Positional therapy for obstructive sleep apnea with NightBalance® - Prospective study

Original Article

Authors

Cláudia Santos
Hospital Garcia de Orta, Almada, Portugal

Ricardo São Pedro
Hospital Garcia de Orta, Almada, Portugal

Henrique Teixeira
Hospital Garcia de Orta, Almada, Portugal

Carla André
Hospital Garcia de Orta, Almada, Portugal

Luís Antunes
Hospital Garcia de Orta, Almada, Portugal

Abstract

Objective: To verify whether there is an improvement in the severity of positional obstructive sleep apnea and hypopnea syndrome (POSA) after positional therapy (PT) with NightBalance® device.
Materials and methods: Patients diagnosed with POSA, according to the Cartwright criteria, between January 2022 and October 2023, by type 3 polysomnography performed in the ENT department of Hospital Garcia de Orta were included. The inclusion criteria were age over 18 years, adherence to treatment with NightBalance® for at least 60 days. Patients who did not complete the study period or who preferred other therapeutic modalities for OSA were excluded.
Results: 11 patients completed the study. We obtained, on average, a reduction in AHI from 16.76/h to 9.27/h, $p<0.05$. 64% of patients were good responders to PT with a reduction in AHI, on average, from 15.11/h to 5.07/h, 57% of them having an AHI<5/h. In the responding population, we obtained an improvement in AHI, ODI and remaining in a non-supine position, $p<0.05$.
Conclusions: Positional therapy with NightBalance® is a good therapeutic option to be considered in patients with mild and moderate POSA, allowing the patient to remain in a non-supine position, with a reduction in the AHI and an improvement in the ODI.

Keywords: Sleep apnea, positional sleep apnea, positional therapy, NightBalance®

Introduction

Obstructive sleep apnea (OSA) is characterized by episodes of airflow reduction (hypopnea) or cessation (apnea) due to upper airway obstruction during sleep. These episodes can lead to deterioration and fragmentation of sleep, resulting in excessive daytime sleepiness and other symptoms, such as nonrestorative sleep, insomnia, frequent nocturnal

Correspondence:
Cláudia Santos
claudia.20.santos@gmail.com

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awakening, fatigue, headache, and potential impairment of concentration, memory, and mood[1]. OSA is a multifactorial condition associated with significant comorbidities, including hypertension, acute myocardial infarction, stroke/transient ischemic attack, and diabetes mellitus, among others[1]. The gold standard for diagnosis is polysomnography (PSG). This test classifies apnea according to the Apnea-Hypopnea Index (AHI) or the number of apnea episodes/hour into mild (5–15), moderate (15–30), and severe (>30)[1].

OSA is diagnosed when the AHI is ≥15, even in the absence of symptoms, due to increased cardiovascular risk, or when AHI is >5 and <15 and accompanied by symptoms (excessive daytime sleepiness or at least two other symptoms) or associated with comorbidities[1].

Some patients may show improvement with changes in the sleeping position, leading to the recognition of a distinct subtype: positional OSA (POSA). POSA was first described by Cartwright in 1984 and is defined by an AHI in the supine position that is at least twice of that in the non-supine position[2].

More recently, Frank et al. proposed the Amsterdam Positional OSA Classification (APOC) to better identify patients eligible for positional therapy (PT). APOC requires a diagnosis of OSA based on the American Academy of Sleep Medicine criteria with at least 10% of the total sleep time spent in both the best (lateral) and worst (supine) sleep positions. It comprises three categories: APOC I, when the AHI in the best position is <5; APOC II, when the AHI in the best position is less severe than the AHI in the worst position; and APOC III, when the AHI is ≥40 with at least a 25% reduction in the best position[3,4].

Although Cartwright's definition is one of the earliest, it remains widely accepted and is still used in many centers, including in this study protocol. We defined exclusive POSA as cases where the AHI in the best sleep position is <5, consistent with the APOC I criteria[3–5].

The prevalence of POSA varies depending on the diagnostic criteria used, with rates ranging between 20% and 75% in patients with OSA[5]. POSA is more common in patients with mild–moderate OSA, particularly among male patients with a lower body mass index (BMI), smaller neck and abdominal circumference, fewer symptoms, and fewer comorbidities than their respective counterparts[5,6].

