

Mandibular Exercises for the Prevention of Temporomandibular Disorder During Mandibular Advancement Device Therapy in Obstructive Sleep Apnea Patients: a Randomized Controlled Trial

ORIGINAL

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Abstract

Objective: This study aimed to evaluate the efficacy of mandibular exercises for the prevention of temporomandibular disorder (TMD) during Obstructive Sleep Apnea (OSA) treatment with mandibular advancement device (MAD) in patients without TMD symptoms.

Material and methods: Nineteen subjects with mild to moderate OSA were included. Patients were randomized into two groups: a control group and a support therapy group. Both groups received the MAD at 75% of their maximum protrusion. The support therapy group was instructed to perform mandibular exercises two times per day. Pain was assessed by an analogical pain scale during progressive protrusion at the 4th, 12th and 16th week. The Research Diagnostic Criteria for Temporomandibular disorders (RDC-TMD) were applied at the initial evaluation and at 16th week. Student's t-test, paired t-test, ANOVA, Friedman's ANOVA and chi-square were performed for statistics analyses.

Results: A total of 19 subjects, 10 in the support therapy group and 9 in the control group completed the protocol. According to the analogical pain scale and the RDC-TMD, none of the patients from either group experienced temporomandibular pain.

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Conclusion: Both groups did not develop TMD symptoms, mandible exercise as support therapy did not influence the prevention of TMD.

Keywords

Oral appliance; Sleep Apnea, Obstructive; Temporomandibular Disorder; Mandibular Exercises; Prevention.

Introduction

Obstructive sleep apnea (OSA) is characterized by recurrent, partial or complete obstruction of the upper airway during sleep, it causes sleep fragmentation and hypoxemia [1]. In order to normalize the apnea and hypopnea index (AHI), a treatment with MAD (mandibular advancement devices) can be required. MADs are indicated for patients who have primary snoring, mild to moderate OSA or for those patients who do not have a good result with Continuous Positive Airway Pressure (CPAP) or who are poor candidates for CPAP use [2]. In milder cases it can lessen daytime symptoms and improve parameters in quality of life, as well as cardiovascular and neurocognitive function [3-5]. Nonetheless, it has been reported that MAD therapy can provide undesirable effects [6-8].

A very common adverse effect of treatment with MAD is pain and discomfort in the masticatory muscles and/or temporomandibular joint over the short [6-8] and medium term [6]. The pain has been described as mild, transient and tends to disappear over time in patients who use a MAD for long duration [6-9]. This discomfort has been described as a factor related to non-adherence and interruption of MAD treatment [6]. Furthermore, a randomized parallel controlled trial of 2 years MAD and CPAP treatment showed a higher incidence of temporomandibular disorder (TMD) pain at the second month of MAD use [10].

Temporomandibular disorder (TMD) refers to a group of functional and/or structural problems in

the masticatory muscles, temporomandibular joints and other associated structures [11]. The most common symptoms of TMD is muscle pain [11]. As a TMD treatment, mandibular exercises are effective to reduce temporomandibular pain and improve coordination, strength and mobility [11, 12]. Therefore, the aim of this study was to investigate the efficacy of mandibular exercises in preventing TMD pain over 4 months of MAD in patients without TMD symptoms in the previous 1 month.

Materials and Methods

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent: Informed consent was obtained from all individual participants included in the study.

Funding

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Competing and Conflicting Interests

All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

Patient Selection

OSA subjects were selected from the center for sleep breathing-related disorders of Association Fund to Encourage Research in São Paulo (SP), Brazil. The current study was in accordance with the Helsinki declaration and was approved by the Ethics Committee of UNIFESP (0162/06). All subjects signed a written informed consent form to participate in the experiment.

The inclusion criteria were: both genders, age between 18 and 65 years old, non obese (body mass index (BMI) ≤ 30 kg/m²), apnea and hypopnea index (AHI) between 5 and 30 diagnosed by in-laboratory polysomnography and absence of signs or symptoms of TMD based on the Research Diagnostic Criteria for TMD (RDC-TMD) [13], with pain during palpation in less than 3 muscular/joint sites and a negative answer to question "Have you had pain in the face, jaw, temple, in front of the ear or in the ear in the past month?"

