

Comparison of CPAP Titration Pressures as Obtained by Split Night Study versus Auto-CPAP Titration at Home for 2 Weeks

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ABSTRACT

PURPOSE: The growing epidemic of sleep-related breathing disorders plus the high cost of polysomnography has led most labs across the country to switch to split-night studies (SNS). This has resulted in significant reduction in time allowed for titration. Hence the final effective pressure (Pe_{ff}) as obtained by SNS may not reflect the ideal pressure needed to consistently overcome the sleep airflow limitation. This may potentially lead to therapeutic failure and poor compliance. Auto-CPAP has emerged as potential alternative which may provide a more physiological background to identify the optimal pressure for CPAP therapy.

METHODS: 33 consecutive patients diagnosed with Obstructive apnea hypopnea syndrome (AHI > 15/hr) after undergoing split-night study in sleep laboratory were prescribed a 2-week Auto CPAP trial (Resmed Auto Set T). The pressures obtained by SNS (Pe_{ff}) were compared to optimal pressures (95th percentile) and Maximum pressures (100th percentile) as obtained by Auto-CPAP trial at home for two weeks. We also looked at pressure differences after segregating patients into positional / non-positional sleep apnea and patients requiring pressures below or above 10 cm H₂O. Demographics and patient preferences were also recorded.

RESULTS: Out of 32 patients (one patient was excluded due to noncompliance with Auto-CPAP) 72% were males. Mean BMI was 36.5 and Mean time spent on CPAP titration was during SNS was 159.8 min. Mean AHI (Apnea hypopnea Index) at final CPAP pressure (Pe_{ff}) was 1.5 versus 6.1 with Auto-CPAP (P<0.001). Mean pressure on (Pe_{ff}) on SNS titration was 8.8 (1.7) cm of H₂O versus mean 95th percentile pressure on Auto-CPAP of 11.3(1.4) cm of H₂O (P<0.001) and mean maximum pressure on Auto-CPAP of 12.5(1.6) cm of H₂O (P<0.001). We also found the pressure differences were more profound in the patient group with initial pressure requirements of 10 cm H₂O or less. We also found no significant difference between positional and non-positional groups.

CONCLUSION: There is a significant difference in therapeutic pressures noted between CPAP titration by SNS and subsequent Auto-CPAP trial for 2 weeks.

CLINICAL IMPLICATIONS: By allowing greater sleep sampling time and a physiological background, use of Auto-CPAP device to derive maximum optimal pressures may provide an appropriate alternative to SNS.

Keywords: Auto-CPAP, Split- night polysomnography, Position dependent Sleep apnea, Sleep stage Dependent sleep apnea

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Introduction

Obstructive sleep apnea (OSA) is a common sleep disorder. Up to 5 % of the adult population are believed to be suffering from OSA. (1) Diagnosis of this condition is by overnight polysomnography. (2) Current treatment of choice for OSA is positive airway pressure therapy.

Due to increasing costs of diagnostic polysomnography, many sleep labs are using split- night protocols which entails diagnosis in the first half of the night followed by positive airway pressure titration in the second half.

One study comparing full night titration with split night titration found concurrence in 78 % of cases(3), however other study reported lower accuracy of 60 % .(4) These studies were done in University/Academic setting with highly trained staff. Higher degree of technical skill is required to perform accurate diagnostic and therapeutic testing in a single night. (5) It is possible that accuracy may be lower in community based sleep labs. This may potentially lead to inaccurate titration.

The other option which has been investigated is home titration by auto-CPAP. Studies have compared optimal pressures between manual titration and auto CPAP and found to be comparable. (6, 7, 8) Teschler's study reported a difference of 1 cm H₂O between the auto-CPAP recommended pressures and manually derived pressure (auto- CPAP derived pressure being higher. (9) All the above studies have compared to full night manual titration. There has been no study to our knowledge comparing auto-CPAP derived pressures to pressures derived from split- night protocol.

We conducted a community based nonrandomized crossover study to compare the optimal pressures derived from split -night study versus home-based auto-CPAP titration for 2 weeks. We also looked at differences between positional /sleep stage dependent apnea and those without.

