

COMPARISON OF TWO EXPIRATORY PRESSURE RELIEF SYSTEMS OF CPAP DEVICE FOR OSA TREATMENT

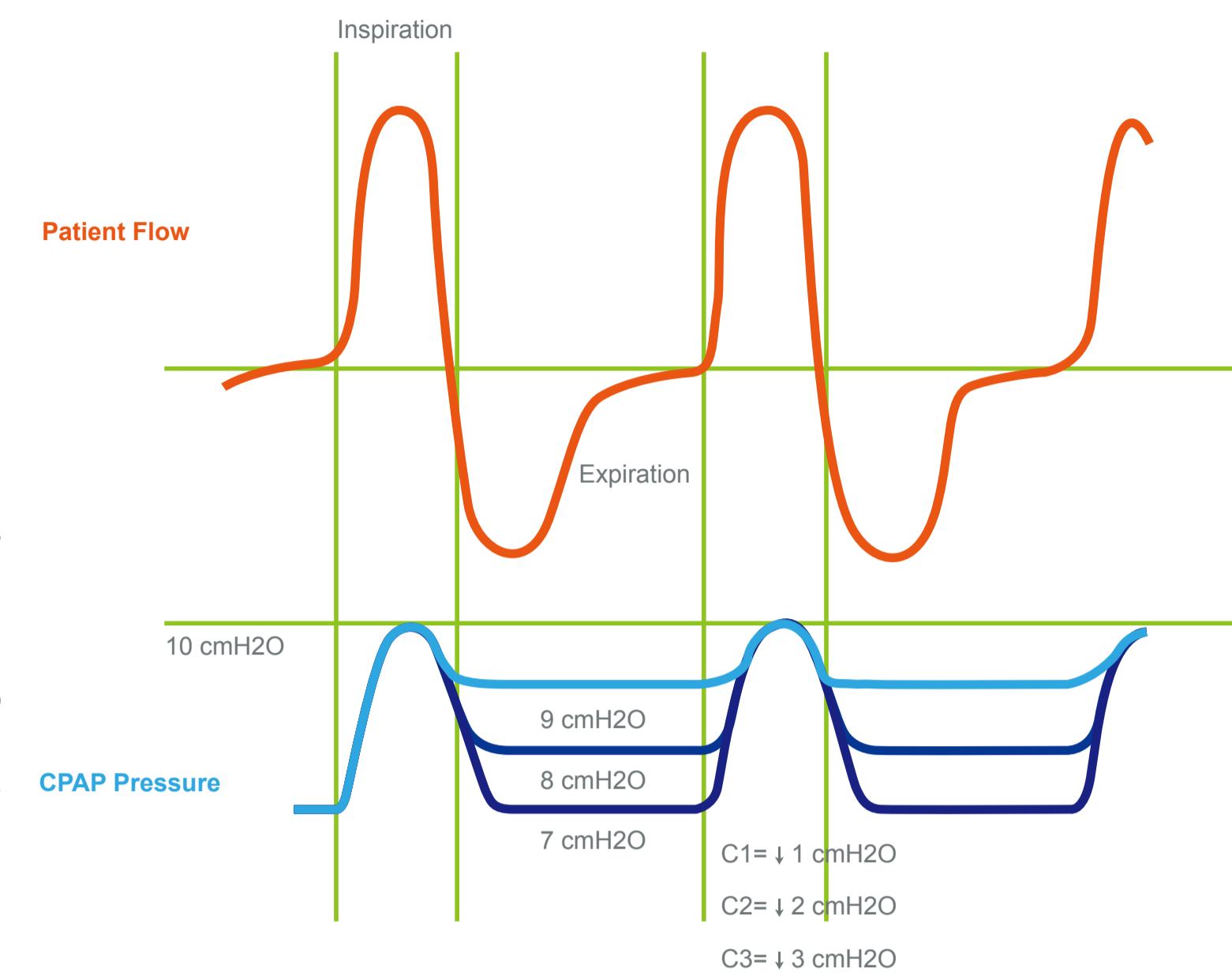
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BACKGROUND

Obstructive sleep apnea (OSA) is a sleep disorder that is caused by repetitive, short-duration blockages of the upper airway, resulting in episodic cessation of breathing (apnea) or reduction in airflow (hypopnea), both of which may lead to arousal from sleep. In the United States, an estimated 9% and 24% of women and men, respectively, aged 30 to 60 years have at least mild OSA. The overall prevalence of mild and moderate OSA is estimated at 20% and 7%, respectively, in Western countries.

Auto-adjust positive airway pressure (APAP) is the most effective non-surgical treatment for OSA. Research shows that APAP decreases daytime sleepiness, especially in those with moderate to severe OSA.

To enhance the treatment comfort of CPAP therapy among OSA patients expiratory pressure relief system (EPRS) has been adopted to several CPAP devices. PVA and C-Flex are two EPRS technology developed by APEX and Philips/Respironics Inc. respectively. In this study we compare the efficacy and treatment comfort between PVA and C-Flex systems among 25 severe OSA patients.