The exclusion criteria were: alcoholism, use of psychoactive drugs, habits or professions that lead to sleep deprivation or alteration of the sleep/wake cycle, other sleep disturbances, previous OSA treatment (MAD, surgery or CPAP), dental status that would compromise the MAD's retention, active periodontal disease, primary dental care needs, protrusive displacement < 5 mm and limited opening of the mouth.

Protocol

After selection, 19 subjects were randomized into Support Therapy group (STG) (n=10) or Control group (CG) (n=9). All subjects were assessed by Epworth Sleepiness Scale (ESS) [14], quality of life inventory (Short Form Health Survey/SF-36) (SF-36) [15]; RDC-TMD [16, 17]; panoramic and cephalometric radiographs, dental cast models and photos.

All patients received the same custom-made titrable MAD, the Brazilian Dental Appliance (BRD) [18]. All MADs were set at 75% of patient's maximum protrusion (max. PT) and subsequently they advanced progressively the mandible 1 mm per week until the achievement of the maximum comfortable protrusion (MCP). After maximum comfortable protrusion, the subjects returned every 15 days until 16 weeks of the MAD usage.

The Support Therapy (ST) consisted of mandibular exercises twice per day (morning and night), consisting of 3 series of five repetitions for each movement. The **figure 1** show the exercises protocol.

Figure 1: Exercises used for coordination and stretching. Movements of opening and closing the mouth with tongue limitation (a), lateral movements against mild hand resistance (b and c), opening the mouth against hand resistance (d), and opening forced assisted by fingers (e).



Both groups were instructed to filled out a MAD compliance diary every morning for all 120 days of treatment. The Compliance was determined based on the percentage of nights that the MAD was used.

All patients completed a sleep diary, as well as a MAD compliance diary. At the 16th week of treatment, the subjects filled out the Epworth Sleepiness Scale (ESS) [14], the quality of life inventory (Short Form Health Survey/SF-36) (SF-36) [15], the RDC-TMD [16, 17] and also made a polysomnography. Evaluation of the diaries and the pain scale were undertaken at the weeks 1, 4, 12 and 16.

Clinical assessment for TMD was made using the Research Diagnostic Criteria for Temporomandibular Disorders (RDC-TMD) [16, 17] was made by one dentist who was blinded to the patient allocation group.

Polysomnography

A computerized polysomnographic apparatus (Embla[®]) was used to record the following sleep parameters: electroencephalography (EEG - C3-A2, C4-A1, O2-A1, O1-A2); sub-mentonian and tibial electromyography (EMG); bilateral electrooculography (EOG); and electrocardiography (ECG modified V1 derivation). Breathing was monitored by a nasal cannula that gauged airflow by pressure transduction. Oral flow was measured by a thermal sensor, and chest and abdominal movements were recorded by a non-calibrated breathing plethysmography. For oxygen hemoglobin saturation, an infrared pulse oximetry reader was placed on the one of the subject's tip fingers. Body position was recorded by a sensor placed over the region of the sternum, and lastly, snoring was measured by a tracheal microphone. According to the previous criteria, the following parameters were evaluated: sleep staging [19], respiratory events, arousals [20] and leg movements [21].

Statistical analysis

The Statistica computer program (version 6.1; Statsoft, Inc., Tulsa, OK, USA) was used for the

statistical analysis. For normally distributed data, we adopted Student's t-test for independent samples, the paired t-test for comparisons within the same group, or ANOVA for repeated measures to compare between evaluation times. When data did not present a normal distribution, non-parametric test was adopted: Friedman's ANOVA for evaluation of visual analog scale pain. The chi-square test was used to compare qualitative variables. P values <0.05 were considered significant.

