ผลงาน

เพื่อขอกำหนดตำแหน่งพยาบาลผู้ชำนาญการพิเศษ

๕.๑.๓.๒ (ผลงานวิจัย)

Adjustable thermoplastic oral appliance versus positive airway pressure for obstructive sleep apnea

ของ

นางสาววิมลทิพย์ ศรีเจริญ

สังกัดฝ่ายการพยาบาล โรงพยาบาลศิริราช

คณะแพทยศาสตร์ศิริราชพยาบาล มหาวิทยาลัยมหิดล

Adjustable thermoplastic oral appliance versus positive airway pressure for obstructive sleep apnea

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เรื่อง **Adjustable thermoplastic oral appliance versus positive airway pressure for obstructive sleep apnea**

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(รศ.นพ.วิชญ์ บรรณหิรัญ)

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(รศ.นพ.เชิดชัย นพมณีจำรัสเลิศ)

ลงชื่อ.....

(นางสาวนงค์เยาว์ นุชนารถ)

ลงชื่อ.....

(นางสาววิมลทิพย์ ศรีเจริญ)

ลงชื่อ.....

(ศ.คลินิก พญ.จีระสุข จงกลวัฒนา)

ลงชื่อ.....

(ศ.คลินิกเกียรติคุณ นพ.โชคชัย เมธีไตรรัตน์)

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เรื่อง **Adjustable thermoplastic oral appliance versus positive airway pressure for obstructive sleep apnea**

ของ รองศาสตราจารย์ นายแพทย์วิชญ์ บรรณหิรัญ

เพื่อขอแต่งตั้งให้ดำรงตำแหน่ง.....

สาขาวิชา โสต นาสิก ลาริงซ์วิทยา

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ชื่อ รองศาสตราจารย์ นายแพทย์วิชญ์ บรรณหิรัญ สัดส่วนงาน ร้อยละ ๕๐

หน้าที่ความรับผิดชอบ Conception and design, data acquisition, analysis and interpretation, drafting, critical revisions, and final approval

ชื่อ รองศาสตราจารย์ นายแพทย์ปารยะ อาศนะเสน สัดส่วนงาน ร้อยละ ๑๐

หน้าที่ความรับผิดชอบ Conception and design, interpretation, critical revisions, and final approval

ชื่อ รองศาสตราจารย์ นายแพทย์เชิดชัย นพมณีจำรัสเลิศ สัดส่วนงาน ร้อยละ ๑๐

หน้าที่ความรับผิดชอบ Conception and design, interpretation, critical revisions, and final approval

ชื่อ คุณนงเยาว์ นุชนารถ สัดส่วนงาน ร้อยละ ๕

หน้าที่ความรับผิดชอบ Data acquisition, analysis and interpretation, and final approval

ชื่อ คุณวิมลทิพย์ ศรีเจริญ สัดส่วนงาน ร้อยละ ๕

หน้าที่ความรับผิดชอบ Data acquisition, analysis and interpretation, and final approval

ชื่อ รองศาสตราจารย์ แพทย์หญิงจีระสุข จงกลวัฒนา สัดส่วนงาน ร้อยละ ๑๐

หน้าที่ความรับผิดชอบ Conception and design, interpretation, critical revisions, and final approval

ชื่อ ศาสตราจารย์ คลินิก นายแพทย์โชคชัย เมธีไตรรัตน์ สัดส่วนงาน ร้อยละ ๑๐

หน้าที่ความรับผิดชอบ Conception and design, interpretation, critical revisions, and final approval

๑. ลงชื่อ.....
(รองศาสตราจารย์ นายแพทย์วิชญ์ บรรณหิรัญ)
วันที่.....เดือน.....พ.ศ.....

๒. ลงชื่อ.....
(รองศาสตราจารย์ นายแพทย์ปารยะ อาศนะเสน)
วันที่.....เดือน.....พ.ศ.....

๓. ลงชื่อ.....
(รองศาสตราจารย์ นายแพทย์เชิดชัย นพมณีจำรัสเลิศ)
วันที่.....เดือน.....พ.ศ.....

๔. ลงชื่อ.....
(คุณนงเยาว์ นุชนารถ)
วันที่.....เดือน.....พ.ศ.....

๕. ลงชื่อ.....
(คุณวิมลทิพย์ ศรีเจริญ)
วันที่.....เดือน.....พ.ศ.....

๖. ลงชื่อ.....
(รองศาสตราจารย์ แพทย์หญิงจีระสุข จงกลวัฒนา)
วันที่.....เดือน.....พ.ศ.....