OBJECTIVES

Primary Aim:

To determine whether the PVA system (APEX Medical Corp., New Taipei City, Taiwan) yields similarly therapeutic benefit to OSA subjects receiving C-Flex system therapy.

Secondary Aims:

- To compare the AHI, RERA and oxygen desaturation index (ODI) between PVA and C-Flex systems.
- To compare the sleep quality and comfort between PVA and C-Flex systems.

METHODS

- This was a randomized, prospective, single blind, cross-over study of XT Auto with PVA (APEX) and REMStar Auto with C-Flex (Philips/Respironics)
- An overnight polysomnography to obtain data of hypnogram, respiratory events (Apnea, Hypopnea and RERA) and O₂ desaturation.
- Questionnaire to assess patient comfort after each night study were conducted.
- Subject enrolled criteria

Inclusion criteria:

- Severe OSA Patients with apnea hypopnea index (AHI) ≥ 40 /h and is currently receiving CPAP therapy.

Exclusion criteria:

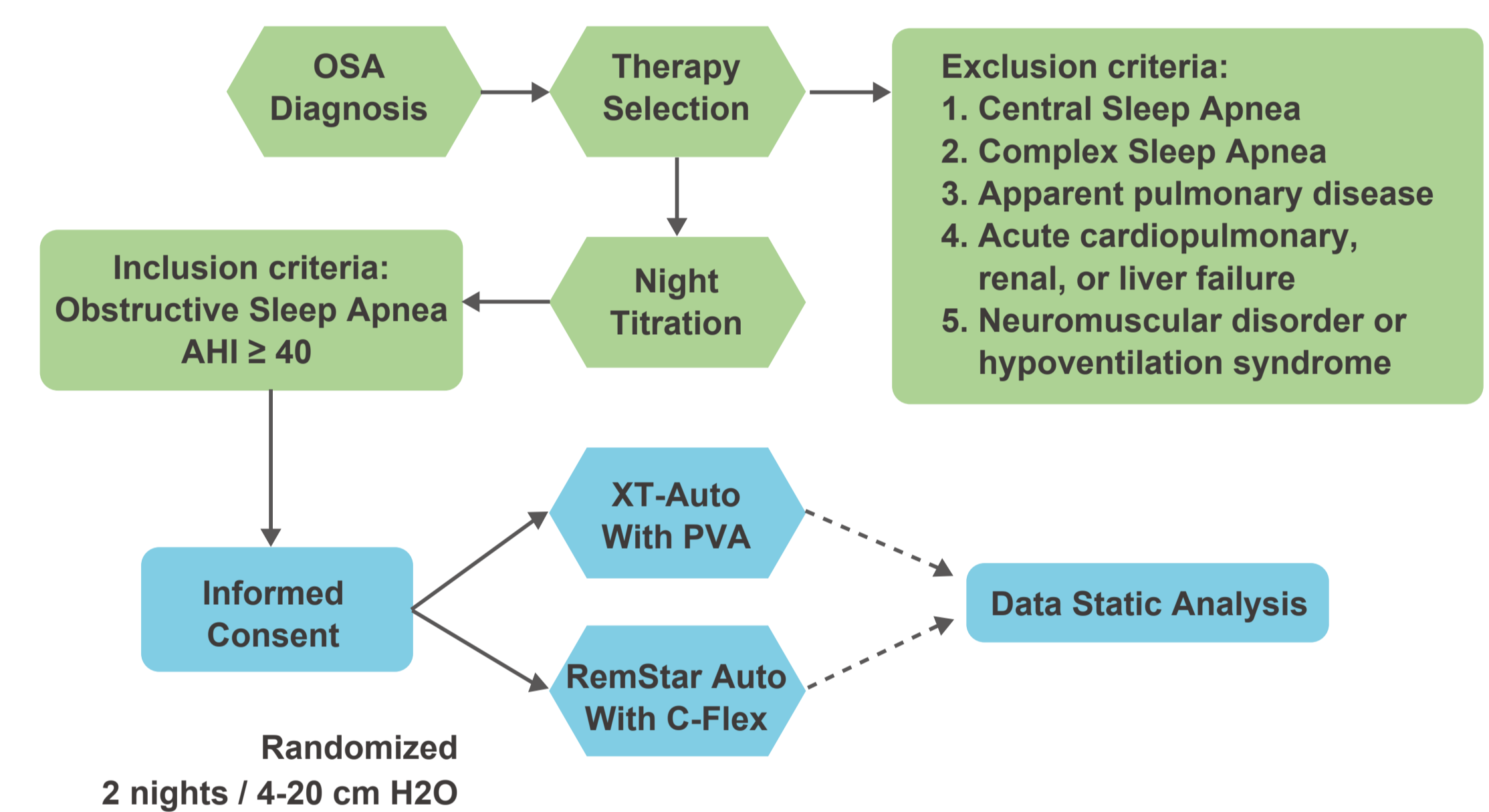
- Apparent pulmonary disease, such as asthma, chronic obstructive pulmonary disease (COPD), interstitial pulmonary disease, tuberculosis, pneumonia, etc.
- Acute cardiopulmonary, renal, or liver failure
- Neuromuscular disorder or hypoventilation syndrome

