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Impact of an Obstructive Sleep Apnea Education Program on Continuous Positive Airway (CPAP) Adherence A Pilot Study

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Abstract

Obstructive Sleep Apnea (OSA) is an under diagnosed and common disorder that is associated with an increased risk of adverse cardiovascular events and neurocognitive impairment. Management of OSA includes treatment goals to promote optimal sleep and reduction of cardiovascular risk. Continuous Positive Airway Pressure (CPAP) therapy is the mainstay of treatment for OSA. Adherence to CPAP therapy mirrors the rates of adherence seen in other chronic diseases, with up to 50% of OSA patients abandoning therapy within one year. The aim of this pilot study is to investigate if implementation of a comprehensive educational OSA program improves CPAP adherence in OSA patients. Theoretical frameworks utilized for this study includes Knowles Theory of Adult Learning and the Triandis Theory of Interpersonal Behavior. The Knowles Theory incorporates the adult principles of self-directed and relevant learning that can be incorporated into a CPAP curriculum. The Triandis Theory proposes that intentions are immediate antecedents of behavior and habit formation which is inherent in CPAP adherence. Studies have consistency emphasized the importance of education for OSA patients that require CPAP. Strategies to improve CPAP adherence include providing education and support during the first two weeks of therapy when the risk abandoning therapy is highest. Descriptions of educational content is lacking in the literature and without an established curriculum, it is difficult to measure if CPAP adherence is related to education. This pilot study methodology measured CPAP adherence utilizing technology mediated comprehensive OSA education for eight newly diagnosed OSA patients compared to eight OSA patients who receive OSA standard care. Knowledge was measured pre and post OSA education in the treatment group. Smart card technology was utilized to measure actual CPAP hours after one month of use. A paired 2 tailed t test demonstrated improvement in OSA knowledge between pre-test and post-test in treatment group which was significant with $p<0.05$.Preliminary data demonstrated that an odds ratio analysis with 5 of the 16 CPAP compliance reports shows adherence improved by a 2 to 1 ratio with the intervention group compared to the control group.

Keywords: Continuous Positive Airway Pressure; Obstructive Sleep Apnea; Excessive Daytime Sleepiness; Polysomnography; Hypopnea Index; Electro Encephalogram

Abbreviations: OSA: Obstructive Sleep Apnea; CPAP: Continuous Positive Airway Pressure; EEG: Electro Encephalo Gram; EDS: Excessive Daytime Sleepiness; AHI: Apnea/Hypopnea Index

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Introduction

Background and Significance

Obstructive Sleep Apnea (OSA) is a common disorder and is associated with an increased risk of adverse cardiovascular events, neurocognitive impairment, vehicular and workplace accidents, increased healthcare utilization and decreased productivity. OSA incidence in the U.S. is estimated to be 4% in adult men and 2% in adult woman. One in four adults is at risk for OSA [1]. Individuals with untreated OSA experience 2.8 times more hospitalizations and 7 times more car crashes with a 60% rate of injury and or death [2]. The cost of OSA related motor vehicle crashes in 2000 was estimated at 15.9 billion. OSA is a major public health concern in the United States and worldwide. The estimated annual cost of treating the medical consequences of OSA is 3.4 billion in the U.S. alone [3]. OSA is a sleep disorder characterized by repetitive episodes of upper airway obstruction and reduction in ventilation. With the onset of sleep, muscle tone decreases leading to narrowing of the airway. The tongue and soft palate partially or completely obstruct the pharynx and contribute to episodes of apnea or hypopnea which cause a recurrent pattern of sleep interruption and arousals followed by restored breathing. OSA is defined as the presence of at least 5 episodes of apnea (cessation of breathing) or hypopnea of at least 10 seconds per hour during sleep. Hypopnea is defined as a drop in respiratory flow by 30 % or greater from baseline lasting 10 seconds or more, associated with a drop in oxygen saturation of 4% or greater from pre-event baseline. Individuals with OSA may have as many as 200-400 episodes occurring during 6-8 hours of sleep. OSA is associated with excessive daytime sleepiness (EDS) and poor quality of life due to chronic sleep deprivation. In addition to sleep loss, OSA individuals may have memory or learning difficulties completing daily tasks, diminished executive functioning and have problems with relationships and employment. They may also be depressed, irritable and experience sexual dysfunction [4]. Intermittent periods of hypoxia that occur with apneic episodes places ischemic and oxidative stress on the cardiovascular system and contribute to complications such as MI, CVA, arrhythmias, HTN, pulmonary HTN, heart failure and sudden death [4]. Higher leptin levels are found in patients with untreated OSA. Leptin is a hormone that plays a key role in regulating energy intake and expenditure including appetite and metabolism. Despite the weight reducing effects of leptin, obese patients are also found to have elevated levels of leptin. It is thought that obesity along with OSA increases resistance to the effects of leptin.Sleep fragmentation, hypoxia, hypercapnia, and acidosis lead to excessive daytime sleepiness (EDS), and profound cardiovascular and metabolic consequences. These patho physiologic and cellular changes lead to increased mortality, decreased quality of life and shorter life expectancy [5].

