Developments in diagnosis and treatment of obstructive sleep apnea

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5 The predictive value of drug-induced sleep endoscopy for treatment success with a mandibular advancement device or positional therapy for patients with obstructive sleep apnea

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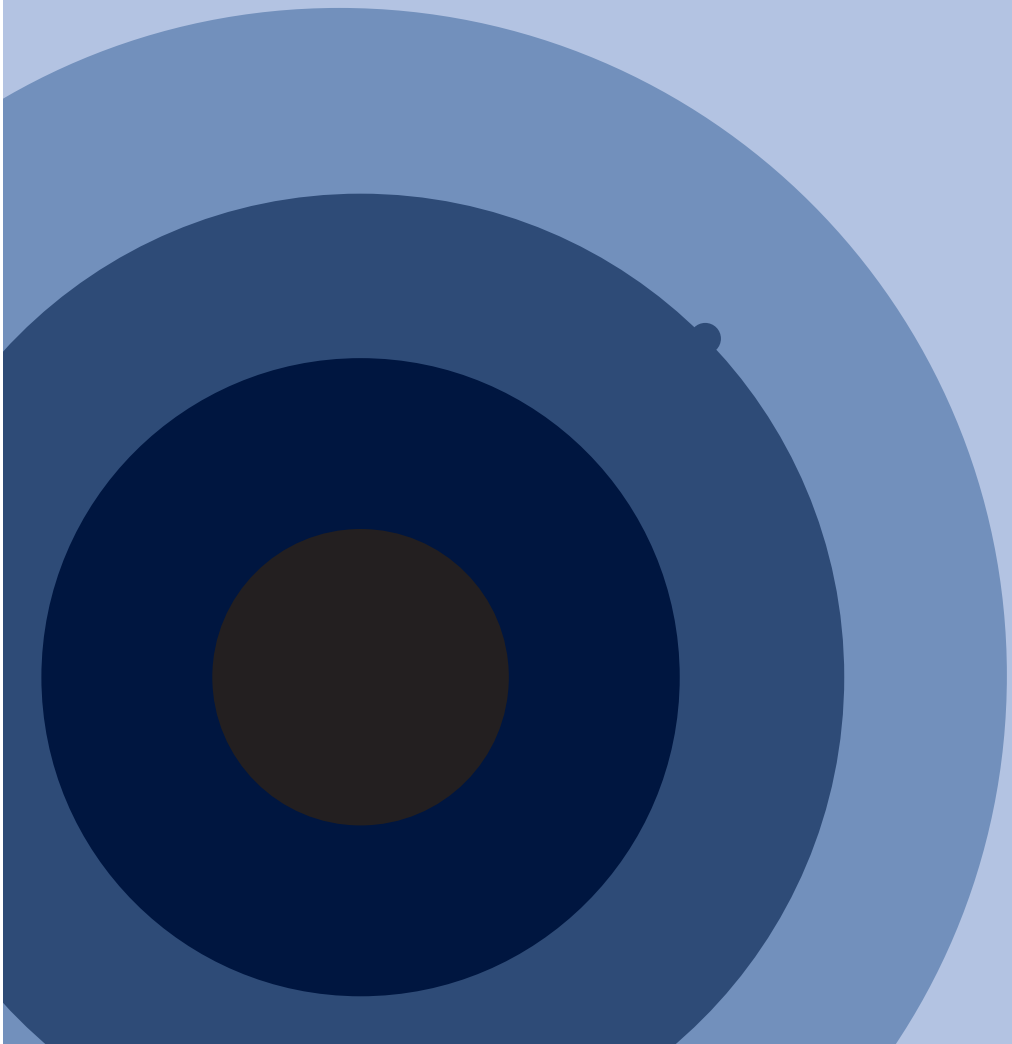


ABSTRACT

Purpose As drug-induced sleep endoscopy (DISE) can provide additional diagnostic information on collapse patterns of the upper airway, it is widely used in patients with obstructive sleep apnea (OSA). Although more controversial, DISE might also predict the success of treatment with a mandibular advancement device (MAD) and/or positional therapy (PT). In 2018 we proposed a prediction model to investigate the predictive value of passive maneuvers during DISE – such as jaw thrust and changes in body position – on upper airway patency. Based on the outcomes of various studies, we then adjusted our DISE protocol to better mimic the effect of a MAD, PT, or combination of both. The aim of this study to verify whether our adjustments would increase the value of DISE as a selection tool.