Methods

Patient Selection

Thirty three consecutive patients found to have obstructive sleep apnea and willing to undergo CPAP therapy as treatment for their sleep disordered breathing were enrolled. Inclusion criteria was adult patients with

newly diagnosed obstructive sleep apnea and AHI > 15 events per hour. Exclusion criteria included age < 18yrs, pregnant females, Dementia and patients with recent major surgeries, strokes or myocardial infarction in the last 60 days preceding the split-night study. Patients having acute cardiopulmonary symptoms (Defined as dyspnea at rest, angina) were also excluded. The study was approved by institution review board of Meriter Hospital, Madison, Wisconsin (AASM- accredited Sleep Lab) and informed consent was taken from each participating subjects. Subjects were recruited from October 2003 to June 2004.

Procedures

Subjects were recruited from Sleep disordered Center at Meriter Hospital (Madison, Wisconsin) on which a split-night study (SNS) was performed using a 15 channel polysomnographic recorder. We recorded Central and Occipital electroencephalogram (3 channels), Chin electromyogram (1 channel), electro-oculogram (2 channels), thoraco-abdominal excursions, anterior Tibialis electromyogram (2 channels), snore channel, naso-oral airflow (thermocouple and pressure trace), Electrocardiogram, oxygen saturations by pulse oximetry (Nelcor N-200 (DC input) Monitoring Equipment included Sensor Medics Alpha Digital Sleep System with Omega 24 amplifier.

During the treatment portion of the study, well trained and experienced sleep technicians titrated the CPAP based on sleep lab established protocol which included gradual increase in titration pressures to eliminate apneas, hypopneas and snoring. A minimum of 15 minutes titration was required before increase in pressure if needed. Technicians were required to achieve titration in both supine position and REM sleep in all patients.

Subjects who qualified auto-CPAP titration portions of the study were set-up and educated at home for the use of the auto-CPAP unit. Subjects were educated regarding leaks and given a phone number to call for trouble-shooting. The auto-titration unit was set at minimum pressure of 5 cm of H₂O and Maximum pressure of 20 cm of H₂O.

The auto-titration unit used in this study was the AutosetT (Resmed, Sydney, Australia). This unit was selected because of its potential to respond appropriately to different breathing patterns. (10). AutosetT detects and responds to apnea, hypopnea and flow limitation.

Apnea is defined as >75% reduction in flow for at least 10 sec. Hypopnea was defined as 50-75% reduction in flow for 10 sec. The unit increases pressure by 0.2 cm H₂O per breath (up to 2 cm per 15 seconds). The pressure can increase upto 10 cm of H₂O to resolve an apneic event. If the apnea is still not resolved the device will let the apnea resolve spontaneously without increases the pressures further. After 10 cm H₂O the AutosetT will respond only if there are signs of flow limitations (snoring, increased pressure in the circuit). Flow limitation is detected by flattening of the inspiratory flow curve. Upon normalization the pressures reduce gradually to baseline over a period of 1 hr.

Study Design

After undergoing a split-night polysomnography, qualifying patients were set-up for a two-week in-home auto-CPAP titration study. A respiratory technician called each subject after one week to ensure usage of the device and to answer questions. After two weeks the subjects returned the auto-CPAP and information from the auto-CPAP was downloaded for analysis. The subjects were then started on fixed CPAP on pressures determined by the split-night protocol. After another two weeks patients were called to answer a scale-based questionnaire.

Data Collection and Analysis

Patient demographics and characteristics including BMI were recorded at the time of clinic visit before the split-night study. The AHI for each subject was calculated during both diagnostic and therapeutic portion of the SNS. During the therapeutic portion of the SNS, total time on CPAP and final CPAP pressure was obtained. Information downloaded from Auto-CPAP machine included days and hours of usage, median leakage, pressure at 95th percentile (optimal pressure), Max pressure and median pressures and mean AHI (defined above in Procedures).

The mean data from all subjects were averaged and then segregated for analysis into a) those with final CPAP pressure of 10 cmH₂O or below (Group 1) and those with a final CPAP pressure above 10 cmH₂O (Group 2), and b) into non-positional and positional groups. Positional or sleep stage dependent apnea/hypopnea was defined as 100% increase in AHI on change of position (a change from side to supine or change of sleep stage [NREM to REM] sleep.)