Results

A total of 87 consecutive patients with OSA (41 M/46 F) referred for treatment with MADs were evaluated, and 45 of them were excluded because of TMD pain. Of the 42 remaining subjects, 20 were excluded due to periodontal disease or insufficient teeth. Three subjects dropped out, one male in the support therapy group because of personal problems; and one male and one female in the control group, who did not give reasons for dropping out. The final sample was composed of 19 subjects, being 5 women (26.3%) and 14 men (73.7%), with a mean age of 44 ± 9 years old and a mean BMI of 25 ± 3 kg/m².

After randomization, the Control Group (CG) consisted of 9 subjects, and the Support Therapy Group (STG) consisted of 10 subjects. The anthropomorphic characteristics of baseline are described in **Table 1**; the only differences between groups at

Table 1. General characteristics of the control and support therapy groups at baseline.

	Control Group	Support Therapy Group
	n=9	n=10
Gender (M/F)	7 / 2	7 / 3
Age (years)	42.3 ± 3.2	45.6 ± 2.7
BMI (kg/m ²)	26.1 ± 0.7	24.9 ± 1.0
Epworth scale	9.6 ± 2.2	11.4 ± 1.7
AHI	13.5 ± 0.8	17.3 ± 2.3

	Control Group	Support Therapy Group
	n=9	n=10
SF-36		
Physical function	61.0 ± 13.2*	88.6 ± 2.9*
Role limitation due to physical problems	50.1 ± 13.4	77.7 ± 10.4
Pain	78.1 ± 7.7	74.8 ± 7.9
General health perception	54.5 ± 12.2	72.5 ± 5.9
Vitality	61.9 ± 9.8	63.6 ± 7.6
Social function	73.8 ± 8.8	77.8 ± 9
Role limitation due to emotional problems	70.8 ± 16.0	78.6 ± 12.1
Mental health	78.9 ± 5.9	68.7 ± 4.5

Data described in mean and standard deviation. BMI = Body mass index, AHI = apnea/hypopnea index, SF-36 = Short Form Health Survey; (Student's t-test): * = p<0.05 between the groups. (chi-square test): # = p<0.05 between the groups.

baseline was Physical functioning domain of SF-36 and the lower score of CG compared to STG (Table 1).

At the baseline comparison, the polysomnography variables from both groups did not differ. The AHI was significantly reduced between baseline and the final follow-up in both groups (Table 2).

There was not any significant difference between groups or between assessments regarding to MAD compliance in the 4 appointments (weeks 1, 4, 12 and 16) (table 3). No significant difference was found in exercise compliance over time.

Table 4 describes the results of the Epworth Sleepiness Scale and SF-36 between the 2 groups, comparing the baseline and final follow-up. The STG presented a statistically significant reduction in Epworth score after treatment. The SF-36 changes with treatment were observed in Physical function-

Table 2. Comparison of baseline and final polysomnographic variables between the control group and support therapy group.

	Control group (Baseline)	Control group (Final)	Support therapy group (Baseline)	Support therapy group (Final)
AHI	13.5 ± 0.8**	6.7 ± 1.8**	17.3 ± 2.3*	7.5 ± 1.0*
Mean SpO ₂	95.5 ± 1.3	96 ± 1,1	94.5 ± 1.1	96 ± 0.8
Lowest SpO ₂	88.1 ± 4.4	90.4 ± 1,7	87 ± 4.5	89.4 ± 4.2
SE (%)	81.0 ± 3.8	86.9 ± 2.4	84.0 ± 2.7	87.8 ± 2.7
E1 (%)	4.6 ± 0.9	5.1 ± 1.3	4.8 ± 1.5	3.2 ± 0.6
E2 (%)	56.1 ± 3.9	55.4 ± 2.3	55.4 ± 2.8	58.5 ± 2.2
E3 (%)	21.8 ± 4.3	21.3 ± 1.7	17.3 ± 2.5	17.4 ± 2.0
REM (%)	17.6 ± 2.2	18.2 ± 2.5	19.3 ± 1.8	22.1 ± 1.5
Arousal index	12.6 ± 2.4	13.2 ± 2.2	14.6 ± 2.9	11.9 ± 1.7

Data described in mean SD .AHI = apnea/hypopnea index , SE= sleep efficiency.CG=Control group; STG=Support therapy group.(Paired t-test): * = p<0.05 between baseline and after treatment in support therapy group. (Paired t-test): ** = p<0.05 between baseline and after treatment in control group.