Although continuous positive airway pressure (CPAP) therapy remains the gold-standard treatment for OSA[1], adherence is generally low, especially among patients with mild or moderate disease or those with comorbidities, with adherence rates ranging between 30% and 60%[7]. PT is an alternative for patients diagnosed with POSA. It aims to prevent the patient from sleeping in the supine position and uses various devices with variable efficacy, such as special pillows, t-shirts with a tennis ball or roll, and vibratory devices used on the chest or neck[8–10]. NightBalance ® is a recently developed PT device consisting of a chest strap with a position sensor and vibratory technology that prevents sleeping in the supine position, thereby addressing the positional component of sleep apnea[10].

The primary objective of this study was to compare the AHI, oxygen desaturation index (ODI), number of snoring events, symptoms, and sleep quality before and after PT to evaluate the effectiveness of NightBalance® in the treatment of POSA.

Materials and methods

This prospective study evaluated patients diagnosed with POSA between January 2022 and October 2023. The data were collected from the electronic medical records and PSG database of the Department of Otolaryngology of Hospital Garcia de Orta (HGO).

Eligible patients signed an informed consent form after being fully informed of the study's objectives and conditions.

The HGO provided participants with the NightBalance® device during the study period. The inclusion criteria were age ≥18 years, diagnosis of POSA based on Cartwright's criteria using type 3 PSG, ownership of a smartphone with the NightBalance® application installed, and adherence to

treatment for at least 60 consecutive days. Patients who did not complete the study or received other treatment for OSA were excluded.

The following characteristics were analyzed: age, sex, BMI, comorbidities, anatomical features (e.g., increased neck circumference), and severity of OSA (mild, moderate, or severe). The following parameters were assessed before and after PT: AHI, ODI, number of snoring events, OSA-related symptoms, and sleep quality.

Symptoms were evaluated using the Epworth Sleepiness Scale (ESS), and sleep quality was evaluated with the Pittsburgh Sleep Quality Index (PSQI-PT), both validated for the Portuguese population[11,12]. The severity and parameters of sleep apnea were assessed using type 3 PSG with six channels: nasal airflow sensor, pulse oximeter, thoracic and abdominal effort belts, body position sensor, and microphone. Apnea was defined as a ≥90% reduction in the nasal airflow for ≥10 s. Hypopnea was defined as a ≥30% reduction in the airflow associated with oxygen desaturation ≥3%, also lasting at least 10 s.

Statistical analysis was conducted using the SPSS® software version 25 . A p-value < 0.05 was considered statistically significant.

Results

Of the 159 patients diagnosed with POSA, 16 were selected for the study and provided written informed consent after being fully briefed on the study's objectives and protocol. Among these, four patients (25%) discontinued participation due to poor adaptation to PT and reported discomfort and nocturnal awakenings caused by the device's vibration mechanism, which prompted changes in the sleeping position. Another patient opted for surgical treatment and was excluded from the study. Consequently, data from 11 patients who completed the study were analyzed.

The average age of the patients was 53 years (standard deviation [SD] ± 8.13; range: 36–63). Of the 11 participants, four were women (36.36%) and seven were men (63.64%). Table 2 shows the characteristics of the study population, including age, sex, BMI, comorbidities, anatomical alterations, and OSA severity. Before PT, seven patients were classified as mild OSA (AHI 5–15), three as moderate (AHI 15–30), and one as severe (AHI >30).

PT success with NightBalance® was defined as achieving an AHI <5 or reduction in AHI by at least 50% compared to baseline. Associations between the patient characteristics and therapy success were analyzed. Symptom severity and sleep quality were assessed using the ESS and PSQI-PT, respectively.

Table 1
Inclusion and exclusion criteria for the prospective study on PT for POSA using the NightBalance® device

Prospective study – Nightbalance®	
Inclusion criteria	**Exclusion criteria**
- Diagnosis of POSA between January 2022 and October 2023, based on type 3 PSG conducted at the HGO Department of Otorhinolaryngology - Diagnosis of POSA according to Cartwright's criteria - Age ≥18 years - Smartphone with the NightBalance® application installed - Adherence to NightBalance® treatment for ≥60 consecutive days	- Discontinuation of NightBalance® treatment during the study period - Use of NightBalance® for less than 60 consecutive days - Surgical intervention for snoring and sleep apnea after OSA diagnosis - Use of CPAP or mandibular advancement device during the study period

Abbreviations: CPAP, continuous positive airway pressure; HGO, Hospital Garcia de Orta; PSG, polysomnography; OSA, obstructive sleep apnea; POSA, positional obstructive sleep apnea; PT, positional therapy.

