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An interim oral appliance as a screening tool during drug-induced sleep endoscopy to predict treatment success with a mandibular advancement device for obstructive sleep apnea

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Abstract

Purpose Previous studies have shown a wide range of efficacy (29 to 71%) of a mandibular advancement device (MAD) in the treatment of obstructive sleep apnea (OSA). Currently, the ability to preselect suitable patients for MAD therapy based on individual characteristics related to upper airway collapsibility is limited. We investigated if the use of non-custom interim MAD during drug-induced sleep endoscopy (DISE) could be a valuable screening tool to predict MAD treatment outcome.

Methods In a single-center prospective study including a consecutive series of patients with OSA, we compared DISE outcomes with a MAD in situ with polysomnography results after 3 months of using the same MAD that was used during DISE.

Results Of 41 patients who completed the study, the median apnea–hypopnea index (AHI) was 16.0 events/h [IQR 7.4–23.4]. Respiratory outcomes on polysomnography, including apnea index (AI), total AHI, AHI in supine position, and oxygen desaturation index, all significantly improved after 3 months of MAD treatment. With complete improvement of the upper airway obstruction with the MAD in situ during DISE in supine position, patients were 6.3 times more likely to be a responder to MAD treatment compared to patients with a persisting complete obstruction, although not statistically significant (OR 6.3; 95%CI 0.9–42.7; $p = 0.060$).

Conclusion The potential predictive value with regard to MAD therapy outcomes of the use of an interim MAD during DISE would be an important finding, since the prediction of MAD therapy outcome is of great clinical and scientific interest. A study with a larger cohort should be performed to further investigate our findings.

Keywords Obstructive sleep apnea · Sleep-disordered breathing · Mandibular advancement device · Treatment success · Drug-induced sleep endoscopy

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Introduction

Various options are available for treatment of obstructive sleep apnea (OSA). The most commonly used non-invasive treatment options are continuous positive airway pressure (CPAP), mandibular advancement device (MAD) therapy, and positional therapy (PT) [1]. If an invasive treatment option such as upper airway surgery is considered, a drug-induced sleep endoscopy (DISE) is performed before surgery to investigate the level(s), configuration, and severity of obstruction of the upper airway [2]. Potential obstruction sites of the upper airway are the velum, the oropharynx, the base of the tongue, and the epiglottis. All above-mentioned therapies influence these obstructions sites in a different manner [3].

If OSA is treated with a MAD, the aim is to improve the upper airway patency by protruding the lower jaw and tongue. This will increase the cross-sectional airway dimensions and consequently reduce snoring and airway obstructions [4].

Previous studies have shown a wide range (29 to 71%) of efficacy of a MAD. This wide range can be partially explained by differences in pre-treatment severity and criteria to define success [5]. Currently, the ability to preselect patients suitable for MAD therapy based on individual characteristics related to upper airway collapsibility is limited. At this point, relevant variables that have been studied related to the prediction of treatment outcome with a MAD include body mass index (BMI), apnea–hypopnea index (AHI), age, gender, cephalometric parameters, polysomnographic measures, and observations that are made during DISE [6, 7]. Observations during DISE include investigation of the effect of a manual protrusion of the lower jaw—the so-called jaw thrust maneuver. However, using this maneuver to predict treatment success has been criticized due to the fact that the degree of manual mandibular advancement is not completely representative for the effect of a MAD and not fully reproducible [8]. This may result in an overestimation of the effect of MAD treatment [9]. In addition, a jaw thrust maneuver does not account for the vertical displacement of the mandible as a result of the MAD [10]. Others argue that if a treatment is considered that does not improve all potential obstructive upper airway levels, identification of the upper airway collapse patterns is a crucial diagnostic element [11].

In the past few years, a new-generation interim MAD has been developed, which can easily be fitted within 15 min by a trained dentist and is titratable and less expensive than custom-made MADs. It has the great advantage above a simulation bite that it can also be used as interim treatment at home, in contrast to simulation bites used in previous studies. These features allow for comparing the effect of a MAD during DISE with its actual treatment effect after a certain treatment period. If this MAD turns out to be a more accurate screening tool during DISE, two positive developments arise: (1) MAD treatment success might increase due to better patient selection and (2) if a patient is a suitable candidate, she/he can experience the benefits and possible disadvantages of MAD therapy, directly after the DISE procedure, before a more expensive custom-made MAD is applied.

Bearing this in mind, we hypothesized that the use of the new-generation MAD during DISE may be a valuable screening tool to predict MAD treatment outcome. We investigated this hypothesis, by comparing DISE outcomes with MAD in situ with polysomnography (PSG) results after 3 months, using the same MAD.