๗. ลงชื่อ.....
(ศาสตราจารย์ คลินิก นายแพทย์โชคชัย เมธีไตรรัตน์)
วันที่.....เดือน.....พ.ศ.....

หมายเหตุ ขอรับรองว่าเป็นความจริง

The Laryngoscope

Adjustable Thermoplastic Oral Appliance Versus Positive Airway Pressure for Obstructive Sleep Apnea

Wish Banhiran, MD; Paraya Assanasen, MD; Cherdchai Nopmaneejumrudlers, MD; Nongyoaw Nujchanart, RN; Wimontip Srechareon, RN; Cheerasook Chongkolwatana, MD; Choakchai Metheetrairut, MD

Objectives/Hypothesis: To compare outcomes of continuous positive airway pressure (CPAP) and the adjustable thermoplastic mandibular advancement splint (AT-MAS) for obstructive sleep apnea treatment.

Study Design: Randomized crossover, noninferiority, tertiary center setting.

Methods: Fifty patients with a mean age of 49.5 ± 10.6 years were enrolled. Inclusion criteria were age ≥18 years, apnea-hypopnea index (AHI) ≥5 events/hour, and oxygen saturation ≥70%. Exclusion criteria were temporomandibular joint disorders, severe periodontitis, inadequate teeth, and unstable medical diseases. Treatment intolerance was considered a failure. Two-week periods without treatment were followed by questionnaires and randomization into two groups: CPAP/AT-MAS (25) and AT-MAS/CPAP (25). After 6 weeks of intervention, questionnaires and home WatchPAT monitoring were performed. Following each 2-week washout period, patients crossed over to the other treatment followed by similar procedures. Primary outcomes involved the scores from the Functional Outcomes of Sleep Questionnaire (FOSQ). Secondary outcomes were AHI, side effects, and treatment adherence.

Results: Seven patients withdrew from this study: five (AT-MAS intolerance) and two (lost follow-up). There was no significant difference among FOSQ scores, particularly on global scores, between both treatments (0.57, 95% confidential interval of difference: −0.15 to 1.29). Mean AHI decreased from pretreatment 39.2 ± 2.53 to 2.56 ± 0.49 and 12.92 ± 2.05 events/hour while using CPAP and the AT-MAS, respectively ($P < .05$). Most common side effects of CPAP were dry throat and inconvenience to carry, whereas those of the AT-MAS were jaw pain and excessive salivation.

Conclusions: Both devices improved short-term quality of life similarly; however, the AT-MAS was not as efficacious as CPAP on resolving sleep-test parameters. The AT-MAS might be considered only a temporary treatment alternative.

Key Words: Obstructive sleep apnea, quality of life, thermoplastic, mandibular advancement splint, Somnoguard, oral appliances, boil and bite, Asian, Thai.

Level of Evidence: 1b.

***Laryngoscope*, 00:000–000, 2017**

INTRODUCTION

Obstructive sleep apnea (OSA), if left untreated, may lead to adverse consequences including poor quality of life (QOL),[1–3] traffic accidents,[4] and cardiovascular morbidities.[5] Although continuous positive airway pressure (CPAP) is considered the first-line treatment, patients compliance is low.[6,7] Oral appliances (OAs) have become possible alternatives. They are simpler devices designed to enlarge the pharyngeal airway by advancing the mandible and tongue forward. In the literature, several outcomes using OA therapy are comparable to outcomes with CPAP.[8–17] Furthermore, OAs are smaller and more portable. According to current practice guidelines, OAs should be recommended for adult OSA patients who prefer OA therapy or for those with CPAP intolerance.[6,18,19]

A custom-made mandibular advancement splint (C-MAS) is the most commonly used OA, with reported success rates of 30% to 86%, depending on the design and outcome measurement.[8–10,13–15,17,20–22] Additionally, a C-MAS has higher compliance and preference scores when compared to CPAP, even though they are not as efficacious in reducing the apnea-hypopnea index (AHI).[11–13,16] Recently, several studies have failed to show any significant differences between these devices and CPAP when comparing 24-hour mean blood pressure, daytime sleepiness (DS), and QOL.[8–16,21] However, a C-MAS is often more costly and less accessible than thermoplastic, "boil-and-bite" mandibular advancement splints, which are prefabricated and have a simpler design. Even though previous studies have shown poorer outcomes with boil-and-bite mandibular advancement splints as compared to a C-MAS, most devices in these studies were actually nonadjustable (monobloc) devices.[19,23,24] Recently,

From the Department of Otorhinolaryngology (W.B., P.A., C.C., C.M.), Siriraj Sleep Center (W.B.), Department of Medicine (C.N.), and the Department of Nursing (N.N., W.S.), Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand.

