New Screening Questionnaire to Assess Obstructive Sleep Apnea in a Population Attending a Multidisciplinary Craniofacial Pain Center

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Abstract

Purpose:
The objective of this research study was to propose a new screening questionnaire to assess obstructive sleep apnea (OSA) in a group of subjects attending a multidisciplinary Craniofacial Pain Center.

Methods:
This was a cross-sectional clinical study designed to evaluate the use of a new screening questionnaire (NQ) consisting of 15 items based on literature and standard of care clinical evaluation at a multidisciplinary craniofacial pain center in a dental school. The new questionnaire was compared with a supplemental questionnaire (SQ) previously validated (*"STOP"* questionnaire). Cross tabulation, sensitivity, specificity, positive and negative predictive values were obtained with standard methods, comparing the questionnaires to the results from at-home sleep studies using a portable sleep monitor which determined the presence of obstructive sleep apnea based on the apnea hyponea index (AHI) and respiratory disturbance index (RDI). The Cronbach alpha was calculated for each questionnaire as a measurement of internal reliability.

Results:
The NQ was administered to 50 subjects. 70% were women. The study population had a mean age of 46.1 years (SD 12.0), mean body weight mean of 163.0 pounds (SD 36.0), mean BMI of 27 (SD 6.0), and mean neck size of 15.0 inches (SD 2.0). Home sleep study was performed and the presence of OSA was defined based on both AHI and RDI, using a cutoff of 5. According to AHI, 54% of the subjects were identified as having OSA; according to RDI, 88% were identified as having OSA. Three items from the NQ 4,7,13showed statistical significant associations ($P \leq .005$) with AHI-defined OSA. No items were statistically significantly associated with RDI-defined OSA.

Conclusions:
The findings from this study showed statistical significant value from three items on screening for obstructive sleep apnea. These items may be useful when combined with the supplemental questionnaire to create a new modified screening questionnaire to identify subjects at risk of obstructive sleep apnea.

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Introduction

Obstructive Sleep Apnea (OSA) is a condition characterized by repetitive episodes of upper airway obstruction that occur during sleep, often resulting in reduction of blood oxygen saturation and arousals from sleep. It is a phenomenon during which a person stops breathing for more than ten seconds during their sleep due to airway collapsibility. [1] Sleep apnea is classified as apnea of obstructive origin and apnea of central origin, which is characterized by recurrent episodes of apnea during sleep resulting from temporary loss of inspiratory effort. The term central sleep apnea is used to describe both the pattern of an individual event and the clinical disorder characterized by repeated episodes of apnea during sleep resulting from the temporary loss of ventilatory effort.[2, 3] Central apneas are defined as pauses in breathing without ventilatory effort, a complete loss of electromyographic activity of the respiratory muscles during an apnea would be expected. [4] Our research investigation focuses on sleep apnea of obstructive origin.

Obstructive sleep apnea is a common disease that is largely under-diagnosed and untreated with significant implications for cardiovascular disease,[5] mortality,[6] and economic impact.[7] Population-based epidemiological studies have estimated the prevalence and severity spectrum of undiagnosed obstructive sleep apnea, and have found that even mild obstructive sleep apnea is associated with significant morbidity. [8]

Classification and Characteristics of Obstructive sleep apnea

In 2005 the American Academy of Sleep Medicine (AASM) the leading professional academy of Sleep in the United States, published a revised form of the International Classification of Sleep Disorders (ICSD-2). [9] The Goals of the ICSD-2 are to describe all currently recognized sleep and arousal disorders, and to base the descriptions on scientific and clinical evidence. The international classification lists eighty-five sleep disorders, listing obstructive sleep apnea under the category of sleep-related breathing. [9]

Obstructive sleep apnea is associated with snoring, which represents near collapse of the upper airway, high resistance to airflow, and rapid vibration of the soft tissues of the airway. An apnea event is characterized by a complete collapse of the upper airway for at least 10 seconds with persistent effort to breathe; an hypopnea event is characterized by a partial collapse of the upper airway during sleep, defined as a 30% or greater reduction in airflow and a 4% desaturation. [10] The severity of obstructive sleep apnea is measured by the apnea-hypopnea index (AHI), obtained by counting the total number of apneas and hypopneas during sleep and dividing that by hours of sleep. An AHI lower than five events per hour of sleep is normal, an AHI of five to fifteen events per hour of sleep indicates mild OSA, an AHI of fifteen to thirty events per hour of sleep indicates moderate OSA, and an AHI greater than thirty events per hour of sleep indicates severe OSA.[1]

Pathophysiology of Airway Control

One key feature of sleep is suppression of upper airway muscle activity; sleep-related decreases in upper airway dilator muscle force is thought to lead to pharyngeal narrowing or closure in patients with obstructive sleep apnea.[11-13] In humans, the upper airway from the posterior end of the nasal septum to the epiglottis, has relatively little bony support. The pathophysiology leading to pharyngeal collapse involves a combination of anatomic and physiologic influences that tend to collapse the upper airway. [14] The pharyngeal airway is a collapsible tube that depends on transmural pressure across the pharyngeal wall for its patency. The forces necessary to maintain an adequate upper pharyngeal patency or collapse the upper airway are intraluminal pressure and extraluminal pressure, respectively. Intraluminal pressure is negative pressure generated by the diaphragm during inspiration and extraluminal pressure results from gravitational force acting on the tissues and bony structures surrounding the airway. [15-17] The above information helps to understand the way upper airway function and possibly identify the areas with more propensity to upper airway collapsibility.

Intraluminal pressure will inherently reduce airway patency during each inspiration. The diaphragmatically generated negative pressure diminishes airway size depending on the muscle function of the airway walls and opposing dilating forces. The airway pressure required to collapse the pharyngeal airway has been described by the critical closing pressure (Pcrit), a concept developed by Schwartz and colleagues. [18, 19] To examine the relationship between Pcrit and the development of upper airway occlusion, Schwartz and colleagues examined the relationship between maximal inspiratory airflow and nasal pressure. At varying levels of

subatmospheric pressure applied to a nasal mask during sleep, maximal inspiratory airflow decreased in proportion to the level of nasal pressure. When nasal pressure fell below a Pcrit, subjects demonstrated upper airway occlusion terminated by arousals from sleep. Critical closing pressure is not a product of hypopharyngeal pressure but rather the pressure generated by respiratory muscles that can reduce upper airway size, but generally not collapse the airway. [18, 19]

Subatmospheric intraluminal pressure is the most widely accepted theory of upper airway obstruction during sleep. According to the balance of forces theory, upper airway obstruction occurs when the collapsing intraluminal pressure generated by the thoracic muscles exceeds the dilating of stiffening forces generated by upper airway dilators muscles. This is based on the landmark study by Remmers *et al*.,[14] showing that obstructive apnea occurs when genioglossus muscle activity decreases and negative pressure continues to be generated. The previous information helps to understand how the intraluminal pressure tends to have an effect on the upper airway by creating negative forces from the diaphragmatic muscles.

Extraluminal pressure also increases transmural pressure and promotes obstruction of the upper airway; examples of collapsing extraluminal pressure include passive gravitational forces generated by the craniofacial structures or adipose tissue surrounding the upper airway.[20-23] The occurrence of complete upper airway obstruction in the absence of negative intraluminal pressure suggests that the upper airway collapsed due to extrinsic pressure. Isono *et al*.,[24] compared the mechanism of the pharynx of anesthetized, paralyzed normal subjects and patients with obstructive sleep apnea. The pharynx was maintained at atmospheric intraluminal pressure in

normal subjects and required negative intraluminal pressure for closure. In contrast, patients with obstructive sleep apnea demonstrated positive closing pressure (the pharynx was closed at atmospheric intraluminal pressure) thus the surrounding extraluminal pressure might induce upper airway obstruction during sleep. The extraluminal forces explain how external pressure and gravity influence the upper airway patency. There are several anatomical and physiological factors that promote the occurrence of episodes of obstructive apnea during sleep. In addition to the above, there are several local anatomical abnormalities such as decrease of activation of the autonomous nervous system, obesity, and central nervous system depression from alcohol or drug consumption. [25] The previous information helps to clarify the influence of muscle relaxation and gravitational forces against the upper airway.

Sleep apnea of obstructive origin

Obstructive sleep apnea is characterized by recurrent episodes of partial or complete upper airway obstruction during sleep. This manifests as a reduction in or complete cessation of airflow despite ongoing inspiratory efforts. The lack of adequate alveolar ventilation usually results in oxygen desaturation. The events are often terminated by arousals. The most common daytime symptom of obstructive sleep apnea is excessive sleepiness that is thought to be related to sleep disruption and possibly to recurrent hypoxemia. [26, 27]

Patients may demonstrate a lack of respiratory effort during the initial apnea period followed by gradually increasing effort against an occluded upper airway. [1] The first knowing description of

obstructive sleep apnea in the literature is attributed to W.H. Broadbent, a London physician, who first described obstructive sleep apnea in 1877. [28]

Prevalence of Obstructive Sleep Apnea

Population-based epidemiological studies have estimated a high prevalence and wide severity spectrum of obstructive sleep apnea. Data from the Wisconsin Sleep Cohort Study, a longitudinal study of the natural history of cardiopulmonary disorders of sleep were used to estimate the prevalence of undiagnosed sleep-disordered breathing among adults. [29] A random sample of 602 employed men and women aged 30 to 60 years was studied by overnight polysomnography to determine the frequency of episodes of apnea and hypopnea per hour of sleep. The study measured age and sex-specific prevalence of sleep disordered breathing using three cutoff points for the apnea-hypopnea score (> 5, >10, and >15). The estimated prevalence of sleep-disordered breathing, defined as an apnea-hypopnea score of 5 or higher, was 9% for women and 24% percent for men. It was estimated that 2% of women and 4% of men in the middle-aged work force met the minimal diagnostic criteria for the sleep apnea.

Edward *et al*., [30] found results showing the prevalence of sleep apnea in women to be 1.2%, and 3.9% in men.I In the first phase of their study, a sample of adult women (age > 20 years) was randomly selected from telephone households in two counties of southern Pennsylvania (Dauphin and Lebanon). Telephone households were selected using the Mitofsky-Waksberg two-stage random digit dialing procedure, excluding households previously evaluated in the study of

men. Telephone interviews were conducted with 12,219 age-eligible women residing in the sample households. The questionnaire used in this interview included basic demographic information as well as questions assessing the five risk factors for sleep apnea (snoring, daytime sleepiness, obesity, hypertension, and menopause). In the second phase of the study, a random sample from the 12,219 women previously interviewed by telephone was selected for study in a sleep laboratory to assess the presence of sleep apnea.

