A 90-Day Adherence Study in Newly Diagnosed CPAP Patients using a Soft Cloth CPAP Mask vs. a Traditional Nasal CPAP Mask

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Purpose

Obstructive sleep apnea (OSA) is a common and serious condition leaving patients at risk for comorbidity and mortality.

Continuous positive airway pressure (CPAP) is the therapy of choice.

Adherence remains problematic for many patients. When defined as ≥ 4 hours per night for 70% of nights, adherence is estimated between 50-80%.

Early adaptation has been demonstrated to predict long-term adherence. Consistent nightly CPAP use is associated improved health outcomes.

Many mask options are available for patients. A recent Cochrane review (Chai, Pathinathan & Smith, 2011) states "the optimum form of CPAP delivery interface remains unclear".

Few studies have looked at mask choice as an important modifiable risk factor for non-adherence. To our knowledge, no studies to compare a traditional nasal mask (TM) to a cloth nasal mask (CM) have been done.

This pilot study was undertaken to compare CPAP usage and 90 day adherence rates between these mask types.

Methods

A single center, prospective, parallel study was undertaken to compare CM (SleepWeaver Advance, Circadiance, Export PA) to a TM (Comfort Gel Nasal Mask, Phillips-Respironics, Andover, MA).

Cloth Mask

Traditional Gel Mask

This TM was chosen as representative of the category of "gel masks". Ethics approval was obtained from the IRMC IRB. All subjects signed informed consent.

Participants

A convenience sample of CPAP naive patients were targeted for enrollment. Inclusion criteria included the following: ≥ 21, diagnosis of OSA, medically stable. Exclusion criteria included the following: requiring supplemental oxygen, history of having a previous sleep study, current PAP user and using full face interface.

Intervention

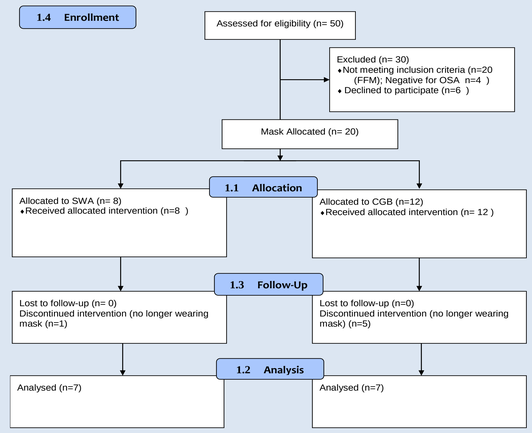
Subjects were allocated to either a CM (Group 1, even days) or the TM (Group 2, odd days). Routine, standard of care was offered. Subjects agreed to wear assigned masks during the trial. No other special instructions or interventions were required by the DME or sleep center.

Outcome Measures

The primary outcome measure was the objective measure of therapy adherence at 90 days and hours of CPAP usage per night.

Conclusions

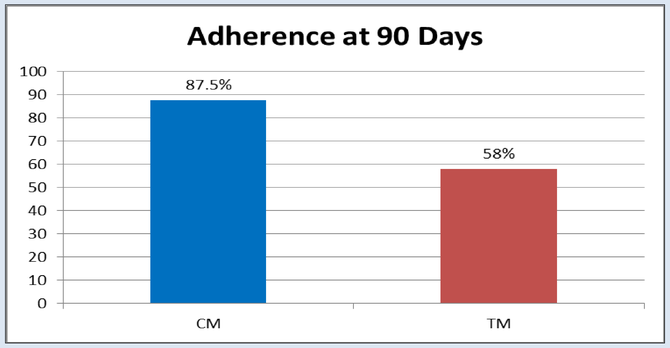
A total of 50 subjects were enrolled between May, 2010 and July of 2012.