Methods This single-center retrospective cohort study involved a consecutive series of patients with OSA. Patients were included if a DISE had been performed in supine and non-supine sleeping position and with and without a boil-and-bite MAD *in situ* between December 2018 and February 2020. The VOTE scoring system was used to evaluate the obstruction at four levels of the upper airway.

Results Ninety-four patients were included with a median apnea-hypopnea-index (AHI) of 16.2 (events/hr). As a temporary MAD during DISE reduced obstruction by 54% and jaw-thrust by 57%, both mimicked the effect of the custom-made MADs referred to in the literature, which reduces the AHI by 60%. Head-and-trunk rotation reduced obstruction by 55% thus mimicked the effect of PT, which is known to reduce the AHI by 50%.

Conclusion A jaw thrust, a temporary MAD and head-and-trunk rotation during DISE all seem to mimic the treatment effects of MAD and PT. These findings might be of added value when choosing OSA treatment. To prove the predictive value of these maneuvers during DISE, a prospective study should be performed.

Keywords: obstructive sleep apnea, sleep-disordered breathing, mandibular advancement device, positional therapy, treatment success, drug-induced sleep endoscopy

INTRODUCTION

According to disease severity, diagnostic findings and patient preference and health, several treatment modalities for obstructive sleep apnea (OSA) are available (1). The most commonly used is continuous positive airway pressure (CPAP); viable conservative alternatives are a mandibular advancement device (MAD) and positional therapy (PT). Depending on disease severity and the origin of the upper airway collapse, an invasive alternative – upper airway surgery – is considered. (2-4)upper-airway(5-7). In some cases, these treatment modalities can be combined to achieve optimal results (8).

To evaluate what kind of upper airway surgery is needed, additional information on collapse patterns of the upper airway can be provided by performing a drug-induced sleep endoscopy (DISE) (9-11). Although it is more controversial, DISE might also be a selection tool for MAD treatment or for example PT combined with upper airway surgery.

In 2018 we proposed a model to predict treatment success by evaluating the effect of different passive maneuvers on collapse patterns of the upper airway patency during DISE (12). The two maneuvers investigated were jaw thrust and lateral head rotation which are used in our current practice to imitate the expected treatment effect of a MAD and PT. On the basis of studies performed on the treatment effect of MADs and PT, we concluded that jaw thrust overestimated the treatment effect of a MAD and lateral head rotation underestimated the expected treatment effect of PT.

To predict treatment success of conservative treatment modalities, we based two additional studies on these outcomes in order to establish the applicability of passive maneuvers during DISE. Our first study compared lateral-head and-trunk rotation with lateral head rotation only and its effects on upper airway obstruction(13). We concluded that for patients with OSA independent from their sleeping position (NPP) the outcomes were similar, for patients with position dependent OSA (PP) head-and-trunk rotation was more reliable. In the second study we compared jaw thrust and the use a temporary boil-and-bite MAD and its effects on upper airway obstruction (14). We concluded that on tongue base and epiglottis level the effect of jaw thrust was greater (i.e., that there was less obstruction) than that of a boil-and-bite MAD.

Based on these findings, we adjusted our DISE protocol to better mimic the effect of a MAD and PT. The purpose of the current study was to verify whether our adjustments increase the value of DISE as a selection tool.

METHODS

Study participants

We collected data for this single-center retrospective cohort study during two prospective studies that are described in the introduction(13, 14).