Prevalence of OSA increases with age greater than 55. OSA has a two to three fold increase in individuals 65 years and older. Men are five times more likely to have OSA, but this gap narrows significantly in woman after menopause. Certain ethnicities including African Americans and certain Pacific Islanders have higher rates of OSA. This observation is independent of body weight. The incidence of OSA in Asians is similar to that in the U.S., despite lower body mass indexes. These observations in the Asian population suggest differences in craniofacial structure. A significant risk factor for OSA is obesity, particularly truncal obesity with neck circumference >17 inches in men and >16 inches in woman (70% of OSA individuals are obese) [5]. Increased BMI and neck circumference cause loading of the airway and with the addition of decreased muscle tone during sleep, limits airway patency. Upper airway anatomy can also affect OSA risk such as nasal and /or oral anatomical obstruction (nasal polyps or enlarged tonsils), craniofacial abnormalities such as micrognathia, retrognathia, macroglossia or pendulous uvula and a high Mallampati Score (crowded upper airway).Alcohol and sedative use contribute to OSA through their relaxant effect on the muscles of the upper airway. Smoking increases risk of OSA with heavy smokers at greatest risk. Other risk factors include family history and pre-existing co morbidities such as HTN, CAD, T2DM/insulin resistance, GERD, hypothyroidism, anxiety, depression, mood disorders and PTSD [2,4]. Clinical features of OSA include loud cyclic snoring, nocturnal choking or gasping, periods of breathing cessation (usually observed by bed partner), increased snoring and breathing cessation while in supine position, restless sleep, repetitive awakening, thrashing body movements, excessive daytime sleepiness, unintentional sleeping, fatigue, nocturia, decreased libido, sexual dysfunction, impaired concentration, moodiness, irritability, depression and morning headache [1]. The diagnostic process is guided by screening and appropriate referral for sleep studies. The STOP-BANG inventory is a simple and reliable office based screening tool that combines symptoms, history and physical examination to recognize individuals at risk for OSA. If a patient is positive for three or more STOP-BANG factors, the probability of OSA is high enough to warrant sleep study testing [5]. Polysomnography (PSG) is the gold standard in diagnosing OSA. PSG is usually a full night in laboratory study that measures a multitude of physiological parameters while the patient sleeps. Parameters include EEG (electroencephalogram), EOG (electro-oculogram),

respiratory effort, air flow, EKG, and pulse oximetry. At times, a split-night in laboratory sleep study is done with the first part of the night utilizing the same physiologic parameters as the full night study to diagnose OSA. The second half of the night is used for titration of Continuous Positive Airway Pressure (CPAP). This is useful to expedite OSA diagnosis and treatment. This also eliminates the necessity a second night in laboratory stay for CPAP titration and is proposed as effective alternative to the full night study. However, with the split night study there is an increased risk of false negative PSG result. Home sleep testing has emerged as a cost saving and convenient alternative in diagnosing OSA. Home sleep studies have important limitations. They do not monitor EEG or EOG, so therefore sleep arousals, wakefulness or sleep as well as REM sleep cannot be detected. False negative rates have been reported as high as 17% and false positive rates between 2-31% [5]. Insurance providers are increasingly only paying for home sleep studies for cost containment purposes.

Severity of OSA is classified into mild, moderate and severe. The average number of number of apneas and hypopneas per hour of sleep is the apnea/hypopnea index (AHI).OSA is diagnosed if the AHI is 5 or more in the presence of symptoms such as excessive sleepiness, fatigue, inattention, or other signs of disturbed sleep or if the AHI is greater than 15 in asymptomatic individuals. Mild OSA is an AHI of 5-15, moderate OSA is an AHI of 16-30 and severe OSA is an AHI of greater than 30[1]. Management of OSA includes treatment goals to promote optimal sleep function and to educate patients about risk factors and OSA treatment. Patients need to be informed of the consequences of cognitive impairment and cardiovascular risks related to OSA. Weight loss is an important long range goal as obesity strongly correlates with OSA. A 10 % weight loss is associated with a 26% decrease in AHI. It is also important to manage and treat co-morbidities such as HTN, CVD, heart failure, diabetes, hypothyroidism, GERD and psychiatric disorders [5]. Lifestyle changes need to be encouraged such as smoking cessation and avoidance of CNS depressants (alcohol, sedatives) along with a low fat, high plant based diet and exercise. Good sleep hygiene should be emphasized such as allowing sufficient time for sleep, keeping regular hours and ensuring the bedroom is conductive to sleep. Side or prone sleeping using pillows or positional devices can be used to reduce airway collapse [5]. Positive Airway Pressure (PAP) therapy, which commonly includes CPAP are the most effective treatment for moderate to severe OSA. Devices include CPAP, bi-PAP and automated adjusted devices such as APAP. Oral appliances may be useful for patients with mild OSA who do not have symptoms of excessive daytime sleepiness or other symptoms of OSA. Oral appliances advance the mandible and tongue forward to improve airway patency during sleep [5].

If OSA is compounded with a crowded airway or obstruction, surgery may be warranted. Anatomical obstructions may require removal of enlarged tonsils, adenoids or nasal polyps. For craniofacial abnormalities, uvulopalatopharyngoplasty, laser assisted uvulopalatopharyngoplasty, tissue volume reduction, genioglossal advancement and maxillomandibular advancement. Although surgery may be initially appealing to patients as a permanent solution, it is not the first or best option. Surgical success varies, especially with craniofacial surgeries. Surgeries are also associated with risks, especially in patients with multiple co-morbidities [5]. PAP devices are the most common mode of treatment for OSA. PAP/CPAP is the pneumatic splinting of the upper airway to counter the tendency to collapse. Pressurized room air is delivered via a close fitting nasal or oro-nasal mask [1]. CPAP is the modality of choice, although bi level PAP (BiPAP) may be used for CPAP intolerant patients. For dry air conditions, most devices have humidification capability with sensors that allow humidity adjustment. If the patient experiences discomfort from too much pressure when CPAP is initiated, a ramp up mechanism allows CPAP to start after the patient falls asleep and gradually increase until set pressure is reached. All devices have recording cards or modems that allow data collection on use. Various insurance providers require this data collection for confirmation of CPAP use [5].CPAP only controls obstructed breathing while an appropriately pressurized mask remains in place. A single night of missed treatment is sufficient for daytime deficits to return [6].

Long term adherence to PAP therapy is a major concern because diminished adherence or therapy abandonment result in diminished benefit and recurrence of OSA. Non-adherence rates are reported at 50% with 20-30% of patients stopping CPAP during first two weeks of therapy [7]. Issues related to non-adherence include adjustment to device, mask fit, claustrophobia, noise, air leaks, air swallowing, skin irritation, nasal dryness, difficulties troubleshooting problems and inadequate education and support [8].

There are some comparisons that can be made between CPAP adherence and medication adherence. According to the Agency for Healthcare Research and Quality (2011), poor medication adherence is common with 20-30 % of medication prescriptions never filled and 50% of medications for chronic disease not taken as prescribed. This lack of adherence is not only prevalent but also has

profound effects on individual and population-level health("Medication adherence interventions:Comparative Effectiveness," 2011). Benefits of CPAP therapy are significant for reduced morbidity and mortality, particularly cardiovascular complications. CPAP lowers cardiovascular risk parameters, including HgbA1c, C-reactive protein, homocysteine, total cholesterol, LDL and ApoB/ApoA ratio. CPAP lowers blood pressure and improves daytime sleepiness, quality of life measures, cognitive function and depression [5]. Consequences of failed therapy for OSA individuals are dramatic with increased risk of MI, CVA, heart failure, pulmonary hypertension, arrhythmias, worsening hypertension, increase in Body Mass Index (BMI), insulin resistance, sudden death and decreased life expectancy. There is also the increased risk of vehicular and workplace injuries or death [9].