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Send correspondence to Wish Banhiran, MD, Department of Otorhinolaryngology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand 10700. E-mail: wish.ban@mahidol.ac.th, wishbanh@gmail.com

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a newer adjustable thermoplastic mandibular advancement splint (AT-MAS) has been introduced. This device can be adjusted to advance mandibular position with potential outcomes comparable to a C-MAS, but is less expensive.[19,22,25] However, in consideration of the paucity of data of this new device, there was a need for more studies. The primary objective of this study was to compare disease-specific QOL outcomes using the AT-MAS versus CPAP. The secondary objective was to compare DS, symptoms, sleep parameters, side effects, compliance, and intolerance with both treatments.

MATERIALS AND METHODS

Study Design

This randomized, crossover, noninferiority study was conducted at the Department of Otorhinolaryngology, Faculty of Medicine, Siriraj Hospital between October 2014 and March 2016 after obtaining approval from the Siriraj Institutional Review Board (SIRB) and research grant funding from Faculty of Medicine, Siriraj Hospital. Signed, written, informed consent was obtained before recruitment into the study.

Subjects

Inclusion criteria were patients aged ≥18 years, AHI of ≥5 events/hour, and the lowest oxygen saturation ≥70% based on diagnostic polysomnography (PSG) level 1. Exclusion criteria were patients with temporomandibular joint (TMJ) disorders, severe periodontitis, inadequate teeth (<3 in each quadrant), and unstable medical problems (e.g., cardiopulmonary diseases, cancer, dementia). Intolerance to side effects of either CPAP or the AT-MAS was considered a treatment failure.

Interventions

During routine follow-up visits after PSG, all patients diagnosed with OSA in our snoring clinic were reevaluated for treatment planning, including discussions regarding at least a 1-week CPAP trial versus other possible treatment alternatives barring any contraindications. Those who accepted for CPAP therapy, but also needed other treatment options were introduced and enrolled into the study by research assistants following ethical instruction of the SIRB. The study began with a 2-week period without treatment followed by administration of questionnaires regarding symptoms, relevant information, Functional Outcomes Of Sleep Questionnaire (FOSQ), and Epworth Sleepiness Scale (ESS). The patients were then randomly assigned to either CPAP or AT-MAS therapy (open label) for 6 weeks, followed by post-treatment questionnaire administration and home WatchPAT (Itamar Medical Ltd., Caesarea, Israel) monitoring while wearing the devices. After a 2-week washout–no treatment period, the patients switched to the other treatment (CPAP or AT-MAS) for 6 weeks followed by similar procedures (Fig. 1).

CPAP

CPAP was administered using Transcend AUTO (Somnetics International, New Brighton, MN) with the pressure set at 5 to 15 cm H_2O (Fig. 2). All patients were fitted with a properly sized mask and received CPAP education prior to treatment. They were instructed to use the devices nightly as tolerated and to inform our personnel to correct any adverse effects.

Adjustable Thermoplastic Mandibular Advancement Splint

An AT-MAS (SomnoGuard AP; Tomed, Bensheim, Germany),[19,22,25] was used in this study. The device kit contained two separate prefabricated trays filled with a thermoplastic material (Fig. 3). Fitting procedures were performed by an otolaryngologist in the clinic according to the manufacturer's instructions, which included boiling the prefabricated trays for 3.5 minutes, cooling them to room temperature for half a minute, taking bite impressions for half a minute, and then rehardening the trays in cold water for half a minute. Attachment of the separate trays was done by inserting an adjustable screw from the lower tray into a groove in the upper tray. The patients were then asked to use the AT-MAS nightly and to attend follow-up visits with an otolaryngologist to receive adjustments for optimal symptoms with the fewest side effects. When needed, remolding of the AT-MAS, trimming of any excessive parts, and adjusting of the screw were done.