In these studies patients were included if OSA was diagnosed confirmed by PSG and when a DISE had been performed in supine and non-supine sleeping position and with and without a boil-and-byte MAD *in situ* between December 2018 and February 2020. Patients were excluded if data on DISE observations was incomplete, in case of central sleep apnea (> 50% of central apneas), or if they spent less than 10% of their total sleeping time (TST) in the supine or non-supine position during their PSG.

MyTAP

To simulate the treatment effect of a custom-made MAD we used a temporary boil-and-byte MAD. The type of temporary MAD we used was a MyTAP (My Thorton Adjustable Positioner, Airway Management Inc., Dallas, TX, USA). Both dental arches are covered by the two separate trays which can be easily adjusted using the boil-and-bite system. The trays can be fixed in a protrusive position by a single screw (covered in plastic). After fitting both trays the patient was instructed to advance the device in maximal comfortable protrusive position by twisting the screw. When the maximal comfortable position was researched, the level of protrusion displayed on the device was notated and used during DISE.

DISE procedure

The DISE was executed by an ENT resident who performed all the endoscopies for this study. We used a quiet and dark room. A nurse anesthetist controlled the sedation using propofol medication, standard anesthetic equipment and a target-controlled infusion pump to reach the desired sedation depth. On average patients were asleep for 15 minutes. A flexible laryngoscope was used to examine the upper airway. The procedure started with the patient laying in lateral head-and-trunk position and subsequent rotation to the supine position, both with the MyTAP *in situ*. After this part of the procedure, the MyTAP was removed and the upper airway was observed in both positions with and without manually performed jaw thrust with an estimated 70% of maximal protrusion.

Classification system

We used the VOTE scoring system to evaluate the potential obstruction at four levels of the upper airway, namely velum (V), oropharynx (O), tongue base (T), and epiglottis (E) (11). The obstruction severity was defined in three categories: no collapse (0; less than 50% obstruction), partial collapse (obstruction between 50 and 75%), or complete collapse (>75% obstruction). For the configuration of the obstruction there are also three options; anterior-posterior (AP), lateral or concentric collapse. Figure 1 shows an overview of the potential obstruction levels, severity and configuration.

Figure 1 - The VOTE classification (11)

Structure	Obstruction severity[a]	Configurationc		
		Antero-posterior	Lateral	Concentric
Velum				
Oropharynxb				
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

To perform analysis we gave points to all the potential collapse patterns;:
- 0 points: no obstruction
- 1 point: partial lateral or AP obstruction
- 2 points: partial concentric obstruction or complete lateral or AP obstruction
- 4 points: complete concentric obstruction

We chose to score 4 point for a complete concentric collapse (CC) because several studies proved that this corresponds with less treatment success of a MAD (15, 16). Therefore and to be able to compare our results, we used the same scoring system as described in our first study by Vonk et al. (12);

Definitions

Patients were considered having position dependent OSA (PP) if the AHI in non-supine sleeping position was less than 50% of the AHI in the supine position (13). If OSA severity was independent from sleeping position patients were regarded non-positional patients (NPP).

Ethical considerations

All procedures followed were in accordance with the ethical standards for human experimentation, and with the Declaration of Helsinki of 1975. To protect personal information, data on study subjects was encoded after collection, and then stored Informed consent was not required for this type of study

Statistical analysis

Statistical analysis was performed using SPSS (version 26), SPSS Inc, Chicago, IL. Quantitative data were reported as mean and standard deviation (SD), or, if not normally distributed, as median (Q1, Q3). The Kolmogorov-Smirnov Test was used to determine whether continuous variables were normally distributed. A p-value of < 0.05 was considered to indicate statistical significance. To compare baseline characteristics between NPP and PP, the unpaired t-test was used if data was normally distributed, and the Mann-Whitney U test if it was not normally distributed.