A treatment goal for effective CPAP use is a minimum of 4 hours per night at least 5 days (70%) of the week [10]. Electronic monitoring with Sim card or modem download is the most accurate measure of adherence [1]. Patient self- reports of CPAP use and sleep logs can also be helpful. The Epworth Sleepiness Scale (ESS) and questionnaires such as the 6-Question Moorehead-Ardelt II QOL can be utilized to assess and monitor daytime sleepiness and quality of life. The ESS and 6-Question Moorehead-Ardelt II QOL Questionnaire are validated tools used extensively in OSA research [11,12]. Pharmacologic management for residual or ongoing daytime sleepiness, such as modafinil may also be used to augment treatment [1].

Strategies to improve PAP/CPAP adherence include providing education and support during the first two weeks of therapy when the risk abandoning therapy is highest [8,13]. Educational programs need to include information such as treatment of OSA, risks and consequences of untreated OSA, dispelling myths, sleep hygiene, CPAP treatment, equipment management, acclimating to CPAP, desensitization, troubleshooting and managing commonly encountered problems. Also, individuals need to know when and who to call for assistance before a decision is made to abandon therapy (Johnson, 2008).It is also important for early and regular follow up with a Primary Care Provider and/or Sleep Specialist. Support groups, telephone follow up and home visits by Sleep Technicians can be of great benefit in managing problems and establish early patterns of CPAP use [14].

OSA management includes assessing the level of adherence with treatment outcomes. CPAP is demanding therapy to undertake and patients require a high level of input and support during the initial phase of therapy [1]. A comprehensive educational program to improve CPAP adherence is an important component in caring for this population. Early intervention strategies for patients initiating CPAP therapy may have a better likelihood of improving adherence rather than intervening later in the course of therapy when a pattern of poor adherence has already been established [1].

Research Question

Will newly diagnosed adult patients with Obstructive Sleep Apnea (OSA) who receive a comprehensive OSA educational program have improved adherence with Continuous Positive Airway Pressure (CPAP) compared to newly diagnosed adult patients who do not receive a comprehensive (OSA) educational program?

Theoretical framework: The two theoretical frameworks that apply to Obstructive Sleep Apnea (OSA) are Knowles Theory of Adult Learning and the Triandis Theory of Interpersonal Behavior.

Knowles Theory of Adult Learning is based on principles of andragogy which is the art and science of helping adults to acquire knowledge that leads to learning [15]. Knowles outlines six principles of adult learning as [15]:

- Adults are internally motivated and self- directed.
- Adults bring life experiences and knowledge to their learning experiences
- Adults are goal oriented.
- Adults seek relevance in their learning.
- Adults are practical.
- Adults want to be respected.

According to Knowles [16], as adults mature they move away from dependency toward self- direction. However, adults may be dependent in certain temporary situations. Adults grow and develop as they accumulate an increased reservoir of experience. They attach more meaning to learning that they obtain from experience than learning acquired passively [17]. Adults are performance oriented and learn more with teacher guided discussion, case studies, active problem solving, field experiences and experimentation. Adults become ready to learn when they experience a need to learn in order to cope more effectively with real life tasks and problems. Adult learners view education as a process of developing increased competence to achieve their full potential. They aim to build knowledge and skills to future learning situations [17].

Knowles describes adults as self-directed learners with learning tasks largely within the control of the learner.

Adult learners strive to be empowered to accept personal responsibility for their own learning, self-autonomy and individual choice. Initial success sets the stage for future successes. Learners must have the opportunity to develop and practice skills that directly improve learning. These skills include identifying knowledge and gaps, asking questions, appraising new information and critical reflection of their own learning [17].

Knowles suggests that self-directed learning should include developing the learner's capacity to be self-directed. It is no longer reasonable to simply transmit what is already known, but to develop the skills of inquiry. Learners need to be proactive and responsible for their own learning. Newly diagnosed Obstructive Sleep Apnea (OSA) adult patients who require Continuous Positive Airway Pressure (CPAP) need to effectively learn about OSA, risk factors associated with no treatment, how OSA affects their personal health and how to use and manage CPAP equipment. Knowles Theory of Adult Learning incorporates the adult principles of learning that can be incorporated into a curriculum for OSA patients to be successful in their CPAP use. Technological developments have influenced adult learning with technology used as both a delivery system and a content area. The principles of adult learning can be used in the design of technology-based instruction to make it more effective. Media directed learning utilizes technology to convey learning to adults which is convenient, easy to use and familiar. Learners can move through lessons anytime, anywhere and at their own pace [18]. A computer based educational program on OSA and CPAP use can be a very effective teaching method for adult learners.

The Triandis Theory of Interpersonal Behavior proposes that intentions are immediate antecedents of behavior and habits are essential to mediate behavior. Intentions and habits are moderated by facilitating factors. Behavior is a function of intention, expectation of consequences, habitual responses, situational constraints and conditions. Intention and habit formation is also influenced by moral beliefs, emotional drives, self–concept, cognitive function and social factors such as norms and roles [19]. According to the Triandis Theory, human behavior is formed by three components: intention, facilitating conditions and habit. Intention refers to a person's motivation regarding a specific or given behavior. Facilitating conditions represent perceived factors in the environment that will impede or promote a specific behavior. Habit refers to how frequently or routinely a specific behavior becomes. Habit reinforces a specific behavior and behavior reinforces habit. Triandis defines habit as "situation-behavior sequences that are or have become automatic, so that they occur without self-instruction". In the Triandis theory, behavioral intention is comprised of attitudinal and normative beliefs. Attitudinal beliefs consist of two dimensions: affect and perceived consequences. Affect represents the emotional state that the individual experiences about a specific behavior, whereas perceived consequences refer to instrumental consequences of the behavior.