WatchPAT

WatchPAT is a wrist-worn device that combines peripheral arterial tonometry, pulse oximetry, and actigraphy to analyze sleep stages and respiratory-related parameters using an automatic algorithm. WatchPAT is a simple, reliable alternative to PSG for sleep monitoring that circumvents interscorer variability issues.[26]

FOSQ

The FOSQ is a 30-item self-administered disease-specific QOL questionnaire used to assess the impact of sleep on five domains: general productivity, vigilance, social outcome, activity level, and sexual relationships.[27] The mean score of each domain subscale ranges from 1 to 4, and the mean global score ranges from 5 to 20, with lower scores representing worse QOL. In this study, we used the validated Thai version of the FOSQ with permission.[2,27]

ESS

The ESS is a self-administered questionnaire used to assess the chance of dozing during eight common situations. The total score ranges from 0 to 24, with lower scores indicating a lower degree of sleepiness. In this study, we use the validated Thai version of the ESS with permission.[28,29]

Symptoms Questionnaire and Relevant Information

A visual analog scale (VAS) was used to assess snoring intensity and snoring frequency (0 = no snoring and 10 = maximal snoring). Adverse treatment side effects were classified by a self-reported severity scale: none, mild (little discomfort, ignorable), moderate (discomfort leading to occasional interruption in device use), and severe (discomfort leading to treatment discontinuation). Treatment compliance was evaluated by a self-reported questionnaire documenting the frequency and length of time that the assigned device was used.

Primary Outcome

The primary outcome was assessed by comparing CPAP FOSQ scores with AT-MAS FOSQ scores after 6 weeks of