Since we wanted to compare our results with those of our previous study, we used the same methods to analyze our findings (12). To calculate the effect of the passive maneuvers on upper airway obstruction we used the previously described scoring systems. For the comparison of the overall effect of these maneuvers the total sum VOTE score was calculated by summing the different scores for obstruction severity at each obstruction level. The total sum VOTE score was analyzed as ordinal data.

The data on total sum VOTE scores in different positions, with and without maneuvers, and with and without MyTAP, was analyzed using Wilcoxon signed ranks tests. The differences in sum VOTE scores between the subgroups was analyzed using a chi-square test or if the cells had an expected count less than 5, a Fisher's exact test was used.

Due to the shape and distribution of the outcome variable (i.e., sum VOTE score), a Poisson regression model was constructed to analyze the associations of supine

and lateral position, with and without maneuvers. Generalized estimating equations (GEE) were used to correct for multiple measurements per person, because earlier studies have shown possible effects of gender, age, BMI, AHI and position dependency on the VOTE score (18). The reported incidence rate ratios (IRRs) were adjusted for these variables.

RESULTS

In total, 94 patients were included for analysis. A majority were male (89%); patients' mean age was 47.0±11.9 years, mean BMI was 27.1±3.1 kg/m2. The median AHI was 16.2 events per hour. Nineteen patients were diagnosed as NPP, the remaining 75 patients were PP. These two groups significantly differ regarding the AHI in the supine and non-supine positions. NPP had a significantly lower AHI in supine position compared to PP (15.9 vs 33.5 events per hour, p=0.002) and vice versa; PP patients had a significantly lower AHI in non-supine position (5.9 vs 14.4 events per hour, p=0.000). Baseline characteristics are shown in table 1.

Table 1 - Baseline Characteristics

	Total (n=94)	**NPP (n=19)**	**PP (n=75)**	***p*-value**
Age (y)	47.0 ± 11.9	46.2 ± 10.1	47.2 ± 12.3	0.747
Gender (female/male)	14/84	4/15	10/65	0.471
BMI (kg/m2)	27.1 ± 3.1	28.2 ± 3.5	26.8 ± 3.0	0.099
AHI (events/hr)	16.2 (10.4, 24.9)	13.5 (9.4, 31.1)	16.4 (10.5, 24.9)	0.796
AHI supine (events/hr)	30.3 (16.1, 51.7)	15.9 (8.3, 34.4)	33.5 (20.0, 52.3)	0.002$^{\delta}$
AHI non-supine (events/hr)	7.6 (2.7, 14.5)	14.4 (9.1, 26.4)	5.9 (2.2, 12.8)	0.000$^{\delta}$
TST supine (%)	39.4 (26.4, 54.4)	47.3 (38.1, 54.6)	37.5 (25.8, 50.5)	0.101

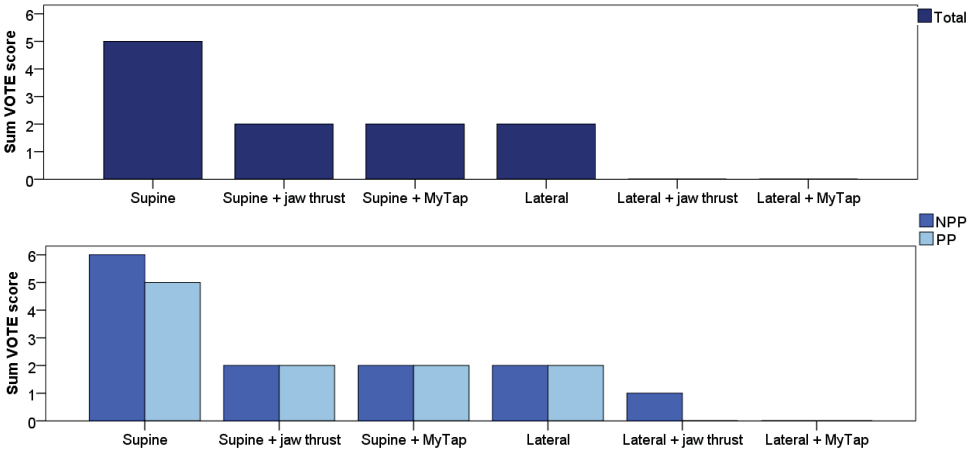
NPP: non-positional patients, PP: positional patients
Normally distributed: Mean ± SD, Not normally distributed: Median (Q1, Q3)
$^{\delta}$statistically significant difference NPP versus PP (*p*-value < 0.05)

