

Sleep positional therapy

## Reducing AHI and increasing adherence in patients with positional OSA

## 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 hypoxemia, hypercarbia, increased activity of the sympathetic nervous system and arousals from sleep. Common symptoms of OSA are loud snoring and, due to the arousals, excessive daytime sleepiness.<sup>1</sup> The risk of obstructions can be increased when sleeping on one's back.<sup>2</sup>

OSA is commonly treated with continuous positive airway pressure (CPAP), which delivers pressurized air to the airway to prevent breathing disturbances. CPAP therapy holds the airway open like a pneumatic splint. Adherence is a common issue with CPAP therapy, with up to 60% of patients reporting nonadherence to treatment.<sup>3</sup>



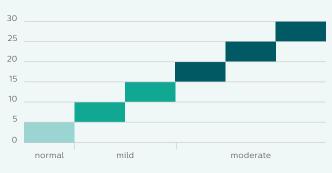
Nonadherence with PAP therapies ranges from **29%-83%**<sup>3,4</sup>



Positional OSA 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 positional OSA was present in 53% of the general population and in 75% of those with OSA. When positional OSA subjects slept in a nonsupine position, 36% of them had an apnea-hypopnea index (AHI) of less than 5, and 47% were at less than 10.<sup>5</sup>

Positional OSA exists when a patient's supine AHI is two or more times that of AHI in other sleeping positions.<sup>6</sup>





## Treatment approach

Positional OSA can also be treated with sleep position therapy (SPT) using the clinically validated NightBalance. When it detects that a patient is sleeping on his or her back, the NightBalance sends a gentle vibration to prompt a change in sleeping position without disturbing sleep.<sup>7,8</sup>

As instances of supine sleep cease, breathing disturbances decrease and fewer symptoms of positional OSA are present. A recent study in patients with positional OSA reported that

## **Clinical validation**

 Treating exclusive POSA (ePOSA) with NightBalance SPT was compared to autoadjusting positive airway pressure (APAP) therapy in 117 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.<sup>6</sup>

 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 positional OSA and was well tolerated by patients.<sup>7</sup>

adherence with NightBalance was significantly higher than with PAP and the effectiveness was similar across all categories of AHI severity.<sup>6</sup>



Over a 3-month period, the effectiveness of the SPT was compared to oral appliance therapy (OAT) in patients with mild-to-moderate positional OSA. 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.</li>

**Conclusion:** After 3 months, SPT and OAT were equally effective in reducing the AHI, and adherence was high in both groups.<sup>9</sup>

 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.</li>

**Conclusion:** The efficacy of SPT for patients with mild-to-moderate positional OSA endured throughout the 12-month period and was comparable to the efficacy of OAT. Adherence to the treatment remained high in both groups.<sup>10</sup>

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