Davies and Stradling analyzed 12 studies of Obstructive Sleep Apnea prevalence in Western populations and, using conservative approaches to account for methodological differences, estimated that 1% to 5% of adult men have Obstructive Sleep Apnea syndrome. [31] The 2005 National Sleep Foundation poll, which included 1,506 adults (775 women) with a mean age of 49 years, showed that one in four individuals of a representative sample of US adults are at risk to develop Obstructive Sleep Apnea, 9% of women and 24% of men had an Apnea hypopnea index of >5 events per hour, and 44% of men 28% of women were habitual snorers. [32] The risk of significant sleep-disordered breathing rises both with BMI [33] and with age. [8] The previous information shows the importance of identifying this medical condition through screening and diagnostic methods.

Medical Comorbidities of Untreated Obstructive Sleep Apnea

Obstructive Sleep Apnea and Hypertension

The idea of obstructive sleep apnea as an independent risk factor for hypertension has always been controversial because of multiple confounding variables for hypertension that are usually

also characteristic of patients with obstructive sleep apnea, such as age, gender, body mass index, alcohol use and smoking.

Nieto *et al,*. assessing the association of sleep disordered breathing, sleep apnea, and hypertension in a large cohort of middle-aged and older persons, using a cross sectional analyses of participants from the sleep heart health study, a community based multicenter study conducted between November 1995 and January 1988 with a total of 6132 subjects recruited from ongoing population-based studies aged >_40 years; 52.8% of females with the main outcome of apnea hypopnea index obtained by unattended home polysomnography, and presence of hypertension, defined as resting blood pressure of at least 140/90 mm Hg or use of antihypertensive medication; the results showed a mean systolic and diastolic blood pressure and prevalence of hypertension increased significantly with increasing sleep disordered breathing measures. After adjusting for BMI, neck circumference, waist-to –hip ratio, alcohol intake, and smoking, the odds for hypertension, comparing the highest category of apnea hypopnea index (>_ 30 events per hour) and the lowest category (<1.5 events per hour), was 1.37 (95% confidence interval 1.03-1.83; p for trend= .005. In stratified analyses, associations of hypertension with either measure of sleep-disordered breathing were seen in both genders, older and younger ages, all ethnic groups, and among normal-weight individuals. Weaker and non-significant associations were observed for self-reported history of habitual snoring. [34]

George et al. published a prospective cohort study in 2009. The study analyzed data from 2,470 participants who at baseline did not have hypertension (defined as blood pressure of at least 140/90 mm Hg or taking antihypertensive medication). The apnea hypopnea index was measured

by overnight in-home polysomnography. The study estimated odds ratios of developing hypertension during 5 years of follow up according to baseline apnea hypopnea index. The odds ratios for incident hypertension increased with increasing baseline apnea hypopnea index; this relationship was attenuated and not statistically significant after adjustment for baseline body-mass index. Although not statistically significant, the observed association between a baseline apnea hypopnea index greater than 30 and future hypertension (odds ratio: 1.51, 95% confidence interval: 0.93-2.47) does not excluded the possibility of a modest association. The authors of this study concluded that, among middle-aged and older persons without hypertension, much of the relationship between apnea hypopnea index and risk of incidence hypertension was accounted for by obesity. After adjustment for body mass index, the apnea hypopnea index was not a significant predictor of future hypertension. [35] These studies demonstrate the controversy of the association between OSA and hypertension. Future research is needed to clarify these controversies.

Obstructive Sleep Apnea and Cardiovascular Disease

There is a growing research evidence for an independent association between obstructive sleep apnea and cardiovascular disease. Peker, Y *et al*., [36] explored the incidence of cardiovascular disease in subjects with and without obstructive sleep apnea utilizing a consecutive sleep clinic cohort of 182 middle-aged men (mean age 46.8) with and without obstructive sleep apnea. All subjects were free of hypertension or other cardiovascular disease, pulmonary disease, diabetes mellitus, psychiatric disorders, alcohol dependency, as well as malignancy at baseline. Data were collected via the Swedish hospital discharge register covering a seven-year period before

December 31 1998, as well as questionnaires. Effectiveness of obstructive sleep apnea treatment initiated during the period as well as age, BMI, systolic and diastolic blood pressure at baseline, and smoking habits were controlled for; the study concluded that the risk of developing cardiovascular disease is increased in middle-aged obstructive sleep apnea subjects independently of age, BMI, smoking, and systolic and diastolic blood pressure. This study showed a significant correlation between cardiovascular disease and OSA, and differs from the studies done to identify the association between hypertension and OSA.

Obstructive Sleep Apnea and Diabetes

Sleep-disordered breathing is commonly found in patients with type two diabetes. West et al., [37] in a study published in 2006, conducted a study to estimate the prevalence of obstructive sleep apnea in men with type two diabetes. Men with type two diabetes from local hospital and selected primary care practitioner databases, received questionnaires about snoring, apnoeas, and daytime sleepiness based on the Berlin questionnaire. Selected respondents had oximetry to establish whether they had obstructive sleep apnea. 1682 men were sent questionnaires and 56% replied. 57% scored as high risk and 39% as low risk for obstructive sleep apnea, results were verified by detailed sleep studies. BMI and diabetes were significant independent predictors of obstructive sleep apnea. The authors concluded that obstructive sleep apnea is highly prevalent in men with type 2 diabetes, most are undiagnosed and diabetes itself may be a significant independent contributor to the risk of obstructive sleep apnea.

A report from the International Diabetes Federation task force on epidemiology and prevention

of diabetes, published in 1998, [38] strongly recommends that health professionals working in type two diabetes and sleep disordered breathing adopt clinical practices to ensure that a patient presenting with one condition is considered for the other.

Babu et al., [39] in a study published in 2005, studied changes in interstitial glucose levels and measured hemoglobin levels in 25 patients with type 2 diabetes using a 72-hour continuous glucose monitoring system, before and after continuous positive airway pressure (CPAP) treatment for sleep disordered breathing. Their results showed a reduction on postprandial glucose values at breakfast and dinner with CPAP treatment; in subjects who used CPAP for more than 4 hours per night, the reduction in hemoglobin was significantly correlated with days of CPAP use. There was no such correlation in subjects who used CPAP for 4 hours or less per day. Their findings suggested that sleep disordered breathing is pathophysiologically related to impaired glucose homeostasis, and that CPAP can be an important therapeutic approach for diabetic patients with sleep disordered breathing. The evidence of an association between diabetes and obstructive sleep apnea emphasizes the need for increased awareness of screening for obstructive sleep apnea in patients reporting the presence of diabetes attending medical or dental settings.

Obstructive Sleep Apnea and Erectile Dysfunction

Erectile Dysfunction (ED) has been mentioned as a symptom of obstructive sleep apnea syndrome as early as 1977, and has been reported since then by others. [42, 44, 46] Erectile dysfunction (ED) is age related, specially it is common in men between 50 and 75 years old, [40] and is also common in men with chronic diseases like diabetes mellitus. [41] Guilleminault et al.

[42] were the first to report ED ejaculatory problems or low libido in men with obstructive sleep apnea, they estimate that 48% of men with obstructive sleep apneas have these problems. Schmidt *et al*. [43] were the first to identify sleep apnea in patients presenting with erectile dysfunction. The prevalence of obstructive sleep apnea in erectile dysfunction patients was confirmed by Pressman *et al*. [44] who diagnosed sleep apnea in nine out of 31 (29%) patients presenting with impotence.

Erection occurs after sexual stimulation by an increase in parasympathetic activity that leads to a release of neurotransmitters from the cavernous nerve terminals and relaxing factors from the endothelial cells of the penile vasculature. [45] This results in smooth muscle relaxation in the arteries and arterioles supplying the erectile tissue and a several-fold increased in blood flow to the penis. Penile venous outflow is simultaneously occluded by a venous compression mechanism, maintained by the penile tunica albuginea. Smooth muscle relaxation is brought about by the release of nitride oxide (NO) from both the endothelial cells and neural tissue supplying the corpora cavernosum. The endothelial dysfunction present in people with sleep apnea makes it difficult the production/ liberation of nitric oxide, resulting damage in the relaxation of the trabecular smooth muscle of the cavernosum corpus, resulting in erectile dysfunction.

Goncalves *et al*. [47] evaluated the effect of one month of continuous positive pressure (CPAP) in a subgroup of obstructive sleep apnea patients with erectile dysfunction and compared this subgroup with age- and BMI-matched OSA patients without erectile dysfunction. Their study

concluded that erectile dysfunction in obstructive sleep apnea is related to nocturnal hypoxemia, and about 75% of obstructive sleep apnea patients with erectile dysfunction treated with nasal CPAP showed remission of their ED at one-month follow up, resulting in significant improvement in quality of life.

Obstructive Sleep Apnea and Mortality

Evidence is increasing that sleep apnea poses an independent risk for death, particularly from cardiovascular disease. Campos-Rodriguez *et al*. [48] performed an historical cohort study of 871 patients in whom obstructive sleep apnea had been diagnosed by sleep study between 1994 and 2000, and who had been treated with positive air pressure therapy. Patients were followed up until 2001, the mean age was 55.4, the mean apnea hypopnea index was was 55.1, and 80.9% were men. To assess whether mortality was influenced by positive air pressure therapy compliance, patients were assigned to one of the following categories: < 1 hour per day; 1-6 hours per day; or > 6 hours per day. By the end of the follow up period (mean duration 48.5 months), 46 patients died. The five year cumulative survival rates were significantly lower in patients who did not use positive air pressure (compliance <1 hour) than in those who used the positive air pressure device for >6 hours per day. The study concluded that mortality rates in obstructive sleep apnea patients who did not receive positive air pressure therapy were higher compared with those treated with positive air pressure and were moderately or highly compliant with therapy. A trend in survival across compliance categories was found. Patients died mainly from cardiovascular disease. Based on this study, it is celar that it is important to identify the possible presence of obstructive sleep apnea in order to decrease mortality due to undiagnosed OSA.