Statistical Analysis

A separate One-way analysis of variance (ANOVA) statistical analysis was performed on the demographic data, on the subjects as a whole, on the data when segregated into Group 1 and Group 2 and the data when segregated in non-positional and positional groups (SigmaStat). In the process of analysis, it was uncovered that the pressure data was not normally distributed. As a result, a log normal function was applied to all the pressure data to transform the data to a normal distribution before reapplication of the one-way ANOVA statistical model. Due to the number of times the same values were used in more than one statistical analysis the overall P value ($P < 0.05$) for statistically significant was adjusted for the number of comparisons so that actual P value was less than 0.01. Post-hoc analysis between groups was performed using the Dunnett's test. All values are presented as means with standard deviations unless otherwise noted.

Results

A total of 33 patients were evaluated. The data from one subject was excluded because it did not meet the minimal required compliance criteria. 72% of the patients (23) were males. For both sexes, the overall mean age was 48.3 (± 10) with a mean BMI of 36.5 (± 7). The mean time spent on CPAP titration during the split night study for both sexes was 159.8 (± 52) min. The mean baseline AHI was 53.3 (± 29) events/hr (Table 1). There were no significant differences in age BMI, CPAP duration, and AHI between males and female patients.

Table 1

	Male (mean \pm SD)	Female (mean \pm SD)	Combined (mean \pm SD)
# subjects	23 (72%)	9 (28%)	32
Age (yrs)	49.3 \pm 9	45.7 \pm 13	48.3 \pm 10
BMI	36.0 \pm 6	37.5 \pm 8	36.5 \pm 7
CPAP Titration Duration (min)	160.3 \pm 51	158.3 \pm 56	159.8 \pm 52
Baseline AHI (events/hr)	52.7 \pm 27	54.6 \pm 35	53.3 \pm 29

The optimal pressure (95th percentile) as determined by the Auto-CPAP (11.3 \pm 1.4 cmH₂O) was typically 2 cmH₂O higher than the manually titrated CPAP (SNS) (8.8 \pm 1.7 cmH₂O) ($P < 0.001$) (Figure 2)). The

maximum pressure (100th percentile) as determined by the Auto-CPAP machine was typically 3 cmH₂O higher (12.5 ± 1.6 cmH₂O; P < 0.001) than the optimal pressure as determined by SNS (Figure 1 and Figure 2).

Figure 3. Mean (± 95% CI) values for patients with CPAP below 10 cmH₂O (CPAP < cmH₂O, n = 22) and patients with CPAP above 10 cmH₂O (CPAP > cmH₂O, n= 10) CPAP, APAP 95%, APAP Max, and APAP Median are defined in Figure 1.

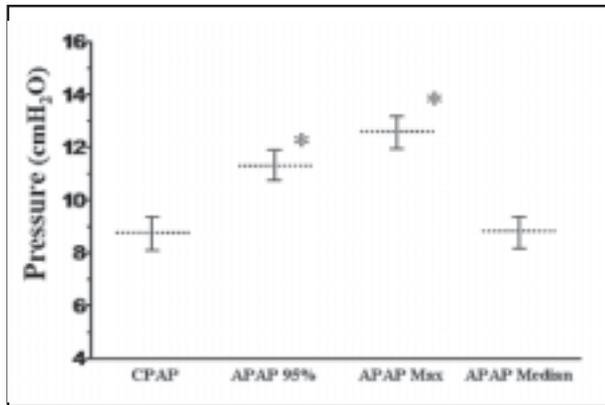


Fig. 1: Results of all patients final continuous positive airway pressure (CPAP) from a splint-night diagnostic and therapeutic/titration study, and the results from 2 week trial on auto-titrating CPAP (APAP) machine. APAP 95%, APAP Max, and APAP Median are defined in the text. Dotted line represents mean values with 95% confidence interval error bars for each group. * indicates that mean values are significantly differently from CPAP means.

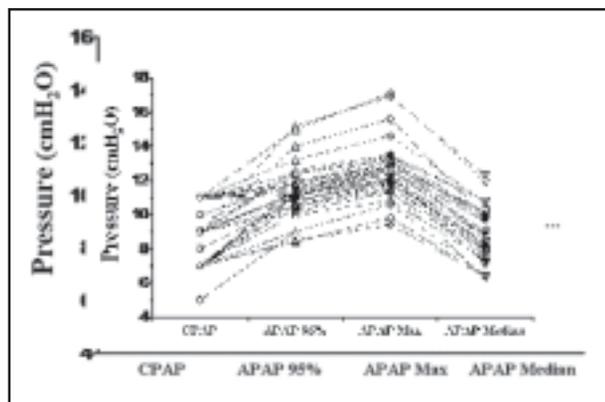


Fig. 2: Individual patient's final CPAP from a splint-night diagnostic and therapeutic/titration study and a 1-week trial on APAP. APAP 95%, APAP Max, APAP Median defined in text.