Participants used the NightBalance® device for an average of 6 h per night. Therapeutic success was achieved in seven patients (63.64%), with four or them (36.36%) achieving an AHI <5, indicating resolution of OSA. Among these four patients, three initially had mild OSA and one moderate OSA. Only one participant experienced worsening of AHI (from 6.3 to 8.5); however, it remained within the mild OSA classification. We use the Fisher's exact test to evaluate whether characteristics such as BMI; neck and abdominal circumferences; tobacco and alcohol consumption; use of sedative or hypnotic medications; cardiovascular, respiratory, or metabolic diseases; and diagnosis of exclusive-POSA (E-POSA) were associated with PT failure. No statistically significant associations were identified ($p > 0.05$). PT outcomes were evaluated using questionnaires and type 3 PSG, which analyzes AHI, ODI, percentage of time in the non-supine position, and snoring prevalence (Tables 3 and 4, Figure 1). On an average, AHI decreased from 16.76 to 9.27, and ODI decreased from 14.67 to 10.68. The percentage of time spent in the non-supine position increased significantly, from 40.81% to 69.25%. Snoring prevalence showed a non-significant reduction, from 18.65% to 17.85% ($p = 0.896$).

Among the 11 participants who completed the study, five (45.45%) reported initial difficulty in adapting to the device due to awakenings triggered by its vibrations. Two participants (18.18%) reported back pain from sleeping in the lateral decubitus position, while four (36.36%) experienced no discomfort. Patients who reported increased awakenings did not have worse PSQI-PT scores.

Overall, no improvement was observed in ESS (symptoms) or PSQI-PT (sleep quality) scores. However, 36.36% patients experienced an improvement of at least 2 points in the ESS scores, and 27.27% an improvement of at least 2 points in the PSQI-PT scores.

To assess potential differences in PT outcomes based on the OSA severity, results were stratified by the baseline severity as mild or moderate. In patients with mild OSA, PT led to statistically significant reductions in the AHI and ODI, as well as an increase in time in the non-supine position (Table 5). AHI decreased from 10.17 to 6.01, while time in the non-supine position increased from approximately 40% to 70.5%. In patients with moderate OSA, a statistically significant reduction was observed only in the AHI, which decreased from 22.27 to 7.3 (Table 5).

Table 2
Characteristics of the study population

Patient no.	Age	Sex	BMI	NC	AC	Tobacco	Alcohol	S/H	CD	RD	MD	Pre-AHI	E-POSA
1	36	M	26	37	91	no	no	no	no	no	no	13.4	yes
2	56	F	28.7	37	102	yes	no	no	no	no	no	13.1	yes
3	63	F	25.6	35	92	yes	yes	yes	no	yes	no	20.9	no
4	54	M	26.9	45	103	yes	yes	no	no	no	no	11.5	yes
5	44	M	25.4	38	90	yes	yes	yes	yes	no	yes	25.2	no
6	46	M	29.1	41	106	no	no	no	yes	no	no	12.8	yes
7	57	F	26.9	37	94	no	yes	yes	no	no	yes	20.7	yes
8	63	F	26.5	37	90	no	no	yes	no	no	no	6.3	yes
9	62	M	21.2	38	90	no	no	no	no	no	no	8.6	yes
10	55	M	28.1	44	100	no	no	no	yes	no	yes	46.4	no
11	53	M	26.7	40	100	no	no	no	no	no	no	5.5	yes

