Case Study

Provent EPAP: An Alternative to NCPAP treatment for Obstructive Sleep Apnea.

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BACKGROUND:

Obstructive Sleep Apnea (OSA) is a disorder manifest by repetitive episodes of either complete upper airway obstruction (apnea) or partial upper airway obstruction (hypopnea) during sleep. Untreated OSA is considered to be a potentially reversible contributing factor for hypertension, heart attacks, strokes, atrial fibrillation, sudden death, diabetes, excessive daytime sleepiness, motor vehicle accidents, impaired cognitive functioning and decreased quality of life.[1,2] Nasal continuous positive airway pressure (NCPAP) has long been considered to be the gold standard of treatment for OSA. However, a significant percentage of patients either do not tolerate NCPAP or are noncompliant with NCPAP. A variety of oral appliances and surgical procedures have been developed as alternative treatments to NCPAP. However, the results of these appliances and/or surgical procedures have been unpredictable and generally far less successful than NCPAP.[1,2]

Nasal expiratory positive airway pressure (EPAP) marketed as Provent Therapy (Ventus Medical Inc, Belmont, CA) is a single use EPAP device containing a mechanical valve with a very low inspiratory resistance but a high expiratory resistance applied to each nostril with adhesive to provide a seal (figures 1&2).[3] Several recent studies have documented the effectiveness of EPAP in the treatment of OSA.[3,4,5,]

CASE REPORT

HISTORY/PHYSICAL:

The patient is a 53 y/o male who presented with a H/O snoring, restless, non-refreshing sleep, increased nocturnal awakenings, cognitive difficulty and excessive daytime sleepiness. He was previously diagnosed with severe restless limb syndrome and periodic limb movements during sleep (RLS/PLMS), chronic insomnia (both sleep onset and maintenance), alcohol dependent sleep disorder and hypnotic dependent sleep disorder, with the patient typically using OTC sleeping pills, Percocet and alcohol to induce sleep and repeating his Percocet 1-2 times throughout the night. On examination, he was 71.5 inches tall, weighed 218 lbs and had a BMI of 29.9 kg/m.sq. He had a deviated nasal septum with nasal turbinate hypertrophy, an elongated, droopy soft palate and enlarged uvula with a Mallampati score of 3+ and a neck circumference of 16 3/4 inches.

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POLYSOMNOGRAPHY:

His initial PSG (with use of Unisom and Percocet 10-650 at 21:10 and repeating Percocet 5-325 at 03:14)) revealed severe, supine predominant OSA with an apnea-hypopnea index (AHI) of 44 (supine 57; non-supine 9) and a SaO2 nadir of 83% (15.7% of total sleep time [TST] spent at SaO2 of <90%). Sleep efficiency was 85.6% with an increase in stage N1 and a decrease in N3. His RLS / PLMS were well controlled on this PSG.

MANAGEMENT:

Over the ensuing 2 years, his weight remained relatively stable (214-218 lbs). He was initially placed on NCPAP after a NCPAP PSG at 9 CWP using a Swift NP with a chinstrap and heated humidifier resulted in an AHI of 3 with a SaO2 nadir of 94%. Despite the addition of nasal steroid and antihistamine sprays, increased humidification and several mask style changes, he remained intolerant to NCPAP complaining of a dry throat, mask discomfort and difficulty exhaling. He subsequently underwent a BiPAP PSG which revealed an AHI of 0 and a SaO2 nadir of 93% on BiPAP at 13/10 CWP. Despite the addition of both Lunesta 3 mg and Rozerem 8 mg and several more mask changes, he discontinued using BiPAP after 2 months.

Over the next few months he tried a mandibular advancement device (MAD) and after all adjustments were completed a PSG using Percocet 20-650 mg, Lunesta 3 mg, Clonazepam 1 mg and a MAD revealed an AHI of 13 (supine 31; non-supine 10) and a SaO2 nadir of 86%. Given the incomplete control of his OSA, combined with a complaint of gagging and excessive salivation with his MAD, he was then changed to a "full breath solution" oral appliance (OA) that did not advance the mandible but rather kept the bite in a neutral position with a tail that protruded the tongue in a forward position. In addition, the patient achieved his greatest weight loss, down to 203 lbs. A PSG using Percocet 20-650 mg, Lunesta 3 mg and Clonazepam 1 mg with his OA at his lowest weight under my care revealed an AHI of 23 (supine 33; non-supine 16) and a SaO2 nadir of 81%.

It was then recommended that the patient add positional therapy with "snore balls" to keep him off of his back during sleep and a trial of EPAP. A PSG with the patient's weight back up to 214 lbs was performed utilizing positional therapy, Percocet 20-650 mg, Lunesta 3 mg and Clonazepam 1 mg, his OA and EPAP. Despite the use of "snore balls" he slept entirely on his back but the AHI was nonetheless reduced to 5 and the SaO2 nadir was 83% (4.9% of TST spent at SaO2 of <90% compared with 15.7% on his diagnostic PSG). At follow-up evaluation after 6 months of using the combination of Percocet 20-650 mg, Lunesta 3 mg, Clonazepam 1 mg, an OA and EPAP (subjectively all night and every night), the patient stated that he was sleeping better with decreased awakenings, improved cognition, better mood, less irritability and a decrease in daytime sleepiness.

At a routine follow-up 3 months later, the patient informed me that shortly after his last office visit, he lost his OA and did not want to go to the expense of replacing it. He had been wearing the EPAP alone for the past 3 months and emphatically stated he was doing as well if not better than when using the OA and EPAP together. A PSG using Percocet 20-650 mg, Clonazepam 1 mg and EPAP supported the patient's claim with an AHI of 3 and a SaO2 nadir of 85% (5.5% of TST spent at SaO2 of <90%). It should be noted that serial Epworth scores were not provided because in spite of his complaint of daytime sleepiness, his Epworth scores were always between 2 and 4.