Table 3. MAD compliance and exercise compliance between control and support therapy group. Data expressed in percentage of the nights.

	Groups	1 st week MAD of 75%	4 th week	12 th week	16 th week maximum protrusion
Control group	MAD compliance	87.0 ± 0.8	88.5 ± 0.8	96.3 ± 0.8	92.0 ± 0.8
Support therapy group	MAD compliance	87.5 ± 0.7	84.6 ± 0.7	81.0 ± 0.7	80.9 ± 0.7
	Exercise compliance	80.1 ± 0.7	75.5 ± 0.7	60.2 ± 0.7	64.8 ± 0.7

Data w in mean SD .(Repeated measures ANOVA): * = p<0.05 between times in each group. (ANOVA): ** = p<0.05 between the groups at each time

Table 4. Questionnaires at baseline and after intervention for both groups.

	Control group (Baseline)	Control group (Final)	Support therapy group (Baseline)	Support therapy group (Final)
Epworth scale	9.6 ± 2.2	8.0 ± 1.8	11.4 ± 1.7*	8.4 ± 1.1*
SF-36				
Physical functioning	61.0 ± 13.2**	72.3 ± 11.7**	88.6 ± 2.9	85.7 ± 6.3
Role limitation due to physical problems	50.1 ± 13.4	78.1 ± 14.5	77.7 ± 10.4	79.5 ± 10.0
Pain	78.1 ± 7.7	75.0 ± 6.6	74.8 ± 7.9	76.9 ± 5.1
General health perception	54.5 ± 12.2	72.6 ± 6.5	72.5 ± 5.9*	81.1 ± 4.0*
Vitality	61.9 ± 9.8	66.9 ± 9.1	63.6 ± 7.6	71.4 ± 8.0
Social functioning	73.8 ± 8.8	75.0 ± 12.3	77.8 ± 9	89.0 ± 6.0
Role limitation due to emotional problems	70.8 ± 16.0	70.8 ± 13.3	78.6 ± 12.1	78.8 ± 1.3
Mental health	78.9 ± 5.9	67.5 ± 9.7	68.7 ± 4.5	75.3 ± 4.3

Data described in mean SD.(Paired t-test): * = p<0.05 between baseline and after treatment in Support therapy group. (Paired t-test): ** = p<0.05 between baseline and after treatment in Control group.

Table 5. Comparison of visual analog scale pain values between control and support therapy group.

	1 st week MAD of 75%	4 th week	12 th week	16 th week maximum protrusion
Control group	0.0 ± 0.0	0.3 ± 0.3	0.0 ± 0.0	0.0 ± 0.3
Support therapy group	0.2 ± 0.2	0.1 ± 0.1	0.1 ± 0.1	0.0 ± 0.0

(Friedman's ANOVA): * = p<0.05 between times in each group. (Friedman's ANOVA): ** = p<0.05 between groups at each time

ning for the CG group and in general health perception for the STG.

The visual analog scale of pain at the first week (at 75% of maximum mandible advancement) in either group and when compared with the values at the 4th, 12th, and 16th weeks showed no significant differences, the groups did not present any differences between each other at any time (**Table 5**). Regarding the evaluation of RDC-TMD, we observed that none of the patients developed TMD pain.

Discussion

This is the first randomized controlled clinical trial which proposed to use jaw exercises to prevent temporomandibular pain in individuals who use MAD and had no previous TMD. This study is important because temporomandibular pain is a very common side effect related to MAD [8, 22, 23] and it is a factor of non-adherence and interruption of

MAD treatment [7]. While there is a tendency of prescribing exercises to patients, we understand with our current study that, for patients without previous TMD, there is no need for exercises and we can decrease the burden on patients undergoing MAD treatment.