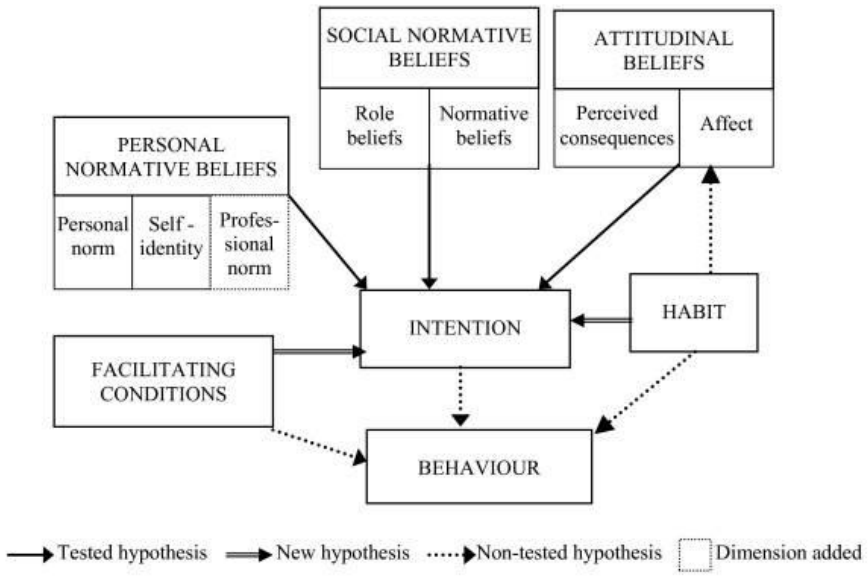

Figure 1: Theoretical Model Adapted from Triandis' Theory of Interpersonal behaviour.

The Triandis Theory of Interpersonal Behavior suggests that intention emerges from knowledge of OSA, treatment management with CPAP and risks of non-adherence. Patients following routines and practicing repeated health care actions will eventually establish habitual behaviors. Educational interventions which informs patients about CPAP benefits, consequences of non-adherence and guides a habitual routine of CPAP use may result in improved adherence [2]. These theories can serve as theoretical frameworks to improve OSA outcomes and CPAP adherence. Facilitating learning, engaging in self-care practices and developing habitual behaviors help to promote adherence to improve health and reduce CV risks in OSA patients. Continuous Positive Airway Pressure (CPAP) therapy is the mainstay of treatment for moderate to severe OSA. Adherence to CPAP therapy is often less than ideal and mirrors the rates of adherence seen in other chronic diseases, with up to 50% of OSA patients abandoning therapy within one year [20]. Strategies to improve CPAP adherence include providing education and support during the first two weeks of therapy when the risk abandoning therapy is highest [9,13]. Educational programs need to include information such as treatment of OSA, risks and consequences of untreated OSA, dispelling myths, sleep hygiene, CPAP treatment, equipment care, acclimating to CPAP/desensitization, troubleshooting and managing commonly encountered problems, adverse effects and when and who to call for help [9]. OSA management includes assessing the level of adherence with treatment outcomes. CPAP is a complex demanding therapy to undertake and patients require a high level of input and support during the initial phase of therapy. With limited education typically given to an OSA patient, who is likely to be sleep deprived, the patient is expected to remember all of the functions of the equipment and use CPAP for 7 to 8 hours daily [21]. A comprehensive educational program to improve CPAP adherence is an important component in caring for this population. Early intervention strategies for patients initiating CPAP therapy may have a better likelihood of improving adherence rather than intervening later in the course of therapy when a pattern of poor adherence has already been established [1]. Utilizing the Triandis Theory of Interpersonal Behavior, intention emerges from knowledge of OSA, treatment management with CPAP and risks of non-adherence. Patients following routines and practicing repeated health care actions will eventually establish habitual behaviors [7]. Knowles Adult Educational Theory interventions informs patients about CPAP consequences of non-adherence and helps to establish CPAP use, which may result in improved adherence [17].

Review of the Literature

Key words utilized in this literature search were: Adults, Obstructive Sleep Apnea (OSA), Continuous Positive Airway Pressure (CPAP), Adherence and Education. Medline, PubMed, Cochrane, Journals @ Ovid, MD Consult databases were accessed. There were 287 journal sources identified with 20 articles utilized for this review of literature. The most frequently cited definition of CPAP adherence was first used by Kribbs, et al. [22], which is defined as "CPAP use for greater than or equal to 4 hours daily for 70% of night' [22]. Centers for Medicare and Medicaid Services adopted this definition as their measure of acceptable adherence [21]. More recent studies have established that increased hours of CPAP use are likely to further improve symptoms. Weaver [23] demonstrated a clear association in the number of daily CPAP hours and normalization of three commonly used measures of sleepiness and functional status in 149 patients with severe OSA. These measures were the Epworth Sleepiness Scale (ESS), Multiple Sleep Latency Test (MSLT) and the Functional Outcomes of Sleep Questionnaire (FOSQ), which are commonly used and validated tools in sleep research. This study found that the threshold level of nightly CPAP use was 4 hours for the ESS, 6 hours with the MSLT and 7.5 hours with the FOSQ [23]. A number of studies have attempted to identify contributing factors and predictors for CPAP adherence. While some studies have found relationships between age, sex, severity of disease, degree of sleepiness, and socioeconomic status to subsequent adherence to CPAP, however these findings are not consistent [24]. A study by Sin, et al. (2002) [25] found that female sex, older age and improvement in Epworth Sleepiness Scale (ESS) were associated with an increase in CPAP adherence [25]. A more recent study by Budhiraja, et al. [14] reported that younger age and African American race were associated with lower adherence, but there was no association with sex or disease severity [14]. While there is evidence that improved daytime sleepiness is associated with improved CPAP adherence, there is only weak evidence that disease severity of OSA is associated with improved adherence [11]. Simon, et al. [26] and Platt, et al. [27] reported lower socioeconomic status was closely associated with low initial acceptance of CPAP and low overall adherence. Specific tailoring of CPAP support and patient education is needed to increase adherence to therapy [7,27]. Wild, et al. [28] suggests that cognitive constructs and beliefs (social cognition, health values, locus of control and self-efficacy) correlate with health behaviors. Evaluating these factors may be more productive than focusing on demographic factors. The study done by Brostrom, et al. [29] found that patients with Type D personality patients had significantly higher complaints of adverse effects