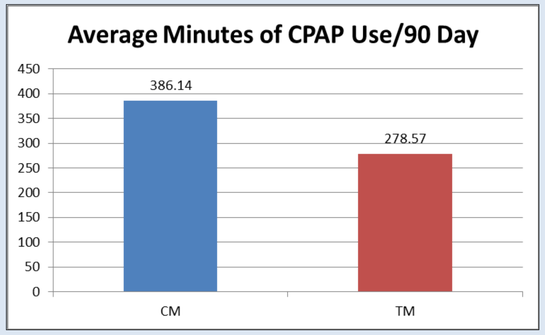
Data analysis was conducted on 14 subjects, who completed the trial (7 per group.)

Characteristics	CM (n=7)	TM (n=7)
Age	47.8	45.5
Gender	5 Female	4 Female
BMI (p=0.10)	37.8	44.5
AHI (p=0.75)	26.1	30.1
ESS (p=0.13)	8.5	11.7

At the 90 day period, 7/8 (87.5%) patients allocated the CM continued to use the mask compared to 7/12 (58%) patients allocated the TM.



Subjects using the CM had more average daily minutes of use (386.14 min, range 279-484 versus 278.57, range 92-402). Although not statistically significant (p=.07), the increase of 107 minutes may have clinical importance. Patients used the CM more and were more likely to continue with therapy than the TM.



A future study with larger sample sizes will be required to provide additional evidence regarding the selection of CM as a first line interface for patients with OSA. Some limitations to this study are the small sample size and the odd/even day allocation.

Clinical Implications

Mask type can have an impact on 90 day adherence and usage in patients on CPAP therapy. Consideration of non - traditional masks may provide an alternative for some patients as a first line therapy.

A Randomized Study of a 90-Day Adherence in Newly Diagnosed CPAP Patients using a Soft Cloth CPAP Mask vs a Hard Plastic CPAP mask

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Abstract

Background: Obstructive sleep apnea (OSA) is a common and serious chronic condition. The most recent estimated prevalence rates for the Wisconsin Sleep cohort for moderate to severe sleep apnea (≥AHI 15) are 10% for men aged 30-49 and 17% for those aged 50-70; in women 3% and 9% respectively. Continuous positive airway pressure (CPAP) continues to be the therapy of choice. Adherence remains problematic. One area of adherence which can be addressed is the patient interface (i.e. masks). **Methods:** A single center, prospective, study to compare the SleepWeaver Advanced (SWA, Circadiance Export, PA) to the Comfort Gel Nasal Mask (CGM, Phillips-Respironics, Andover, MA) in patients newly diagnosed with sleep apnea and titrated with the assigned mask. **Results:** 20 subjects participated (11 female), 12 subjects were randomized to receive the CGM; 8 subjects received the SWA. 7/12 were using the CGM at 90 days (58%), 7/8 were using the SWA at 90 days (87.5%). On average, the minutes of use per night were higher in the SWA group 386.1 minutes of use per night compared to 278.5 minutes evidencing an improvement of 107 minutes of CPAP use.

Introduction

Obstructive sleep apnea (OSA) is a common and serious chronic condition. In 1993, the Wisconsin Sleep Cohort study reported a prevalence of 4% in men with an AHI of 5 or greater with daytime sleepiness and 2% in women (Young, Palta, Dempsey, Skatrud J,Weber , Badr, 1993). The most recent estimated prevalence rates measured in this same cohort for those demonstrating moderate to severe sleep apnea (≥ 15) are 10% for men aged 30-49 and 17% for those aged 50-70; in women 3% and 9% respectively (Peppard, Young., Barnet, Palta, Hagen, Hla,2013). Thus the prevalence of this condition has significantly increased over the past 20 years. Continuous positive airway pressure (CPAP) continues to be the therapy of choice. CPAP is highly efficacious in alleviating OSA, however, long term effectiveness in reducing health consequences such as hypertension, insulin resistance, type II diabetes and neurocognitive deficits lies with the patient's usage of same and self-management at home. A recent study (Somers, Peterson, Sharma & Yarumchuk, 2011) demonstrated adherence at 4 months was 28% and at one year, 7%. However, La Piana et al. (2011) using a very rigorous and disciplined educational approach resulted in 80% adherence at the first year, and thus ongoing determinants of non-adherence should be explored and opportunities for improvement exist.