In our study, both groups did not show any development of TMD pain. Many studies which evaluated side effects did not assess previous TMD pain or did not exclude this condition of the sample based on a strict evaluation criteria, the RDC-TMD. The previous assessment of temporomandibular joint is important since the etiology of TMD is multifactorial [24] and the frequency of the presence of TMD has been described to be as high as 52% of untreated sleep apnea patients [25].

Few studies assessed systematically TMD by RDC-TMD in a short MAD follow up [6, 8, 10]. One study showed 24% of subjects developed TMJ pain when using MAD for 2 months compared with 6% of

those using CPAP [10]. Another study did not show increase of TMD pain at an average of 118 days of treatment with MAD, but showed increase of TMD pain in analyzed dropout at 208 days [6] and one research realized in 2010 did not find increase in TMD pain at week 6 and month 6 after titration of MAD [8].

In our study, no dropouts occurred because of pain, and none of the subjects felt temporomandibular pain. We assessed TMD by RDC-TMD at 4 months of treatment, which is similar to 118 days follow up of a study realized in 2013 [6]. On the other hand, our follow up is in a different time comparing to 2 months of follow up of another study [10]. However, we used a visual analog scale at the 2 months interval, at the time of 118 days follow up [6], and we did not show increase of TMD pain in any of the groups. One hypothesis of this difference in the findings is that our sample consisted of patients who did not have TMD for 30 days before treatment with MAD.

Some studies have been published about exercises to aid MAD treatment [26, 27]. It has been showed that the positive effects of two kinds of mandibular exercises on occlusal contacts and bite force in patients who used MAD [26]. The effectiveness of mandibular exercises to control pain in patients who were submitted to treatment with MADs and already had diagnosis of TMD has also been demonstrated [27]. In our study, mandibular exercises were used to prevent temporomandibular pain. However, we did not find any pain related to MAD short-term, this findings need to be confirmed in a larger sample size with similar baseline characteristics.

According to the study's results, the MAD population did not show TMD pain and the exercises were not required to prevent TMD. However, mandibular exercises therapy improved general health perception and sleepiness and control group improved physical functioning. Studies showed mandibular exercises and speech therapy improved quality

of life in CPAP and MAD therapy [27, 28]. There is an improvement on CPAP compliance and functional capacity domain after speech therapy associated with CPAP compared to patients who use only CPAP [28]. In pain patients, mandibular exercises are effective to improve complain to MAD and improve general health perception, role limitation due to emotional problems, mental health compared with placebo therapy [27].

Therefore, patients who did not have previous TMD appear to be good candidates for treatment with MAD, without the need of mandibular exercise as a support therapy to prevent pain or to improve adherence, but others studies are necessary to confirm this statement. However, the results allow us to suggest that OSA patients undergoing MAD therapy require specific evaluations for TMD, which could influence treatment protocol.

Our study is the first trial to systematically and carefully assess the impact of mandibular exercises on the temporomandibular complex in patients undergoing MAD treatment who had no TMD symptoms in the previous 1 month. Although, it has some limitation, as the sample size was small, the results were highly consistent in our sample. Also the diagnosis of TMD by RDC-TMD was made by only one examiner, still we have assured that the examiner was blinded to the group allocation.

Conclusion

The control group and the exercise group did not show any development of TMD symptoms over 4 months of MAD use and mandible exercise as support therapy did not influence the prevention of TMD.

Abbreviation

AFER: Association Fund to Encourage Research
AHI: Apnea and hypopnea index
BRD: Brazilian Dental Appliance
CG: Control group

CPAP: Continuous Positive Airway Pressure
ECG: Electrocardiography
EEG: Electroencephalography
EMG: Electromyography
EOG: Electrooculography
ESS: Epworth Sleepiness Scale.
Fig.: Figure
MAD: Mandibular advancement devices
OSA: Obstructive sleep apnea
RDC -TMD: Research Diagnostic Criteria for Temporomandibular disorder
SF- 36: Short Form Health Survey
ST: Support therapy
STG: Support therapy group
TMD: Temporomandibular disorder

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