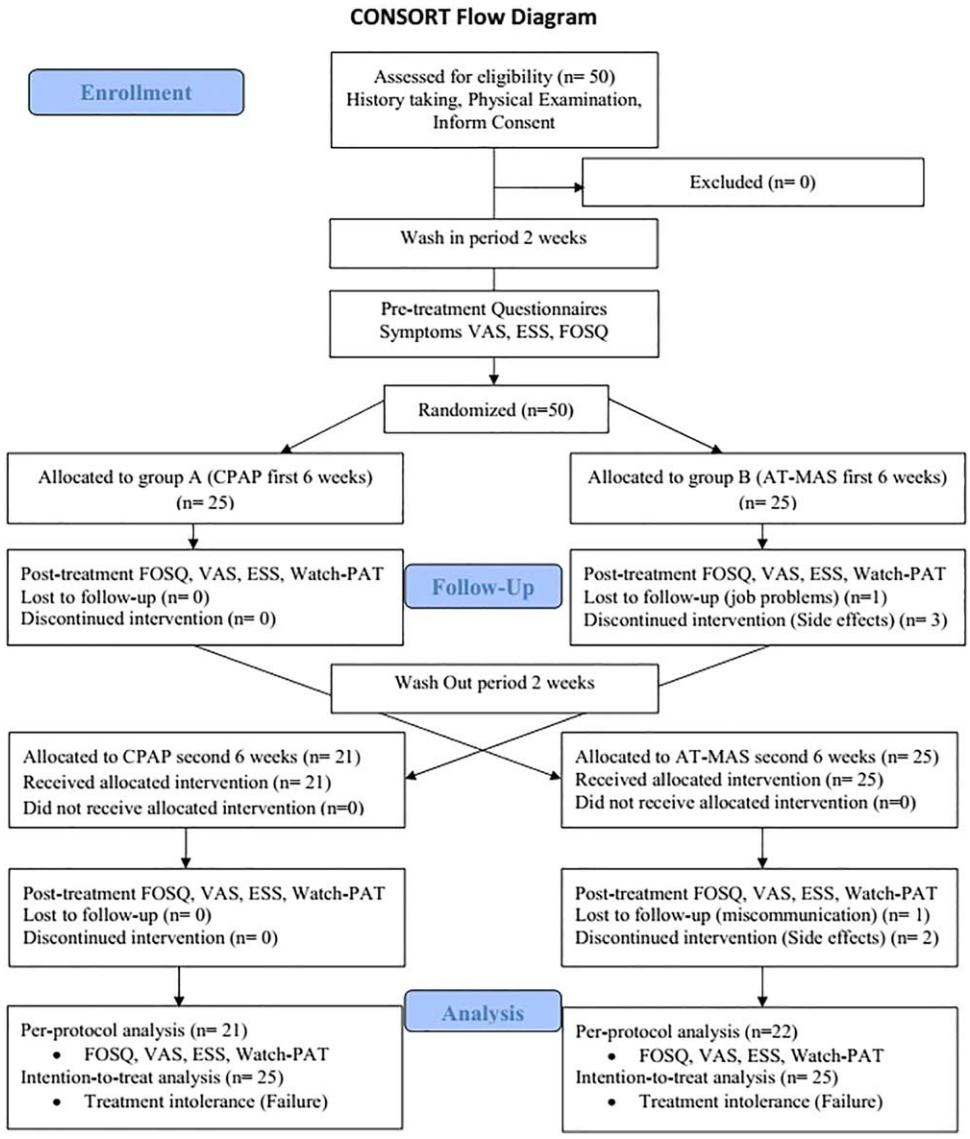

Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) flowchart of patients. AT-MAS = adjustable thermoplastic mandibular advancement splint; CPAP = continuous positive airway pressure; ESS = Epworth Sleepiness Scale; FOSQ = Functional Outcomes of Sleep Questionnaire; PAT = peripheral arterial tonometry; VAS = visual analog scale. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

Fig. 2. Transcend AUTO continuous positive airway pressure (Somnetics International, New Brighton, MN). [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

treatment. Estimated margins for 95% confidence interval (CI) of meaningful clinical differences between both interventions were accepted at level of $\geq$10%.

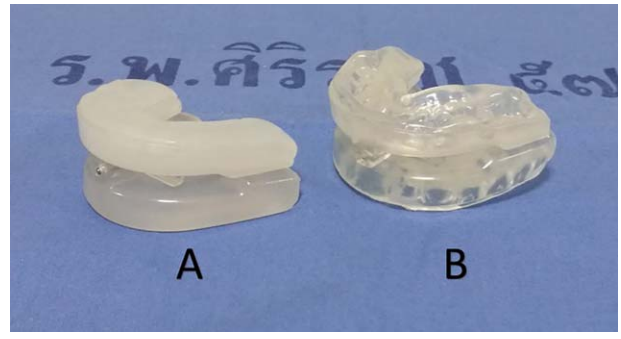

Fig. 3. Adjustable thermoplastic mandibular advancement splint (Somnoguard AP; Tomed GmbH, Cologne, Germany). (A) Before fitting. (B) After fitting. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

TABLE I.
Baseline Demographic Data.

	Group A, n = 25, CPAP/AT-MAS	Group B, n = 25, AT-MAS/CPAP	*P* Value
Age, yr	47.1 ± 11.0	52.2 ± 9.8	.91
Body mass index (kg/m^2)	27.6 ± 4.7	26.0 ± 4.2	.19
Severity of snoring VAS scores	7.3 ± 2.1	7.3 ± 1.9	.96
Frequency of snoring VAS scores	4.9 ± 2.9	4.8 ± 2.4	.96
ESS scores	12.4 ± 5.0	9.9 ± 4.8	.08
FOSQ scores			
General productivity	3.3 ± 0.6	3.2 ± 0.7	.86
Social outcome	3.6 ± 0.7	3.7 ± 0.7	.34
Activity level	3.0 ± 0.5	3.2 ± 0.7	.31
Vigilance	2.5 ± 0.8	2.9 ± 0.8	.15
Sexual relationship	2.6 ± 1.3	2.8 ± 1.5	.71
Global scores	15.0 ± 2.9	15.8 ± 3.0	.34
Polysomnographic findings			
Total sleep time (min)	361.2 ± 84.5	334.6 ± 106.1	.33
Sleep efficiency (%)	84.8 ± 9.2	84.2 ± 12.7	.85
Stage N3 (%)	11.8 ± 11.7	10.8 ± 7.8	.73
Stage REM (%)	13.7 ± 6.3	12.4 ± 7.4	.53
Apnea-hypopnea index	39.0 ± 27.7	39.3 ± 23.4	.97
Respiratory disturbance index	43.4 ± 26.2	41.2 ± 22.0	.75
Oxygen desaturation index	28.9 ± 27.6	27.5 ± 25.3	.85
Mean oxygen saturation (%)	95.3 ± 1.8	95.2 ± 1.7	.82
Minimal oxygen saturation (%)	83.4 ± 6.0	82.7 ± 6.9	.70
Time oxygen saturation ≥90 (%)	96.3 ± 10.0	96.3 ± 6.2	.98

AT-MAS = adjustable thermoplastic mandibular advancement splint; CPAP = continuous positive airway pressure; ESS = Epworth Sleepiness Scale; FOSQ = Functional Outcomes of Sleep Questionnaire; REM = rapid eye movement; VAS = visual analog scales.

