

# Comparison of the Clinical Outcomes between Unattended Home APAP and Polysomnography Manual Titration in Obstructive Sleep Apnea Patients

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**Objective:** To compare the clinical outcomes and determine the difference in therapeutic pressure between Automatic positive airway pressure (APAP) and polysomnography manual titration.

**Material and Method:** Fifty patients of obstructive sleep apnea (OSA), moderate to severe cases, were randomized into two groups of intervention: 95-percentile pressure derived from APAP titration and an optimal pressure derived from manual titration. Clinical outcomes were assessed before and after four weeks.

**Results:** The average 95-percentile pressure derived from APAP titration was  $11.7 \pm 0.3$  cmH<sub>2</sub>O with median mask leak 1.3 L/min. The average optimal pressure derived from manual titration was  $8.2 \pm 0.3$  cmH<sub>2</sub>O. Pearson correlation analysis showed weak positive correlation ( $r = 0.336$ ,  $p = 0.017$ ). The Epworth Sleepiness Score (ESS), Quality of life tests: PSQI (Pittsburg Sleep Quality Index), and SF-36 (Medical Outcomes Study 36-Item Short-Form Health Survey) were improved significantly in both groups, but there were no statistical significant differences between groups.

**Conclusion:** An APAP titration is an effective method of pressure determination for conventional CPAP therapy and shows no difference in clinical outcomes comparing the standard titration.

**Keywords:** Obstructive sleep apnea, Manual titration, Autotitrating, Positive airway pressure

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Obstructive sleep apnea (OSA) is a common disorder in middle-aged populations<sup>(1)</sup>. It interferes with quality of life and increases risks of cardiovascular morbidity and mortality<sup>(2-8)</sup>. Diagnosis is made by polysomnography and the mainstay treatment is continuous positive airway pressure (CPAP)<sup>(9-12)</sup>. The standard method for determining the optimal CPAP pressure is manual titration with polysomnography in a sleep laboratory<sup>(13,14)</sup>. Importantly, the optimal CPAP pressure will improve daytime symptoms and patient compliance with treatment. Due to the limitation of waiting time and expenditure, the widespread use of ambulatory methods for pressure determination in the home is increasing<sup>(15-18)</sup>.

Automatic positive airway pressure (APAP) devices are the technology that monitor physiological

variables and offer the information such as pressure use, leak, and residual apnea/hypopnea events. The use of APAP titration to determine a fixed CPAP pressure is potentially useful and comfortable for many sleep physicians. A recent study confirmed that home APAP titration is more cost-effective than manual titration<sup>(17)</sup>. The large RCT study showed similar clinical outcome improvement between the use of APAP titration and manual titration. However, this trial studied selected severe OSA cases<sup>(15)</sup>. In practice, the majority of OSA patients using CPAP have moderate to severe disease. Based on an optimal duration for titration, it still is controversial. The study of unattended APAP titration found that a 1-week trial was as efficient as a 2-week period, whereas another study showed a high rate of titration failure (54%) in 1-night titration<sup>(18,19)</sup>.

The primary aim of the present study was to compare the clinical outcomes between APAP titration in unattended setting at home, and manual titration in standard setting. The secondary aim was to determine the difference in CPAP pressure between the two groups.

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## Material and Method

### Study population

After approval of the institution review board, 50 patients of moderate to severe degree of OSA were enrolled. The exclusion criteria were patients with chronic obstructive pulmonary disease, congestive heart failure, obesity hypoventilation syndrome, patients with previous palatal surgery or tracheostomy, sedative drugs usage, alcohol addiction, and refusal to participate in the study.

The baseline data was recorded for every patient including age, body mass index, Epworth Sleepiness Score (ESS), Quality of life tests: PSQI (Pittsburg Sleep Quality Index) and SF-36 (Medical Outcomes Study 36-Item Short-Form Health Survey). All patients underwent manual titration with polysomnography in a sleep laboratory, and APAP titration at home for seven days. The subjects were randomized into APAP titration group, and manual titration, as well as the clinical outcome was assessed before and 4-week follow-up visit.

### Automatic titration

The nasal device, S9-AutoSet™ (ResMed, Australia), was used at home for seven days. After a 1-week trial, the information including 95-percentile pressure, residual AHI, and median mask leaks were recorded. The satisfactory APAP titration was defined as the titration that records more than four hours a night, and reduces apnea-hypopnea index (AHI) less than 10 events per hour with median mask leak less than 24 L/min<sup>(17,20)</sup>.

