Mandibular Advancement Devices
Rate of Contraindications in 100 Consecutive Obstructive Sleep Apnea Patients

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Mandibular advancement devices (MAD) should be contraindicated (Clark GT, Sleep Med Rev 1998;2:163–174) if there are: (1) insufficient teeth to support the device, (2) periodontal problems inducing tooth mobility, (3) active temporomandibular joint (TMJ) disorder, and (4) limited maximum protrusive distance (< 6 mm). The aim of the present study was to evaluate the proportion of the obstructive sleep apnea population that exhibits any contraindication (CI) to MAD. For this study there were 100 unselected adult patients consecutively diagnosed by polysomnography in a tertiary sleep laboratory. Clinical and radiologic evaluation of the dental, periodontal, and TMJ status of these 100 patients were performed by two expert maxillofacial surgeons, blind to each other, permitting the identification of MAD CIs. The two maxillofacial surgeons agreed on MAD absolute CIs in 96 of the 100 patients. CIs were identified in 34% of the patients. The nature of the CIs systematically referred to an insufficient number of remaining teeth (mean number of teeth lost: 7.8 ± 6.1 with 31 patients having had more than 10 teeth removed). The tooth avulsions were significantly higher in contraindicated compared with noncontraindicated patients (16 ± 8 versus 4 ± 3, p < 0.00001). Periodontal abnormalities coexisted with dental CI in approximately half of the patients. A TMJ disorder was considered as significant enough to lead to CI in two patients. Dental and periodontal care was needed in 16 patients before the use of MAD was considered. Conclusions were that primary CIs were present in 34% of 100 consecutive patients, mainly owing to dental problems. Moreover, another subgroup of patients (16%) required close supervision and follow-up to avoid impairment of preexisting TMJ and dental problems. Such a high rate of CI should be considered when the overall efficacy of oral appliances is compared with other treatments, such as surgery or nasal continuous positive airway pressure.

Keywords: mandibular advancement device; contraindications; sleep apnea; treatment

Nasal continuous positive airway pressure (nCPAP) is considered as the reference treatment for moderate-to-severe obstructive sleep apnea syndrome (OSAS). However, nCPAP remains a chronic treatment exposing to frequent side effects with a potentially poor acceptability in some subgroups of patients (1). Uvulopalatopharyngoplasty represents the more widely used surgical procedure, but demonstrates a maximum rate of efficacy of only 40% (2). This success rate is even lower (5%) when the level of collapse is in the retrolingual area (2). Step-by-step maxillofacial surgery has been designed to advance the base of the tongue, thus enlarging the hypopharyngeal area (3). Phase 1 corresponds to a mandibular osteotomy with genioglossus advancement and hyothyroidopexy, usually associated with an uvulopalatopharyngoplasty (3). The rate of efficacy of Phase 1 is probably no more than 20% to 50% of the patients (4). Maxillomandibular advancement osteotomy (Phase 2) is indicated in case of failure of Phase 1 or directly in patients demonstrating clear facial dysmorphism. The indications of such a heavy surgical technique are limited to motivated, lean patients with severe OSAS. Thus, in a general population of patients with OSAS, fewer than 5% of the patients are likely to be candidates for a maxillofacial surgery program (4).

In the context of this high failure rate of the most available surgeries and limited acceptance of nCPAP in some subgroups of patients, oral appliances have been proposed as an alternative treatment strategy. Mandibular advancement devices (MAD) are the most efficient oral appliances used to advance the mandible by attaching the inferior dental arch in an anterior position to the maxillary arch (5–10). The American Sleep Disorders Association has standardized the indications of oral appliances in the treatment of OSAS (5): (1) patients with mild OSAS not responding to, or not candidates for, behavioral measures such as weight loss or sleep position; and (2) patients with moderate to severe OSAS who are intolerant of or refuse nCPAP and/or refuse or are not good candidates for surgery.

When a mandibular advancement device is envisaged as treatment for OSAS, subsequent contraindications (CIs) should be taken into account (11): (1) a sufficient number of teeth in each arch is required, with a particular need for posterior teeth to obtain a solid intraoral fixation of the device; (2) untreated periodontal disease or substantial tooth mobility are CIs owing to the risk of dental mobilization; (3) active temporomandibular joint (TMJ) conflict is considered as a formal contraindication, as the device anteriorly displaces the mandible inducing a constraint on the TMJ during sleep; (4) in cases demonstrating a limited maximum protrusive distance (< 6 mm), the efficacy of oral appliances as treatment of OSAS is highly questionable.

The present study was designed to evaluate the proportion of a usual OSAS population exhibiting any type of these CIs.

