



Reducing AHI in patients with positional obstructive sleep apnea

Introduction and relevance

Obstructive sleep apnea (OSA) is a chronic sleep-related breathing disorder characterized by periods of disturbed breathing caused by a partial or complete collapse of the airway. Disturbed breathing results in hypoxia, hypercarbia, activation of the sympathetic nervous system, and arousals from sleep. The two most common symptoms of OSA are loud snoring and, due to the arousals, excessive daytime sleepiness.¹ The risk of obstructions can be increased when sleeping on one's back.²

OSA is commonly treated with continuous positive airway pressure (CPAP), which delivers pressurized air to the airway to prevent breathing disturbances. The CPAP therapy holds the airway open like a pneumatic splint.

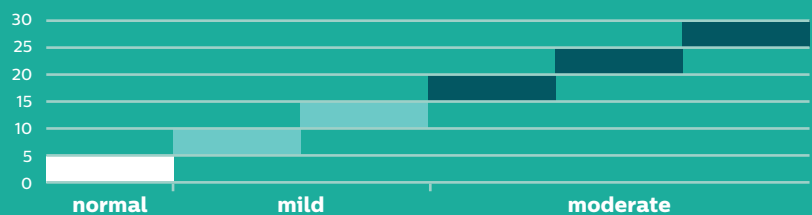
Positional obstructive sleep apnea (POSA) is a different form of OSA in which the vast majority of symptoms occur while sleeping in a supine position (i.e., on the back). A recent study revealed that POSA was present in 53% of the general population

and in 75% of those with OSA. When POSA subjects slept in a non-supine position, 36% of them had an apnea-hypopnea index (AHI) of less than 5, and 47% were at less than 10.³

POSA can also be treated with sleep position therapy (SPT) using the clinically validated NightBalance Lunoa. When it detects that a patient is sleeping on his or her back, the NightBalance Lunoa sends a gentle vibration to prompt a change in sleeping position without disturbing sleep. As instances of supine sleep cease, breathing disturbances decrease and fewer symptoms of POSA are present.

POSA exists when a patient's supine AHI is twice or more in relation to that of other sleeping positions.⁴

AHI ranges:



Clinical Validation

- Treating exclusive POSA (ePOSA) with NightBalance SPT was compared to auto-adjusting positive airway pressure (APAP) therapy in 110 patients in a 6 week randomized, crossover trial. The treatment AHI on SPT was 7.29 and 3.71/hour on APAP, which was within the primary endpoint's delta of 5/hour. Nightly adherence of SPT was significantly greater on SPT (345.3 vs 286.98 minutes).

Conclusion: The AHI during PSG on the NightBalance was not importantly different from a clinical perspective to that on APAP.⁴

- NightBalance SPT was trialed in 36 patients over the course of a month, with 31 of them completing the protocol. Each night, 92.7% of the patients used the SPT for at least 4 hours. The median time spent sleeping in the supine position significantly decreased from 49.9% to 0.0% ($p < 0.001$), and the median AHI decreased from 16.4 to 5.2 ($p < 0.001$). There was no change in sleep efficiency, but daytime sleepiness decreased significantly and quality of life improved.

Conclusion: The SPT provided successful treatment for POSA and was well tolerated by patients.⁵

- Over a 3-month period, the effectiveness of the SPT was compared to oral appliance therapy (OAT) in patients with mild-to-moderate POSA. Randomization placed 99 patients in either SPT or OAT, with 81 of them ultimately completing the study. The median AHI was significantly reduced in both the SPT group (13.0 to 7.0, $p < 0.001$) and the OAT group (11.7 to 9.1, $p < 0.001$). Similar results were also seen in the percentage of patients using the therapy for at least 4 hours, 5 nights per week.

Conclusion: After 3 months, SPT and OAT were equally effective in reducing the AHI, and adherence was high.⁶

- A total of 58 patients with mild-to-moderate sleep apnea from the previous study comparing SPT to OAT completed an extension to a 12-month follow-up. There were 29 patients in each group. The median AHI remained significantly reduced in both the SPT group (13.2 to 7.1, $p < 0.001$) and the OAT group (13.4 to 5.0, $p < 0.001$), and adherence continued to be high.

Conclusion: The efficacy of SPT for patients with mild-to-moderate POSA endured throughout the 12-month period and was comparable to the efficacy of OAT. Adherence to the treatment remained high in both groups.⁷

References

1. Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine, Epstein, L. et al., Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults, *Journal of Clinical Sleep Medicine*, 2009, 5(3):263-276.
2. Davis, K., What you need to know about sleep apnea, January 2018, <https://www.medicalnewstoday.com/articles/178633.php>.
3. Heinzer, R. et al., Prevalence and characteristics of positional sleep apnea in the HypnoLaus population-based cohort, *Sleep Medicine*, 2018, 48:157-162.
4. Berry, Richard B. et al, NightBalance Sleep Position Treatment Device versus Auto-adjusting Positive Airway Pressure for Treatment of Positional Obstructive Sleep Apnea, *Journal of Clinical Sleep Medicine*, Accepted Papers, 2/27/2019.
5. van Maanen, J. et al., The sleep position trainer: a new treatment for positional obstructive sleep apnoea, *Sleep and Breathing*, 2013, 17:771-779.
6. Benoist, L. et al., A randomized, controlled trial of positional therapy versus oral appliance therapy for position-dependent sleep apnea, *Sleep Medicine*, 2017, 34:109-117.
7. de Ruiter, M. et al., Durability of treatment effects of the sleep position trainer versus oral appliance therapy in positional OSA: 12-month follow-up of a randomized controlled trial, *Sleep and Breathing*, 2018, 22:441-450.

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