PROTOCOL:

Title:

VALIDATION OF OMES PROTOCOL WITH OBJECTIVE MEASUREMENT OF OROPHARYNGEAL MUSCLE TONE USING IOPI AND TONGUE DIGITAL SPOON IN SEVERE OBSTRUCTIVE SLEEP APNEA HYPOPNEA SYNDROME.

Background and rationale of the study:

Obstructive sleep apnoea-hypopnoea syndrome (OSAHS) is a significant public health issue characterised by repetitive episodes of airway obstruction during sleep which are associated with snoring, sleep fragmentation, daytime sleepiness, and increased cardiovascular risk (1, 2). It is well established that the most effective treatment for OSAHS is Continuous Positive Airway Pressure (CPAP) (3), which has variable patient compliance. CPAP virtually eliminates OSAHS and snoring, reduces daytime sleepiness, and improves subjective sleep quality (3, 4).

The aetiology of OSAHS is multifactorial and includes anatomical and physiological factors. The upper airway dilator muscles are crucial for maintaining pharyngeal patency and may contribute to the incidence of this medical condition (5,6).

Other treatments for OSAHS include the mandibular advancement device (MAD), conventional surgery, CO2 or radiofrequency laser, or hypoglossal nerve stimulation. There is also some evidence on pharmacological treatments with oxybutynin and atomoxetine, which are currently showing promising results (7), and clinical trials have been carried out with theophylline, acetazolamide and desipramine to reduce the collapse of the upper airway, but without clear effectiveness (8,9).

Myofunctional therapy is a type of treatment applied to patients with orofacial myofunctional disorders, which can interfere with the development or functioning of said structures and functions (10).

The studies reviewed on myofunctional therapy show benefits by promoting changes in dysfunctional muscles of the upper airway (11), which is why it has been successfully proposed to reduce the severity of OSAHS and associated symptoms in adults (12). The potential of myofunctional therapy has also been researched to promote a decrease in the Apnoea-Hypopnoea Index (AHI), a reduction in snoring (13), and an improvement in quality of life (14). In addition, it can be considered as an adjuvant therapy and an intervention strategy to support CPAP adherence (15).

It is currently unknown which patients are the best candidates for this therapy, while there are also instruments such as the OMES (Expanded Protocol of Orofacial Myofunctional Evaluation with Scores), which uses a functional exploration of all the stomatognathic functions to give a score that in patients with OSAHS has proved to be inferior to the controls (16)(17)(18). The myofunctional therapist uses this evaluation to improve the examined items that are in deficit and subsequently perform specific exercises to improve it. However, this test is based on subjective evaluations, contains many items and is difficult to reproduce. We believe that a more concise, objective and reproducible evaluation stems from measurement with the IOPI (Iowa Oral Performance Instrument) of the genioglossus muscle and the orbicular muscle, of which our group already has experience (19)(20), together with the measurement of the motor tone of the genioglossus muscle with the tongue digital spoon (21). These simple measurements can provide patients with information about their condition, serve as therapy response parameters, and objectively transmit the results between professionals.

HYPOTHESIS:

The use of the OMES protocol can be complemented by the values obtained through the IOPI instruments and the tongue digital spoon.

OBJECTIVES:

* The main objective will be to evaluate the function of the stomatognathic musculature of patients with OSAHS by using the OMES protocol, the digital spoon and the IOPI.
* The secondary objectives will be:
	+ To use this protocol to evaluate whether there are differences between the muscles of patients with OSAHS and healthy controls.
	+ To use the IOPI (Iowa Oral Performance Instrument) to measure tongue strength and resistance with the genioglossus and buccinator muscle tone, and evaluate whether there are differences with healthy patients.
	+ To use the tongue digital spoon to measure tongue pressure and evaluate whether there are differences with healthy patients.

METHODOLOGY:

DESIGN:

We designed a prospective, controlled, quasi-experimental pilot study on patients with severe OSAHS .