Clinical manifestations of obstructive sleep apnea

The clinical manifestations of obstructive sleep apnea most commonly reported are excessive daytime sleepiness, snoring, and gastro esophageal reflux. [49]

Obstructive sleep apnea and daytime sleepiness

Daytime sleepiness is one of the most common clinical manifestations of obstructive sleep apnea. Normal sleep fulfills a restorative function and is characterized by a pattern of four sleep cycles during sleep period. The two main categories of sleep include rapid eye movement (REM) and non-rapid eye movement (NREM) sleep. [50] NREM sleep accounts for 75% of total sleep time, and consists of sleep stages one to three. Stages one and two are characterized by a relatively low arousal threshold. Obstructive sleep apnea is usually associated with disturbed sleep architecture, in particular an increase in the quantity and proportion of stage one and two sleep. Stage three sleep is characterized by high amplitude slow electrical brain waves seen on electroencephalograms and a reduction in muscle tone. A reduction in the quality of stage three sleep is typically associated with tiredness and impaired daytime performance. Regulation of autonomic functions, such as temperature, heart rate, blood pressure, upper airway stability, become unstable, even in healthy subjects during REM. Twenty to twenty five percent of the total sleep time is normally spent in REM-sleep. Upper airway obstruction during sleep induces central nervous activation, the so-called arousal, which is usually not noticed by the patient. The more severe the sleep fragmentation, the more likely that daytime sleepiness will be reported by the sleep apnea patient. As the apnea index increases, the amount of REM sleep and the amount

of stage three sleep decreases. This effect is disproportionate, in that stage three NREM sleep maybe totally absent in severe obstructive sleep apnea. [51-53] This information showed the importance of getting a good quality of sleep by getting into all different stages of sleep without interruption to achieve a restful night that will reflect in a better daytime performance the following day.

Obstructive sleep apnea and snoring

Almost all sleep apnea patients snore and their snoring can be extremely loud. A characteristic pattern in sleep apnea is that of loud snoring or brief gasps that alternate with episodes of silence typically lasting 20 to 30 seconds; the complaint of snoring precedes the complaint of daytime sleepiness, and the intensity increases with weight gain and bedtime alcohol intake. [2, 54] A study published in 2009 by Berger et al. [55] examined the natural evolution of primary snoring and obstructive sleep apnea in adult male patients. The authors performed a retrospective analysis of 160 untreated patients with primary snoring and mild, moderate, and severe obstructive sleep apnea who had polysomnographic recordings. The mean time between recordings was 5.1 years (SD: 3). The mean apnea hypopnea index, mean BMI, and lowest arterial oxygen saturation level during rapid eye movement sleep and non-rapid eye movement sleep showed a significant increase in the apnea hypopnea index for primary snoring, mild and moderate obstructive sleep apnea and an insignificant decrease for severe obstructive sleep apnea patients. Stepwise linear regression showed that only BMI and time were significant predictors for apnea hypopnea index change. After adjusting for confounders, multiple regression analysis indicated that age and high

BMI, but not AHI, were significant risk factors for developing hypertension and/or cardiovascular disease. Patients with primary snoring and mild and moderate obstructive sleep apnea had a similar increase in the apnea hypopnea index over time, which depended mainly on weight gain and to a lesser extent, on time. The crucial role of weight gain on the progression of snoring and obstructive sleep apnea shown in the present study in patients is very similar to most of the previous studies that have investigated the evolution of snoring and obstructive sleep apnea in the general population. Thus it is important for the clinician who treats sleep apnea patients to monitor significant clinical symptoms associated with increase in body weight.

Obstructive sleep apnea and gastro esophageal reflux

Gastro esophageal reflux is another frequently observed symptom among patients with sleep apnea. Increased breathing efforts during periods of apnea increase intra-abdominal pressures while making the intra-thoracic pressures more negative. Reflux results when an increased gradient between intra-abdominal and intra-thoracic pressures favors the movement of gastric contents into the esophagus. [56] While reviewing the medical history of patients with a complaint of GERD in medical and dental settings, it is important to screen for obstructive sleep apnea.

Anatomical features increasing the risk of developing Obstructive Sleep Apnea

Clinical examination and radiographic analysis using panoramic and cephalometric studies, computerized tomography, and magnetic resonance imaging have demonstrated that there are many skeletal and soft-tissue structural differences between individuals with and without OSA.

[57] Retro positioning of the tongue is one of the most common features of patients with OSA, the dimension of pharyngeal lumen and the elongation of the uvula and soft palatal draping also seem to play important roles in the partial or complete obstruction of the upper airway. Other anatomical features common to those with obstructive sleep apnea may include maxillo-mandibular retrognathism, receded chin, inferiorly positioned hyoid bone, tonsillar hypertrophy, deviated septum, nasal polyp, and enlarged nasal turbinates. Fatty deposits in the neck and the pharyngeal airway space and the thickness of pharyngeal muscles are additional factors that decrease posterior airway space, narrowing upper airway dimensions, and promoting apnea during sleep [58-66]. Most of these anatomical and radiographic features are possible to identify in dental settings during routins oral exams.

Maxillo-Mandibular Relationships and their effect on upper airway

Anatomic factors such as structural abnormalities in the hard and soft tissues of maxillofacial structures may lead to an increased anatomic upper airway compromise. Maxillo-mandibular harmony is a product of many structural considerations and physiological processes. To achieve a stable maxillo-mandibular relationship, there must be a confluence of balanced muscle action, proper temporomandibular joint position, and distributed guiding contacts of teeth in the closing stroke. Maxillo-mandibular imbalance appears to have a direct relationship with masticatory musculature. Imbalances in the masticatory musculature may affect the postural muscles of the head, and neck and possibly the upper airway. *Mehta et al.* described the ˙The occlusal fencing conceptî whereby the maxilla acts as a "fence" for the mandibular teeth. If the maxilla is constricted, then the mandibular teeth will crowd to accommodate to the space allowed by the maxillary teeth, creating a retrusive position of the lower jaw and increasing the risk for the

narrowing of the upper airway. [67]

Diagnosis of obstructive sleep apnea

The gold standard for the diagnosis of OSA is a laboratory- based overnight polysomnography (PSG) commonly known as a sleep study performed at a hospital based sleep center, this consists of the continuous recording of multiple electro-physiologic and respiratory channels during sleep including brain activity, heart and pulse rate, respiratory airflow, thoracic-abdominal effort, oxygen saturation, legs movement, body position, and snoring . [68-70] The high prevalence of sleep disorders and the increasing recognition of their importance in clinical practice has led to a remarkable increase in the demand for polysomnography services over the recent years. Due to this increase on demand, a variety of portable sleep monitoring devices have been developed and validated against the gold standard polysomnography that allow sleep studies to be performed in the patient's home. [71, 72]

The term portable monitoring encompasses a wide range of devices that can record as many signals as does attended polysomnography or only one signal, such as oximetry. Portable monitoring devices are widely used in locations where patient access to attended laboratory polysomnography is limited or non-existent. Home ambulatory sleep study devices have been used for screening and diagnosis of OSA. [73, 74] The American Academy of Sleep Medicine published guidelines for the use of portable monitors in the diagnosis of obstructive sleep apnea in adult patients, [73] their recommendations are that unattended portable monitoring for the diagnosis of obstructive sleep apnea should be performed only in conjunction with a

comprehensive sleep evaluation. Portable monitoring may be used as an alternative to polysomnography for the diagnosis of obstructive sleep apnea in patients with a high pretest probability of moderate to severe obstructive sleep apnea. Portable monitoring may be indicated for the diagnosis of obstructive sleep apnea in patients for whom laboratory polysomnography is not possible by virtue of immobility, safety, or critical illness. [73] The advantages of portable sleep monitoring devices are that they are easy to use in dental settings and are widely used to screen for obstructive sleep apnea in conjunction with a through clinical examination and evaluation of subjective symptoms.

Treatment Modalities for Obstructive Sleep Apnea

The treatment modalities for the management of obstructive sleep apnea include nasal continuous positive air pressure (NCPAP), oral appliance therapy, surgical procedures, positional therapy, and behavioral therapy.

Nasal Continuous Positive Air Pressure Therapy

Nasal Continuous Positive Air Pressure Therapy (NCPAP) provides continuous positive room air pressure through the nose that runs down the throat preventing upper airway collapse. [75-77] NCPAP was first described as a treatment for obstructive sleep apnea in 1981. [78] Since then NCPAP has become the first-line therapy for patients with obstructive sleep apnea because of its high effectiveness in eliminating upper airway obstruction, thus prevent oxygen desaturation. In the last decade, nasal continuous positive airway pressure (CPAP) has been shown repeatedly to maintain upper airway patency effectively during sleep in patients with obstructive sleep apnea.

[79, 80] Although CPAP therapy is the most efficient non-surgical treatment for patients with obstructive sleep apnea; many patients do not tolerate sleeping with a nose mask or do a mask over the face well, due to the feeling of claustrophobia, allergies to the materials fabricated, inability to move freely during the night, or the need to have an electric outlet near the bed, which makes it difficult for frequent travelers or people who live in areas where electricity is not always available. Therefore even given the high efficacy of NCAPA, it is not always the tolerable alternative for many people suffering obstructive sleep apnea.

Oral Appliance Therapy

Oral appliance therapy is a non-invasive alternative to NCPAP therapy. Oral appliances fabricated by dentists with training in dental sleep medicine are commonly used to reposition the lower jaw forward to increase upper airway patency. [81, 82] Dental professionals have been recognized as being part of the multidisciplinary therapeutic team for the management of obstructive sleep apnea due to their prime position of constant examination of the maxillo-mandibular complex and oropharyngeal areas, helping to identify possible risk factors for the development of a narrow upper airway. [83] The updated practice parameters from the American Academy of Sleep Medicine [81] recommend the use of oral appliances for mild to moderate obstructive sleep apnea and in patients with severe obstructive sleep apnea who do not tolerate NCPAP therapy well.

The mechanism of oral appliance therapy is related to opening the upper airway as demonstrated by imaging and physiologic monitoring. Changes in the occlusion develop in some patients after

prolonged use. In comparison to continuous positive airway pressure, oral appliances are less efficacious in reducing the apnea hypopnea index (AHI), but oral appliances appear to be used more and are preferred over CPAP when the treatments were compared. [84-86]

Surgical procedures for obstructive sleep apnea.