Secondary Outcomes

Secondary outcomes were assessed by comparing the results of CPAP and the AT-MAS after 6 weeks of treatment. These included data from WatchPAT (e.g., AHI, oxygen saturation, sleep stages), ESS, VAS, adverse side effects, and self-reported adherence. Treatment intolerance was reported when patients withdrew from the study due to adverse effects or were lost to follow-up for any reason.

Sample Size Calculation

Sample size calculation was based on the primary outcome (FOSQ global scores) under the hypothesis of noninferiority, randomized crossover trial. Using expected meaningful different scores between both interventions of −1 to +1, a power of 80%, acceptable one-sided error at 0.05, and a standard deviation of 1.5 obtained from previous studies,[2,24] the calculated sample size was initially 20 participants per intervention. However, to control for 25% loss to follow-up, the final number of subjects was increased to 25 per intervention, or a total of 50 patients.

Randomization, Allocation Concealment, and Blinding Methods

The patients were allocated into treatment sequence A or B using sequential numbers of a simple-block computerized randomization algorithm with 1:1 ratio. The sequence A group (25 patients) was assigned to use CPAP before the AT-MAS and the sequence B group (25 patients) was assigned to use the AT-MAS before CPAP (Fig. 1). The sequential numbers were concealed in opaque envelopes. The patients and the researchers were blinded to the sequential numbers before the group assignment but not during the interventions.

Statistical Analysis

Per-protocol analysis for the primary outcomes (FOSQ) and most of the secondary outcomes between the two interventions were calculated by the repeated measures analysis of variance and post hoc Bonferroni's method with reports of the one-sided 95% CI of the mean differences. Intention-to-treat analysis for treatment intolerance or other categorical data were calculated by the McNemar test. The predictive analytics software IBM SPSS Statistics 23 (IBM, Armonk, NY) was used for statistical analysis. Level of significance was set at $P < .05$.

RESULTS

Fifty patients (27 males, 23 females) with a mean age of 49.5 ± 10.6 years (range, 29–73 years) were enrolled in this study. The mean body mass index (BMI) and mean AHI of all patients were 26.8 ± 4.5 kg/m^2 and 39.2 ± 2.53 events/hour, respectively. Twenty-five patients (13 males, 12 females) were allocated into sequence A and the other 25 patients (14 males, 11 females) were allocated into sequence B. Baseline data between the two sequences were not significantly different (Table I). Seven patients were excluded from the study, five due to AT-MAS intolerance (severe pain and discomfort) and two from loss to follow-up (Fig. 1).

TABLE II.
Outcomes of Treatment.

	CPAP, N = 43	AT-MAS, N = 43	Mean Difference (95% CI)	*P* Value
BMI (kg/m^2)	26.56 ± 4.45	26.39 ± 4.36	0.17 (0.06, 0.29)	.005*
Severity of snoring VAS	3.15 ± 0.41	4.46 ± 0.37	−1.30 (−2.45, −0.15)	.03*
Frequency of snoring VAS	3.11 ± 0.41	4.38 ± 0.38	−1.27 (−2.46, −0.08)	.04*
ESS	7.23 ± 0.63	8.49 ± 0.70	−1.26 (−2.47, −0.05)	.41
FOSQ scores				
General productivity	3.49 ± 0.10	3.41 ± 0.13	0.08 (−0.14, 0.30)	.48
Social outcome	3.79 ± 0.08	3.72 ± 0.12	0.07 (−0.10, 0.24)	.43
Activity level	3.45 ± 0.06	3.32 ± 0.07	0.13 (−0.03, 0.29)	.10
Vigilance	2.86 ± 0.13	2.74 ± 0.15	0.11 (−0.07, 0.29)	.21
Sexual relationship	2.56 ± 0.24	2.38 ± 0.24	0.18 (−0.10, 0.46)	.20
Global scores	16.14 ± 0.44	15.57 ± 0.54	0.57 (−0.15, 1.29)	.12
WatchPAT parameters				
Total sleep time (min)	369.95 ± 9.85	370.19 ± 10.51	−0.23 (−21.22, 20.75)	.98
Sleep efficiency (%)	81.88 ± 1.57	82.47 ± 1.13	−0.59 (−3.89, 2.72)	.72
Stage N3 (%)	20.22 ± 0.93	19.57 ± 0.78	0.65 (−1.57, 2.87)	.56
Stage REM (%)	23.91 ± 1.14	25.09 ± 1.04	−1.19 (−4.11, 1.74)	.42
AHI (events/hr)	2.56 ± 0.49	12.92 ± 2.05	−10.36 (−14.33, −6.39)	<.001†
RDI (events/hr)	8.37 ± 0.81	16.84 ± 2.01	−0.85 (−12.34, −4.61)	<.001†
ODI (events/hr)	1.08 ± 0.24	8.32 ± 1.63	−7.23 (−10.51, −3.97)	<.001†
Mean O_2 sat (%)	96.70 ± 0.12	95.70 ± 0.19	1.00 (0.63, 1.37)	<.001†
Minimal O_2 sat (%)	91.76 ± 0.55	85.58 ± 1.01	6.18 (4.12, 8.22)	<.001†
Time ≥90 (%)	99.95 ± 0.03	98.94 ± 0.28	1.01 (0.45, 1.58)	.001*