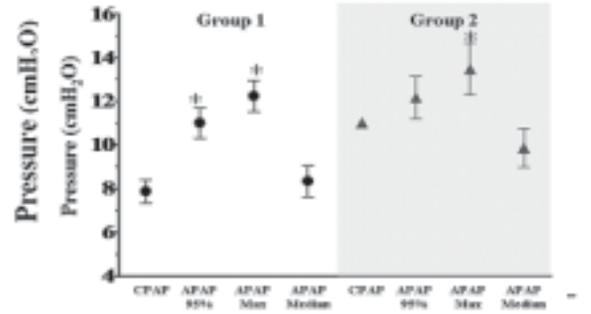


Fig. 3: Mean (± 95% CI) values for patients with CPAP of 10 cmH₂O or below (Group 1, n = 22) and patients with CPAP above 10 cmH₂O (Group 2, n= 10). CPAP, APAP 95%, APAP Max, and APAP Median are defined in the text. * indicates that mean values are significantly differently from same group CPAP means.

The subjects were then segregated into two groups based on those subjects having initial SNS titrated pressures at 10 cmH₂O or lower (**Group 1**) and those titration pressure above 10 cmH₂O (**Group 2**) (Figure 3). In **Group 1**, 78% (18/23) had more than 2 cmH₂O difference between SNS pressure and the pressure at 95th percentile (optimal pressure) of auto-CPAP titration while a 100% (23/23) of the subject's maximal pressure optimum pressure as determined by auto CPAP demonstrated a 2 cmH₂O or greater difference. In **Group 2**, only 22% (2/9) had more than 2 cmH₂O or greater difference between the SNS pressure and the pressure at the 95th percentile of the pressure as determined by auto-CPAP titration while 44% (4/9) of the subject's maximum pressure optimum pressure as determined by with auto-CPAP had more than 2 cmH₂O or greater difference.

We also looked at patients who had positional /sleep stage dependent sleep apnea. 56% of the subjects (18/32) demonstrated positional or sleep stage dependent sleep apnea. 8/32 (25%) had both positional and sleep stage dependent Sleep Apnea. Final mean effective pressure in the positional group as measured by split-night protocol was 8.7 cmH₂O (± 1.9) which was not significantly different from those of the non-positional group (8.9 ± 1.7 cmH₂O). Similarly the final effective mean pressures measured by auto-CPAP at 95th percentile and maximum APAP pressure in positional and non-positional group were not statistically different (11.1 ± 1.1 cmH₂O (positional) versus 11.7 ± 2 cmH₂O, and 12.3 ± 1.1 cm H₂O (positional) versus 12.9 ± 2. cmH₂O,

respectively) (Figure 4).

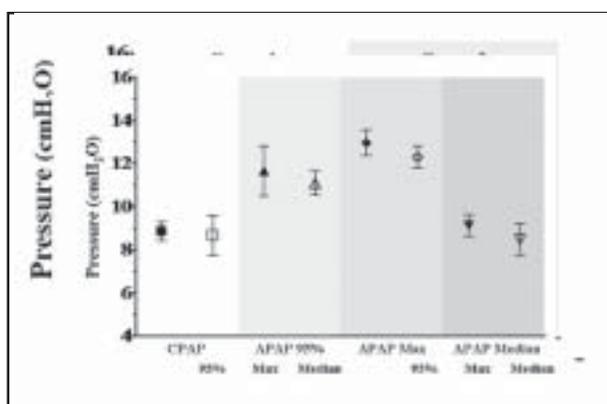


Fig. 4: Mean (\pm 95% CI) values for Non-Positional (closed symbols, $n = 14$) and Positional (see text, open symbols, $n = 18$). CPAP, APAP 95%, APAP Max, and APAP Median are defined in the text.

In a follow-up survey with the subjects conducted during a telephone interview, the subjects were asked to rate auto CPAP versus CPAP on scale of 1 to 10. Mean satisfaction for auto-CPAP was 8.1 and for CPAP 7.1. In comparison of the comfort between CPAP and Auto-CPAP devices, 35% (10/29) rated auto CPAP as more comfortable and 2/29 (6%) rated CPAP as more comfortable. 17/19 (58%) thought there was no difference. When asked about overall preference, 55% (16/29) preferred auto-CPAP, 24% (7/29) preferred CPAP, and 21% (6/29) had no preference.