Surgical procedures of the upper airway are also a viable treatment for selected obstructive sleep apnea patients. Upper airway surgery is an important treatment option for patients with obstructive sleep apnea, particularly for those who have failed or cannot tolerate positive airway pressure therapy. Surgery aims to reduce anatomical upper airway obstruction in the nose, oropharynx, and hypopharynx. Procedures addressing nasal obstruction include septoplasty, turbinectomy, and radiofrequency ablation of the turbinates. Procedures addressing oropharynx obstruction include procedures to reduce soft palate redundancy including uvulopalatopharyngoplasty, uvulopalatal flap, laser-assisted uvulopalatopharyngoplasty, and radio frequency of the soft palate with adenotonsillectomy. Surgical procedure related to hypopharynx obstruction includes genioglossal advancement, hyoid suspension, distraction osteogenesis, tongue radio frequency reduction, and maxillomandibular advancement. Successful surgery depends on proper patient selection, proper procedure selection, and experience of the surgeon. [87-89]

Behavioral modifications

The most commonly recommended behavioral modifications are body weight loss, elimination of upper airway irritants including alcohol, cigarettes, and muscle relaxants, and avoiding

sleeping on the back. [90, 91]

Existing questionnaires to screen for obstructive sleep apnea

Several authors have explored the utility of self-report questionnaires to screen for OSA. A number of screening questionnaires and clinical screening models to identify obstructive sleep apnea have been developed to help identify patients with sleep disorders. [92-99] However, most screening tools have been validated only in patients referred to sleep centers. Patients referred to sleep centers are already suspected of having sleep related disorders, especially obstructive sleep apnea; they are preselected patients and thus a biased population. Screening tools for sleep related disorders developed and validated in the sleep center patient population cannot be applied to other patients without validation in the target patient population. Some of the existing questionnaires are detailed below.

The Berlin questionnaire

The Berlin questionnaire was an outcome of the conference on sleep in primary care, which involved 120 U.S. and German pulmonary and primary care physicians and was held in April 1996 in Berlin, Germany. Questions were selected from the literature to elicit factors or behaviors that, across studies, consistently predicted the presence of sleep disordered breathing. The questionnaire focused on a limited set of known risk factors for sleep apnea. One introductory question and four follow up questions concern snoring and three questions address daytime sleepiness, with a subquestion about sleepiness behind the wheel. One question concerns history of high blood pressure. Patients are also asked to provide information on age, weight, height, sex, neck circumference, and ethnicity. Obesity can be quantified by calculating body

mass index from self-reported weight and height. [100-103]

The Epworth Sleepiness Scale (ESS)

The Epworth sleepiness scale (ESS) is a simple, self administered questionnaire which has been shown to provide a measurement of the subject's general level of daytime sleepiness. The development of the questionnaire utilized 180 adults answering the ESS, including 30 normal men and women as controls and 150 with a range of sleep disorders. They rated the chances that they would doze off or fall asleep when in eight different situations commonly encountered in daily life. In patients with obstructive sleep apnea the ESS scores were significantly correlated with the respiratory disturbance index and the minimum oxygen saturation recorded overnight. ESS scores of patients who simply snored did not differ from controls. [94, 95]

The STOP questionnaire

The STOP questionnaire was developed for OSA screening in surgical patients. Preoperative patients were recruited for this study without a previous diagnosis OSA. Four yes/no questions were used to develope this screening tool. The four questions were related to Snoring, Tiredness during daytime, Observed apneas, and high blood Pressure (STOP). For validation, the questionnaire was evaluated against the apnea hypopnea index from monitored polysomnography. When incorporating body mass index, age, neck circumference, and gender into the STOP questionnaire, it had a high sensitivity, especially for patients with moderate to severe obstructive sleep apnea. [99]

Aim of the Study

More strategies to decrease the high prevalence and associated morbidity of obstructive sleep apnea are needed. Most screening tools have been validated only in patients referred to sleep centers (pre-selected), screening tools for sleep related disorders developed and validated in the sleep center patient population could not be applied to other patients without validation in the target patient population.

Dental professionals have been recognized as being part of the multidisciplinary therapeutic team for the management of obstructive sleep apnea due to the prime position of constant examination of the maxillo-mandibular complex and oropharyngeal areas, helping to identify possible risk factors for the development of a narrow upper airway in addition of the constant opportunity to update medical history and identify possible symptoms related to sleep apnea.

The aim of this study was to develop a new screening questionnaire inexpensive, easy to apply and reproducible to identify sleep apnea based on non- previously used items related to the anatomy and occlusion of the maxillo-mandibular region that may help identify obstructive sleep apnea patients.

Study Design and Methods

The study design was a prospective cohort study. The new screening questionnaire was developed based on the standard of care clinical examination of patients at the craniofacial pain center and literature review. The new questionnaire is a self-reported, forced-choice (yes/no), paper and pen scale that takes approximately 10 minutes to complete, the new questionnaire

consist of 15 items related to stability and comfort of the bite, fatigue of masticatory muscles while chewing, interrelation of upper and lower teeth on mouth closing, missing teeth on the back of the mouth [1], clenching and grinding of teeth [2], difficulty of breathing through the nose [3], loud snoring [4] , neck pain , headaches [5, 6], high blood pressure [7], trouble falling asleep or staying asleep [8], neck collar size [9], medications taken [10], and sleepiness [11].

After completion of the new questionnaire, the *"STOP"* questionnaire" was administered; this questionnaire has been previously validated to screen for obstructive sleep apnea, and consists of a self-report, forced-choice yes/no, paper and pen scale that takes approximately five minutes to complete**,** consisting of 4 yes/no questions related to snoring, tiredness during the daytime, observed apnea during sleep, and hypertension [12, 13].

After the completion of both questionnaires the participants were invited to undergo an overnight sleep study in their home, going to bed at his/her usual bedtime using a portable sleep-monitoring device (Watch-pat Itamar Medical, Inc Framingham, MA. USA) previously validated and FDA cleared to determined the presence of obstructive sleep apnea [14].

The portable monitor has been described elsewhere[15-18] but consists of a battery-powered, wrist-mounted, recording device and software for post acquisition viewing and analysis of the recorded data (Figure 1). The portable sleep monitor included 4 sensors (Figure 2):

- Sensor 1: Snore recording, this sensor contains a microphone designed to record the level of snoring during sleep on a decibels scale, the microphone does not record voice.

- Sensor 2: Body position recording, contains an actigraph for limb movement detection, it will recorded the sleeping body position (supine, prone, right and left side).
- Sensor 3: Oxygen recording, contains a pulse oximeter sensor (Nonin 8000J, Plymouth, Minn). It will detect an oxygen desaturation index (ODI) that represents the number of oxyhemoglobin desaturations of at least 4% per hour.
- Sensor 4: Periphery arthery tonometry recording, using a Pulse Artery Tone (PAT) probe (Itamar Medical Ltd., Caesarea, Israel). The PAT probe applies a uniform pressure field over the distal two thirds of the finger, including the fingertip, which unloads arterial wall tension without causing distal venous pooling and distension, potential sources of venoarterial-mediated vasoconstriction. A transmission mode photoelectric plethysmograph is used to measure the optical density changes associated with pulsatile blood volume changes in the finger.

The presence of obstructive sleep apnea was determined using the universal apnea-hypopnea index (AHI) with a cut off of five respiratory events per hour reported on the sleep study report.

A respiratory event was automatically scored if 1 of 3 criteria is met:

1. PAT amplitude reduction occurred with acceleration in the pulse rate or an increase in wrist activity.
2. PAT amplitude reduction occurred with a 3% or greater oxyhemoglobin desaturation.
3. A 4% or greater oxyhemoglobin desaturation.

4.

The algorithm was developed using previous Watch PAT data collected concurrently with Polysomnography data to optimize event-by-event agreement. Oxyhemoglobin desaturations were quantified automatically in a similar fashion.

The Portable sleep monitor device was delivered to participants with a brochure and a CD contained video demonstration of step-by-step instructions to watch at home; returning mailing supplies were provided at no cost to the participant. Subjects were given a 24-hour phone number to contact the investigator with any questions.

The previously described steps took 20 minutes the day of the visit. The participants returned the portable sleep monitor to our clinic via FEDEX delivery service; after received the portable sleep monitor from the participant, the data was uploaded for automated analysis on a computer using the PAT software (zzz_PATversion 2.0.39.13, Itamar Medical Ltd., Caesarea, Israel).

A sleep report was automatically generated from the software, no manual editing of the automated Watch PAT scoring was performed.

A follow up phone call to the subjects who participated in the study was made after reviewing the automated report from the portable sleep monitor to inform them of the presence or absence of obstructive sleep apnea and to record any adverse event during the use of the sleep monitor.

Recommendations were made to the participant to seek appropriate medical care if obstructive sleep apnea was present. The sleep report from the portable sleep monitor was compared with the score from the new screening questionnaire and the supplemental "STOP" questionnaire.

Population

Subjects seeking care at a multidisciplinary craniofacial pain center at Tufts University School of Dental Medicine, Boston MA were selected randomly; no local or outside advertisements was utilized.

50 adults with age greater than 18 years were included in this research study. Subjects were able to read, understand, and they signed the Tufts University IRB informed consent to participate in research and able to follow the study protocol.

Subjects were excluded if they were unable to understand and sign the Tufts University IRB informed consent, inability to understand the use of portable sleep monitor at their home, and inability to return the portable sleep monitor to our clinic. Subjects were given the option to decline to participate in this study with out affecting their current treatment at the Craniofacial Pain Center.

The sample size was computed to attain a specified level of precision based on a 95% two-sided confidence interval for the overall concordance between the questionnaire and the portable sleep monitor. Assuming a 75% level of concordance between the two classification systems, the sample size 50 would achieve a half-width of .12 for the confidence interval

Data collected

Self-reported demographic information included age, gender, weight, height, ethnicity and race. Self reported medical information included body mass index calculation using body weighs and body height. Self reported hypertension, nasal congestion, depression and anxiety. Self reported medications taking including opiods, muscle relaxants, antidepressive and antianxiety.

Sleep parameters were collected from the sleep report. These were automatically measured and reported by the at-home sleep study which included the presence of obstructive sleep apnea measured by the apnea hypopnea index (AHI) which included the number of apneas plus hypopneas divided between sleep time with a cut off of 5 events per hour. Respiratory disturbance index (RDI), which included the number of apneas plus hypopneas plus respiratory effort, related arousals divided between the sleep time with a cut off of 5 events per hour. Rapid eye movement sleep stage (REM) measured in percentage with a cut off of 20% (normal values 20-25%), and nadir oxygen saturation (Nso2) cut off of 90 %.