DISCUSSION:

OSA is a common disorder with estimates of prevalence ranging from 2-4% of the adult population. Over 90% of individuals with OSA have yet to be diagnosed or treated. NCPAP remains the gold standard of treatment for OSA. However, noncompliance remains the primary obstacle to successful treatment with NCPAP. Compliance, defined as using NCPAP for >4 hours a night for at least 70% of the nights remains problematic. Depending upon the source, compliance estimates range from 40-90%[1,6].

Alternatives to NCPAP have included various surgical modifications to the upper airway and a variety of oral appliances. Surgery is painful, costly and delivers unpredictable results. Oral appliances are costly and also deliver unpredictable results. In an evidence based review of 87 previously published

studies of the use of OAs in OSA, Ferguson found success, defined as the reduction of the AHI to <10, in only 52% of patients. Adherence in using the OA nightly at the end of 1 year was 77%[2]. In a meta-analysis of previously published studies of surgical modification of the upper airway for OSA, Aron found Uvulopalatopharyngoplasy (UP3) to be at best effective in treating <50% of patients with OSA. Efficacy (depending upon which study is cited) generally included a reduction of the AHI to <10-15 or a reduction in the pre-operative AHI by >50%, with or without a reduction in the Epworth score to <10[7]. When a more stringent definition of success, such as a post-treatment reduction of the AHI to <5 is used, the success rates are often substantially reduced.

A recent study showed EPAP to be effective after 3 months with a 51% treatment success[3]. Another study (yet to be published[8]) of 131 patients across all severity groups (median AHI 25.8), showed a reduction of the AHI to <10 in 80.7%. NCPAP remains the "gold standard" of treatment for OSA being virtually 100% effective in eliminating both snoring and OSA in most patients. However, given such a wide range of compliance, we are often presented with the dilemma of prescribing an effective treatment that isn't being used consistently versus a less effective treatment that is used more often. Subjective reports of compliance for the Provent EPAP Therapy are as high as 88%[4]. Given the substantial cardiovascular and metabolic morbidity and mortality associated with untreated OSA, an effective alternative to NCPAP is highly desirable. In those patients who are either noncompliant or intolerant to NCPAP, Provent Therapy may just be the best alternative.

This case study is interesting for several reasons. First, multiple modalities were required over an extended period of time in order to achieve successful control of his OSA. When the patient first entered my practice he was taking high doses of opiates combined with OTC sleeping aids and alcohol to treat his insomnia and RLS. Despite numerous reports of the association of opiates and Biot's respirations,[9,10] the so called atrial fibrillation of sleep apnea, this patient did not show evidence of significant central apneas or ataxic respiratory effort. Multiple drug trials including Dopamine agonists and Gabapentin were tried in an attempt at lowering the patient's usage of Percocet. However, he did not tolerate Dopamine agonists (complaining of nausea) or Gabapentin (complaining of disequilibrium). The addition of Clonazepam offered him significant reduction of anxiety associated with his insomnia and also reduced (both subjectively and objectively) his RLS/PLMS allowing a discontinuation of both OTC and prescription hypnotic agents. He was eventually able to discontinue the use of alcohol as a sleeping aid. A thorough neurologic evaluation including EMG/NCS and spinal MRI was performed and ruled-out a neurologic cause for his RLS.

On a personal note, I have found EPAP to be a useful adjunctive treatment even in those patients who are not adequately controlled with EPAP alone. I have used EPAP in conjunction with steroid and/or anti-histamine nasal sprays, EPAP with Breath-Rite nasal strips and as in this case, in conjunction with various MADs or OAs. As EPAP is a relatively new product, there are no validated protocols available for follow-up. I treat all patients with a fairly straight forward approach and this applies to EPAP as well. Since I start all EPAP trials with a 10 day "trial pack", I have them return for an office visit 1 week into their trial. I encourage them to call me sooner if they are having difficulty adapting to EPAP. At their follow-up appointment they are questioned regarding their sleep quality with EPAP and they are given an Epworth questionnaire. If they tolerate EPAP and subjectively are stable or improved they undergo a PSG using EPAP. As with any of my other OSA patients, during their first year of treatment, I have them follow-up at 3, 6 and 12 months.

I do not routinely repeat PSGs at any pre-defined interval. I question my patients about any changes in their sleeping habits, change in medications or new diagnoses that may affect their sleep quality. If the patients are symptomatic, have medication changes or new diagnoses that may affect their sleep disorder(s) they may undergo a follow-up PSG. After 12 months of stability, they are seen at 3-12 month intervals depending upon their diagnosis and or co-morbid medical conditions. All patients are encouraged to contact my center in between scheduled appointments anytime their sleep quality deteriorates.

CONCLUSION:

OSA is a common disorder associated with potentially serious cardiovascular and metabolic morbidity and mortality and a decrease in quality of life. It is easily diagnosed and there are several

treatment alternatives. While NCPAP remains the gold standard of treatment for OSA, Provent Therapy EPAP appears to fill the gap in alternatives to NCPAP in those patients who either refuse to try NCPAP or fail to comply with NCPAP. In this author's opinion, it is the best alternative to NCPAP for mild-to moderate OSA and there is increasing evidence that it may also be a reasonable approach even in patients with severe OSA. Additional, prospective, randomized trials using Provent Therapy across varying severities of OSA are needed to determine the best utilization of this novel therapeutic intervention.

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