from CPAP therapy and reported a higher rate of continued sleepiness than non D personality patients. Prompt attention and resolution of CPAP adverse effects and self-management strategies to enhance adherence is important in this subset of patients [29]. General approaches to improving CPAP adherence include technological, behavioral and adverse effect interventions. Technological interventions include use of sophisticated delivery modalities such as, auto-titrating Positive Airway Pressure (PAP), bi-level positive pressure and flexible pressure delivery as alternatives to conventional CPAP. However, these modalities have not been shown to contribute significantly to improved adherence over standard CPAP therapy. Comfort techniques and troubleshooting adverse effects such as mask fit, air leakage and nasal congestion are important aspects of CPAP management and contribute to overall adherence [7]. Weaver & Grunstein [11] reported that the use of heated humidification and pressure ramp features for OSA patients with nasal congestion did not significantly impact CPAP adherence. According to Weaver & Grunstein, patient perception of symptoms, improvement in sleepiness and daily functioning may be more important in determining patterns of CPAP use than actual disease severity [11]. Kribbs, et al. [22] reported behavioral interventions such as patient education, systematic desensitization and sensory awareness for claustrophobia has been shown to improve CPAP adherence [22].

Studies done by Smitt, et al. and Richards, et al. (2007) [8] have shown that cognitive behavior and standard education can increase daily CPAP use by 2.9 hours [7]. Cognitive behavioral therapy and motivational strategies positively influence self- management of chronic disease and behavioral readiness to change [21]. The study done by Sin, et al. [25] found an 83% adherence rate (n=233) of equal to or greater than 4 hours per night over the first 3 months of therapy with patient education, intensive follow-up and integrated care. This comprehensive educational program included video instruction depicting information on OSA, symptoms, health consequences, pathophysiology and CPAP devices [25]. Eight studies reviewed utilized educational interventions for OSA patients requiring CPAP. Four of the eight studies demonstrated improved adherence with CPAP education interventions [1,7,8,12,25,30-33]. One study done by Smith I, et al. [7] demonstrated improved adherence with cognitive behavioral therapy, but the utilization of a short course educational program showed no difference in average CPAP use [7]. A study done by Pelletier, et al. [32] investigated using an enhanced educational intervention and relaxation training which showed no difference in adherence between the intervention and control group. This study did show a significant improvement in CPAP hours between week 2 and 6 in the intervention group [32]. A French study done by Meurice P, et al. [30] studied the effects of four educational strategies on CPAP adherence with no difference in adherence between the four groups [30]. Ballard, et al. [33] demonstrated an increase in average nightly CPAP to ≥ 4 hours nightly in previously non adherent OSA patients after providing sleep apnea education along with technical assistance and troubleshooting with CPAP equipment [33]. One pilot study done by Golay, et al. [31] in Switzerland, described an educational program for OSA patients and their partners. Although not statistically significant, results showed improvement of CPAP duration. Most studies do not describe a content outline or curriculum.

Studies have consistency emphasized the importance of education for OSA patients requiring CPAP. However, what that education should include is lacking in the OSA literature. Educational programs can vary greatly from study to study. Media directed learning is also lacking in OSA literature. Without an established outline or curriculum, it is difficult to measure if CPAP adherence is related to education.

Education and regular clinician follow-ups are essential in improving CPAP adherence especially during the first few weeks of therapy when the risks for abandoning therapy is highest [21]. The translation of CPAP clinical assessments need to include review of subjective and objective use, response to CPAP, adverse effects and any other limitations to therapy. Due to the interplay of many factors and complexity of therapy, any identified issues need to be resolved early during therapy. Implementation of adherence interventions is imperative to improve health and functional outcomes in the OSA adult population.

Methods

This pilot study was conducted to determine if a comprehensive educational program improves CPAP adherence in newly diagnosed adult OSA patients compared to OSA patients who receive standard care. Patients were randomly assigned to a control group who received routine OSA care or treatment group who received an OSA media based educational program in addition to receiving standard care. Group assignment was done by consecutive order of presentation. CPAP adherence was measured by data collected from smart card or modem downloads which record actual daily CPAP usage for periods of one month or more. This data was collected and analyzed to determine if there is a

significant difference in CPAP adherence between the experimental and control groups.

Sample

The pilot study participants were verbally recruited by the study investigators at a private ENT practice that specializes in sleep disorders, located in Port Jefferson and Patchogue, N.Y. Recruitment signs describing the study will were posted in the ENT office waiting rooms.

Inclusion criteria-Participants selected for this pilot study were male and female adults aged18 or older, who are newly diagnosed with moderate to severe OSA. Study participants were English speaking, able to read and write in English, had a minimum of High School Diploma or its equivalent and competent to consent to the study. Exclusion criteria- Participants with cognitive impairment, severe visual or auditory impairment or have serious psychiatric conditions that would interfere with their ability to consent to the study and/or participate in an educational learning session. The sample selected for this pilot study was sixteen participants who were randomly assigned by order of consecutive presentation to one of two groups. The control group consisted of eight newly diagnosed OSA patients who received standard OSA care. Standard care includes verbal education and discussion with clarification of misconceptions about CPAP therapy. The experimental group of eight newly diagnosed OSA participants received a OSA media educational program in addition to standard OSA care.

Power Analysis

The probability of committing a Type I error or false positive is denoted as the significance level or alpha (α). The probability of a Type II error or false negative is beta (β). The complement of beta (1-β) is the probability of detecting a true relationship or difference and is the power of a statistical test. The significance level (α) selected is 0.05 (risk of a Type I error). The power level selected is .80 (1-β) which is a conventional standard. With power equaling .80, there is a 20% chance of committing a Type II error. The effect size is the magnitude of the relationship between the research variables. When relationships or effects are strong, they can be detected as significant with smaller sample sizes [34]. With an alpha of .05 and a medium effect size (.06) utilizing at test analyzing mean differences a sample size of 64 is calculated. Since this is a pilot test 10% of the sample size can be utilized. This would be a sample size of 6.4 of 7 participants per group [35]. Eight participants were selected to each group to account for possible participant drop out or recidivism.