SCOPE OF STUDY:

This study will involve patients diagnosed and/or treated at the Pneumology and Otorhinolaryngology Departments at the Quirónsalud Hospital in Marbella and/or the Hospital Campo de Gibraltar, where it will also be conducted.

STUDY POPULATION:

This study will include patients diagnosed with sleep apnoea-hypopnoea at the participating hospitals and who agree to participate in the project.

INCLUSION CRITERIA (CASES):

* Ages between 18 and 75 years.
* Diagnosis of moderate to severe OSAHS (AHI>15) without having had previous experience of said condition and not undergoing treatment due to different circumstances.
* Not having undergone any previous treatment for OSAHS.
* Signed informed consent (IC) form.

INCLUSION CRITERIA (CONTROLS):

Adequate sleep hygiene.

No complaints of snoring.

No complaints of daytime sleepiness.

Epworth Scale <7 points

EXCLUSION CRITERIA FOR BOTH:

* Cognitive or neurological deficit.
* Inability to answer questionnaires.
* Severe alcoholism.
* Presence of craniofacial malformations.
* Active neoplastic disease.
* History of prior orofacial muscle rehabilitation therapy and any prior apnoea treatment which may modify the study results (surgery, MAD, CPAP).

SAMPLE SIZE AND SAMPLING PROCEDURE:

* Calculation of sample size:

The effectiveness of the use of the OMES protocol in the evaluation of patients with moderate to severe apnoea-hypopnoea syndrome will be evaluated with data previously published in studies on this protocol. After the literature review of said studies, the sample size will be 60 subjects (40 in the experimental group and 20 in the control group). The sample size was calculated using the XLSTAT statistical software for Excel.

DEFINITION OF VARIABLES*:*

* The **variables** that we are going to measure in all patients, which are reflected in the data collection table (Annex 1), by applying the EPi Info software will be:
	+ Age
	+ Sex
	+ Weight
	+ Height
	+ Body mass index
	+ Abdominal circumference (at the level of the navel)
	+ Neck circumference (using a flexible tape around the most prominent part, while the patient is standing, with their arms lowered to the sides, head erect and eyes looking ahead)
	+ IOPI measurement of tongue strength and buccinator muscle
	+ AHI
	+ Night-time oxygen desaturation index
	+ Lower oxygen saturation figures overnight
	+ Digital spoon measurement of tongue strength
	+ OMES protocol
* A series of **questionnaires** will be applied to both groups: Friedman Staging System (Annex 1); Epworth Sleepiness Scale (Annex 2); Pittsburgh Sleep Quality Index (Annex 3).

PROCEDURES:

A myofunctional evaluation of the patient diagnosed with OSAHS will be conducted in the same week as the polysomnography is performed. During this evaluation, patients are blindly examined by a speech therapist and their examination is recorded on video for later evaluation.

The patient will sit one metre away from the camera with their feet flat on the floor and their back supported by the backrest. The camera (Sony CCD-TRV138 Handycam camcorder: Sony Electronics, San Diego, CA 92127, USA) will be placed on a tripod at face and shoulder height.

The evaluation with the OMES protocol (Annex 4) will then take place, based on the analysis of the following parameters:

1. Appearance/posture
2. Mobility
3. Functions
	1. Respiration
	2. Deglutition
	3. Mastication

As a result of this evaluation with the already validated protocol, the higher the score, the more normal the patient's stomatognathic system.

Subsequently, the muscle tone of the genioglossus muscle and the buccinator muscle are evaluated, taking three measurements of each one and using the highest value.

Finally, the tone of the tongue muscles is measured with the digital spoon, taking three measurements and using the highest one.

The recordings and the data obtained will also be blindly analysed by another examiner.