Total sum VOTE score

In the total population the median of the sum VOTE score was 6, in the subgroup with NPP it was 6 and in de subgroup with PP 5 points. The median sum VOTE score in NPP was reduced by 66.7% and by 60% in PP (p<0.001) with jaw-thrust or with

the MyTAP in situ. Similar results were found evaluating the effect of rotation from the supine to lateral position. Combining these two maneuvers reduced obstruction by 83.3% in NPP (p<0.001), and complete (100%) in PP (p<0.001).

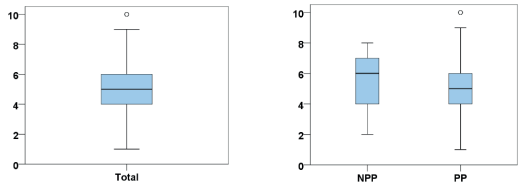
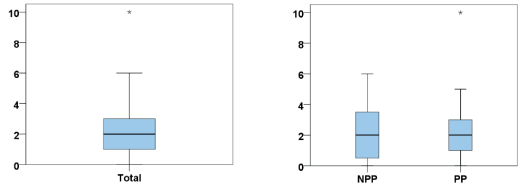
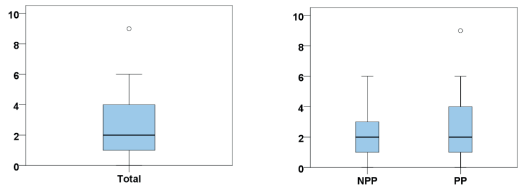
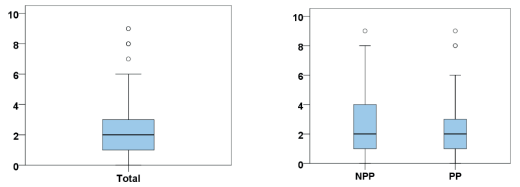
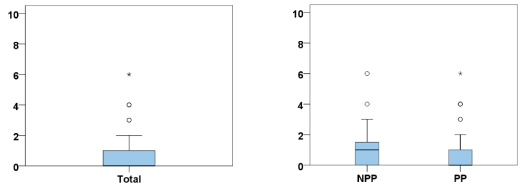
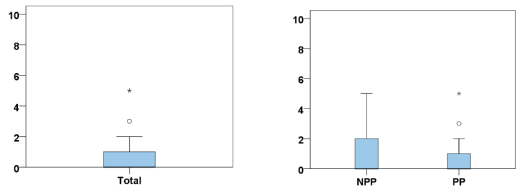
Figure 2 - Average total obstruction and the influence of maneuvers



Sum VOTE score two positions (supine and lateral), with and without manoeuvres (jaw thrust and MyTAP)NPP (non-positional patients) and PP (positional patients)

Comparing the median of the total sum VOTE scores between NPP and PP for each position or each position and maneuver, shows no statistical differences. This is shown in the boxplots of figure 3. Comparing the effect of jaw thrust and MyTAP in supine position, shows no differences between the two groups. Comparing the effect of jaw thrust and MyTAP in lateral position, shows that in NPP the MyTAP had more effect than jaw-thrust, this difference was not statistically significant (p=0.369). These results are shown in figures 2 and 3.