AHI = apnea-hypopnea index; AT-MAS = adjustable thermoplastic mandibular advancement splint; BMI = body mass index; CPAP = continuous positive airway pressure; CI = confidence interval; ESS = Epworth Sleepiness Scale; FOSQ = Functional Outcomes Of Sleep Questionnaire; Mean O_2 sat = mean oxygen saturation; Minimal O_2 sat = minimal oxygen saturation; ODI = oxygen desaturation index; RDI = respiratory disturbance index; REM = rapid eye movement; Time ≥90 = time spent in oxygen saturation ≥90%; VAS = visual analog scale.

*The mean difference is significant at the level of < 0.05.

†The mean difference is significant at the level of < 0.001.

Primary Outcome

There was no statistically significant difference in all dimensions of FOSQ scores between CPAP and the AT-MAS after 6 weeks of treatment (Table II). The mean difference of global FOSQ scores between both treatments was 0.57 with 95% CI ranging from −0.15 to 1.29, which were considered having no clinical meaningfulness (<10%).

Secondary Outcomes

Snoring intensity, snoring frequency, and respiratory-related parameters while using CPAP were significantly better than those of the AT-MAS ($P < .05$) despite higher BMI in the CPAP group. However, there was no statistically significant difference between both treatments in sleep efficiency, stage R, stage N3, and ESS scores at 6 weeks after treatment (additional data in Table II). While using CPAP, 81.8% of patients (38/44) and 97.7% of patients (43/44) had AHI <5 and <15 events/hour, respectively. Whereas, while using the AT-MAS, 30.2% of patients (13/43) and 69.8% of patients (30/43) had AHI <5 and <15, respectively.

Adverse Side Effects, Adherence, and Treatment Intolerance

The most common side effects of CPAP were dry throat and inconvenience with carrying the device, whereas those associated with the AT-MAS were jaw pain and excessive salivation (Table III). Despite having no immediate complications during the initial AT-MAS fitting, five patients withdrew from the study after 1 to 2 weeks because of the side effects (i.e., significant tooth pain, TMJ discomfort, hypersalivation, and device dislodging). Thirty-nine (84.8%) and 37 (82.2%) patients reported the nightly use of CPAP and the AT-MAS over 4 hours, respectively ($P = .009$). Twenty-nine (63.1%) and twenty-seven (60%) patients reported the weekly use of CPAP and the AT-MAS for greater than five nights, respectively ($P = .024$). There was no difference in device tolerance using intention-to-treat analysis: four patients (8%) were intolerant of CPAP and five patients (10%) were intolerant of the AT-MAS ($P = 1.0$). Follow-up after the study showed that 15 patients continued to use both devices, 22 patients continued to use CPAP only, five patients continued to use the AT-MAS only, two patients changed to the C-MAS, one patient changed to uvulopalatopharyngoplasty, and four patients discontinued all definitive treatments.

DISCUSSION

Advantages of OA over CPAP are no requirement for electricity, portable convenience, and suitability for some occupations such as sailors, military workers, and forest rangers. Previous research has shown comparable

TABLE III.
Adverse Side Effects of Device Therapies at the 6th Week.