DISTRIBUTION OF HOSPITAL VISITS:

Visits during the study are distributed as follows:

* SELECTION VISIT: The patient diagnosed with OSAHS at a pulmonology laboratory by means of an initial sleep study (with measurement of baseline AHI, night-time oxygen desaturation index and the lowest night-time oxygen saturation figures) is evaluated vis-à-vis the inclusion and exclusion criteria and then informed about the study. After reading the information and having any doubts solved, the patient accepts and signs the IC form in duplicate, taking one copy home.
* ONE-OFF VISIT: The patient is evaluated by the speech therapist and fills in the sleepiness questionnaires, following which the OMES protocol is applied and the evaluation is carried out with the IOPI and the digital spoon.

DATA COLLECTION AND STATISTICAL ANALYSIS:

The data of the study variables will be collected in a database created for the development of the study. In the statistical analysis, the sample will be described through the distribution of frequencies for the categorical variables, and through measures of central tendency and dispersion, such as the mean (standard deviation) and median (interquartile range) for the quantitative variables. The distribution of quantitative variables will be examined using the Kolmogorov-Smirnov Test. The bivariate study of the association between categorical variables will be carried out using the Chi-Square Test or Fisher's Test when necessary. The differences between quantitative variables will be analysed using the Student's T-Test or ANOVA (for two or more samples, respectively), and non-parametric tests (Mann-Whitney or Kruskal-Wallis) will be used if the variables to be analysed do not follow the normal distribution. The possible correlation between the OMES protocol evaluation and the IOPI values and the digital spoon will be made using the Spearman's Rank correlation coefficient. The consistency and stability of the intra- and inter-rater measurements (reliability coefficient) will be determined using the split-half method. The level of statistical significance will be set at p <0.05.

ETHICAL ASPECTS:

The Research Ethics Committee of the Hospital Provincial de Málaga will review and approve the protocol and the informed consent model for the patient before the study begins. Before performing any of the procedures specified in the study protocol, the participating subject will have signed and dated the informed consent form approved by the Research Ethics Committee.

Access to data and protection of data obtained from the study:

In order to guarantee the confidentiality of the study data, the original data will be stored at the hospital and only researchers and the Research Ethics Committee will have access to it.

This project will be carried out following the guidelines of the Declaration of Helsinki (Fortaleza, 2013) (22) and the Standards of Good Clinical Practice. Personal data will be processed according to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and Organic Law 3/2018 of 5 December on the protection of personal data and guarantee of digital rights.

USEFULNESS AND APPLICABILITY:

The selection criteria could improve with regard to which therapy is more suitable for patients with OSAHS.

WORK PLAN:

The first month, after approval of the study by the Research Ethics Committee, will be dedicated to launching the study, designing the database and coordinating the research team (COR, JMIG, FJGS). Patient evaluation will be carried out by (SA and PFB). The following months will be required to recruit the patients, collect the study variables and input the data into the database (JCM, FBF, VCG and ERR). The statistical analysis of the results will be carried out upon completing the recruitment of the last patient, after which the conclusions will be drafted and the results obtained will be published (communications to national and international conferences, writing and publication of manuscripts in scientific journals) (Entire team).

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Activity (months) | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Launch, database design and coordination |  |  |  |  |  |  |  |  |  |  |  |  |
| Recruitment |  |  |  |  |  |  |  |  |  |  |  |  |
| Data collection and input into databases |  |  |  |  |  |  |  |  |  |  |  |  |
| Statistical analysis and publication of results |  |  |  |  |  |  |  |  |  |  |  |  |

COMMUNICATION PLAN:

After analysing the results obtained, they will be published by sending communications to regional, national and international congresses on otorhinolaryngology, sleep and pulmonology. Manuscripts will be drawn up for submission to national and international scientific journals in the field of otorhinolaryngology and pulmonology.

BUDGET:

The research project will be developed with resources provided by the research team and the participating hospitals. The use of the app will be free for patients participating in the study. This research project does not have external funding.

RESEARCH TEAM:

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Annex 1: Friedman Staging System