One area of adherence which can be addressed is the patient interface (i.e. masks). A recent Cochrane Review (Chai, Pathiathan & Smith, 2011) states "The choice of interface for a particular person will need to be tailored to the individual" and further that "the optimum form of CPAP delivery interface remains unclear". Thus further research is needed in this area. Issues relating to non-adherence include mask issues such as leak, discomfort from the plastic, difficulty using the equipment, feelings of claustrophobia; eye irritation, dry mouth and headaches all of which contribute to non-adherence (Borel, Tamisier, Dias-Domingos, Sapene, et al., 2013; Fung, Martin,, Igodan, Jouldjian,& Alessi, 2013). However, few data are published on masks for use during CPAP (Chai, Patheianthan & Smith, 2011)..

Many types of masks are available for use with CPAP to include nasal, full face (oronasal) and pillow-type which sit just inside the nares. Borel et al. (2013) found that patients using nasal masks demonstrate increased adherence over that of oronasal masks. CPAP masks are typically made from a

variety of rigid and semi-rigid materials such as plastic, silicone and gel like material. CPAP masks also come in a variety of sizes. Fit and preference therefore is an important aspect of the overall patient experience and should receive careful attention.

The Sleep Weaver Advance (SWA) CPAP mask (Circadiance, Export, PA) provides an innovative solution for patients who are prescribed CPAP. The mask is made from soft; air-impermeable cloth which allows for breathability as well as flexibility. The soft-cloth mask intuitively provides for the ability of the patient to have less constraint regarding movement in bed while maintaining the integrity of the seal and thus effectiveness. As noted above, the type of mask can impact the patient's ability to be adherent to therapy. Although, anecdotally, the SWA has proven to be a highly effective and comfortable mask by patients who currently use it, supportive data are lacking to substantiate these testimonials regarding improved satisfaction and/or adherence with this new type of interface.

This pilot study was undertaken to assess objective use of CPAP via CPAP downloads compared to another commercially available mask (Comfort Gel, Phillips-Respironics, Andover, MA). This mask is similar to others that are offered to CPAP patients, thus this pilot study remains relevant to the current population of CPAP users.

Methods

Study Design

This study was a single site, prospective, randomized , open-label study to compare the SWA CPAP mask to the CGB CPAP Mask to ascertain adherence to CPAP use. Ethics approval was obtained from the Indiana Regional Medical Center (IRMC) Institutional Review Board prior to consenting and enrolling subjects.

Participants

A convenience sample of patients over the age of 21 were targeted for enrollment and recruited from new patients entering the IRMC sleep disorders center who met the initial inclusion criteria. Inclusion criteria included the following: ability to sign informed consent, follow directions and being medically stable. Exclusion criteria included the following: requiring supplemental oxygen, history of having a previous sleep study, current PAP user and using full face interface, unable or unwilling to undergo a polysomnogram, significant nasal deformities, inability to use nasal interface, presence of a tracheostomy, presence of acute sinusitis or otitis media on the night of the study, and presence of central sleep apnea on the diagnostic sleep study.

Intervention

Subjects underwent a routine diagnostic polysomnogram, followed by a titration study. At the time of consent, subjects were randomized to either a CGB (Group 1, even days) or the SWA (Group 2, odd days). Following titration, subjects were referred to a local durable medical equipment (DME) company for routine set up and usual care. No special instructions or interventions were required to be used.

Outcome Measures

The primary outcome measure is therapy adherence at 90 days and hours of CPAP usage per night. The data cards/microchips were accessed and downloaded per each CPAP manufacturer's recommended procedures.