Figure 3 - Average total obstruction an the influence of maneuvers

	Total (n=94)	**NPP versus PP** (n=19 versus n=75)	***p*-value**
Supine			0.359
Supine + jaw thrust			0.230
Supine + MyTAP			0.704
Lateral			0.511
Lateral + jaw thrust			0.156
Lateral + MyTAP			0.368

Boxplots describing minimum, Q1, median, Q3, maximum and outliers of sum VOTE score in two positions (supine and lateral), with and without manoeuvres (jaw thrust and MyTAP), with corresponding *p*-value.

NPP: non-positional patients, PP: positional patients

Associations and confounders

The Poisson regression model showed the possible significant associations between supine and lateral position, with and without maneuvers. Applying a jaw thrust or the MyTAP in supine position or rotating head-and-trunk, led to a reduction of the sum VOTE scores by respectively 57%, 54% and 55%. Combining head-and-trunk rotation and a jaw thrust or the MyTAP reduced obstruction by respectively 86% and 89%, compared to the supine position. Adding a jaw-thrust or the MyTAP to the lateral position (head-and-trunk rotation) caused a reduction in obstruction by 69% and 76% respectively. All of these associations were significant ($p<0.001$). No significant differences were found comparing the MyTAP in supine position with a jaw thrust in supine position ($p=0.441$), and comparing the MyTAP in lateral position with a jaw thrust in lateral position ($p=0.299$). The results are shown in table 2, all results are adjusted for possible confounders. No significant associations between the independent variables (gender, age, BMI, AHI and position dependency) and the sum VOTE score were found.

Division of the PP subgroup into supine isolated OSA (non-supine AHI <5) and supine predominant OSA (non-supine AHI ≥ 5) created no significant differences in sum VOTE score; this was not described further in this study.

Table 2 - aIRR (adjusted incidence rate ratio)

Reference position and/or manoeuver	Applied position and/or manoeuver	aIRR*	Difference in sum VOTE score	*p*-value
Supine	Supine + jaw thrust	0.43 [0.37-0.49]	- 57%	<0.001
Supine	Supine + MyTAP	0.46 [0.40-0.54]	- 54%	<0.001
Supine	Lateral	0.45 [0.38-0.54]	- 55%	<0.001
Supine	Lateral + jaw thrust	0.14 [0.10-0.20]	- 86%	<0.001
Supine	Lateral + MyTAP	0.11 [0.08-0.16]	- 89%	<0.001
Lateral	Lateral + jaw thrust	0.31 [0.23-0.41]	- 69%	<0.001
Lateral	Lateral + MyTAP	0.24 [0.17-0.35]	- 76%	<0.001
Supine + jaw thrust	Supine + MyTAP	1.08 [0.89-1.33]	+ 8%	0.441
Lateral + jaw thrust	Lateral + MyTAP	0.80 [0.51-1.23]	- 20%	0.299

aIRR [95% Confidence Interval] describing the association between various reference positions and applied positions, with and without maneuvers, resulting in a percentage of decrease or increase of the sum VOTE score, with corresponding *p*-value.
*Adjusted for gender, age, BMI, AHI and position dependency.

DISCUSSION

This study is performed in addition to a previously proposed prediction model. We have investigated the applicability of passive maneuvers during DISE to predict treatment success of conservative treatment modalities for OSA patients. In the first study, we concluded a jaw thrust overestimates the treatment effect of a MAD and lateral head rotation underestimates the effect of PT (12). Based on these outcomes, two prospective studies were performed, intended to analyze and optimize the passive maneuvers to better imitate the treatment effect of a MAD and PT (13, 14). Using the outcomes of these two studies we adjusted our DISE protocol. With the current study we aimed to verify if with these adjustments we can not only use DISE to predict treatment success for upper airway surgery but also for conservative treatment options.

In this study we found that our adjustments create a better fit for DISE as a selection tool. Using MyTAP caused 54% less obstruction, and jaw thrust caused 57% less obstruction. Both modalities are close to mimicking the expected effect on upper airway obstruction of a MAD, which reduces the AHI by 50% (6). Head-and-trunk rotation reduced obstruction by 55% and thus mimicked the effect of PT, which reduces the AHI by 54% (20, 21).