Discussion

We are not aware of any previous study comparing split-night titration with auto-CPAP titration at home. Our study showed a significant difference (>2 cm) between the final effective pressures determined by split-night titration as compared to auto-CPAP recommended (95th percentile) pressures titrated for 2 weeks at home.

Peak pressures as determined by Auto-CPAP titration were typically 3 cm H₂O higher. These differences are more profound as compared to Teschler et al (9) where the authors found Peak pressures typically 2 cm H₂O higher and recommended pressures typically 1 cm H₂O higher (0.78 ± 0.33). However the comparison was with a full night manual titration rather than split-night protocol typically used these days. We believe that the increased difference in pressures in our study is due to decreased time for titration afforded in a

split-night protocol.

By doing a cross over trial for 2 weeks immediately after the split-night protocol we were confident that baseline characteristics (i.e. BMI) would not change enough to influence the results of the studies.

These differences in pressures between the split-night study and those obtained by Auto-CPAP were more significant in patients with initial manually titrated pressures of 10 cm H₂O or less.

In patients with initial pressures more than 10 cm of H₂O the Auto-CPAP recommended pressures (95th percentile) were typically 1 cm higher (not statistically significant) and median pressures lower than the SNS recommended pressures. These results showed trends similar to study by Massie et al (12) which noted Auto-CPAP 95th percentile and median pressures lower than manually titrated pressures in patients with initial pressure requirements more than 10 cm of H₂O. This suggests that there is more dichotomy between manually titrated pressures (SNS) and auto-CPAP determined pressures when the initially titrated pressure is less than 10 cm of H₂O. Patients who require higher pressures these differences become less significant.

Reduction in AHI in the SNS was 1.5 (3.9) as compared to AHI of 6.1 (2.3) as measured by auto-CPAP trial of two weeks. It is generally believed that AHI as measured by Auto-CPAP is underestimation due to recording time rather than sleep time being used as denominator. This could be explained by the fact that we had high percent of patients with positional or stage dependent sleep apnea (56%). This may have resulted in significant pressure fluctuation. As mentioned above in the Auto-CPAP algorithm, after 10 cm of H₂O pressure the device lets the apneic event be resolved spontaneously. The percentage of combined position and stage dependent Sleep apnea was similar to one observed by Series et al. (11)

Patients with positional or sleep dependent sleep apnea (P) were compared with those without (NP). We hypothesized that due to increased variability of pressures in positional or stage dependent sleep apnea patients, final effective pressures may be even less reliable when measured by split-night protocol. Thus we expected that the differences between the final effective pressures as determined by split-night pressures to be even more profound when compared to final effective pressures measured by auto-CPAP. Though the pressures tended to be slightly higher in non-positional/non stage

dependent patients, the difference was not significant. This could be because of the fact that there is increased variability in times spent at different pressures as suggested by Series et al (11), the time spent at extremes of pressure may not be much.

Better rating, comfort and overall tendency to prefer auto –CPAP machine over CPAP was suggested by the telephonic interviews conducted.

Limitations of the study were the relatively small sample size (32 subjects) and the fact that the subjects were not completely blinded to different machine groups. Also as different Auto-CPAP machines have different algorithms and hence the results of this study should not be extra-polated to other devices. Some bias is expected in the questionnaire response as patients were not blinded to the different devices as mentioned above.

Strength of the study were community based study, cross over design eliminating confounding variables and use of the auto-mated device whose function and response have been validated. (10)

Two studies that have looked into split- night study titration pressures with full night titration found concordance of 78% and 60 %. It is possible the concordance is lower in real life situation.

Conclusions

This study has important clinical implications. Significant Difference in pressures between split-night titration and 2-week auto –titration suggests patients may be under titrated by split-night protocol. This may be important especially in patients with initial recommended pressures 10 cm of H₂O or below. This combined with the fact that Auto CPAP titration is cost effective and reduces long waiting list, a two week auto –CPAP titration could be proposed as alternative to split –night titration. It was also interesting to note that no differences in pressures were seen in patients with positional obstructive sleep apnea. We recommend larger community based trials to confirm these findings.

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