Statistics

The analysis was performed using SPSS version 17.0. The statistical analysis included sensitivity and specificity of the previous validated and new questionnaires, as well as overall percentage of agreement between each questionnaire and the portable sleep monitor. The Cronbach alpha was calculated for each questionnaire as a measurement of internal reliability.

A cross tabulation for each item and the outcome of the portable sleep monitor was calculated. Significant association between the items and the outcome was assessed via Fisher's exact test. Cross tabulation was performed for each pair of items. ROC curve analysis was performed for each questionnaire.

Study Schedule

Visit 1

Discussion of potential participation in this study

Evaluation for inclusion and exclusion criteria for participation in this study

Review of the informed consent form for participation in this study

Informed consent signed

New questionnaire application

Supplemental (STOP) questionnaire application

Instructions for the use of portable sleep monitor

Delivery of portable sleep monitor

Instructions to return sleep monitor via FEDEX (no cost to the participant)

Sleep Study

Sleep data downloaded to the software and automatically analyzed

Follow up

A follow up phone call to the participant was made to inform them of the presence or absence of obstructive sleep apnea, and advice the participant of the appropriate follow up medical care.

Subject Withdrawal and Adverse events

None of the participating subjects withdrew from the study. There were no problems/adverse events during any study protocol.

Informed Consent

The clinical investigation, including the consent form, was reviewed by the Tufts University IRB in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Subject consent was obtained prior to participation in any study procedures as required by the Food and Drug Administration (FDA) GCP guidelines. Subjects were given ample opportunity to read the consent form and to have all questions regarding study conduct answered prior to signing and dating the consent form. Each subject was provided with an exact copy of the informed consent form to retain for his or her records.

Risks and benefits

The risk for participating in this study included the loss of confidentiality, discomfort on the wrist or arm or fingers from the use of the portable sleep monitor. The benefits for participating in this study included been screened for the possible presence of obstructive sleep apnea.
This study added up to the existing literature to determine and identify risk factors during dental appointments using a inexpensive and replicable new questionnaire for the possible presence of obstructive sleep apnea. Participants also contributed to possible advances in knowledge by

utilizing new screening questionnaires for the assessment of obstructive sleep apnea in dental settings.

Confidentiality and Security

Confidentiality and security of each subject's personal information and identification were handled in the following manner:

- Source documents and case report forms were coded and free of subject names.
- Subjects were identified using an ID code made up of the subject's two initials and a three-digit numeral.
- The investigators adhered to HIPAA (Health Insurance Portability and Accountability Act) regulations in order to protect patient data. Every subject was asked to review and sign a HIPAA form.
- All data and forms were stored in a locked cabinet in a locked room upon completion of each subject's screening. The Investigators only viewed the results from the screening. All information about the subject's screening was kept confidential.

Results

Descriptives analysis

The New Screening questionnaire was administered to 50 patients attending the craniofacial pain center at Tufts university school of dental medicine, of which 70% were women. Subjects had a mean age 46.1 years (SD 12.0), a mean body weight of 163.0 pounds (SD 36.0), a mean BMI of 27 (SD 6.0), and a mean neck size of 15.0 inches (SD 2.0). Home sleep study was performed

and was recorded as presence of obstructive sleep apnea based on apnea hypopnea index (AHI) and respiratory disturbance index (RDI), with a cutoff of 5. According to AHI, 54% of the subjects were identified as having OSA; according to RDI, 88% were identified as having OSA **(TABLE I).**

Simple Findings New Questionnaire (NQ)

Sensitivity, specificity, positive predictive value, negative predictive value, and p value of each item were calculated for the new questionnaire. Three items (Item 4 related to clenching and grinding, Item 7 related to snoring, Item 13 related to collar size) showed statistical significant association ($p < 0.005$) with AHI-defined OSA **(TABLE II).**

Association between Item 1 NQ (bite stable and comfortable) and OSA

Item one on the NQ ("Does your bite feel stable and comfortable?") was not statistically significantly associated with the presences of AHI-defined OSA ($p = 0.081$). Among those subjects with AHI-defined OSA, 74.1% answered yes to item one, and among those subject without AHI-defined OSA 47.8% answered yes to item one. The item had a negative predictive value of 63.2%, positive predictive value of 64.5%, a sensitivity of 74.1%, and a specificity of 52.2%.

Association between Item 2 NQ (jaw muscles) and OSA

Item two on the NQ ("Does your jaw muscles feel tired after eating a average meal?") was not statistically significantly associated with the presences of AHI-defined OSA ($p = 0.076$). Among

those subjects with AHI-defined OSA, 22.2% answered yes to item two, and among those subject without AHI-defined OSA 47.8% answered yes to item two. The item had a negative predictive value of 36.4%, positive predictive value of 35.3%, a sensitivity of 22.2%, and a specificity of 52.2%.

Association between Item 3 NQ (upper and lower front teeth) and OSA

Item three on the NQ ("Does your upper teeth cover most of your lower front teeth?") was not statistically significantly associated with the presences of AHI-defined OSA (p = 1.000). Among those subjects with AHI-defined OSA, 77.8% answered yes to item three, and among those subject without AHI-defined OSA 78.3% answered yes to item three. The item had a negative predictive value of 45.5%, positive predictive value of 53.8%, a sensitivity of 77.8%, and a specificity of 21.7%.

Association between Item 4 NQ (clenching and grinding) and OSA

Item four on the NQ ("Do you clench or grind your teeth?") was statistically significantly associated with the presences of AHI-defined OSA (p = 0.014). Among those subjects with AHI-defined OSA, 66.7% answered yes to item four, and among those subject without AHI-defined OSA 95.7% answered yes to item four. The item had a negative predictive value of 10.0%, positive predictive value of 45.0%, a sensitivity of 66.7%, and a specificity of 4.3%.

Association between Item 5 NQ (missing teeth) and OSA

Item five on the NQ ("Do you have missing teeth in the back of your mouth?") was not statistically significantly associated with the presences of AHI-defined OSA (p = 0.537). Among

those subjects with AHI-defined OSA, 22.2% answered yes to item five, and among those subject without AHI-defined OSA 30.4% answered yes to item five. The item had a negative predictive value of 43.2%, positive predictive value of 46.2%, a sensitivity of 22.2%, and a specificity of 69.6%.

Association between Item 6 NQ (nose breathing) and OSA

Item one on the NQ ("Do you have difficulty breathing through your nose?") was not statistically significantly associated with the presences of AHI-defined OSA ($p = 0.332$). Among those subjects with AHI-defined OSA, 33.3% answered yes to item six, and among those subject without AHI-defined OSA 17.4% answered yes to item five. The item had a negative predictive value of 51.4%, positive predictive value of 69.2%, a sensitivity of 33.3%, and a specificity of 82.6%.

Association between Item 7 NQ (snoring) and OSA

Item seven on the NQ ("Do you snore loudly?") was statistically significantly associated with the presences of AHI-defined OSA ($p = 0.005$). Among those subjects with AHI-defined OSA, 63% answered yes to question seven, and among those subjects without AHI-defined OSA, 21.7% answered yes to item seven. The item had a negative predictive value of 64.3%, a positive predictive value of 77.3%, a sensitivity of 63%, and a specificity of 78.3% .

Association between Item 8 NQ (injuries to the neck) and OSA

Item eight on the NQ ("Have you ever had injuries to the head or neck area?") was not statistically significantly associated with the presences of AHI-defined OSA ($p = 0.773$). Among those subjects with AHI-defined OSA, 40.7% answered yes to item eight, and among those subject without AHI-defined OSA 34.8% answered yes to item eight. The item had a negative predictive value of 48.4%, positive predictive value of 57.9%, a sensitivity of 40.7%, and a specificity of 65.2%.

Association between Item 9 NQ (headaches and neck pain) and OSA

Item nine on the NQ ("Do you have ongoing headaches of neck pain?") was not statistically significantly associated with the presences of AHI-defined OSA ($p = 0.272$). Among those subjects with AHI-defined OSA, 44.4% answered yes to item nine, and among those subject without AHI-defined OSA 60.9% answered yes to item nine. The item had a negative predictive value of 37.5%, positive predictive value of 46.2%, a sensitivity of 44.4%, and a specificity of 39.1%.

Association between Item 10 NQ (neck disorders) and OSA

Item ten on the NQ ("Do you have any neck injuries?") was not statistically significantly associated with the presences of AHI-defined OSA ($p = 0.515$). Among those subjects with AHI-defined OSA, 25.9% answered yes to item ten, and among those subject without AHI-defined OSA 17.4% answered yes to item ten. The item had a negative predictive value of 48.7%, positive predictive value of 63.6%, a sensitivity of 25.9%, and a specificity of 82.6%.

Association between Item 11 NQ (blood pressure) and OSA

Item eleven on the NQ ("Do you have a history of hight blood pressure?") was not statistically significantly associated with the presences of AHI-defined OSA (p = 0.085). Among those subjects with AHI-defined OSA, 29.6% answered yes to item eleven, and among those subject without AHI-defined OSA 8.7% answered yes to item eleven. The item had a negative predictive value of 52.5%, positive predictive value of 80.0%, a sensitivity of 29.6%, and a specificity of 91.3%.

Association between Item 12 NQ (difficulty falling sleep or staying asleep) and OSA

Item twelve on the NQ ("Do you have difficulty falling asleep or staying asleep?") was not statistically significantly associated with the presences of AHI-defined OSA (p = 1.000). Among those subjects with AHI-defined OSA, 51.9% answered yes to item twelve, and among those subject without AHI-defined OSA 52.2% answered yes to item twelve. The item had a negative predictive value of 45.8%, positive predictive value of 53.8%, a sensitivity of 51.9%, and a specificity of 47.8%.

Association between Item 13 NQ (collar size) and OSA

Item number thirteen (Collar size bigger than 17 inches for males and bigger than 15 inches for females) was statistically significantly associated with the presences of AHI-defined OSA (p =

0.012). The item had a negative predictive value of 56.8% and positive predictive value of 84.6%, with a sensitivity of 40.7%, and specificity of 91.3%.

