VALIDATION OF THE OMES QUESTIONNAIRE COMPARED TO OBJECTIVE MEASUREMENT OF OROPHARYNGEAL MUSCLE TONE USING THE IOPI MANOMETER, SANDWAY MANOMETER, AND DIGITAL SPOON

Background and Justification of the Study

Obstructive Sleep Apnea-Hypopnea Syndrome (OSAHS) is a significant public health problem characterized by repeated episodes of upper airway obstruction during sleep, associated with snoring, sleep fragmentation, daytime hypersomnolence, and increased cardiovascular risk. It is well established that the most effective treatment for OSAHS is Continuous Positive Airway Pressure (CPAP), although patient compliance is variable. CPAP virtually eliminates OSAHS along with snoring, reduces daytime sleepiness, and improves subjective sleep quality.

The etiology of OSAHS is multifactorial, including both anatomical and physiological factors. Upper airway dilator muscles are crucial in maintaining pharyngeal patency and may contribute to the occurrence of the disease.

Other treatments for OSAHS include mandibular advancement devices (MAD), conventional surgery with CO_2 laser or radiofrequency, and hypoglossal nerve stimulation. There is also some evidence supporting pharmacological treatments with oxybutynin and atomoxetine, which currently show promising results, and clinical trials have been conducted with theophyllines, acetazolamide, and desipramine to reduce upper airway collapsibility, though without clear effectiveness.

Myofunctional therapy is a treatment modality applied to individuals with orofacial myofunctional disorders that may interfere with the development or functioning of related structures and functions.

Studies on myofunctional therapy show benefits by promoting changes in dysfunctional upper airway muscles, and it has been successfully proposed to reduce the severity of OSAHS and associated symptoms in adults. The potential of myofunctional therapy has also been explored for reducing the Apnea-Hypopnea Index (AHI), snoring, improving quality of life, and as an adjunctive treatment and intervention strategy to support CPAP adherence.

Currently, it is unclear which patients are best suited for this therapy. There are questionnaires such as OMES (Expanded Protocol of Orofacial Myofunctional Evaluation with Scores), which, through functional evaluation of all stomatognathic functions, provide a score that has been shown to be lower in OSAHS patients compared to controls. This evaluation serves as a guide for myofunctional therapists to target and improve specific deficient items through exercises. However, this test is based on subjective evaluations,

includes many items, and is difficult to reproduce. We believe that a more concise, objective, and reproducible evaluation can be achieved using the Sandway manometer or the IOPI (Iowa Oral Performance Instrument) to assess the genioglossus and orbicularis oris muscles—tools our group has experience with, with prior approval by this Committee (25/02/21). These measurements will be compared with genioglossus muscle tone assessed using a validated and widely used digital kitchen spoon. These simple measurements can help patients become aware of their condition, serve as therapy response parameters, and objectively communicate results among professionals. Curtis et al. conducted a similar project using a low-cost manometer to facilitate accurate feedback in dysphagia therapy exercises. Our group has already conducted a study with the digital spoon, IOPI, and OMES questionnaire, and we aim to conduct a similar study including a low-cost manometer for home follow-up of exercises aimed at treating OSAHS.

Hypothesis

The use of the OMES questionnaire can be complemented by the values obtained through measurement instruments such as the IOPI device, digital manometer, and digital spoon.

Objectives

The primary objective is to evaluate the function of the stomatognathic musculature in patients with OSAHS using the OMES questionnaire, the digital spoon, and the IOPI® and Sandway® manometers.

Secondary objectives include:

- - Assess whether differences exist in the musculature of patients with OSAHS versus healthy controls using this questionnaire.
- - Measure IOPI (Iowa Oral Performance Instrument) values assessing strength and resistance of the tongue and buccinator muscles and evaluate differences with healthy patients. Comparisons will be made between the IOPI® and Sandway® manometers.
- - Measure tongue pressure using the digital spoon and assess differences with healthy patients.

Methodology

Design

We have designed a prospective, controlled, quasi-experimental pilot study involving patients with moderate to severe OSAHS.

Study Setting

Patients diagnosed and/or treated in the Pulmonology and Otolaryngology departments at Quirónsalud Hospital in Marbella and/or Hospital Campo de Gibraltar will participate in this study, which will take place in the facilities of these healthcare centers.

Study Population

Patients diagnosed with obstructive sleep apnea-hypopnea syndrome (OSAHS) at the participating centers who consent to participate will be included.

Inclusion Criteria (Cases)

- - Age between 18 and 75 years
- - Diagnosis of moderate to severe OSAHS (AHI >15) with no previous treatment experience
- - No prior treatment for OSAHS
- - Signed informed consent (IC)

Inclusion Criteria (Controls)

- - Adequate sleep hygiene
- - No complaints of snoring
- - No complaints of daytime sleepiness
- - Epworth Sleepiness Scale < 7 points

Exclusion Criteria for Both Groups

- - Cognitive or neurological deficits
- - Inability to complete questionnaires
- - Severe alcoholism
- - Presence of craniofacial malformations
- - Active neoplastic disease
- - History of orofacial muscle rehabilitation or prior OSA treatment (surgery, MAD, CPAP)

Sample Size and Sampling Procedure

Sample size calculation: The effectiveness of using the OMES questionnaire to evaluate patients with moderate to severe obstructive sleep apnea-hypopnea syndrome (OSAHS) will be assessed using previous published data on this questionnaire, the validation data from the digital spoon, and comparative data from previous studies. Based on this prior literature review, a sample size of 60 subjects (40 experimental group, 20 control group) has been determined. The sample size was calculated using the XLSTAT software for Excel.