Methods

Study participants

We conducted a prospective mono-center study. Patients with OSA (AHI ≥ 5 events/h, diagnosed by an overnight PSG) were included prior to DISE if they were ≥ 18 years. Patients were excluded if they had reversible morphological upper airway abnormalities (e.g., enlarged tonsils), previous MAD therapy, central sleep apnea syndrome (> 50% of central apneas as confirmed by PSG), (severe) periodontal disease or tooth decay (confirmed by clinical and radiographic examination), temporomandibular joint pain, restrictions in maximal mouth opening (< 25 mm) or in protrusion of the mandible (< 5 mm), or if they were partially or completely edentulous (less than 8 teeth in upper and lower jaw). After giving written informed consent, the MAD was fitted chairside in maximum comfortable protrusion (MCP). The MCP was determined by protruding the lower jaw (by twisting the screw in the frontal area of the device) until patients started to experience pain or discomfort in their teeth, jaw, or muscles. From the determined MCP, the device was retracted 1 mm. Subsequently, DISE was performed with the MAD in situ. Regardless of the observations made during DISE, the MAD was subsequently prescribed for a follow-up of 3 months. Patients were stimulated to protrude the MAD during the first month until the determined MCP. During the consultation after the first months of treatment, the amount of protrusion was checked, and patients were asked if there were any complaints. After 3 months, the treatment effect was determined by PSG.

Definitions

The effect of the MAD during DISE was defined using the VOTE scoring system with and without the MAD. Complete

improvement was defined as no obstruction left with MAD in situ. Improvement from complete to partial obstruction during DISE was defined as partial improvement. If on any level a complete obstruction was present, the effect was defined as no improvement.

Complete MAD treatment success was defined as a post treatment AHI < 5 events/h. In case of an AHI reduction of > 50% compared to baseline AHI, treatment outcome was defined as partial success. If neither of the above mentioned criteria for success were met, patients were considered non-responders.

Ethical considerations

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the Declaration of Helsinki of 1975. Data on study subjects was collected and stored encoded to protect personal information. Informed consent was obtained for all patients prior to inclusion. The study was approved by the national medical ethical committee (MEC-U; NL64738.100.18) and by the local ethics committee of OLVG hospital.

New generation MAD: MyTAP™

The MyTAP™ (My Thorton Adjustable Positioner, Airway Management Inc., Dallas, TX, USA) is a new generation non-custom MAD which utilizes all the features of a custom-made MAD. It consists of two separate trays of hard plastic framework fitted with ThermAcryl™ (Airway Management Inc., Dallas, TX, USA) material, which fully covers the upper and lower dental arches. The protrusive mechanism used in MyTAP™ is a single point mid-line traction. The MyTAP™ moves the mandible forward by a single screw (covered in plastic) with a protrusive range of over 20 mm. Titration, both protrusive and vertical (up to 12 mm with adjustment stops), can be easily adjusted by the clinician or patient. The MyTAP™ was fitted by the same trained dentist (JUV) for every patient in this study. When the maximal comfortable position was reached, the level of protrusion displayed on the device was recorded and used during DISE. During the first 4 weeks, patients were instructed to advance the device to this maximal comfortable position by twisting the screw.

DISE procedure

In this study, we added the use of the interim MAD to our standard DISE protocol to be able to test our hypothesis [2]. All of the DISEs were executed in a quiet and dark room, by the same ENT resident (PB), a nurse anesthetist, and an assistant. The desired sedation depth was reached using propofol medication and a target-controlled infusion pump. Patients slept approximately 15 min. Assessment of the upper airway, using a flexible laryngoscope, started with the patient lying on his/her right side (lateral head-and-trunk position) with the interim MAD in situ, after which the patient was turned to his/her back (supine position). Subsequently, we carefully removed the interim MAD and performed our standard DISE procedure with assessment of the upper airway in supine and non-supine position, both with and without a jaw thrust (manually performed with estimated 70% of maximal protrusion).

Classification and additional system

For the assessment of potential obstructions of the upper airway, the VOTE scoring system was used [13]. At four levels of the upper airway, namely velum (V), oropharynx (O), tongue base (T), and epiglottis (E), the obstruction severity and configuration were determined. The obstruction severity was defined as zero (no collapse: < 50% obstruction), one (partial collapse: 50–75% obstruction), or two (complete collapse: > 75% obstruction). The configuration of the collapse was either anterior–posterior (AP), lateral, or concentric. Figure 1 shows an overview of the potential obstruction levels, severity, and configuration.