Randomization

The masks were randomized using open allocation method of an odd (CGB)-even (SWA) day scheme. The patients were assigned their mask on the days on which they consented to participate

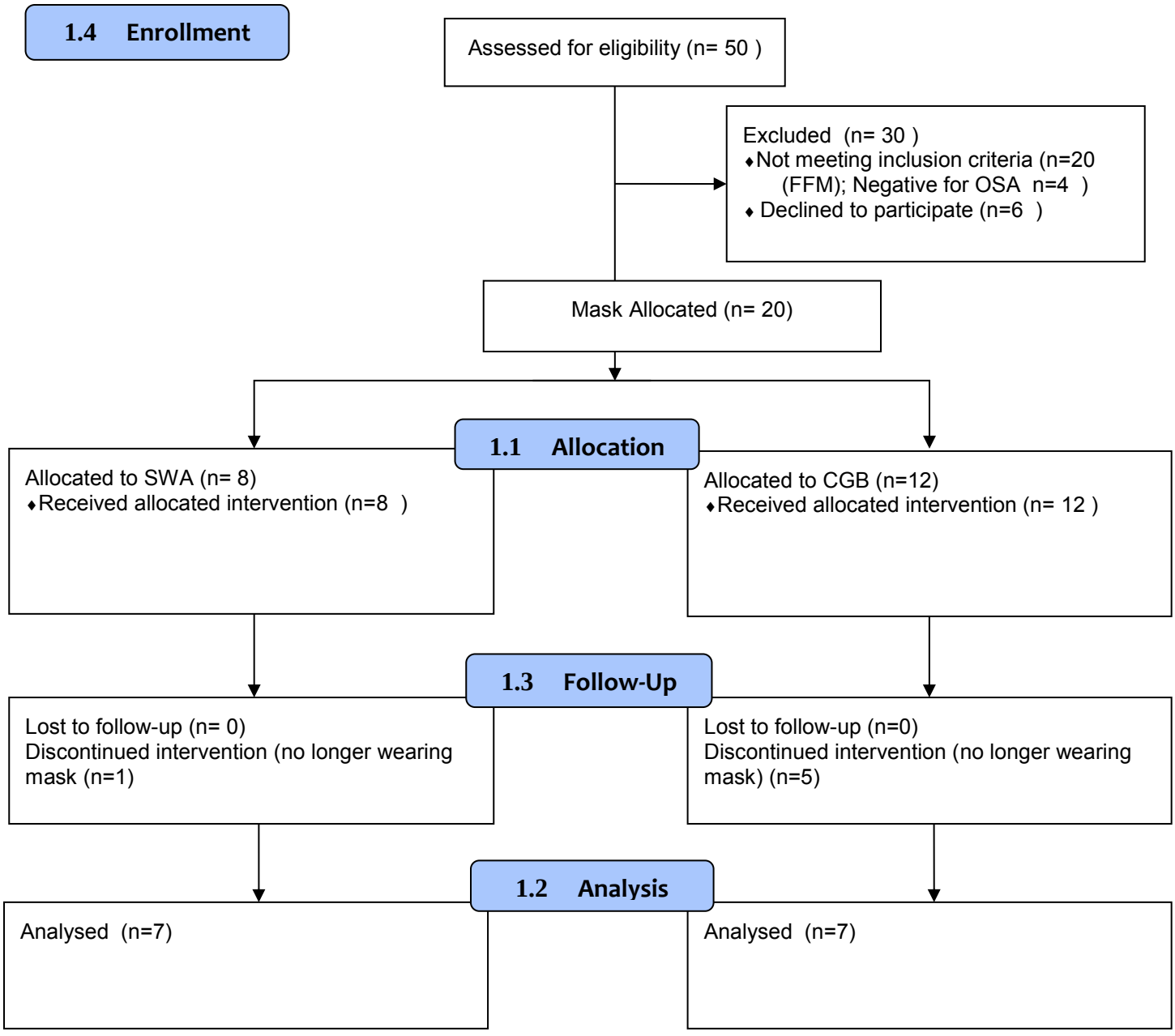
Recruitment and Follow-Up

Recruitment was terminated when a total of 20 subjects were allocated a mask type. Subjects were followed for up to a period of 12 weeks post the titration study.