Definition of Variables

The following variables will be measured in all participants and recorded in the data collection table (Annex 1), using the EPiInfo software:

- - Age
- - Sex
- - Weight
- - Height
- - Body Mass Index
- - Abdominal circumference (at the navel)

- - Neck circumference (measured with a flexible tape at the most prominent part, with the patient standing, arms at sides, head upright and looking forward)
- - IOPI measurements of tongue and buccinator muscle strength
- - Digital manometer measurement
- - Apnea-Hypopnea Index (AHI)
- - Nocturnal desaturation index
- - Lowest oxygen saturation during sleep
- - Digital spoon measurement of tongue strength
- - OMES questionnaire score

Both groups will complete the following questionnaires: Friedman Stage (Annex 1), Epworth Sleepiness Scale (Annex 2), and Pittsburgh Sleep Quality Index (Annex 3).

Procedures

A myofunctional evaluation will be conducted during the same week as the patient's polygraphy/polysomnography test. During this assessment, patients will be blindly examined by a speech therapist and the examination will be video recorded for further evaluation.

Next, the OMES questionnaire (Annex 4) will be applied, analyzing parameters such as posture or appearance, mobility, breathing pattern, swallowing, and chewing. This validated questionnaire provides a higher score for more normal stomatognathic function.

Subsequently, muscle tone of the genioglossus and buccinator muscles will be evaluated using IOPI® and Sandway® manometers, taking three measurements each and using the highest value.

Finally, tongue muscle tone will be measured with the digital spoon, again taking three measurements and using the highest value.

Recordings and data will also be analyzed by a second blinded examiner.

Visit Schedule

Study visits are scheduled as follows:

SELECTION VISIT: In patients diagnosed with OSAHS in a sleep study at a pulmonology lab (measuring baseline AHI, nocturnal desaturation index, and lowest nighttime oxygen saturation), inclusion and exclusion criteria are assessed. The patient is informed about the study, all questions are answered, and the informed consent (IC) is signed in duplicate. One copy is given to the patient.

SINGLE VISIT: The patient is evaluated by the speech therapist, completes the sleepiness questionnaires, and undergoes the OMES evaluation, digital manometer assessment, IOPI, and digital spoon testing.

Data Collection and Statistical Analysis

Study variable data will be recorded in a custom database. Descriptive statistics will include frequency distribution for categorical variables and mean (standard deviation) or median (interquartile range) for quantitative variables. Quantitative variable distributions will be evaluated using the Kolmogorov-Smirnov test.

Bivariate analysis between categorical variables will use Chi-square or Fisher's exact test as appropriate. Quantitative variable comparisons will use Student's t-test or ANOVA (for two or more samples), and non-parametric tests (Mann-Whitney or Kruskal-Wallis) when data are not normally distributed.

Correlation between OMES scores and values from IOPI, digital manometer, and digital spoon will be analyzed using Spearman's correlation coefficient. Intra- and inter-examiner reliability will be assessed using split-half reliability analysis. Statistical significance will be set at $p<0.05$. SPSS version 24 will be used for all analyses.

Ethical Considerations

The Research Ethics Committee (REC) of the Provincial Hospital of Malaga must review and approve the protocol and informed consent form before the study begins. Before any procedure, participants must sign the approved informed consent document.

Access to and protection of study data: To ensure data confidentiality, original records will be stored at the hospital and only accessible to researchers and the REC.

This study will follow the Helsinki Declaration guidelines (October 2024) and Good Clinical Practice standards. Personal data will be processed according to the EU Regulation 2016/679 and Spanish Law 3/2018 on Personal Data Protection and Digital Rights Guarantee.

Utility and Applicability

This study could improve selection criteria for the most appropriate therapy in OSAHS patients. It forms the research project for the doctoral thesis of Dr. Eduardo Correa.

Side Effects or Complications

No side effects or complications are expected, as only conventional assessments routinely performed in speech therapy and dysphagia units will be used.

Work Plan

In the first month following REC approval, the study will be launched, the database created, and the research team coordinated (COR, JMIG, JC, LRA, and EC). Patient evaluations will be conducted by (VCG and SA). In the following months, patients will be recruited, variables recorded, and data entered into the database (all team members). Statistical analysis will be performed after the last patient is recruited, followed by drafting conclusions and disseminating results via conferences and publications.

Dissemination Plan

After analyzing the results, findings will be disseminated through presentations at regional, national, and international conferences in otolaryngology, sleep medicine, and pulmonology. Manuscripts will also be submitted to national and international scientific journals.

Budget

The research project will be funded using resources from the research team and participating centers. No external funding has been secured.

Research Team

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