Operational Definition of Variables

Independent variable: Comprehensive CPAP education program, a media based 15 minute educational video describing OSA, CPAP treatment goals and benefits and troubleshooting problems.

Dependent variable: CPAP usage-average number of hours each night and average number of days used over a month period. CPAP adherence definition used in the literature and by Medicare is PAP use of 4 hours or greater per day for 70% of days (data is downloaded from smart card in PAP device or accessed by modem).

Instruments

OSA computer mediated educational program was shown to participants randomly assigned to the treatment group. As part of treatment fidelity, the educational video was narrated by the Board Certified Sleep Specialist Physician who is the provider for the recruited OSA patients. The narration was read from a script which was based on learning objectives and educational outline. The script was written by the Sleep Specialist Physician and the study investigators. The OSA media based educational program was edited and power point slides added to emphasize key points of OSA and CPAP therapy.

The pre and post- test – 10 question paper/pencil test was written at a 6th grade reading level by the study investigators based on learning objectives of the OSA educational program curriculum. The pre and post-test is a non-validated tool, however expert review of content validity of exam questions were reviewed and approved by the Sleep Specialist Physician. The same test was administered to participants prior to and after viewing the OSA educational video program.

Equipment and Study Protocol

Positive Airway Pressure (PAP) consists of Continuous Positive Airway Pressure (CPAP), Bi-Level Airway Pressure (BiPAP) or Automated Positive Airway Pressure (APAP) delivery methods, one of which is specifically ordered by the Sleep Specialist Physician. PAP machines, tubing, masks and data cards/modems are manufactured by Fisher & Paykell, Resmedor Respironics. The PAP machines and its equipment are inspected by the manufacturer prior to being purchased by their distributors or Durable Medical Equipment (DME) Company. All machines have a manufacturer's serial number for tracking or in case of a recall. The DME Company is contacted by the practice's Sleep Coordinator (based on the patients insurance) when a patient has a prescription for PAP therapy. The patients were contacted

and appointments made with the company's Respiratory Therapist or technician to set up PAP equipment and activation in patients' home. The Respiratory Therapist or technician preformed a quality assurance check of all machines, operation and equipment, including the devices' smart card/modem according to the manufacturer's recommendations. Each PAP device had a product manual that was given to the patient. The equipment, setup, masks, tubing, humidification and smart card or modem were set up in the patient's home-usually the bedroom. The patient was instructed on the equipment set up, use, cleaning, changes for tubing and mask, mask fit, maintenance and troubleshooting. PAP machines manufactured and used for the study population complied with electromagnetic compatibility requirements (IEC60601-1-2) for residential, commercial and light industry environments and met the Federal Aviation Administration requirements. Malfunction of the equipment may occur if the device is damaged or used not in accordance of the manufacturer's guidelines.

Approximately 75 % of patient's PAP adherence is monitored via a smart card and 25 % via a modem. The smart card is a credit card sized memory card that records data when the PAP device is on and the mask is applied to the patient's face. The smart card records data only when pressure is activated and it does not record if mask is still on but removed from face. This Card was removed from the PAP machine and sent to the DME Company one month after initiation of PAP where the data was downloaded and then sent via computer to the practice's Sleep Specialist Physician. Data was stored on a computer file for analysis of adherence. Access to the smart card required a secure password and pin number. Smart cards had the patient's name, date of birth and information of PAP hours by date. Data also included frequency or occurrences of hypopneas and apneas. This data was reviewed and analyzed by the Sleep Specialist and discussed with patient at a follow-up visit.

The computer modem interface was also utilized for adherence data. Data was recorded similar to the smart card, the PAP device records only when the mask is applied to the subjects face and pressure is activated. The use of a modem is determined by the PAP machine and insurance provider. PAP adherence can be viewed and monitored in real time by the Sleep Specialist Physician. This access occurs via computer with a secure password and pin number specially assigned to the provider. The patients were aware of this capability and gave consent for this monitoring. Wireless modems cannot be utilized in areas that have inadequate satellite signal. Also, monitoring cannot be done if internet access is down or if the participant does not have a computer. PAP adherence was reviewed similarly as the smart card, at one month post initiation of PAP by the Sleep Specialist Physician.

Adherence data was analyzed at one month after CPAP was initiated. CPAP hours were analyzed and recorded on data sheet with subject identifier by code (assigned code at study onset). Adherence was compared between the control and experimental group.

Intervention

OSA media based educational video program objectives and outline is as follows:

At the end of lesson, the learner will be able to:

- Describe characteristics of OSA.
- State risk factors for untreated OSA.
- Summarize benefits of CPAP therapy.
- Identify symptoms that may improve with CPAP use.
- Outline basic equipment care requirements.
- Troubleshoot potential problems with CPAP equipment or malfunction.
- Describe situations to contact Sleep Specialist Provider or Home Care Company.

➢ **OSA characteristics- obstruction of relaxed airway muscles during sleep**

Outline

A. Severity of OSA/diagnosis on sleep study
1. Mild, moderate, severe OSA
B. Breathing cessation/reduced oxygen levels
C. Effects on heart, brain and blood vessels
D. Lack of restorative or REM sleep

➢ **OSA risk factors and associated disorders**

A. CV risk- high BP, heart attack, stroke, irregular heart rhythm
B. Diabetes
C. Decreased life expectancy
D. Obesity
E. Depression
F. Quality of life
1. Daytime sleepiness/fatigue
2. Increased incidence of accidents/drowsy driving
3. Impaired thinking and concentration
4. Decreased productivity
5. Social/relationship issues
6. Depression

➢ **CPAP treatment and goals**

A. Normalizes sleep/feel rested
B. Reduces CV risk factors
C. Weight loss and exercise
D. Improved safety and driving
E. Improved productivity and functioning

F. Lifestyle changes
G. Mask interface and comfort
1. Mask types-nasal, full face or nasal pillows- masks may be changed
2. Desensitization/acclimating to mask
H. Positive Pressure Airway mechanics

1. Splints airway open with positive pressure
2. Humidification
I. Machine types
1. CPAP- Continuous Airway Pressure
2. APAP- Automated Positive Airway Pressure- ramp up/down feature
3. BIPAP- Bi level Positive Airway Pressure- different pressures during inspiration and expiration