METHODS

Patients

This prospective study included 100 consecutive adult patients (20 females) having undergone a polysomnography, in a tertiary sleep laboratory, for suspected sleep disordered breathing.

Polysomnography

All the patients underwent a full night polysomnography (see online data supplement). Continuous recordings were taken of electroencephalogram readings with electrode positions C3/A2-C4/A1-Cz/O1 of the international 10–20 Electrode Placement System, eye move-
ments, chin electromyogram, and electrocardiogram with modified V2 lead. Airflow was measured with nasal pressure, associated with the sum of buccal and nasal thermistor signals. Respiration was monitored with uncalibrated inductance plethysmography. An additional signal of respiratory effort (i.e., pulse transit time or esophageal pressure) was recorded concurrently. Oxygen saturation was measured using a pulse oximeter (Biox-Ohmeda 3700; Ohmeda, Liberty Corner, NJ).

The polysomnogram was scored manually according to standard criteria (12–14). Episodes of apnea were defined as complete cessation of airflow for more than 10 seconds and hypopnea as a decrease of more than 50% in nasal pressure signal lasting for at least 10 seconds, or a decrease of more than 30% associated with a decrease of more than 3% in oxygen saturation, or a microarousal. Apnea–hypopnea events were classified as central, obstructive, or mixed according to the absence or presence of breathing efforts associated with apneas and the increase or decrease in respiratory efforts associated with hypopneas.

Evaluation of CIs of MAD

Data acquisition. Each included patient underwent a systematic clinical and radiologic dental, periodontal, and TMJ evaluation. The analyzed items for TMJ clinical and radiological evaluation are shown in Figure 1.

Profile TMJ X-rays were performed with a Planmeca PM 2002. Dental panoramic X-rays focused on TMJ were obtained on the mouth both closed and maximally opened.

The items analyzed for dental and periodontal clinical and radiologic evaluation are shown in Figure 2. Dental panoramic X-rays were performed with the mouth held open at 5 mm using a stick. Previous results found in historical control subjects (15) were used as reference in the general population for further comparison with our patients with OSAS.

Data analysis. The same sleep physician (FXP) systematically examined the patients before the polysomnography. The maximum protrusive distance was measured using a caliper rule. During the physical examination, the same items were collected and stored in the patient’s chart. Clinical charts and X-rays were then analyzed by two maxillofacial surgeons who were blind to each other, experts in the field of OSA, and usual prescriptors of mandibular devices. Their interobserver reliability had been previously tested in 15 patients, with agreement in 92% of the cases for MAD CIs. Finally, these CIs were separated into dental, periodontal, or owing to TMJ disorders.

Statistical Analysis

Different subgroups of patients were compared using the Mann-Whitney or the two-sample t test. The Chi-square test was used for comparison of qualitative variables. All results are shown as mean ± SD. Statistical significance was accepted for p < 0.05.

RESULTS

Patient Characteristics

Anthropometric and sleep data (mean ± SD) of the 100 patients (20 females) are summarized in Table E1 (see online data supplement). The whole group presented as moderately obese middle aged symptomatic OSAS (apnea–hypopnea index = 42 ± 29 events per hour). Their mean age was 49 ± 12 years. Mean Epworth sleepiness scale value was 9.5 ± 4.5. A total of 96% of the patients complained of snoring. 22% being treated for hypertension.

Temporomandibular Joint, Dental, and Periodontal Status

Clinical and radiological TMJ abnormalities are summarized in Table 1.

TMJ pain and noise prevalence and maximum active jaw protrusion values were not significantly different when comparing OSAS with historical controls (15). At least one radiological abnormality was found in 35% of the patients with 9% demonstrating more than one type of X-ray lesion. An active TMJ disorder associating pain and clicking as well as limited mouth opening and protrusion, was present in only two patients. These patients also had a history of TMJ dislocation and presented TMJ destruction on X-rays (see Figures 1 and 2).

Dental and Periodontal Status

A regular dental follow-up, according to questionnaire and clinical examination, was effective in 61% of the patients with satisfactory dental hygiene in 60% of the cases. Spontaneous dental pain existed in 12% of the patients; 77% of the patients have already had teeth avulsions. The mean number of teeth lost was 7.8 ± 6.1 with 31 patients having more than 10 teeth removed (Table 2).

Absolute CIs of MAD

The two maxillofacial surgeons were in agreement regarding MAD absolute CIs in 96 of the 100 subjects. Of these patients, 34 of 96 (36%) were contraindicated. The motivation for these CIs systematically referred to an insufficient number of remaining teeth (Table E2, see online data supplement). The tooth avulsions, predominantly in the back of the mouth (27 out of 34 patients), were significantly higher in contraindicated compared with noncontraindicated patients (16 ± 8 versus 4 ± 3, p < 0.00001). Periodontal abnormalities coexisted with dental contraindication in approximately half of the pa-
tients (44% and 41% for Surgeons 1 and 2, respectively) (Table E2). Among the six patients with a TMJ dislocation history (Table 1), only two were contraindicated owing to clinical and radiological associated signs leading to the diagnosis of severe underlying TMJ disease. One of these two complained of active rheumatoid arthritis. There were no significant differences in the rate of CIs when comparing men and women.

