Prediction of Outcome with Oral Appliance Therapy for Obstructive Sleep Apnea Using In-Home Mandibular Titration

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ABSTRACT

Rationale: Oral appliance therapy (OAT) resolves sleep apnea in only 50-60% of cases, pointing to the need to prospectively identify therapeutic responders. We sought to assess the accuracy of an auto-titrating mandibular positioner (AMP) with machine learning to predict therapeutic outcome and an efficacious mandibular positioner.

Methods: Two independent populations (Phase 1: n=149; Phase 2: n=53) of participants with obstructive sleep apnea (OSA) participated in a prospective, blinded clinical trial. Data from Phase 1 were used to develop the predictive method, and data from Phase 2 were used to evaluate its accuracy. Each participant underwent two full-night AMP studies in the home using a temporary dental appliance, and each was treated with a custom oral appliance. Therapeutic outcome sleep tests were performed after full clinical adjustment. Prediction of therapeutic outcome was derived from the analysis of a machine learning method (Random Forest).

Results: Using oxygen desaturation index (ODI) of less than 10 hr⁻¹ as outcome as the criterion of therapeutic success, predictive accuracy was as follows for Phase 1: sensitivity: 85%; specificity: 93%; positive predictive value: 97%; negative predictive value: 72% and accuracy: 88%. Of participants correctly predicted to respond to OAT, the target protrusive position proved to be an efficacious position in 86% of cases.

Conclusions: Data from an unattended, in-home sleep study with an auto-titrating mandibular positioner, analyzed by a machine learning method, accurately identifies OSA patients who will respond to OAT. The study also provides a therapeutic target protrusive position that is efficacious in the majority of OAT responders.

METHODS

• Prospective, blinded (physician and dentist), controlled study involving two sequential, independent populations (Phase 1: n=149; Phase 2: n=53)
• Between the two study phases, 8 (4%) participants were unable to collect sufficient AMP data (conclusive) and 15 were lost to follow-up, leaving a final study population of 139 participants (n=131 for Phase 1; n=48 for Phase 2)
• Broad inclusion criteria (ODI > 10 hr⁻¹; BMI < 45 kg/m²)
• 2–3 full night tests with an AMP in the home with automated prediction of therapeutic outcome and efficacious mandibular position
• All participants received an oral appliance (Phase 1: SomnoMed; Phase 2: MicrO) set to target protrusion (default position 70% for predicted non-responders)
• Participants were tested at target, then further protracted in 1–2 mm increments until therapeutic success (ODI < 10 hr⁻¹) or until clinical limits of protrusion were reached
• Machine learning (Random Forest) was used to predict accuracy
• Phase 1 data were used to train the Random Forest; Phase 2 data were used to evaluate the Random Forest machine accuracy

RESULTS

Figure 2. Baseline OSA severity and therapeutic outcome of study participants (Phases 1 and 2 combined; n=179).

Figure 3. Distribution of baseline ODI and BMI for Phase 1 and Phase 2 study participants (n=179).

Figure 4. ODI at baseline and final therapeutic position for predicted successes (left panel) and predicted failures (right panel) for Phase 2 study participants (n=48).

Figure 5. Positive and negative predictive values, sensitivity, and specificity of Phase 2 data (n=48). Overall accuracy was 88%

DISCUSSION

Our results show that an AMP can be used in unattended studies to predict OAT outcome and an efficacious mandibular position. Data from 179 participants (2–3 study nights per participant) showed that the AMP home studies were feasible, well-tolerated, and safe. Random Forest machine learning analysis trained on Phase 1 data and applied to Phase 2 data resulted in a predictive accuracy of 88% and a positive predictive value of 97%. 86% of Phase 2 study participants were successfully treated at target.

CONCLUSIONS

• We have developed an AMP system suitable for unattended sleep studies
• Data from 179 study participants using 2 different oral appliances shows good accuracy in identifying favorable candidates for OAT and determining an efficacious mandibular position

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Participant Baseline Characteristics

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<thead>
<tr>
<th>Phase 1 (n=131)</th>
<th>Phase 2 (n=48)</th>
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<tbody>
<tr>
<td>Age (yrs)</td>
<td>49.8±10.6</td>
</tr>
<tr>
<td>Females/Males</td>
<td>21/110</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>30.3±4.2</td>
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<tr>
<td>ODI (events/hr⁻¹)</td>
<td>25.4±11.3</td>
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<tr>
<td>SaO₂ (%)</td>
<td>92.1±15.5</td>
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