➢ **CPAP adherence**
A. Treatment goals
1. 4 hours minimum at least 5 nights week- more is better including naps
2. Establish routine/habit of use
3. Importance of first few weeks
4. Acclimating to pressure/pressure adjustments
B. Sleep Etiquette
1. Sleep routine
2. Allow adequate sleep time
3. Conducive environment
4. Avoidance of alcohol, caffeine, smoking
5. Partner support
C. Compliance reports –monitoring of CPAP use
1. Smart card download
2. Modem technology
➢ Equipment care requirements
A. Cleaning
B. Change tubing/mask, nasal pillow system every 6 months
C. Change chinstrap, headgear every 6 months
➢ Troubleshooting problems and equipment malfunctions
A. Air leaks
B. Pressure discomfort
C. Claustrophobia
D. Skin irritation
E. Nasal congestion
F. Frequent awakening
➢ Contact provider and /or home care company if experiencing problems/questions
➢ Pre and Post-tests (see addendum)

Data Collection Procedures

Patients were consecutively recruited by order of presentation for this pilot study after in-lab or home sleep study was conducted and a diagnosis of moderate to severe sleep apnea was determined. After the sleep studies were completed, patients met with the Sleep Specialist Physician. The diagnosis of OSA, sleep study data and treatment options were discussed. After recruited patients consented to the study, they were randomly assigned to one of two groups, a control group receiving standard OSA care and the treatment group who in addition to standard OSA care received a OSA media based educational program. Participants were randomly assigned by order with number codes of 1, 3, 5, 7, 9, 11, 13, 15 to the control group and number codes of 2, 4, 6, 8, 10, 12, 14, 16 to the treatment group.

Patients who were are randomly assigned to the treatment group remained in the office and received a 10 question pre- test (paper/pencil multiple choice questions) prior to viewing the OSA media based educational program on a computer lap top with audio, then took the same test after viewing the OSA media based educational program via video/DVD. A quiet, well lit room in the practice is selected for the study participant to take the tests and view the video program. Pre and post-tests are administered by the study principle investigator or co-investigator who also set up and activated the OSA media based education program with the appropriate sound level. A back up lap top computer was available if the primary lap top failed to work. The study principle investigator or co-investigator remained in the area during the testing and viewing of the OSA media educational program to monitor the process and assist if there were any technical problems with the exam and/or video program. The study co- investigator was instructed by the principle investigator on the study protocol which included the procedure of administering the exams and showing the OSA media based educational program for consistency and reliability.

The identical ten question pre and post-test are graded as 1 point with each correct answer and 0 for each incorrect answer. The test score is a sum of correct answers ranging from 0-10. Scores of 8-10 indicates good/excellent knowledge of OSA.A score of 6-7 indicates fair knowledge of OSA. Scores of 0-5 indicates poor knowledge of OSA.

The pre and post tests are graded and recorded by the study investigator. Participants were identified by their assigned codes. The demographic identifiers associated with assigned codes, consents, pre-post tests and CPAP adherence reports were stored in a secured area.

Patients were informed prior to the initiation of CPAP that smart card or modem adherence data will be collected and analyzed by the Sleep Specialist Physician. The smart card was mailed by the patient to the DME Company (a self-addressed stamped envelope is provided to

patient).Patients was contacted by phone as a reminder to send card in. Patients with wireless modem monitoring were also contacted by phone or mail to remind them that their data will be accessed and analyzed by the Sleep Specialist Physician.

Data Analysis

Demographic data was collected to include age, gender and race. Other data includes OSA severity, Epworth Sleepiness Scale (ESS), Body Mass Index (BMI), Apnea Hypopnea Index (AHI), OSA severity, CPAP usage and adherence. Confidentiality was strictly maintained with no name or identifying information written on any data collection forms.

An analysis of pre and post educational test scores were compiled and analyzed. A paired two tailed t test was utilized to compare pre and post scores which were significant for increase in scores in the post test group. An odds ratio was utilized to analyze if comprehensive OSA education increases the chance of CPAP adherence.

Null hypothesis - There will be no difference between OSA patients' CPAP adherence rates who receive a comprehensive OSA education program and OSA patients' CPAP adherence who do not receive a comprehensive OSA education program (Ho:$\mu_a=\mu_\beta$).

Alternate hypothesis- There will be a difference between OSA patients' CPAP adherence rates who receive a comprehensive OSA education program and OSA patients' CPAP adherence who do not receive a comprehensive OSA education program (Ha:$\mu_a\neq\mu_\beta$).

A paired T test was utilized to compare if there is any difference between the pre and post- tests. A probability of a=.05 was selected with degrees of freedom (df) of 7. If the computed value of the test statistic is larger than the tabled value, the results are statistically significant. If the computed value of the test statistic is smaller, the results are not significant. This data was analyzed using SPSS.

Odds ratio is the odds of an event in one group to the odds of an event in another group. Odds ratios can be computed when the independent variable is not dichotomous [34]. Odds ratio was utilized as the statistical tool in this study due to small sample. The sample size of sixteen would be under powered for analysis of CPAP adherence data utilizing a Chi- Square statistical tool. Logistic regression coefficients or odds ratio can be utilized to make predictions for the dependent variable. Logistic regression predict likelihoods measured by probabilities, odds or log–odds, logistic regressions require binary dependent variables (CPAP adherence=yes/no). Probabilities range from 0 to 1, odds range from 0 to infinity. Odds ratio is a ratio at 2 values of the independent variable (OSA education) that are one unit apart. This indicates how many times higher the odds of occurrence for each one unit increase in the independent variable [36-38].

Results

Sixteen patients were consecutively recruited to this pilot study with eight randomly assigned to the control group and eight randomly assigned to the treatment group. One patient declined CPAP treatment. Demographic and diagnostic data is shown in table 1.The majority of patients were white married males, 75 % had home sleep studies, 50 % had moderate OSA and 50% had severe OSA. Most of the participants had moderate levels of day time sleepiness and were obese.

A paired 2 tailed t test demonstrated improved learning between the pre-test and post-test in the treatment group who viewed the OSA video educational program (n=8) which is significant at <0.05 (Table 2).