In contrast with our expectation, the use of MyTAP imitated the effect of a custom-made MAD not better than a jaw thrust did. In an earlier study, we compared the extents to which jaw thrust and MyTAP reduced obstruction at different levels of the upper airway (14). We found only moderate agreement: while jaw-thrust caused less obstruction at hypopharyngeal level, it was less effective at retropalatal level than MyTAP. In the current study we intended to focus on the total extent of obstruction as potential predictor for treatment success. Therefore, differences in effect on the various levels of the upper airway between the two modalities were less important to answer our question.

Head-and-trunk rotation, which mimics the effect of PT, caused 55% less obstruction. This reflects the expected effect better than the 33% decrease of only head rotation found by Beelen et al. (13). Head-and-trunk rotation caused more reduction in sum VOTE score in NPP, compared to PP, which is slightly surprising since PSG would suggest less dependency of position movements (19). This effect is partly caused by the higher ‘baseline’ sum VOTE score in supine position in the NPP-group of six compared to five in de PP group. In both groups the residual sum VOTE score

after moving head-and-trunk is two. Because NPP started with an higher score, this reduction is more than for PP. When considering effects of sleeping position, one must also consider the effect of REM sleep. Oksenburg et al. concluded that during REM sleep while in supine position more apneas occur. Therefore the effects of sleeping position is more dominant than effects of REM sleep.

When dividing de PP subgroup into supine isolated OSA (non-supine AHI <5) and supine predominant OSA

Vonk et al. (12) made a subdivision of position-dependent patients (PP) in supine isolated supine predominant OSA. A significant reduction of the median total sum VOTE score was found when comparing the effect of only head rotation in these subgroups, in favor of the supine isolated group (50% reduction). In contrast, we found no significance differences between supine isolated and supine predominant. Zhu et al. also found that head-and-trunk rotation was more effective in reducing the AHI than head rotation only (23). Moreover a 90% rotation of the head only is for many patients not comparable to the natural lateral sleeping position.

Head-and-trunk rotation combined with a jaw thrust reduced the AHI by 86%. This overestimates the effect of combined treatment of a MAD and PT in which a 73% decrease in AHI would be expected (20). Vonk et al found a reduction of 83% of jaw thrust combined with only head rotation (12).

Clinical relevance

DISE is an invasive diagnostic procedure. Sutherland et al. recently performed a study on awake multimodal phenotyping to predict MAD treatment outcome (24). They concluded awake assessments limit utility for clinical prediction models and suggest future work should be focused on sleep-related assessments.

Cost wise, performing a jaw thrust is less expensive than using MyTAP to predict treatment outcome. In addition fitting the MyTAP requires more time and expertise, from a dentist. Nevertheless, the degree of mandibular protrusion with jaw thrust is subjectively estimated by the team performing the DISE. It's often regarded as an imprecise and uncontrolled maneuver. With both a boil-and-bite MAD and a definitive custom-made MAD, the degree of protrusion can be pre-set, which leads to a more objective and reproducible value. compared to jaw thrust.

Limitations

A limitation of this retrospective study is that only one person scored the DISE videos. The VOTE system is subjective and a relatively coarse size. A prospective study must be done to investigate our outcomes. Videos should then be scored by another doctor too. Furthermore, predictions made during DISE should be compared to follow-up outcomes on treatment instead of comparing with literature outcomes.

CONCLUSION

In summary, the effect on upper airway patency of a jaw thrust, a temporary MAD and head-and-trunk rotation during DISE are in line with what we had expected based on treatment outcomes of a MAD and PT. These outcomes might be of added value when choosing between the various treatment options for patients with OSA. To prove the predictive value of these maneuvers during DISE, a prospective study should be performed. We are currently following the patients in our cohort who opted for a MAD, and will compare their PSG outcomes with the expected decrease in obstruction on the basis of this study.

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