Association between Item 14 NQ (collar size) and OSA

Item fourteen on the NQ ("Is your collar size bigger than 17" males or 15" females?") was close to statistically significantly associated with the presences of AHI-defined OSA ($p = 0.548$). Among those subjects with AHI-defined OSA, 25.9% answered yes to item ten, and among those subject without AHI-defined OSA 34.8% answered yes to item fourteen. The item had a negative predictive value of 42.9%, positive predictive value of 46.7%, a sensitivity of 25.9%, and a specificity of 42.9%.

Association between Item 15 NQ (sleepiness) and OSA

Item ten on the NQ ("Do you feel yourself drift off, or your eyes get heavy while driving, watching TV, sitting or reading in a quiet room?") was not statistically significantly associated with the presences of AHI-defined OSA ($p = 0.776$). Among those subjects with AHI-defined OSA, 59.3% answered yes to item fifteen, and among those subject without AHI-defined OSA 52.2% answered yes to item ten. The item had a negative predictive value of 50.0%, positive predictive value of 57.1%, a sensitivity of 59.3%, and a specificity of 47.8%.

Simple Findings Supplemental Questionnaire (SQ)

Sensitivity, specificity, positive predictive value, negative predictive value, and p value of each item were calculated for the supplemental questionnaire. No items from the SQ showed statistical significant association (p = >0.005) with AHI-defined OSA **(TABLE III).**

Association between Item 1 SQ (snoring) and OSA

Item number one (Do you snore loud? Louder than talking or your snore can be hear through closed door?) was not statistically significantly associated with the presences of AHI-defined OSA (p = 0.241). The item had a negative predictive value of 53.1% and positive predictive value of 66.7%, with a sensitivity of 44.4%, and specificity of 73.9%.

Association between Item 2 SQ (tiredness) and OSA

Item number thirteen (do you often feel tired, fatigue or sleepy during daytime) was not statistically significantly associated with the presences of AHI-defined OSA (p = 1.000). The item had a negative predictive value of 43.8% and positive predictive value of 52.9%, with a sensitivity of 66.7%, and specificity of 30.4%.

Association between Item 3 SQ (witnessed apneas) and OSA

Item number thirteen (has anyone observed you stop breathing during the night?) was not statistically significantly associated with the presences of AHI-defined OSA (p = 0.012). The item had a negative predictive value of 56.8% and positive predictive value of 84.6%, with a sensitivity of 40.7%, and specificity of 91.3%.

Association between Item 4 SQ (blood pressure) and OSA

Item number thirteen (do you have or are you being treated for hight blood pressure?) was not statistically significantly associated with the presences of AHI-defined OSA ($p = 0.525$). The item had a negative predictive value of 50.0% and positive predictive value of 64.3%, with a sensitivity of 33.3%, and specificity of 78.3%.

Association between Gender, BMI and OSA

Gender showed no association with AHI-defined OSA ($p = 0.121$), having a BMI of 25 or greater showed a statistically significant association with AHI-defined OSA ($p = 0.002$). As BMI increases, the odds of having an AHI of at least five increases **(TABLE IV).**

Association between New and Supplemental Questionnaire and RDI

None of the items on the new and supplemental questionnaire were statistically significantly associated with RDI-defined OSA **($p > 0.005$).**

Cross tabulation between similar items

Cross tabulation of the similar items on the NQ and the SQ showed these items to be highly associated ($p < 0.001$ for all three comparisons). Items related to snoring had a negative predictive value of 92.9% and a positive predictive value of 72.7%, with a sensitivity of 88.9%, specificity of 81.3%. Items related to tiredness had a negative predictive value of 63.6% and a positive predictive value of 92.9%, sensitivity of 76.5% and specificity of 87.5%. Items related

to high blood pressure had a negative predictive value of 97.5% and a positive predictive value of 80.0%, sensitivity of 88.9, and specificity of 95.1% **(TABLE VI).**

Discussion

Currently, several systemic diseases such as HIV, cardiovascular disease and some cancers show manifestations in the oral tissues and screening/examination for them by dentist is considered standard of care. (J Dent Educ. 73(1): 38-52 2009, Rebecca S. Wilder et al.) One more aspect which could be easily screened by dentist would be OSA. OSA is relatively easier to screen with a good questionnaire. The questionnaire of this sort has not been utilized in earlier investigations. The aim of this study was to develop a new questionnaire to identify OSA, the questionnaire was developed at a craniofacial pain center in a dental school.

Subjectives and objectives items were used to identify the patients at risk for OSA. Items that were statistically significant were the most objective, i.e., those that would require a judgment on the part of a patient or clinician, e.g., BMI, neck size, high blood pressure. In contrast, subjective items not only failed to be predictive, but also were significant in the opposite direction (NQ item four). There may be two different explanations for this phenomenum.
This might be expected in a population with documented marked somatic concern, i.e., a chronic population with a primary complaint of pain in the craniomandibular region. Patients with persistent pain frequently report a range of somatic symptoms, and sleep disorder symptoms are commonplace.

They might be more likely to endorse items (NQ Item four) such as “clenching and grinding.” While some of these symptoms may be present in a TMD population due to the typical comorbidities associated with chronic pain such as depression, anxiety, somatic overconcern, and poor sleep hygiene, their expected high frequency would not necessarily predicted to a presence of a higher incidence of OSA. Indeed, this population may response in a negative or pathological fashion to most items presented to the, and thereby compromise any assessment data that primarily relies on subjective report.

Another possible explanation is relatively new in the field of sleep disordered breathing. There is evidence that bruxism may actually be a protective reflex of the body to maintain upper airway by bringing the mandible forward to open obstructions of the airway during sleep (**Lavigne, Archives of Oral biology 2007)**. Laxity of the mandibular musculature and cervical inputs allow the mandible to slip posteriorly during sleep and increase the potential of sleep disordered breathing and airway closure. Much as in CPR where the first step is to open airway by bringing the mandible forward manually it is postulated that the body attempts to achieve this by tensing up the masticatory and cervical musculature and protuding the mandible. The clenching and bruxing is the substrate used to achieve this goal. If this is the case further investigations should look to the protective nature of Bruxism for sleep issues instead of focusing solely on the dental adverse concequences of this as a “habit”.

This could provide a valuable tool for investigation of sleep disordered breathing. Teeth grinding or bruxism tends to occur during microarousals (**Lavigne, Archives of Oral biology 2007)** and occurs mainly during light sleep.

Association between OSA and item 7 which ask the question regarding loud snoring was statistically significantly associated with the presences of AHI-defined OSA, our findings correlates with a previous study by Berger et al. [55] where they examined the natural evolution of primary snoring and obstructive sleep apnea in adult male patients, stepwise linear regression showed that only BMI and time were significant predictors for apnea hypopnea index change. Patients with primary snoring and mild and moderate obstructive sleep apnea had a similar increase in the apnea hypopnea index over time, which depended mainly on weight gain. Our findings also correlate with the previous described study regarding increased BMI, our study showed that having a BMI of 25 or greater showed a statistically significant association with AHI-defined OSA. As BMI increases, the odds of having an AHI of at least five increases.

Our statistical significant findings regarding the association between OSA and item 13 which ask the question regarding neck size for male and female correlates also with previous studies (Daltro, Endocrinol Metabol 2006) (Villa, Gaceta Medica Mexicana 2004) and (Valencia-Flores, Endocrinol Nutr 2001) where they concluded that patients diagnosed with obesity and increased in neck diameter are at important risk factor for OSA.

No statistical significance was found on the use of the new screening questionnaire as a whole to identify OSA based on AHI or RDI.

Conclusions

The findings from this study showed statistical significant value for the use of selective items from the new questionnaire on screening for OSA. The discussion also addresses possible reasons why a population with marked somatic concern may bias particular subjective items commonly included in OSA questionnaires. Further the possibility of sleep bruxism as a protective reflex has been suggested and may require further investigations.

Three items from the NQ were statistical significant, those that were targeted toward the assessment of objective, morphological factors typically shown to be risk factors with OSA. These may be useful combined with the supplemental questionnaire (STOP), with a focus on less reliance on subjective predictors when a population of chronic pain patients is being assessment. Our study have several limitations, one is that the current study took place in only one office setting, another limitation of the study had a small sample size. Further research is necessary to explore the use of the statistical significant items from the new questionnaire in combination with the supplemental questionnaire previous validated for OSA.

List of Tables

Table I Descriptive Statistics New Questionnaire (NQ)

The New Screening questionnaire was administered to 50 subjects of which 70% were women. Subjects had a mean age 46.1 years (SD 12.0), a mean body weight of 163.0 pounds (SD 36.0), a mean BMI of 27 (SD 6.0), and a mean neck size of 15.0 inches (SD 2.0). Obstructive sleep apnea based on apnea hypopnea index (AHI) mean 11.0 (SD 13.4) and respiratory disturbance index (RDI) mean 16.0 (SD 12.4),. According to AHI, 54% of the subjects were identified as having OSA; according to RDI, 88% were identified as having OSA respectively.

n=50
women= 70%

	N	Minimum	Maximum	Mean	SD
AGE	50	19	70	46.1	12.0
Body Weight	50	103	231	163.4	35.9
BMI	50	16.4	44.1	26.7	5.9
Neck Size	49	12.6	19.0	15.3	1.6
AHI	50	.0	68.4	11.0	13.4
RDI	50	2.2	68.4	16.0	12.4
REM	50	.0	38.2	22.4	9.3
Nadir S02	50	87	97	92.4	2.2

AHI: Apnea hypopnea index, RDI: Respiratory disturbance index, Nadir S02: Oxygen desaturation, REM: Rapid eye movement sleep, AGE: measured in years, BMI: body mass index, Neck Size: Measured in inches, Body Weight: Measured in pounds, N: number of subjects, SD: standard deviation.

Table II Simple findings new questionnaire (NQ)

Sensitivity, specificity, positive predictive value, negative predictive value, and p value of each item were calculated for the new questionnaire. Three items (Item 4 related to clenching and grinding, Item 7 related to snoring, Item 13 related to collar size) showed statistical significant association ($p < 0.005$) with AHI-defined OSA.