Statistical analysis

Statistical analysis was performed using SPSS v26 (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp). Quantitative data were reported as mean and standard deviation (SD) if normally distributed or as median and interquartile range [Q1, Q3] if not normally distributed. To determine whether continuous variables were normally distributed, the Shapiro–Wilk Test was executed. To compare outcomes of the

Structure	Obstruction severity [a]	Configuration [c]		
		Antero - posterior	Lateral	Concentric
Velum				
Oropharynx [b]		■		■
Tongue Base			■	■
Epiglottis				■

a. Obstruction severity : 0 = no obstruction; 1 = partial obstruction; 2 = complete obstruction
b. Oropharynx obstruction can be distinguished as related solely to the tonsils or including the lateral walls
c. Configuration noted for structures with degree of obstruction > 0

Fig. 1 The VOTE classification

baseline PSG and follow-up PSG, a paired *t* test was executed in case of normally distributed data and the Wilcoxon signed-rank test in case of not normally distributed data. A logistic regression analysis was executed to investigate the predictive effect on treatment outcome of the MAD during DISE in supine and lateral positions. For comparison, the same was done for jaw thrust. To investigate whether specific variables were potential predictors for treatment outcome or dropout, an independent sample *t* test was executed in case of normally distributed data and the Mann Whitney *U* test in case of not normally distributed data. A *p* value of <0.05 was considered to indicate statistical significance.

Results

In total, 58 patients were included; 17 did not complete follow-up. Nine were lost to follow-up because the study visits were considered too time-consuming; three patients did not tolerate sleeping with the interim MAD; in one patient, there was no effect on the complaints; and therefore, the patient was not motivated to use it during the full follow-up, one other patient reported tooth pain, and three patients reported discomfort of the device as reason to discontinue treatment. Forty-one patients completed the study. Their baseline characteristics are shown in Table 1. The majority was male (83%), median age was 51 years, the mean BMI was 26.1 kg/m^2, and the median pre-treatment AHI was 16.0 [7.4; 23.4].

Respiratory outcomes measured by a PSG, including AI, total AHI, AHI in supine position, and ODI, all significantly improved after 3 months of MAD treatment (Table 2). Complete treatment success was achieved in 14 (34%) patients and partial success in 7 (17%) patients. Thus, 21 (51%) patients could be defined as responder to MAD treatment, and 20 (49%) as non-responder.

With complete improvement of the upper airway obstruction with the MAD in situ during DISE in supine position, patients were 6.3 times more likely to be a responder to MAD treatment compared to patients with a persisting complete obstruction (OR 6.3; 95%CI 0.9–42.7; $p=0.060$). If a partial obstruction remained, the chance of being a responder to MAD treatment was 1.8 times higher compared to patients with a persisting complete obstruction at any level (OR 1.8; 95% CI 0.4–7.5; $p=0.421$). If no improvement was found, the chance of being a responder was 0.16 (95%CI 0.9–42.7; $p=0.060$) (Table 3). With complete improvement of the upper airway obstruction with the jaw thrust maneuver during DISE in supine position, patients were not more likely to be a responder to MAD treatment compared to patients with a persisting complete obstruction (OR 1.0; 95% CI 0.2–6.0; $p=1.000$). This outcome was not significant either.

From the other known predictors for treatment outcome, in this study, only age differed significantly ($p=0.028$) between the responders (41 [38; 53] years) and non-responders (54 [47; 56] years). BMI, AHI > 30 events/h, and a complete concentric collapse did not differ significantly between both groups (Table 4).

Comparing potential predictive values for treatment outcome between patients who completed follow-up and who did not, BMI was significantly ($p=0.043$) lower in the dropout group. Age and pre-treatment AHI did not differ significantly (Table 5).

Table 1 Patient characteristics

	Total
Number of patients (*N*)	41
Sex (% female)	17%
Age (years)	51 [38; 54]
BMI (kg/m^2)	26.8 ± 2.8
Pre-treatment AHI (events/h)	16.0 [7.4; 23.4]

Data presented as mean ± SD or median [Q1; Q3]