5. Study design.

- Eligible outpatient subject's severity of OSA was confirmed by full Polysomnography (PSG) investigation in the Division of Clinical Respiratory Physiology of Taipei Veterans General Hospital.
- Subjects were allocated to receive XT Auto with PVA and REMStar Auto with C-Flex under polysomnographic monitoring in a randomized order at least for two nights in the clinical sleep laboratory.
- All subjects should be received the APAP Therapy at least two nights, and each APAP Therapy should extended over 6 hours.
- Questionnaire is filled out while in the next morning.

- All statistical analyses were performed by using SPSS 11.0 statistical software (SPSS Inc., USA), and use the paired t-test to calculated differences between the between PVA and C-Flex systems

Study design



RESULTS

Table1. Patient demographics and clinical characteristics

	Demographics	Clinical Characteristics
Gender		
Males	92% (23/25)	
Females	8% (2/25)	
Age (years)	46.8 ± 10.3	
Body Mass Index	30.3 ± 5.8	
RDI		70.4 ± 25.4
Mean SpO ₂		72.1 ± 8.1

Table2. Comparison of Polysomnographic Results

Subjects (N=25)	PVA	C-Flex	P Value
	Mean ± SD	Mean ± SD	PVA vs. C-Flex
AHI (#/h)	2.39 ± 2.51	1.56 ± 2.46	NS (0.08)
RERA	2.20 ± 3.24	1.57 ± 1.67	NS (0.28)
O ₂ Desaturation Index (#/h)	2.17 ± 2.40	1.17 ± 1.70	SS (0.02)
Mean SpO ₂ (%)	96.14 ± 1.06	96.43 ± 1.20	NS (0.10)

Table3. Sleep Quality Evaluation

Subjects (N=25)	PVA	C-Flex	P Value
	Mean ± SD	Mean ± SD	PVA vs. C-Flex
Total time in bed (min)	375.43 ± 15.06	378.46 ± 20.04	NS (0.40)
Sleep period time (min)	368.55 ± 16.97	370.76 ± 23.59	NS (0.54)
Total sleep time (min)	328.70 ± 62.11	336.81 ± 41.38	NS (0.34)
Sleep Efficiency (%)	89.86 ± 7.86	89.15 ± 10.37	NS (0.64)
Stage Change	150.71 ± 36.90	148.26 ± 42.19	NS (0.63)
REM (% SPT)	18.28 ± 7.14	18.39 ± 8.48	NS (0.93)
SWS (%SPT)	6.10 ± 6.20	7.85 ± 7.55	SS (0.04)
Arousal Index	19.07 ± 9.96	16.54 ± 7.89	NS (0.14)

Table4. Numerical rating scale of Sleep Quality and Adverse Effect

Subjects (N=25)	PVA	C-Flex	P Value	
	Mean ± SD	Mean ± SD	PVA vs. C-Flex	
Sleep Quality	Sleep Depth	5 ± 1.11	4 ± 1.33	SS (0.03)
	Sleep duration	5 ± 1.17	4 ± 1.35	NS (0.11)
	Awakenings during the night	4 ± 1.54	4 ± 1.59	NS (0.77)
	Sleep Stability	5 ± 1.12	5 ± 1.29	NS (0.14)
Adverse Effect of Device	Pressure deliver from device cause patient breathing difficulty	4 ± 1.01	4 ± 1.19	NS (0.06)
	Noise of expiratory pressure from device	4 ± 0.87	4 ± 0.84	NS (0.43)
	Pressure change cause patient's thoracic (chest) cavity stress	4 ± 0.85	4 ± 1.05	NS (0.27)
	Awake frequently	3 ± 1.57	3 ± 1.45	NS (0.97)
	Abdominal distention after wake up	4 ± 0.78	4 ± 1.05	NS (0.41)
	Dryness of mouth	4 ± 1.39	3 ± 1.72	NS (0.26)

CONCLUSION

This study shows that PVA and C-Flex systems that provide pressure relief technology are comparable in terms of alleviating respiratory events and sleep fragmentation. Both PVA and C-Flex demonstrate equivalent effective OSA therapy that in a sleep laboratory setting based on AHI, RERA and O₂ desaturation index analysis. In this study, PVA and C-Flex showed similarly beneficial effects on sleep quality by measuring of total time in bed, sleep period time, total sleep time, sleep efficiency, number of stage change, REM content and arousal index. However, SWS content was slightly lower for PVA. The subjective impression on sleep quality and adverse effects surveyed by the numerical rating scale questionnaire showed no difference between PVA and C-Flex systems.

Thus, XT Auto with PVA and REMStar Auto with C-Flex were shown to be substantially equivalent in performance.