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Remotely controlled mandibular positioning during drug-induced sleep endoscopy towards mandibular advancement device therapy: feasibility and protocol

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Abstract

Background: Research demonstrated the potential of a remotely controlled mandibular positioner (RCMP) during sleep studies in individual patients suffering from obstructive sleep apnea (OSA), by determining the effective target protrusive position (ETPP) of the mandible as well as predicting the probability of following successful mandibular advancement device (MAD) treatment.

Objective: To perform a feasibility study with RCMP during drug-induced sleep endoscopy (DISE) for determination of ETPP.

Patients/Methods: Ten patients with OSA (50% male; age 54 ± 9.5 y; BMI 26.9 ± 2.1 kg/m²; Apnea-Hypopnea Index 28.4 ± 13.2 events/hour of sleep) were enrolled prospectively. Dental RCMP trays were fitted during wakefulness. Maximal protrusion and edge-to-edge positions were measured. Upper airway collapsibility was scored during DISE, including full-range mandibular RCMP titration, within 45 minutes. ETPP was defined as mandibular threshold position of stable upper airway in absence of snoring, oxygen desaturation and apneas.

Results: RCMP trays were retentive and no adverse reactions occurred. RCMP was fitted intraorally prior to sedation with maxillar and mandibular trays in edge-to-edge position. Upon sedation, reversed titration took place followed by progressive protrusion until ETPP was noted. In one patient ETPP was not within mandibular range of motion. In one patient RCMP was removed during due to clenching.

Conclusions: The results of this study illustrate that it is feasible to use RCMP during DISE and determine ETPP within 45 minutes. In addition, optimization of the RCMP design for DISE and comparative research with poly(somno)graphy would be useful to further validate the use of RCMP during DISE.

Keywords (max 6)

Sleep-disordered breathing, sedation, mandibular protrusion, mandibular position, titration, upper airway collapse

1. Introduction

Mandibular advancement devices (MAD) used in the treatment of obstructive sleep apnea (OSA) rely on mandibular protrusion promoting airway widening, increase in pharyngeal dilator muscle activity, decreased upper airway resistance and decreased pharyngeal collapsibility[1, 2].

Custom titratable MAD are recommended for gradual mandibular protrusion[1, 3] after fitting. MAD titration has to be carried out individually to search for optimal mandibular protrusion, respecting patients' physical limits, and is guided by the evolution in subjective symptoms and/or objective measurements[4]. In daily clinical practice titration is a time-consuming 'trial-and-error' procedure taking several weeks to months[4]. Larger advancement is often related to higher efficacy and smaller vertical opening is associated with decrease in pharyngeal collapsibility[2, 5]. Although the effect of protrusion is reported to be dose-dependent, it is not always associated with corresponding reduction in apnea-hypopnea index (AHI). Furthermore the effect of MAD treatment varies largely between patients[6].

The concept of remotely controlled mandibular positioner (RCMP) during overnight sleep studies was introduced to determine effective target protrusive position (ETPP) in individual patients to prospectively predict treatment success with MAD[4, 7]. Literature has shown a greater reduction in AHI with custom titratable MAD after RCMP-titration as compared to conventional titration methods[7]. Nothing is known yet on the used of RCMP during induced sleep. The present study checks upon the feasibility using RCMP during drug-induced sleep endoscopy (DISE) for instant determination of ETPP.

2. Patients and Methods

2.1 Study setting and patient characteristics

Ten patients with OSA (50% male; age 54 ± 9.5 y; BMI 26.9 ± 2.1 kg/m²; Apnea-Hypopnea Index 28.4 ± 13.2 events/hour of sleep) were enrolled prospectively. All patients were clinically examined during wakefulness by experienced ENT surgeons and specialized dentists. Subsequently impression trays of a commercially available RCMP (MATRx™, Zephyr Sleep Technologies Inc., Calgary, Canada) were filled with a high-viscosity bite registration material (Blu-Mousse®, Parkell inc., Edgewood, New York, United States of America), mimicking MAD but connected to RCMP controlled man-operated software. The Medical Ethics Committee of Antwerp University Hospital approved this study.

2.2 DISE protocol

The ruler connected to the RCMP motor needed to be calibrated to rule out day-to-day variation due to environmental factors such as room temperature or humidity. This procedure ensured the mandibular movement could be read out on the ruler (*Figure 1*). Patients were positioned supine in a hospital bed in an operating theatre. RCMP-trays were fitted in edge-to-edge position to avoid muscle tension. During DISE, electrocardiography, blood pressure and oxygen saturation were monitored continuously. A flexible fiberoptic nasendoscope (flexible fibrescope type ENF-GP, Olympus Europe GmbH, Hamburg, Germany) was introduced by one experienced ENT surgeon in awake patients to evaluate differences between awake and sedated upper airway state. DISE was subsequently performed in semi-dark and silent environment. Sedation was induced by intravenous administration of midazolam (bolus injection of 1.0 to 2.0 mg) and propofol through target-controlled infusion system (2.0 to 3.0 µg/mL), aiming at target sedation: the transition to unconsciousness similar to stage 2 sleep, assuring absence of patients' eyelash reflex after stimulation by means of a gentle brush. Findings were noted using a uniform upper airway scoring system evaluating level of snoring, presence of apneas, degree of oxygen saturation, degree and configuration of obstruction(s) at level of palate, oropharynx, tongue base, hypopharynx and epiglottis[8]. When target sedation was reached, protrusion of the mandible with RCMP was initiated softwarewise in increments of 1 mm towards maximal comfortable protrusion (MCP) as determined before. If a stable upper airway in absence of snoring, oxygen desaturation and apneas was evaluated with RCMP in MCP, the mandible was remotely retruded 2 mm, a process referred to by the authors as "reversed titration". If the upper

airway was still stable, reversed titration was continued. If the upper airway collapsed, snoring, desaturations or apneas occurred, RCMP was protruded 1 mm. After every protrusive or retrusive movement the RCMP protrusion was checked on the RCMP ruler (*Figure 1*), to assure correct position of RCMP while the upper airway was evaluated[8]. This approach was repeated until ETPP could be determined, defined as the minimal mandibular threshold position of a stable upper airway in the absence of snoring, oxygen desaturation and apneas.