**MAD Temporary CIs and Recommendations for Specific Follow-up in the 62 Noncontraindicated Subjects**

Depending on the degree of alveolar resorption and the severity of tooth mobility, some patients were only temporarily contraindicated. Thus, before the use of MAD could be considered, dental care was essential for 16 of 62 patients according to Surgeon 1, and for 18 of 62 patients according to Surgeon 2. There were 10 and 15 patients for Surgeons 1 and 2, respectively, who needed a very close follow-up during the first weeks of treatment to prevent an exacerbation of preexisting moderate TMJ conflict.

**DISCUSSION**

This report is the first study to have systematically examined the rate of primary CIs of MAD in a large consecutive group of 100 patients with OSAS who have been referred to a tertiary sleep center. The rate of contraindication represented 34% of the patients, which was mainly associated with insufficient tooth number and periodontopathy coupled with tooth mobility. Moreover, another subgroup of patients (15%) needed a very close follow-up during the first weeks of treatment to prevent an exacerbation of preexisting dental problems or moderate TMJ conflicts.

**MAD CIs**

*Rate of CIs—Implications when comparing therapeutic strategies for OSAS.* Contraindications to mandibular advancement devices are often pointed out in the literature (5–8, 11), but the precise rate and the reasons for these CIs are rarely reported in detail. For example, for the authors of the recent (and largest) study (8) evaluating MAD efficacy in 134 pa-

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**TABLE 1. CLINICAL AND RADIOLOGIC TMJ ABNORMALITIES**

<table>
<thead>
<tr>
<th></th>
<th>Patients (n = 100)</th>
<th>Historic Control Subjects* (n = 265)</th>
<th>p</th>
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<tbody>
<tr>
<td>TMJ clinical evaluation</td>
<td></td>
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<tr>
<td>Pain, % of patients</td>
<td>13%</td>
<td>12%</td>
<td>NS</td>
</tr>
<tr>
<td>Click, % of patients</td>
<td>16%</td>
<td></td>
<td></td>
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<tr>
<td>Noise, % of patients</td>
<td>29%</td>
<td>39%</td>
<td>NS</td>
</tr>
<tr>
<td>Lateral shift at mouth opening, % of patients</td>
<td>14%</td>
<td>6%</td>
<td>&lt;</td>
</tr>
<tr>
<td>Dislocation history, % of patients</td>
<td>8.4 ± 2.6</td>
<td>7.8 ± 2.6</td>
<td>NS</td>
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<tr>
<td>Maximal active protrusion, mm</td>
<td>46.8 ± 6.6</td>
<td></td>
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<tr>
<td>TMJ X-rays</td>
<td></td>
<td></td>
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<tr>
<td>Pinching, % of patients</td>
<td>12%</td>
<td></td>
<td></td>
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<tr>
<td>Geodes, % of patients</td>
<td>11%</td>
<td></td>
<td></td>
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<tr>
<td>Destruction, % of patients</td>
<td>2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pterygoid spicula increase, % of patients</td>
<td>12%</td>
<td>5%</td>
<td>&lt;</td>
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*See reference 13.*
tients, an oral appliance was deemed to be suitable for those subjects who had more than 8 to 10 teeth per arch and were in good periodontal health. In that study, as in others, we do not know how many patients have been excluded due to contraindication, and the effects of treatment are not thus evaluated in an intention-to-treat fashion. This point is crucial, particularly when overall efficacy of oral appliances is compared with alternative treatments such as surgery or nCPAP. Whereas 8% to 15% of the patients refused nCPAP after a first night trial, in a randomized crossover study 24% of the patients were immediately unable to continue to wear their MAD even after adjustments were made (7). When patients with apnea were asked in different studies whether they would prefer to use MAD or nCPAP, the answer was generally that the majority of them preferred MAD (7). However, whereas compliance with MAD is based only on self-reports of use or nonuse, a variety of studies to date tend to demonstrate that long-term acceptance of MAD is not greater than nCPAP compliance (16–19). Finally, nCPAP has the advantage of having almost no absolute CIs compared with the 34% of primary CIs found for MAD.