BMI body mass index, AHI apnea–hypopnea index

Table 2 PSG at baseline versus PSG at 3 months follow-up with MAD in situ

	PSG baseline *N* = 41	PSG follow-up *N* = 41	*p* value
Total AI (events/h)	5.2 [2.3; 11.1]	1.2 [0.5; 5.6]	0.002*
Total AHI (events/h)	16.0 [7.4; 23.4]	7.8 [3.1; 15.9]	0.001*
Supine AHI (events/h)	24.9 [10.6; 39.6]	10.7 [3.9; 23.1]	< 0.001*
Non-supine AHI (events/h)	6.7 [2.4; 15.3]	4.4 [1.5; 10.7]	0.162
% of TST in supine position	39.1 [24.9; 54.4]	42.8 [27.6–53.4]	0.401
ODI (3%, events/h)	17.1 [9.0; 26.8]	7.0 [2.5; 13.3]	< 0.001*
Mean saturation (%)	95.0 [94.0; 96.0]	95.0 [93.5; 96]	0.300
Lowest saturation (%)	86.0 [82.0; 90.0]	88.0 [84.5; 90.5]	0.216

Data presented as median [Q1; Q3]

AI apnea-index, *AHI* apnea–hypopnea index, *PSG* polysomnography, *TST* total sleeping time, *ODI* oxygen degeneration index

*$p<0.05$, by Wilcoxon signed-rank test

Discussion

This is the first study investigating not only the positive, but also the negative predictive value with regard to MAD treatment success of a non-custom titratable MAD

Table 3 Predictive value of the MAD and jaw thrust regarding treatment outcome

Position	Improvement DISE	Responder ($n=21$)	Non-responder ($n=20$)	Odds ratio (95% CI)	p value
Supine MT	No	5 (24)	9 (45)	*ref*	*.169**
	Partial	9 (43)	9 (45)	1.8 (0.4–7.5)	*.421*
	Complete	7 (33)	2 (10)	6.3 (0.9–42.7)	*.060*
Supine JT	No	6 (29)	6 (30)	*ref*	*.988**
	Partial	11 (52)	10 (50)	1.1 (0.3–4.5)	*.895*
	Complete	4 (19)	4 (20)	1.0 (0.2–6.0)	*1.000*
Lateral MT	No	3 (14)	3 (15)	*ref*	*.936**
	Partial	0 (0)	4 (20)	-	-
	Complete	18 (86)	13 (65)	1.4 (0.2–8.0)	*.716*
Lateral JT	No	2 (10)	4 (20)	*ref*	*.232**
	Partial	3 (14)	6 (30)	1.0 (0.1–9.0)	*1.000*
	Complete	16 (76)	10 (50)	3.2 (0.5–20.8)	*.223*

Data are presented as *N* (%)

MT MyTAP, *JT* jaw thrust, *ref* reference

*Overall p value

Table 4 Predictors known to influence MAD treatment outcome

	Responder ($N=21$)	Non-responder ($N=20$)	p value
BMI	26.0 ± 2.6	27.6 ± 2.9	0.462
AHI > 30	3 (14%)	4 (20%)	0.697
Age	41 [38; 53]	54 [47; 56]	0.028*
CCC	5 (24%)	4 (20%)	0.719

Data presented as mean ± SD or median [Q1; Q3]

BMI body mass index, *AHI* apnea–hypopnea index, *CCC* complete concentric collapse

*$p<0.05$

Table 5 Potential predictors for dropout

	Complete follow-up ($N=41$)	Dropout ($N=17$)	p value
BMI	26.8 ± 2.8	26.4 ± 3.9	0.043*
Age	51 [38; 54]	54 [38; 61]	0.215
Pre-treatment AHI (events/h)	16.0 [7.4; 23.4]	16.1 [8.6; 19.8]	0.707

Data presented as mean ± SD or median [Q1; Q3]

BMI body mass index, *AHI* apnea–hypopnea index

*$p<0.05$

used during DISE, which can subsequently be used as an interim MAD at home. This study showed that if the obstruction of the upper airway in supine position completely disappeared while applying the MAD during DISE, patients were 6.3 times more likely to be a responder to MAD treatment compared to patients with a persisting complete obstruction during DISE. This also applies the other way round; if the obstruction of the upper airway in supine position persist while applying the MAD during DISE, patients were 6.3 times more likely to be a non-responder to MAD treatment compared to patients with complete improvement of the obstruction during DISE. However, the above-mentioned findings were not statistically significant ($p=0.060$). The findings with regard to the predictive value of the MAD on obstruction of the upper airway in lateral position showed no significant differences either. A possible explanation could be that the majority of patients (68%) had position-dependent OSA in this study sample, which consequently means that there were less patients with an obstruction in lateral position [14]. Therefore, the sample-size for cases with improvement was smaller. Comparing the outcomes of applying a MAD with a jaw thrust, one can conclude that the jaw thrust has no predictive value, since none of the outcomes on the predictive value were significant.