### Manual titration

The optimal titration was defined as titration that reduces AHI less than five events per hour for at least 15-min duration in supine rapid eye movement (REM) sleep. The residual AHI at the optimal titration was also recorded.

### Data analysis

The statistical analysis was performed using the Epidata software (version 3.1) and R software (version 2.13.0). The primary outcome was to compare the clinical outcomes between two groups at 1-month of fixed pressure CPAP treatment. Wilcoxon rank sum test was used to compare ESS, PSQI, SF-36 scores, compliance, attitude, ease between the two groups. The secondary outcome was to compare the CPAP pressure chosen by manual titration and APAP titration. Unpaired t-test was

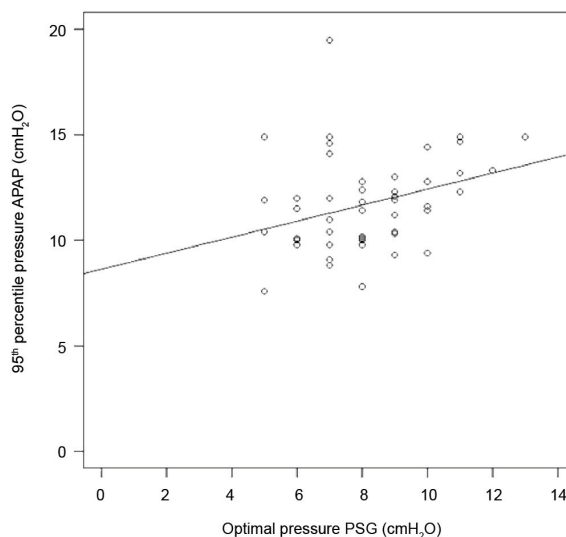
also used to compare between two techniques. The correlation was analyzed by using Pearson correlation coefficient. A p-value of less than 0.05 was statistically significant.

## Results

Fifty patients were included into the present study. Ages ranged from 29 to 68 years with male predominance in 45 patients (90%). The baseline characteristics had no statistical significance in both groups such as age, body mass index, Friedman tongue position, Epworth Sleepiness Scale, and Polysomnography: apnea index (AI), hypopnea index (HI), apnea-hypopnea index (AHI), rapid eye movement apnea-hypopnea index (REM AHI), and lowest oxygen saturation).

The average 95-percentile pressure derived from APAP titration was  $11.7 \pm 0.3$  cmH<sub>2</sub>O (mean of  $8.6 \pm 0.3$ , and maximum pressure of  $12.9 \pm 0.3$  cmH<sub>2</sub>O) with residual AHI of 2.4 events per hour, and median mask leak 1.3 L/min. The average optimal pressure derived from manual titration was  $8.2 \pm 0.3$  cmH<sub>2</sub>O with residual AHI of 1.3 events per hour. The majority of the subjects (90%) had residual AHI less than five events per hour.

The pressure derived from APAP titration method was higher than a manual titration method. Pearson correlation analysis found weak positive correlation ( $r = 0.336$ ) as shown in Fig. 1 and there were statistically significant difference between both



**Fig. 1** Graph showed the weak positive correlation between both methods of pressure determination ( $r = 0.336$ ).

**Table 1.** Comparison of clinical outcomes after a 4-week CPAP treatment between two groups

Outcomes	Manual titration (n = 23)	APAP titration (n = 23)	p-value
ESS			
Pre-treatment	12 (7, 15.5)	10 (7, 16)	0.982
Post-treatment	5 (2.5, 7.5)*	5 (1.2, 8.5)*	0.954
PSQI			
Pre-treatment	5 (3, 7)	5 (3,8)	0.956
Post-treatment	3 (2, 3.5)*	3 (2, 5.8)*	0.246
SF-36			
Pre-treatment	117 (107, 129)	121 (115.5, 130)	0.391
Post-treatment	133 (126, 143)*	135.5 (128.2, 142.8)*	0.820
Satisfaction	8 (6.5, 10)	8 (8, 9)	0.872
Ease of CPAP use	8 (7, 10)	8 (7.5, 9)	0.873

Data were presented as median (IQR = interquartile range)

\* p<0.001 compared with pre-treatment

groups (p = 0.017). The mean difference of pressure from both methods was 3.5±0.4 cmH<sub>2</sub>O.