Statistical Methods

Descriptive statistics were used to describe the population and the data. Data from the subjects completing the study at the 90 day period is reported.

Participant Flow Chart



Results

Baseline Data

The following (Table 1) represents the baseline data for the subjects who completed the study.

Characteristic	SWA (mean) n=7	CGB (mean) n=7
Age	47.8	45.5
Gender	5 Female	4 Female
BMI	37.8	44.5
AHI	26.1	30.1
ESS	8.5	11.7

Table 1

90 Day Usage Analysis

Table 2 provides the objective data downloaded from the data collection cards installed in the CPAP machines. Data were downloaded per manufactures guidelines. The data was accessed at 12 weeks during an in-clinic visit.

	SleepWeaver	Comfort Gel
Subjects using CPAP at 90 Days	7 of 8 (87.5%)	7 of 12 (58%)
Utilization (min / night)* p=0.07	n=7(mean) 386.1 Min (Range 279-484 Min)	n=7 (mean) 278.5 Min (Range 92-402 Min)

Table 2

These data demonstrate that a larger percentage of patients who used the SWA were adherent with their therapy at 90 days than those who used the Comfort Gel over the 90 day period and further, that the average subject's nightly utilization was greater with an average of 107 minutes more for the SWA. These data support the hypotheses that the SWA provides a highly efficacious means of delivering CPAP therapy.

Adverse Events Summary

There were no unanticipated adverse events.

Discussion

Limitations

A lower than expected sample size was recruited. This in part was due to the high number of subjects requiring a full-face mask which was exclusionary.

Generalizability

The population was recruited from a community based sleep disorders center and thus is representative of the intended use and population for the mask. This included adults from both genders who demonstrated a diagnosis of OSA.

Interpretation

The design and construction of the cloth mask is fundamentally different than all other commercially available hard plastic CPAP masks. The cloth mask design uses the properties of a balloon to provide a leak free seal with no pressure points. The cloth material is moisture vapor breathable allowing perspiration to be wicked away from the patient's skin and making the mask cool and dry to wear. The design is light and flexible allowing the user to move around in bed without the mask interfering with their sleep. We hypothesized that these advantages would provide better comfort for the newly diagnosed sleep apnea patient and eliminate some of the obstacles to achieving 90-day

adherence. The data from this pilot study provide a good foundation and warrant the attention of the field of sleep medicine. Additional studies will be required to address the limitations and problems encountered in this study.

The objective data from those subjects who continued to use the CPAP machines at 90 days demonstrates that those allocated the SWA had a much higher average of minutes of machine usage (386.1 versus 278.7, difference of 107 minutes). While not statistically significant (p=0.07), 107 minutes of additional usage may prove to have clinical significance. There are data to support that the increased use of CPAP improves outcomes (Weaver, Maislin, Dinges, Bloxham, George , Greenberg et al., 2007). In addition, at the 90 day period, more subjects (87.5 vs. 58%) continued using the SWA mask compared to those using the more traditional style.

Conclusion

The Sleep Weaver Advance users showed higher usage / night over the Comfort Gel users (107 Minutes). The Sleep Weaver Advance users showed higher 90-day adherence compared to the Comfort Gel users. (87% versus 58%). This may lead to improved clinical outcomes as early use of CPAP leads to better adherence (Budhiraja, Parthasarathy, Drake, Roth, Sharief, Budhiraja, …& Hudgel, 2007). Considering that mask selection is a key element in helping newly diagnosed CPAP patients maintain long term adherence, Sleep Weaver Advance should be considered as a first line therapy for the titration and treatment of OSA in newly diagnosed patients. The results of this pilot study indicate that further trials with larger samples sizes of patients should be conducted which compare the cloth mask to that of more traditional mask types.

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