Vroegop et al. investigated the added value of a simulation bite to predict MAD treatment success during DISE, instead of the standardly used jaw thrust maneuver [11]. The investigators concluded that during DISE, usage of a simulation bite set to MCP may be an effective method to predict MAD treatment success. In 2020, Cavaliere et al. performed a similar study, including patients with more severe OSA. In this study, MAD treatment success was high, i.e., 91% [12]. Both studies suggest a positive predictive value with regard to MAD treatment success using a simulation bite during DISE. However, patients were only included for follow-up if they had a positive response on upper airway patency with a simulation bite in situ. Therefore, the negative predictive value of these findings during DISE on MAD treatment outcomes remains unclear and not investigated.

In this study population, the majority of the respiratory parameters were significantly improved at 3-months follow-up, with a treatment response of 51%. Comparing these results to previously mentioned studies, our response rate was lower. The study population of Vroegop et al. [11] was comparable to ours regarding pre-treatment AHI. The number of treatment responders in their study was higher (69%), which might be explained by the fact that patients without improvement on simulation bite were excluded from subsequent MAD therapy. In the "predicted response group," 83% of the patients were responders. Vroegop et al. [11] did not find similarity between jaw-trust and the simulation bite.

There are several studies that have evaluated the predictive value on MAD treatment success, for example, by a remotely controlled mandibular protrusion device or by using a simulation bite during DISE [11, 12, 15]. Although their study methods seem comparable to this study, they did not included patients who did not have improvement of upper-airway obstruction during DISE with the simulation bite in situ. Therefore, the negative predictive value of these findings could not be assessed. We did choose to do so and were therefore able to establish that non-responders during DISE were indeed more likely to be non-responders to MAD treatment after 3 months of follow-up.

The present study is part of a larger series. We have performed several studies regarding this new-generation MAD [8, 10]. For example, we have investigated whether or not there was an agreement between this MAD effect and jaw thrust and concluded that agreement was only slight to moderate [10]. We have also investigated the objective and subjective treatment effect of this new-generation MAD and compared it to a custom-made MAD. We concluded that the effect of both MADs is comparable [16]. If the current study had shown a statistically significant predictive value of this new generation MAD during DISE, it would have consequently predicted not only its own treatment success, but, given the similarity, also that of a custom-made MAD.

Limitations

This study has limitations. Due to the high dropout rate, the sample size of patients who completed follow-up was small. This study was performed during the COVID-19 pandemic, which led to changes in consultations. Some consultations were online while others were delayed or canceled. Less contact with the patients may have caused lower adherence or larger dropout rate. In addition, this study focused on a secondary outcome of a larger research project, and the sample size was calculated for the primary outcome measurements [16]. The small sample may have caused the absence of statistically significant outcome with regard to the predictive value of the MAD during DISE. As age was found to be significantly different between the responders and non-responders, correcting for age in the logistic regression would have been more accurate. However, the sample size was not sufficiently large to do so. Our study sample had a relatively low AHI and BMI compared to the general population with OSA. Therefore, we could not directly translate these outcomes to the average population. It must also be noted that examination of the upper airway by performing DISE attempts to simulate natural sleep, but sedated sleep is not the same as natural sleep. Therefore, findings during DISE may differ from the actual situation during the night.

Clinical relevance

If our preliminary findings were statistically significant, it would create major screening opportunities and consequently increase treatment success of a MAD. The MAD would then be applied prior to a DISE performed to investigate surgical considerations. If no obstruction remained with the MAD in situ in supine position, patients would be advised and instructed to wear the MAD for at least 3 months, with a 6.3 times higher change of favorable treatment outcome. In addition, using this new-generation MAD allows the patient to start treatment directly after DISE. Within the first months, patients could experience the (subjective) benefits and possible disadvantages of MAD therapy before a more expensive custom-made MAD would be made. Consequently, this MAD could be an efficient and cost-effective means for screening treatment eligibility.

Conclusion

The potential positive and negative predictive value of an interim MAD during DISE with regard to MAD therapy outcomes is an important finding, since the prediction of MAD therapy outcome is of great research interest. A study with a larger cohort should be performed to investigate the clinical consequences of this study's findings.

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Data availability The data that support the findings of this study are available upon reasonable request.

The study is registered with Netherlands Trial Registers (NL64738.100.18).

Declarations

Ethics approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (METC) and with the 1964

Helsinki declaration and its later amendments or comparable ethical standards. The study was approved by the national medical ethical committee (METC) and by the board of directors (IRB) of OLVG hospital (WO18.168).

Consent to participate Informed consent was obtained from all individual participants included in the study.

Conflicts of interest Dr. A. Hoekema is medical advisor for Airway Management Inc., SomnoMed, and Zephyr Sleep Technologies.
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All other 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.

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