PROTOCOL TITLE: The efficacy of a new mathematical formula to predict continuous positive air pressure with an oronasal mask interface.

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none

BACKGROUND

Continuous positive airway pressure (CPAP) is the most effective treatment for obstructive sleep apnea (OSA). Untreated apnea is associated with a variety of health problems including congestive heart failure, stroke, pulmonary and systemic hypertension, cancer, and mortality. The current "gold standard" of diagnosis and treatment for OSA includes an in-laboratory diagnostic polysomnogram, followed by a second polysomnogram to titrate the appropriate CPAP, if significant OSA is detected on the baseline study.

Due to the expense of two laboratory studies, and the inconvenience to patients of coming into the laboratory twice, several groups have attempted to develop predictive models determining pressure requirement based on a diagnostic polysomnogram and anthropometric measures alone, avoiding the need for a laboratory CPAP titration study. The previously published models generally use measures from the baseline polysomnogram, such as the number of respiratory events and various oxygen parameters; most models have also added physiological characteristics of the patient, such as (but not limited to) neck size and body mass index (BMI).

STUDY DESIGN

Subjects will currently have a moderate to severe Apnea-hypopnea index (AHI)

The Apnea-Hypopnea Index or Apnoea-Hypopnoea Index (AHI- is an index used to indicate the severity of sleep apnea. It is represented by the number of apnea and hypopnea events per hour of sleep). (above 15) *Scoring of apneas - Score a respiratory event as an apnea when BOTH of the following criteria are met: N1, N2, N3, N4 a) There is a drop in the peak signal excursion by GREATER-THAN OR EQUAL TO 90% of pre-event baseline using an oronasal thermal sensor (diagnostic study), PAP device flow (titration study) or an alternative apnea sensor (diagnostic study) b) The duration of the GREATER-THAN OR EQUAL TO 90% drop in sensor signal is GREATER-THAN OR EQUAL TO 10 seconds. Score an apnea as obstructive if it meets apnea criteria and is associated with absent inspiratory effort throughout the entire period of absent airflow. Score an apnea as central if it meets apnea criteria and is associated with absent inspiratory effort throughout the entire period of absent airflow. Score an apnea as mixed if it meets apnea criteria and is associated with absent inspiratory effort in the initial portion of the event, followed by resumption of inspiratory effort in the second portion of the event. N4 Note 1 - Identification of an apnea does not require a minimum desaturation criterion. Note 2 - If a portion of a respiratory event that would otherwise meet criteria for a hypopnea meets criteria for apnea, the entire event should be scored an apnea. Note 3

- If the apnea or hypopnea event begins or ends during an epoch that is scored as sleep, then the corresponding respiratory event can be scored and included in the computation of the apnea hypopnea index (AHI). This situation usually happens when an individual; has a high AHI with events occurring so frequently that sleep is severely disrupted, and epochs may end up being scored as wake even though less-than 15 seconds of sleep is present during the epoch containing that portion of the respiratory event. However, if the apnea or hypopnea occurs entirely during an epoch scored as wake, it should not be scored or counted towards the apnea hypopnea index because of the difficultly of defining a denominator in this situation. If these occurrences are a prominent feature of the polysomnogram and/or interfere with sleep onset, their presence should be mentioned in the narrative summary in the study. Note 4 - For alternative apnea sensors see tech specifications for Adults. There is not sufficient

evidence to support a specific durations of the central and obstructive components of a mixed apnea thus specific durations of these components are not recommended. *AASM 2015 PROTOCOL Scoring of Hypopneas Score a respiratory event as a hypopnea if all of the following criteria are met. N1, N2, N3. a) The peak signal excursions drop by GREATER-THAN OR EQUAL TO 30% of pre-event baseline using nasal pressure (diagnostic study), PAP device flow (titration study), or an alternative hypopnea sensor (diagnostic study). b) The duration of the GREATER-THAN OR EQUAL TO 30% drop in signal excursion is Greater-Than Or Equal To 10 seconds. c) There is a GREATER-THAN OR EQUAL TO 3% oxygen desaturation from pre-event baseline or the event is associated with an arousal. Subjects once consented and entered into the study, will all have a two-week baseline period in which they will use a nasal mask using an Airsense cpap machine (which records all data). After the two-week period all will switch to a full-face mask with half using the same CPAP pressure and half with a new cpap pressure derived from our formula for the final two weeks. Those placed in the randomized into a new pressure will have an experimental procedure of getting a new pressure.

Primary Objective:

We are testing the efficacy of an algorithm we previously created to adjust continuous positive airway pressure when a mask interface is switched from a nasal to a full face. Our previous studies show that patients using full face masks require more pressure than nasal masks. Based on our clinical experience we think a difference between nasal and full-face mask of 5 events per hour would be clinically significant.

Statistical Considerations:

30 subjects will be recruited at WCMC. 30 subjects will be recruited at all sites. The data will be collected via the machine or via cloud. The main outcome will be AHI, other outcomes with be lowest oxyhemoglobin saturation, (Lowest Sa02). We will compare the AHI of subjects with the formula in place vs. those that don't have the formula. Based on an expected effect size of 1.02 with a two-tailed Alpha=0.05 and a Beta=0.20 using a t-test for independent samples we will need 30-subjects to find a significant difference between treatment and control groups (15-subjects for each group). Our power calculation was based on an anticipated difference between groups of 5 events per hour.

INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria:

Patients will all be recruited at the Weill Cornell Medicine Center for Sleep Medicine.

a. Above 18 years old.

b. AHI above 15.

c. Willing to switch to full face mask post titration.

d. Not currently on a weight loss plan and no intention of beginning a weight loss regimen during the duration of the study

Exclusion Criteria:

a. Younger than 18 years old.

b. AHI below15.

c. Not willing to switch to full face mask post titration. d. Currently on a weight loss plan and / or intention of beginning a weight loss regimen during the duration of the study.

DATA AND SAFETY MONITORING PLAN

Will you be using a medical monitor? *No*

Please justify why no monitor is being used. *Data and safety will be monitored by the PI, via usage data of CPAP machines.*

Will interim analysis be performed? *Yes*

Please specify at what intervals the interim analysis will be performed. *Data will be entered into a database and reviewed on an ongoing basis.*

Please specify to whom the data will be reported. *The data will be reported to the PI.*

Will you be utilizing a Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC)? *No*

Please justify why no DSMB will be utilized. *Data will be monitored and kept by PI.*

Does this study involve the administration of an FDA regulated product, Nutritional supplement or a biological product? *No*