**Reasons for MAD CIs. Insufficient tooth number to support the device.** Partial or complete edentulism represented the major cause of MAD contraindication in our series. Dental epidemiologic studies estimate that edentulism problems in the general population are found in approximately 18% of the 55- to 64-year old subjects (20). In the 65- to 74-year age category, 35% are presently edentulous (20). Moreover, we know that edentulism, per se, may worsen sleep apnea (21). Indeed, removal of dentures or absence of posterior teeth leads to decrease in retroglossal space and are associated with an increase in apnea–hypopnea index (21). Thus, edentulism prevalence is probably higher in patients with OSAS than in a healthy population of the same age. As a consequence, the high rate (34%) of dental MAD CIs that we found, even associated with a one-team experience, is not surprising and is probably relevant to the general population of patients with moderate to severe OSAS.

In cases where there has been a lack of dental hygiene, the back teeth are the first to be damaged, particularly the first and second molars (22). The most commonly retained teeth in the mouth are the six anterior teeth in the lower arch, as partial edentulism is much more common in the upper arch (22). In the present study, the mean number of teeth lost in contraindicated patients was 16, with tooth avulsions located predominantly in the back of the mouth (in 27 out of 34 patients). This preferential posterior and maxillary location of tooth avulsions is particularly detrimental to the adequate anchoring of the most widely used MAD (i.e., two-piece adjustable devices). However, this may vary depending on the type of device used. Most MADs are designed to provide full occlusal coverage of both dental arches, while others provide only partial tooth coverage. These different oral appliances lead to different mechanical constraints for a given tooth. An ideal dental appliance should distribute the stress equally among the teeth of the upper and lower arch. The anterior mandibular positioner (Snore-Guard) does not require posterior teeth, but rather depends on the presence of anterior teeth to anchor the MAD and hold the mandible forward (7). Finally, the tongue-retaining devices can be used even in edentulous patients (7).

Partial or total edentulism remains the principal reason for MAD CIs even if a judicious choice of dental appliance may solve the problem for some subgroups of patients (23).

**Substantial tooth mobility and untreated periodontal disease.** Regarding the potential use of MAD, substantial tooth mobility related to periodontal disease is as deleterious as tooth absence. In the general population, periodontal disease is very widespread. As many as 44% of adults in the United States were found to have gingivitis and more than 13% had periodontal pockets 4–5 mm in depth (24). This is in accordance with our findings where approximately 15% of the patients demonstrated significant periodontopathy leading to MAD contraindication, and an absolute need for dental care in at least 16% of additional subjects. More globally, we found lack of dental hygiene in 40% of patients with OSAS, a condition that obviously favored the occurrence of periodontopathy and edentulism. Edentulism itself in turn contributes to the worsening of OSAS and reduces the number of available therapeutic strategies. What we have learned from examining the dental and periodontal status of our patients with OSAS is that more attention should be paid to dental and periodontal monitoring and care in the prevention and follow-up of sleep breathing disorders.

**Active TMJ.** Because TMJ disorders are systematically presented as formal MAD CIs, the majority of authors take care to identify active TMJ conflicts. As in the general population (15), we found a high incidence of isolated clinical abnormalities such as TMJ pain and noise. However, clinical criteria, pertinent enough for identification of “severe” or “significant” TMJ conflicts, are not clearly established. These criteria vary from one study to another. Our findings showed a frequent discrepancy between clinical complaints and radiologic abnormalities. Thus, our expert surgeons decided to contraindicate only two patients presenting with TMJ pain and clicking as well as limited mouth opening and protrusion. Those patients also had TMJ dislocation history and demonstrated TMJ destruction on X-rays. One of the major difficulties in the field is to separate the clinical or radiologic signs that constitute absolute contraindication for MAD from signs requiring only a close TMJ survey during MAD use. Systematic prospective research addressing MAD long-term complications and side effects is needed (25). Only through this additional research can the sensitivity and specificity of each clinical and radiologic abnormality as a relevant predictive factor for long-term MAD complications be determined. In particular, it is unclear whether the cost/benefit ratio of radiologic and MRI imaging of TMJ is a sufficient indicator for recommending the use of these techniques on a regular basis.

**Oral Appliances for the Treatment of OSAS: Needs for a Multidisciplinary Approach**

Dentists, orthodontists, or maxillofacial surgeons have adequate background and training not only to fit the MAD, but also to identify contraindicated patients and to determine the best modalities for long-term follow-up and adaptation of
therapy. On the other hand, a recent survey on oral appliances mailed to 355 dentists showed that only 18% of patients have the benefit of a posttreatment polysomnography (26). Thus, even if it increases the cost and complexity of such a therapy, multidisciplinary teams are probably needed for an optimal fit of the device, a reduction of side effects, optimal compliance, and a guarantee that objective results are obtained regarding MAD efficacy.

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References