Data utilizing an odds ratio analysis with 5 of the 16 CPAP compliance reports shows CPAP adherence was improved by a 2 to 1 ratio in intervention group who received the OSA media based educational program compared to the control group (Table 3). Preliminary results support the rejection of the null hypothesis, thus supporting the research hypothesis that comprehensive OSA education improves CPAP adherence.

Sample Population	n=16
Race	White=17, AA=1
Gender	Male=14, Female=2
Marital Status	Married=15, Not Married=1
Sleep Study	Home Sleep Study=12, In lab=4
OSA Severity	Moderate OSA=8, Severe OSA=8
Mean Age	50.4
Mean BMI kg/m^2	32.31
Mean ESS Score	7.69
Mean AHI Score	40.49

Demographic Report				
	age	Epworth scale	AHI	BMI
Mean	50.3750	7.6875	40.4938	32.3188
N	16	16	16	16
Std. Deviation	6.19543	24.62172	29.62941	5.16994
Std. Error of Mean	1.54886	6.15543	7.40735	1.29249

Table1: Demographic and Diagnostic Data.

Paired t test Pre and Post Test			
			Pair 1
			OSA pretest total - OSA post- test total
Paired Differences	Std. Deviation		1.30247
	Std. Error Mean		.46049
	95% Confidence Interval of the Difference	Lower	-2.46389
		Upper	-.28611
t			-2.986
df			7
Sig. (2-tailed)			.020

Table 2: Paired t test Pre and Post Test.

Variables in the Equation							
		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	treatment	.693	1.871	.137	1	.711	2.000
	Constant	.000	1.414	.000	1	1.000	1.000
a. Variable(s) entered on step 1: treatment.							

Classification Table[a]					
Observed			Predicted		
			CPAP adherence		Percentage Correct
No	yes				
Step 1	CPAP adherence	no	0	2	.0
		yes	0	3	100.0
	Overall Percentage				60.0
a. The cut value is .500					

Case Processing Summary						
	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
treatment * CPAP adherence	5	31.3%	11	68.8%	16	100.0%

Treatment * CPAP adherence Crosstabulation					
			CPAP adherence		Total
			no	yes	
treatment	control	Count	1	1	2
		Expected Count	.8	1.2	2.0
		% within treatment	50.0%	50.0%	100.0%
		% within CPAP adherence	50.0%	33.3%	40.0%
		% of Total	20.0%	20.0%	40.0%
	intervention	Count	1	2	3
		Expected Count	1.2	1.8	3.0
		% within treatment	33.3%	66.7%	100.0%
		% within CPAP adherence	50.0%	66.7%	60.0%
		% of Total	20.0%	40.0%	60.0%
Total		Count	2	3	5
		Expected Count	2.0	3.0	5.0
		% within treatment	40.0%	60.0%	100.0%
		% within CPAP adherence	100.0%	100.0%	100.0%
		% of Total	40.0%	60.0%	100.0%

Table 3: Variables in the Equation.

Discussion

Analysis of this pilot study demonstrates that comprehensive OSA education improves CPAP adherence. This study demonstrates that a formally developed media based educational OSA program does increase learning as demonstrated by a significant difference in pre and post test scores in the treatment group. These findings are consistent with studies done by Sin, et al., Smith, et al. and Richards, et al. (2009) that OSA education and support improves CPAP adherence [7,25].

Only 5 study participants (31%) submitted their CPAP compliance data at the end of this study. It is unknown if the remaining study participants (79%) continued CPAP therapy. Further studies need to be conducted with larger sample sizes and more diverse populations. Further studies need to compare degree of daytime sleepiness and OSA severity with OSA learning. Studies need to continue to look at strategies to increase adherence beyond the minimum set by Medicare of CPAP usage of 4 hours day 70 % of days per week. The study done by Weaver, et al. (2007) [23] demonstrated that increasing hours of CPAP use beyond the standard set by Medicare, improves quality of life indicators such as day time sleepiness and daily functioning [23]. Sleepy patients who have greater cognitive impairment may have greater difficulty integrating educational messages. Learning strategies need to be modified and adapted to meet the needs of patients based on their ability to learn and cognitive function.

An advantage of media developed OSA education is that these programs can be made available on open access social media sites such as "You Tube". Media formatted educational videos and/or pod casts can be conveniently viewed multiple times at the discretion of patients, their families and health care professionals. Open access education can have a profound impact on reaching exponential numbers of individuals and groups. Open access education holds great promise in promoting positive outcomes for not only the OSA population, but in other groups dealing with challenges in managing chronic diseases.

Study limitations

The main limitation of this study is the small sample size. Another limitation was the study population of mostly white males from a geographically middle class area on Long Island, New York. This sample demographic may not be representative to other groups of OSA patients. This study utilized a first use OSA media based educational program. This educational program needs to be utilized on other groups and settings to establish inter-rated reliability.

Implications for clinical practice

Benefits of CPAP adherence are significant for reduced morbidity and mortality, particularly cardiovascular risk reduction of MI and stroke, hypertension and diabetes. Untreated OSA increases the incidence of depression and neurocognitive impairment. Although CPAP therapy improves health, sleep quality and quality of life, it is a demanding therapy to undertake and requires a high level of input and support. This is especially important during the first weeks of therapy when the risk of abandoning CPAP is highest [7,13]. Intervening early helps to establish a pattern of habitual use of CPAP which will help improve adherence.

A focus on weight control is especially important in the management of OSA given the expanding epidemic of obesity in the U.S. Often patients are able to lose weight more easily after initiation and continued use of CPAP. Improvement in daytime sleepiness and fatigue enhances weight loss and exercise. Alertness as the result of restorative sleep, improves overall safety by dramatically reducing risk of injury and death from motor vehicle crashes and workplace accidents. An expanding body of knowledge clearly demonstrates that treated obstructive sleep apnea has a profound positive impact on public health and safety. Obstructive Sleep Apnea needs to be approached as a chronic disease requiring long term, multidisciplinary management. Early identification and treatment is needed as the number of OSA adults is increasing mostly due to obesity. It is essential to screen and identify patients with OSA early in order to mitigate adverse outcomes. Improving adherence to CPAP will improve outcomes related to OSA and improve quality of life, overall health, life expectancy, safety and cost. Ongoing research is needed to explore and support strategies that will continue to significantly improve and promote desired health outcomes in the OSA adult population.

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