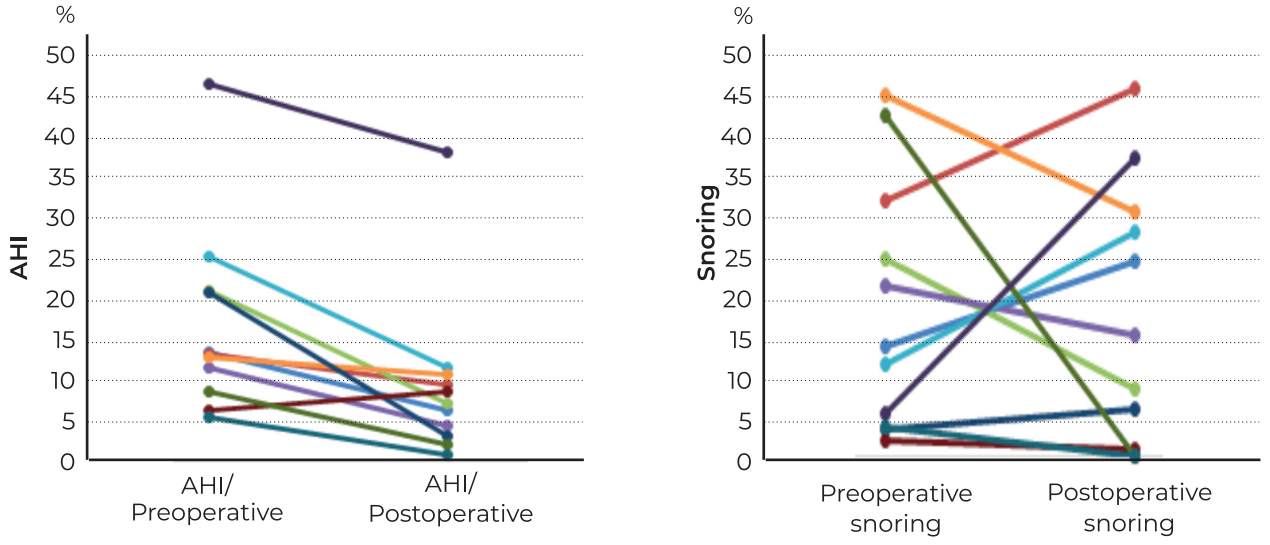
Abbreviations: NC, neck circumference; AC, abdominal circumference; S/H, sedative/hypnotic medication; CD, cardiovascular disease; RD, respiratory disease; MD, metabolic disease; Pre-AHI, Pre-treatment Apnea-Hypopnea Index (AHI); E-POSA, exclusive positional obstructive sleep apnea

Table 3
Outcomes before and after PT with the NightBalance® device (n = 11)

Patient no.	AHI		ODI		Time in non-supine position %		Snoring %		ESS		PSQI-PT	
	Baseline	Post -PT	Baseline	Post -PT	Baseline	Post -PT	Baseline	Post -PT	Baseline	Post -PT	Baseline	Post -PT
1	13,4	6,3	12,2	6,3	28	77,7	13,8	24,3	8	5	5	5
2	13,1	9,4	13,8	10,6	49,2	21,2	32	45,90	12	9	5	5
3	20,9	7,1	19,7	13,3	70	73	24,6	8,5	5	5	11	4
4	11,5	4,4	12,1	5,7	58	75,5	21,4	15,2	16	11	9	5
5	25,2	11,6	27,3	10,9	27,5	63,6	11,4	27,9	21	20	14	16
6	12,8	10,6	16,4	14,4	8,7	39,5	45	30,5	17	14	5	5
7	20,7	3,2	21,2	11,2	40,6	84	3,3	6	12	15	9	9
8	6,3	8,5	5	6,3	31	88	2	1	8	18	15	16
9	8,6	2,1	8,1	2,3	58,7	94	42,6	0	4	4	12	10
10	46,4	38	21	36,5	29,6	47,5	5,4	37,1	9	10	5	5
11	5,5	0,8	4,6	0	47,6	97,7	3,7	0	10	15	4	4

Abbreviations: AHI, Apnea-Hypopnea Index; ODI, oxygen desaturation index; PT, positional therapy; ESS, Epworth Sleepiness Scale; PSQI-PT Pittsburgh Sleep Quality Index

Figure 1
AHI and snoring prevalence before and after PT with the NightBalance® device



Each patient is represented by a line, illustrating the individual changes in the AHI and snoring prevalence before and after PT with the NightBalance® device. AHI, Apnea-Hypopnea Index; ODI, oxygen desaturation index; PT, positional therapy

We also analyzed the subgroup of patients who responded successfully to PT (n = 7), referred to as the responder group in Table 6. In this group, AHI decreased from 15.11 to 5, ODI from 15.03 to 7.1, and time in the non-supine position increased from 47% to 81%, and the changes were statistically significant.

In addition, although the group's overall sleep quality remained poor, it exhibited an average 2-point improvement in the PSQI-PT scores.