After ETPP determination the RCMP was removed. Subsequently, upper airway scoring was performed during 'baseline' state, head rotation observing non-supine-dependent OSA or snoring[9], and chin-lift.

All DISE procedures were instantly processed using a medical video documentation platform (NeBULA™, eSATURNUS nv, Leuven, Belgium) and all stages marked (awake, RCMP edge-to-edge tray position, RCMP protrusion, RCMP retrusion, baseline, head rotation (non-supine), chin-lift).

3. Results

Drug-induced sleep endoscopy (DISE) with remotely controlled mandibular positioner (RCMP) was performed in 10 patients, to determine effective target protrusive position (ETPP) in 8 patients: in one patient snoring, apneas and oxygen desaturations did not resolve within the patients' mandibular range of motion (ROM); in one other patient RCMP needed to be removed due to clenching without the possibility to determine ETPP.

Table 1 depicts mean ETPP at 67% of total ROM. For individual patients an ETPP spread of 37% to 88% of ROM is visualized.

4. Discussion

4.1 Findings and earlier studies

The present study emphasizes the feasibility to perform RCMP-titration under DISE. Patients tolerated the RCMP trays well and no loss of retention occurred during the procedure.

Maximal retrusion, maximal protrusion, ETPP and ROM varied largely between patients (*Table 1*). The mean ETPP trajectory from maximal retrusive position of the mandible, was 7.3 mm, but this is of little clinical value, as ETPP varies largely between patients. If in all patients mandibular protrusion would be set at 7.3 mm 3 patients would have insufficient resolution of snoring, apneas and oxygen desaturations while in 4 patients less protrusion of the mandible would be favorable.

These findings stress the importance and relevance of individualised titration whereas level of protrusion in MAD therapy is currently rather empirical in clinical practice[10]. Prospective prediction of successful MAD treatment outcome is, however, the key issue from both therapeutic and financial perspectives[7]. The potential of RCMP therefore lays in selecting patients for MAD treatment e.g. by prospectively determining ETPP during overnight sleep studies[7, 11].

The ability to determine ETPP in patients during DISE before MAD treatment starts, is thus of great added value to the field, as time consuming titration sleep studies and/or trial-and-error MAD titration periods could be avoided. However, its clinical and predictive power has yet to be confirmed further by performing sleep studies with MAD in the determined ETPP to confirm actual success with MAD.

4.2 Limitations and recommendations

Some limitations of RCMP were encountered especially as to the available ROM of 12 mm, since maximal ROM in some patients exceeded this hardware/software limit (*Table 1*). In RCMP during sleep studies high rates of inconclusive tests (>20%) occurred, 33% was caused due to RCMP maximal protrusive limit was reached[7, 11]. In the present feasibility study, the RCMP procedure only one investigation was inconclusive due to early removal of RCMP following jaw clenching.

Since the bite registration with the trays was carried out prior to the RCMP with DISE, we observed that the trays could shift 1 mm upon refitting without adjusting to intended position and had to be adjusted manually. Another point of attention is bending of extension of the RCMP trays upon further protrusion, requiring control of the actual protrusion versus the software-determined one after each protrusion step, including manual adjustment if necessary.

Slow-continuous protrusion is not possible: the RCMP immediately moves stepwise to the desired next protrusive position. During sedation, protruding in increments of as low as 1 mm caused the mouth floor muscles to contract. Retrusion did not cause such contractions. Slower protrusion in increments of 0.2mm, as done in recent RCMP sleep study trials in reaction to respiratory events[12], would be possible but may be time-consuming. We however suggest to set the maximal registration time of DISE with RCMP at 45 minutes to avoid ergonomical discomfort of examiner, hypersalivation of patient due to the trays, patient movements, arousals and submental tension possibly due to genioglossus muscle traction.

When the RCMP trays were initially inserted in the awake patient just prior to sedation and in the so called edge-to-edge position, the patients all showed an increased reactivity causing jaw movements and a tendency to counteract the RCMP procedure. As soon as such behavior was noted, the RCMP was instructed to retrude as much as possible thereby alleviating this adverse behavior, and the tests were then resumed with incremental protrusion as discussed before.

In the present feasibility study DISE with RCMP was done by one experienced ENT surgeon, to avoid inter-observer variability[13].

We recommend to document with a standardized upper airway protocol with every relevant change in upper airway collapsibility with each protrusive position achieved during the RCMP procedure.

5. Conclusion

The results of the present feasibility study showed the potential of RCMP during DISE and to prospectively determine ETPP, all within 45 minutes.

Comparative research between DISE and sleep studies, also assessing therapy outcome with MAD, are needed to further validate the use of RCMP during DISE.

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