	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	Item 13	Item 14	Item 15
Sens	74.1%	22.2%	77.8%	66.7%	22.2%	33.3%	63.0%	40.7%	44.4%	25.9%	29.6%	51.9%	40.7%	25.9%	59.3%
Spec	52.2%	52.2%	21.7%	4.3%	69.6%	82.6%	78.3%	65.2%	39.1%	82.6%	91.3%	47.8%	91.3%	65.2%	47.8%
PPV	64.5%	35.3%	53.8%	45.0%	46.2%	69.2%	77.3%	57.9%	46.2%	63.6%	80.0%	53.8	84.6%	46.7%	57.1%
NPV	63.2%	36.4%	45.5%	10.0%	43.2%	51.4%	64.3%	48.4%	37.5%	48.7%	52.5%	45.8%	56.8%	42.9%	50.0%
P	.081	.076	.100	.014	.514	.332	.005	.773	.251	.515	.085	.100	.012	.548	.414

Sens = Sensitivity; Spec =Specificity; NPV = negative predictive value; PPV= positive predictive value; P= p value.
Item 1= Does your bite feel stable and comfortable
Item 2= Do your jaw muscles feel tired after eating an average meal
Item 3= Does your upper front teeth cover most of your lower front teeth
Item 4= Do you clench or grind your teeth
Item 5= Do you have missing teeth in the back of your mouth
Item 6= Do you have difficulty in breathing through your nose
Item 7= Do you snore loudly
Item 8= Have you ever had injuries to the head or neck area
Item 9= Do you have ongoing headaches or neck pain
Item 10= Do you have any neck disorders
Item 11= Do you have a history of high blood pressure
Item 12= Do you have trouble falling asleep or staying asleep
Item 13= Is you collar size bigger than 17” (male) or 15” (female)
Item14= Do you take muscle relaxants, pain, anti-anxiety, or anti-depression medications
Item 15= Do you feel yourself drift off, or your eyes get heavy while driving, watching TV, sitting or reading in a quiet room.

Table III Simple Findings Supplemental Questionnaire (STOP)

Sensitivity, specificity, positive predictive value, negative predictive value, and p value of each item were calculated for the supplemental questionnaire. No items showed statistical significant association ($p > 0.005$) with AHI-defined OSA.

	Item 1	Item 2	Item 3	Item 4
Sensitivity	**44.4%**	**66.7%**	**33.3%**	**25.9%**
Specificity	**73.9%**	**30.4%**	**78.3%**	**91.3%**
Positive predictive value	**66.7%**	**52.9%**	**64.3%**	**77.8%**
Negative predictive Value	**53.1%**	**43.8%**	**50.0%**	**51.2%**
P value	**.241**	**1.000**	**.529**	**.152**

Item1 = Do you snore loud? Louder than talking or your snore can be hear through closed door?
Item 2 = Do you often feel tired, fatigue or sleepy during daytime?
Item 3 = Has anyone observed you stop breathing during the night?
Item 4 = Do you have or are you being treated for hight blood pressure

Table IV Cross-tabulation Between Similar Items to Identify AHI of at least 5

Cross tabulation of the similar items on the NQ and the SQ showed these items to be highly associated ($p < 0.001$ for all three comparisons). Items related to snoring had a negative predictive value of 92.9% and a positive predictive value of 72.7%, with a sensitivity of 88.9%, specificity of 81.3%. Items related to tiredness had a negative predictive value of 63.6% and a positive predictive value of 92.9%, sensitivity of 76.5% and specificity of 87.5%. Items related to high blood pressure had a negative predictive value of 97.5% and a positive predictive value of 80.0%, sensitivity of 88.9, and specificity of 95.1%

	Similar Items Snoring	Similar Items Tiredness	Similar Items High Blood Pressure
Sensitivity	88.9%	76.5%	88.9%
Specificity	81.3%	87.5%	95.1%
Positive Predictive Value	72.7%	92.9%	80.0%
Negative Predictive Value	92.9%	63.6%	97.5%
P value	0.000	0.000	0.000

Table V Association between Gender, BMI and OSA

Gender showed no association with AHI-defined OSA (p = 0.121), having a BMI of 25 or greater showed a statistically significant association with AHI-defined OSA (p = 0.002). As BMI increases, the odds of having an AHI of at least five increases.

	Gender	BMI >25
Sensitivity	40.7%	74.1%
Specificity	82.6%	73.9%
Positive Predictive Value	73.3%	76.9%
Negative Predictive Value	54.3%	70.8%
P value	0.121	0.002

List of Figures

Figure 1 Study schedule

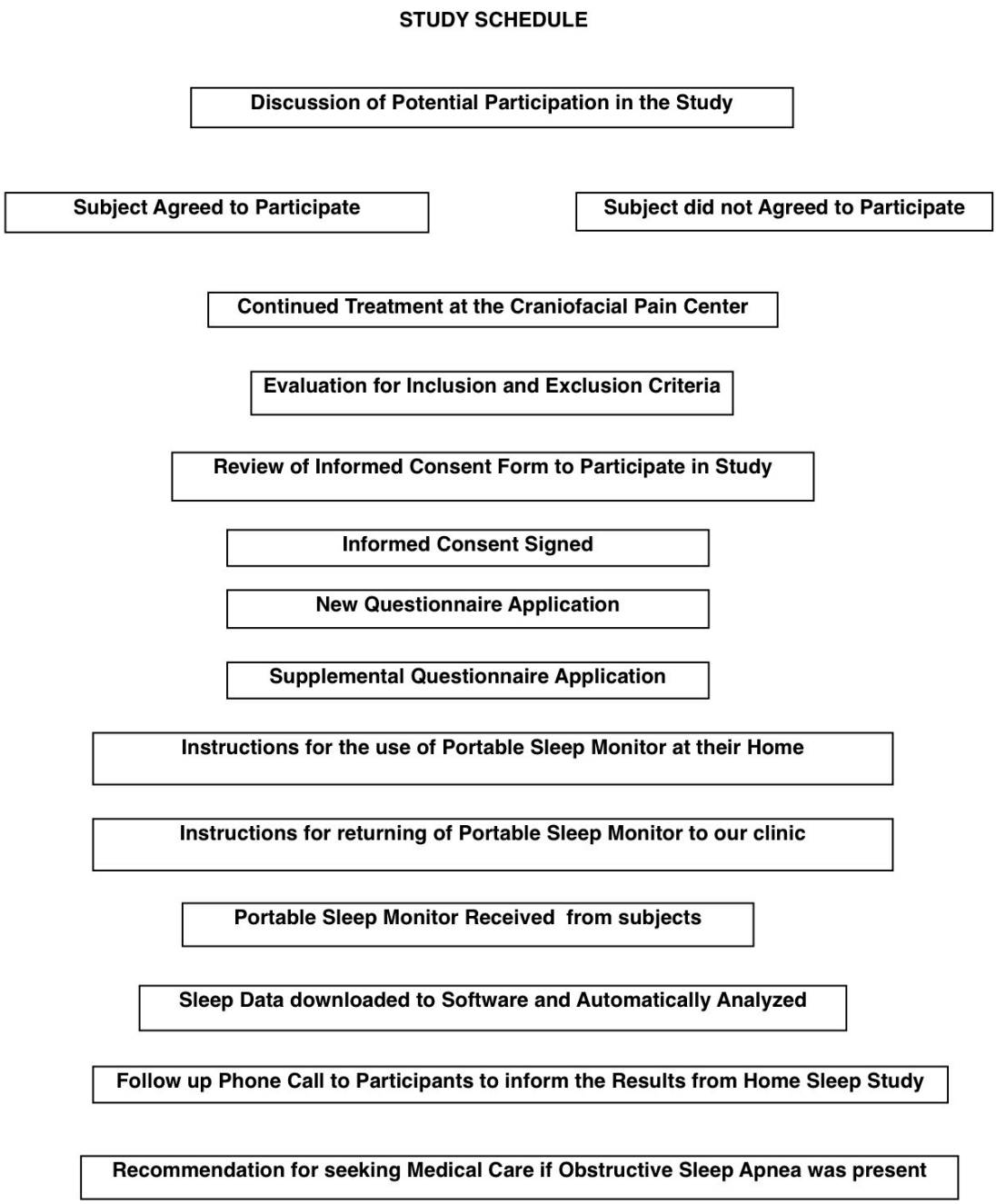


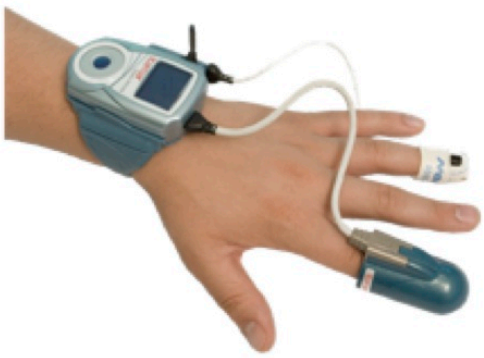
Figure 2 Portable Sleep Monitor

Body sensors.

Sensor one is attached to the base of the neck and measures snoring

Sensor two is attached to the chest bone (males) / above the breast (female) and measures body positioning

Wrist hand sensors, sensor three is attached to the index finger and measures periphery arthery tonometry (PAT signal), sensor four is attached to the ring finger and measures body oxygen level



List of Appendices

Appendix I _New Screening Questionnaire with 15 Items

Screening Questionnaire for Sleep Apnea

ID#_____

Name: _____ DOB:_____ Gender:_____

Race (circle one): Caucasian-Latino-African American-Asian-other_____

Height (inches):_____ Weight (pounds):_____

PLEASE CIRCLE YES OR NO ON THE FOLLOWING QUESTIONS

1- Does your bite feel stable and comfortable ? YES NO

2- Do your jaw muscles feel tired after eating an average meal ? YES NO

3- Do your upper front teeth cover most of your lower front teeth ? YES NO

4- Do your clench or grind your teeth ? YES NO

5- Do you have missing teeth in the back of your mouth ? YES NO

6- Do you have difficulty in breathing through your nose ? YES NO

7- Do you snore loudly ? YES NO

8- Have you ever had injuries to the head or neck area ? YES NO

9- Do you have ongoing headaches or neck pain ? YES NO

10- Do you have any neck disorders ? YES NO

11- Do you have a history of high blood pressure ? YES NO

12- Do you have trouble falling asleep or staying asleep ? YES NO

13- Is your collar size bigger than 17" (male) or 15" (female) ? YES NO

14- Do you take muscle relaxants, pain, anti-anxiety, or anti-depression medications ? YES NO

15- Do you feel yourself drift off, or your eyes get heavy while driving, watching TV, sitting, or reading in a quiet room ? YES NO

Total score:_____

Appendix II Supplemental Questionnaire with 4 Items

STOP Questionnaire
for the Screening of Sleep Apnea

ID# ____/100

Height _____ inches/cm Weight _____ lb/kg

Age _____ Male/Female BMI _____

Collar size of shirt: S, M, L, XL, or _____ inches/cm

Neck circumference_____ cm

1. Snoring
Do you snore loudly (louder than talking or loud enough to be heard through closed doors) ?
Yes / No

2. Tired
Do you often feel tired, fatigued, or sleepy during daytime?
Yes / No

3. Observed
Has anyone observed you stop breathing during your sleep?
Yes / No

4. Blood pressure
Do you have or are you being treated for high blood pressure?
Yes / No

Total Score:_____

Appendix III Instructions for the use of portable sleep monitor

The participants will receive the following instructions for the use of the portable sleep monitor:

☒ STEP 1 SNORE AND BODY POSITION SENSOR

1. Thread the snore and body position sensor through the sleeve of the pajama up to the neck opening.
2. Peel off the paper of the snore sensor (small round sticker). Attach the snore sensor to the base of the neck.
3. Secure the snore sensor in place with medical tape
4. Hold the paper tabs on the back of the body position sensor. Pull the paper tabs all the way off the body position sensor while placing it in the chest bone. *NOTE: For female locate body pisition sensor above breast.*

☒ STEP 2 APPLYING THE WATCH-PAT

5. Apply the device on the non-dominant hand. Place the device upside down on a flat surface, insert wrist and close strap. Do not close wrist strap too tightly.

