O_2 sat (%)	95.4 (94.8, 96.0)	95.6 (94.0, 97.0)	–1.0 (0.5, 1.7)	0.259
TST (minute); mean±SD	342.8±98.9	371.7±67.6	4.0 (–37.0, 83.0)	0.085
Stage N1 (%)	18.0 (11.7, 25.4)	12.0 (9.0, 16.0)	6.1 (–2.0, 13.8)	<0.001
Stage N2 (%)	52.0 (46.0, 62.0)	52.0 (45.0, 60.0)	–1.0 (–6.0, 9.0)	0.681
Stage N3 (%)	7.5 (3.0, 13.0)	13.0 (7.0, 21.0)	3.4 (–0.9, 12.3)	<0.001
Stage R (%)	18.0 (11.1, 22.0)	18.0 (14.0, 23.0)	0.8 (–2.9, 5.4)	0.136

AHI=apnea–hypopnea index; O_2=oxygen; sat=saturation; desat=desaturation; TST=total sleep time; N=non–rapid eye movement sleep; R=rapid eye movement sleep

The median difference is significant at the level of p<0.001 (two–tailed)

Table 2. Subjective outcomes after treatment with custom-made oral appliances

	Pretreatment; median (P25, P75)	Posttreatment; median (P25, P75)	Difference; median (P25, P75)	p-value
ESS	9 (6, 13)	7 (4, 9)	2 (0, 5)	<0.001
VAS snoring loudness (by patient)	5.5 (3.3, 7)	3.2 (1.5,4.4)	1.5 (0.8, 3.1)	<0.001
VAS snoring loudness (by family or bed partner)	6 (4, 7.5)	3.3 (2, 5)	1.5 (0.5, 3.6)	<0.001
VAS snoring frequency (by patient)	5.2 (3, 6.9)	2.7 (1.5, 4.5)	1.2 (0.1, 3.1)	<0.001
VAS snoring frequency (by family or bed partner)	5.5 (3.2, 7.6)	3.4 (2, 5.3)	1.2 (0.2, 3.6)	<0.001

VAS=visual analog scale; ESS=Epworth sleepiness scale

The objective (PSG) and subjective outcomes (ESS and VAS) of OA therapy are shown in Table 1 and Table 2, respectively. According to the criteria, which is a post-treatment AHI of less than 15 events per hour and 50% reduction of AHI compared with pretreatment, treatment was considered a success for 41 out of 67 patients (61%), comprising70%, 56%, and 50% success rates for mild, moderate, and severe OSA patients, respectively. Cure, with a post-treatment AHI of less than five events per hour, was found in 33 patients (49%), of which the cure rate was 82%, 29%, and 16% in mild, moderate, and severe OSA patients, respectively.

The adverse side effects of custom-made OAs found in the present study included TMJ discomfort, which was the most common, dry mouth, excessive salivation, gingival pain, and toothache. However, the patients reported that these effects were mild to moderate, which indicates they were tolerable.

Discussion

Currently, the practice parameters of the AADSM indicate that a custom-made MAD can be considered as the first-line treatment in patients with mild-to-moderate OSA who prefer OA, and in patients with severe OSA who are intolerant to CPAP therapy, if there are no contraindications[9,12-14,19-21]. In Thailand, this practice has also been implemented for about a decade; nevertheless, there is still insufficient data regarding the outcomes of these devices in Thai patients.

The results of the present study showed that there were significant improvements in both subjective and objective outcomes after OA therapy. The post-treatment PSG results showed that the respiratory parameters, especially the mean of AHI and ODI, were significantly decreased while the min O_2 sat was significantly increased, all of which were in accordance with the findings from several previous studies[12,13,20-23]. In addition, there was an improvement in sleep quality represented with a significant decrease in stage N1 and increase in stage N3. However, there is still no consistent data regarding the effects of these devices on the characteristics of the sleep stages. The results of the present study also showed that the subjective outcomes measured by both ESS and VAS

scores of snoring were significantly improved, also corresponding with the previous studies[12,13].

Based on the criteria of a post-treatment AHI of less than 15 events per hour and at least a 50% reduction of AHI, 41 out of 67 patients (61%) were considered to have successful treatment, with rates of 70%, 56%, and 50% in patients with mild, moderate, and severe OSA, respectively. These therapeutic responses were in accordance with a previous study that showed success under the criterion of 50% or better reduction in baseline AHI, with rates of 75%, 71%, and 70% in patients with mild, moderate, and severe OSA, respectively[24], and with another study that showed success under the criteria of post-treatment AHI of less than 10 events per hour and more than a 50% reduction from baseline, with rates of 52.2%, 59.6%, and 42.1% in patients with mild, moderate, and severe disease, respectively[25]. The present study showed that even in patients with severe OSA, half of them could be successfully treated. The present finding corresponds with a previous study[26] of well-selected patients with severe OSA, which reported that a custom-made OA may be an effective treatment, particularly for those who are intolerant to CPAP therapy.

There were some limitations of the present study to note. First, it was a retrospective review from a potentially incomplete data collection, which might have led to yielding results with some bias. Second, the present study did not report the patients' quality of life before and after treatment, which could be important information. However, the present study had one key strength in that it is the first report of the long-term outcomes of custom-made OA therapy evaluated by PSG in Thai patients. To improve the data regarding the effectiveness of these devices, the authors suggest that large and long-term prospective studies and randomized controlled trials should be conducted in the future.

Conclusion

Custom-made OAs significantly improved both the objective and subjective outcomes of OSA patients and may be considered an effective treatment of choice. However, to achieve the optimal outcome with minimal complications, a proper selection of patients and regular follow-up with both a sleep specialist and qualified dentist are required.

What is already known on this topic?

The American Academy of Dental Sleep Medicine (AADSM) currently recommends that the first-line treatment in patients with mild-to-moderate OSA who prefer an OA and patients with severe OSA who are intolerant to CPAP therapy should be a custom-made mandibular advancement device (MAD).

What this study adds?

This is probably the first study to report the outcomes of custom-made MAD for the treatment of OSA in Thai patients under supervision of qualified dentists and sleep specialists.

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Conflicts of interest

The authors declare that they had no conflicts of interest.

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