Adverse Side Effects	None (%)	Mild (%)	Moderate (%)	Severe (%)
CPAP, n = 46				
Nasal congestion/irritation	25 (54.3)	18 (39.1)	3 (6.5)	—
Nasal discharge	34 (73.9)	12 (26.1)	—	—
Dry mouth or throat	11 (23.9)	23 (50.0)	10 (21.7)	2 (4.3)
Difficulty breathing	16 (34.8)	20 (43.5)	8 (17.4)	2 (4.3)
Facial pain (mask contact)	20 (43.5)	20 (43.5)	3 (6.5)	3 (6.5)
Irritated eye (air leak)	32 (69.6)	13 (28.3)	1 (2.2)	—
Facial skin lesion	34 (73.9)	8 (17.4)	3 (6.5)	1 (2.2)
Embarrassment (poor self-image)	18 (39.1)	18 (39.1)	6 (13)	4 (8.7)
Burden from device cleaning	23 (50)	16 (34.8)	7 (15.2)	—
Inconvenience to carry on	13 (28.3)	18 (39.1)	9 (19.6)	6 (13.0)
AT-MAS, n = 45				
TMJ and jaw pain	8 (17.8)	17 (37.8)	14 (31.1)	6 (13.3)
Malocclusion	17 (37.8)	20 (44.4)	6 (13.3)	2 (4.4)
Excessive salivation	8 (17.8)	18 (40.0)	18 (40.0)	1 (2.2)
Halitosis	18 (40.0)	17 (37.8)	10 (22.2)	—
Dry mouth or pharynx	10 (22.2)	19 (42.2)	14 (31.1)	2 (4.4)
Gingivobuccal pain	21 (46.7)	12 (26.7)	9 (20.0)	3 (6.7)
Toothache	14 (31.1)	17 (37.8)	12 (26.7)	2 (4.4)
Device dislodgement	30 (66.7)	10 (22.2)	3 (6.7)	2 (4.4)

AT-MAS = adjustable thermoplastic mandibular advancement splint; CPAP = continuous positive airway pressure; TMJ = temporomandibular joint.

outcomes with OA and CPAP with regard to improvement of DS, QOL, neurocognitive function, and blood pressure.[8–16,21] However, prior studies have focused mainly on the expensive C-MAS. As possibly the first study to compare outcomes between the AT-MAS fitted by an otolaryngologist with CPAP therapy, the results showed no clinically meaningful difference between both devices in terms of FOSQ scores, ESS scores, sleep efficiency, and amount of sleep stages R and N3 after 6 weeks of treatment. Although the AT-MAS had significantly improved AHI and related parameters, the AT-MAS was not as effective as CPAP. Nevertheless, the results of the AT-MAS in this study are better compared with those reported for nonadjustable thermoplastic devices by Vanderveken et al.,[24] Maurer et al.,[23] and Friedman et al.[19]

Abnormal events were reduced to an AHI of <15 and <5 events/hour in 69.8% and 30.2% of patients using the AT-MAS, respectively. Whereas, the same events were reduced to an AHI of <15 and <5 events/hour in 97.7% and 81.8% of those using CPAP, respectively. Our results are comparable to the results of numerous studies reporting that OAs reduce AHI in 30% to 86% of patients and also improve DS and QOL, similar to CPAP.[8–10,13–15,17,20–22,25] Regarding the discordance between the AHI and QOL, it is possible that the AHI obtained in a single night of study does not accurately represent overall patient health, which is a known limitation in OSA patient management.

Although treatment intolerance between CPAP and the AT-MAS was similar in this study, the most common side effects of the AT-MAS were mild jaw pain, excessive salivation, dry mouth, and teeth discomfort, all of which are similar to other OAs.[8,9,14,20,24] The side effects of CPAP were dry throat and inconvenience to carry. Only 10% of patients were intolerant of the AT-MAS, with 4.4% reporting sleep disruption from device dislodgement, which was less than the intolerance associated with nonadjustable the mandibular advancement splint reported by Vanderveken et al.[24] Regarding compliance with CPAP and the AT-MAS, 80% of our patients reported nightly use of the devices ≥4 hours, and over 60% reported weekly use of ≥5 nights. However, the compliance with the AT-MAS was slightly less than those reported for CPAP and the C-MAS in other studies.[13,16] Because the AT-MAS was available in only one size, some patients may have experienced discomfort or inadequate fit. Therefore, development of the AT-MAS in various sizes may provide a better outcome.

There are some limitations of this study. First, the compliance with both devices was self-reported. However, because objective monitoring of AT-MAS usage is not available as it is with CPAP or another type of C-MAS,[30] comparison with similar questionnaires should be fair. Second, the study results represent only short-term data. Finally, most of our patients had severe OSA. Long-term studies in different population are thus suggested.

CONCLUSION

Both CPAP and the AT-MAS improved short-term QOL similarly; however, the AT-MAS was not as efficacious as CPAP on resolving sleep-related respiratory

parameters. These results notwithstanding, provided that there are no contraindications, temporary use of the AT-MAS during some situations may be acceptable given its portability and low cost.

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