☒ STEP 3 APPLYING THE OXIMETER

6. Peel off the paper half way up the two notches
7. Place ring's finger fingertip just before the two notches. Fold the side flaps.
8. Fold the top flap over the finger
9. Fold down the side flap
10. Gently wrap the long flap around the finger (not too tightly)
11. Ensure that the "doted line" is located at the tip of the finger.

☒ STEP 4 APPLYING THE PAT PROBE

12. Insert index finger all the way into the probe until you feel the end

13. Detach and gradually remove the TOP tab all the way out the probe.

14. Detach and gradually remove the BOTTOM tab all the way out of the probe.

STEP 5 TURNING ON THE DEVICE

15. Press the blue bottom firmly until the “Itamar medical” logo appears on the display.

At the end of a short testing you will see GOOD NIGHT!!!

Time elapsed: hours:minutes

Recording you are now ready for sleep, in case there is a problem TEST ABORTED will appear. NOTE: The LCD will turn off after one minute, anytime you press on the button the LCD will light up for one minute. During the night if you need to get up during the night, do not remove the device or sensors.

STEP 6 NEXT MORNING

-The watch-PAT device cannot be turned off.

-Remove the sensors from your hand, your body and your neck.

-Insert all parts back into the Watch-PAT case.

-Follow the instructions to return the Device back via FEDEX service.

Appendix IV Informed Consent

TUFTS UNIVERSITY SCHOOL OF DENTAL MEDICINE
CRANIOFACIAL PAIN CENTER

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

New Screening Questionnaire to Assess Obstructive Sleep Apnea

Principal Investigator: Noshir R. Mehta, DMD
Co-Investigators: Leopoldo P. Correa, BDS
Matthew Finkelman, PhD

You are being invited to take part in a research study involving 100 participants.

Taking part in this research study is totally your choice. You can decide to stop taking part in this research study at any time for any reason. If you stop being in this research study, it will not affect how you are treated at Tufts University School of Dental Medicine / Craniofacial Pain Center.

Please read all of the following information carefully. Ask Dr. Noshir R. Mehta, or his representative, to explain any words, terms, or sections that are unclear to you. Ask any questions that you have about this research study. Do not sign this consent form unless you understand the information in it and have had your questions answered to your satisfaction.

If you decide to take part in this research study, you will be asked to sign this form. You will be given a copy of the signed form. You should keep your copy for your records. It has information, including important names and telephone numbers, to which you may wish to refer in the future.

New things might be learned during this study that you should know about. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you are eligible to participate and agree to be in the study, the Principal Investigator may still choose to stop your participation in this study if he thinks it is in your best medical interest.

If you have question about your rights as a research study subject, call the Tufts Medical Center and Tufts University Health Sciences Institutional Review Board (IRB) at (617) 636-7512. The Institutional Review Board is a group of doctors, nurses, and non-medical people who review human research studies for safety and protection of people who take part in the studies. Federal law requires the Institutional Review Board to review and approve any research study involving humans. This must be done before the study can begin. The study is also reviewed on a regular basis while it is in progress.

This research study has been reviewed and approved by the IRB of Tufts Medical Center and Tufts University Health Sciences.

PURPOSE OF STUDY

The objective of this research study is to propose a new screening questionnaire to assess obstructive sleep apnea in a group of subjects attending a multidisciplinary Craniofacial Pain Center.
The study will be conducted at the Craniofacial Pain Center, Tufts University School of Dental Medicine, 1 Kneeland Street 6th floor, Boston, MA. 02111

This study consists of completing 2 questionnaires and the use of a portable sleep monitor at your home, you will be one of 100 participants enrolled in this study.

PROCEDURES TO BE FOLLOWED
The study design includes a group of subjects seeking care at a multidisciplinary craniofacial pain center at Tufts University School of Dental Medicine. A number of 100 male and female older than 18 years old of age volunteers will be recruited for this study from the clinical patient population at the craniofacial pain center. A new screening questionnaire consisting of 15 items related to stability and comfort of the bite, fatigue of muscles while chewing, interrelation of upper and lower teeth on mouth closing, clenching and grinding of teeth, missing teeth on the back of the mouth, difficulty of breathing through the nose, loud snoring, neck pain, headaches, high blood pressure, trouble falling asleep or staying asleep, neck collar size, medications taken, and sleepiness.

A supplemental screening questionnaire will be use as well; this questionnaire has been previously validated to screen for obstructive sleep apnea, consisting of a self-report, forced-choice yes/no, paper and pen scale that will take approximately less than 5 minutes to complete**,** consisting of 4 yes/no questions related to snoring, tiredness during the daytime, observed apnea during sleep, and hypertension.

After the completion of both questionnaires the you will be invited to undergo an overnight sleep study at their home using a portable sleep monitor device previously validated and FDA cleared to screen and diagnose obstructive sleep apnea.

The portable sleep monitor consist of a hand wrist watch type that will be used in the non-dominant arm, with 4 sensors that will be externally attach in to the following areas:

☒ Base of the neck (front area)
☒ Chest bone (males) / Above the breast (female)
☒ Index finger
☒ Ring finger

You will receive a demonstration and verbal instructions on how to appropriable use the portable sleep monitor, instructions on how to return the portable sleep monitor device to our clinic will be covered; this will take approximately 20 minutes.

The Portable sleep monitor will be delivery to participants with a brochure and a CD containing

video demonstration step-by-step instructions to review at home; returning mailing supplies will be provided at no cost to the participant. A 24 hours help desk phone number from the portable sleep monitor manufacturer will be available. The craniofacial pain center answering service phone number will be available that will connect with the investigator for after clinic hours questions.

You will return the portable sleep monitor back to the clinic at no cost via FEDEX service, after receiving the portable sleep monitor from the participant, the sleep report will be analyzed. You will receive a follow up phone call to inform them of the presence or absence of obstructive sleep apnea, and advice you of the appropriate follow up medical care.

RISKS
This is a non-invasive, non-experimental study.
There are no risks involved on filling out the 2 questionnaires.
The risks of using the portable sleep monitor are: Wrist or arm discomfort from applying the strip from the watch type device to tight, and irritating sensation on the finger

BENEFITS
The benefits of this research study are to help identify risk factors for obstructive sleep apnea; develop and use of new screening questionnaire to identify the possible presence of obstructive sleep apnea.

ALTERNATIVES
If you should decline to participate in this study, you can continue to be treated at The Craniofacial Pain Center.

WHOM TO CONTACT
In case you have any problems or questions please contact Dr. Noshir R Mehta or Dr. Leopoldo P. Correa at 617-636-3421 (daytime) 617-636-6817 (after clinic hours).

RESEARCH RELATED INJURY
Emergency medical treatment will be given to you if you are hurt or get sick as a direct result of being in this research study. You or your insurance carriers are to pay for any such medical care. Any needed medical care is available at the usual cost. All needed facilities, emergency treatment, and professional services are available to you, just as they are to the general public. There are no plans to pay for your treatment if you get hurt or sick as part of this study. The institution has not set aside any money to pay for a research-related injury or illness.

COSTS
There are no costs associated with participation.

PAYMENT
No payments will be made for your participation in this studyPRIVACY AND

CONFIDENTIALITY

If you agree to take part in this research study, your personal information will not be given to anyone unless we get your permission in writing. It will only be given if the law requires it. It will also only be given for regular hospital treatment, payment, and hospital management activities. We will make every effort to keep your information private, but it cannot be totally guaranteed. Certain government agencies and the Institutional Review Board of Tufts Medical Center and Tufts University Health Sciences may check records that identify you. This might include your medical or research records and the informed consent form you signed. The records of this study might also be reviewed to make sure all rules and guidelines were followed.

PARTICIPANT'S STATEMENT

I have read this consent form and have discussed with Dr. Noshir R. Mehta or his representative the procedures described above. I have been given the opportunity to ask questions, which have been answered to my satisfaction. I understand that any questions that I might have will be answered verbally or, if I prefer, with a written statement.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study.

I understand that my participation is voluntary. I understand that I may refuse to participate in this study. I also understand that if, for any reason, I wish to discontinue participation in this study at any time, I will be free to do so, and this will have no effect on my future care or treatment by my physicians or this hospital.

I understand that in the event I become ill or am injured as a result of participating in this research study, medical care will be provided to me. However, such medical care will not be provided free of charge, even if the injury or illness is a direct result of this research study. I understand that no funds to provide financial compensation for research-related injury or illness are available.

If I have any questions concerning my rights as a research subject in this study, I may contact the Institutional Review Board at (617) 636-7512.

I have been fully informed of the above-described study with its risks and benefits, and I hereby consent to the procedures set forth above.

I understand that as a participant in this study my identity and my medical records and data relating to this research study will be kept confidential, except as required by law, and except for inspections by the U.S. Food and Drug Administration which regulates investigational drug/ device studies, and the study sponsor.

_____ _____

Date Participant's Signature

I have fully explained to _____ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____ _____

Date Principal Investigator or Representative's Signature6565

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