Forty-six in 50 patients, 23 of APAP titration and 23 of manual titration, were prescribed a fixed pressure CPAP and completed the follow-up period with outcome assessment. Four patients refused to use CPAP. The clinical outcomes were compared after a 4-week treatment in both groups. The ESS, PSQI, and SF-36 scores were improved significantly in both groups, but had no statistically significant differences between the groups. The ease of CPAP use and satisfaction were similar in both groups, as demonstrated in Table 1. The CPAP adherence, defined as usage of more than 4 hours a night and at least five days a week, was 17/23 subjects (73.9%) in APAP and 18 (78.3%) in manual titration. The side effects were similar as nasal blockage, dry mouth, sore throat, dry eyes, and discomfort.

### Discussion

The present study found that the using of 95-percentile pressure provided the statistical improvement in the ESS, PSQI, and SF-36 as similar as the using of optimal pressure. However, the 95-percentile pressure derived from APAP titration method was significantly higher than manual titration method, with similar to another study<sup>(21)</sup>. The study of partially attended APAP titration comparing with standard methods showed the majority had a pressure difference between groups less than 1 cmH<sub>2</sub>O<sup>(22)</sup>, without significant leaks. As similar with previous studies, the 95-percentile pressure was effectively to eliminate apnea and hypopnea events<sup>(23-25)</sup>.

The limitation of the present study was the small sample sizes, and a short follow-up time. Besides, there was relatively little information about the safety and efficacy of unattended APAP titration in patients with COPD, congestive heart failure, or obesity hypoventilation.

In conclusion, An APAP titration is an effective method of pressure determination for conventional CPAP therapy and shows no difference in clinical outcomes comparing the standard titration.

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### What is already known on this topic?

The standard method for determining the optimal CPAP pressure is manual titration with polysomnography in a sleep laboratory. However, the use of home APAP titration is still controversial and has less evidence for support.

### What this study adds?

This report confirmed the use of home APAP titration for pressure determination in moderate to severe OSA patients without comorbidities. However, this study found the higher pressure difference between APAP and manual titration, comparing with previous studies.

### Potential conflicts of interest

None.

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เปรียบเทียบผลที่ได้รับทางคลินิกระหว่างเครื่องเป่าความดันลมแบบปรับความดันอัตโนมัติใช้ที่บ้านกับเครื่องเป่าผลตรวจการนอนหลับแบบปรับความดันลมด้วยมือในผู้ป่วยภาวะหยุดหายใจขณะหลับชนิดอุดกั้น

กรองทอง วงศ์ศรีตรัง, สุเมธ เพ็ญกำลูน

**วัตถุประสงค์:** เปรียบเทียบผลที่ได้รับทางคลินิกและหาความแตกต่างในความดันการรักษาระหว่างกลุ่มใช้เครื่องเป่าความดันลมแบบปรับความดันอัตโนมัติและปรับความดันด้วยมือ

**วัสดุและวิธีการ:** ผู้ป่วยภาวะหยุดหายใจขณะหลับชนิดอุดกั้นจำนวน 50 ราย ระดับความรุนแรงปานกลางถึงมาก ได้รับการสุ่มเป็นสองกลุ่มตามวิธีปฏิบัติ ใช้ค่าความดันลม 95 เปอร์เซ็นต์ไทล์ จากเครื่องเป่าความดันลมแบบปรับความดันอัตโนมัติและความดันที่เหมาะสมจากการปรับด้วยมือ ประเมินผลทางคลินิกก่อนและหลังรักษา 4 สัปดาห์

**ผลการศึกษา:** ค่าเฉลี่ยความดันลม 95 เปอร์เซ็นต์ไทล์ มีค่า  $11.7 \pm 0.3$  เซนติเมตร น้ำและค่าลมรั่วเฉลี่ย 1.3 ลิตรต่อนาที ค่าเฉลี่ยความดันที่ได้จากการปรับด้วยมือมีค่า  $8.2 \pm 0.3$  เซนติเมตรน้ำ การวิเคราะห์ความสัมพันธ์เพียร์สันแสดงความสัมพันธ์ทางบวกแบบแปรบาง ( $r = 0.336, p = 0.017$ ) สำหรับคะแนนการนอน Epworth ดัชนีคุณภาพการนอน Pittsburg และแบบสำรวจสุขภาพแบบสั้น 36 รายการ ผลที่ได้รับทางการแพทย์ของทั้งสองกลุ่มดีขึ้น แต่ไม่มีความแตกต่างอย่างมีนัยสำคัญระหว่างกลุ่ม

**สรุป:** การใช้เครื่องเป่าความดันลมแบบปรับความดันอัตโนมัติและปรับความดันด้วยมือ ให้ผลที่ได้รับทางคลินิกดี แต่ไม่มีความแตกต่างระหว่างกลุ่ม

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