Table 4
Average parameters before and after PT with the NightBalance® device (n = 11)

Parameters evaluated	Results (average values)		
Age	53		
Male %	63,64		
BMI	26,46		
NC	39		
AC	96,18		
	Baseline	**Post-PT**	**p-value***
AHI	16,76	9,27	0,001
AHI in non-supine position	3,58	2,97	0,609
Non-supine position %	40,81	69,25	0,003
ODI %	14,67	10,68	0,124
Min. SO2 %	82,82	79,27	0,712
Average SO2 %	93,95	94,17	0,402
Snoring %	18,65	17,85	0,896
ESS	11	11	0,437
PSQI-PT	9	8	0,312

* Calculated using the Student's t-test.
Abbreviations: AHI, Apnea-Hypopnea Index; ODI, oxygen desaturation index; PT, positional therapy; ESS, Epworth Sleepiness Scale; PSQI-PT Pittsburgh Sleep Quality Index; BMI, body mass index; NC, neck circumference; AC, abdominal circumference.

Table 5
Average parameters before and after PT in patients classified as mild (n = 7) and moderate (n = 3) OSA

Mild OSA	Baseline	Post-PT	p-value*	Moderate OSA	Baseline	Post-PT	p-value*
AHI	10,17	6,01	0,016	**AHI**	22,27	7,3	**0,007**
AHI in non-supine position	1,65	3,14	0,195	**AHI in non-supine position**	6,63	1,83	0,092
Non-supine position %	40,17	70,51	0,032	**Non-supine position %**	46,03	73,53	0,157
ODI %	10,31	6,51	0,010	**ODI %**	22,73	11,8	0,064
Min. SO2 %	86	81,43	0,001	**Min. SO2 %**	81,67	74,67	0,478
Average SO2 %	94,56	95,01	0,55	**Average SO2 %**	92,47	92,53	0,967
Snoring %	22,93	16,7	0,413	**Snoring %**	13,1	14,13	0,923
ESS	11	11	0,947	**ESS**	13	13	0,635
PSQI-PT	8	7	0,310	**PSQI-PT**	11	10	0,603

* Calculated using the Student's t-test.
Abbreviations: OSA, obstructive sleep apnea; AHI, Apnea-Hypopnea Index; ODI, oxygen desaturation index; PT, positional therapy; ESS, Epworth Sleepiness Scale; PSQI-PT Pittsburgh Sleep Quality Index

Discussion

In recent years, there has been growing recognition of POSA within the scientific community. Identifying this condition is crucial, as it enables the possibility of alternative therapeutic strategies, particularly PT. PT technology has evolved since its introduction in the 1980s, with techniques such as the tennis ball method or positioning pillows, approaches with adherence rates ranging

Table 6
Average values of responders before and after PT with the NightBalance® device (n = 7)

Responders	Baseline	Post-PT	p-value*
Age	53		
Male %	71,43		
BMI	25,53		
NC	38,57		
AC	94,28		
AHI	15,11	5,07	0,001
AHI in non-supine position	3,36	1,73	0,248
Non-supine position %	47,2	80,79	0,002
ODI %	15,03	7,1	0,002
Min. SO2 %	84,28	77	0,264
Average SO2 %	93,94	94,67	0,417
Snoring %	17,26	11,7	0,481
ESS	11	11	0,915
PSQI-PT	9	7	0,221

* Calculated using the Student's t-test.
Abbreviations: AHI, Apnea-Hypopnea Index; ODI, oxygen desaturation index; PT, positional therapy; ESS, Epworth Sleepiness Scale; PSQI-PT Pittsburgh Sleep Quality Index; BMI, body mass index; NC, neck circumference; AC, abdominal circumference.

from 10% to 40%. This evolution has led to the development of more comfortable and effective devices that exert minimal impact on the sleep architecture, thereby improving treatment adherence[13,14]. Evidence suggests that PT reduces subjective sleepiness and enhances sleep quality in patients with mild–moderate POSA[14].

Cartwright et al.[13] proposed that patients could learn to avoid the supine position after undergoing PT. While some may not require continued use of positional devices, others may benefit from periodic or consistent training to reinforce non-supine sleeping behavior.

PT is reversible and free of adverse effects. It should effectively reduce the AHI, be well tolerated, and ideally not disturb sleep, sometimes even improving it[14]. However, long-term adherence remains low. Van Maanen and de Vries[15] conducted a study with 145 participants with mild–moderate POSA using PT for 6 months and reported an adherence rate of 64.4%.

In our study, participants underwent PT for an average of 6 h per night. Nevertheless, four participants (25% of the initial sample) withdrew due to difficulty in adapting to the vibration-based technology. Among the patients who completed the study, five (45.45%) reported difficulty in adapting due to vibration-induced awakenings, two (18.18%) complained of lower back pain related to lateral positioning, and four (36.36%) reported no discomfort. Patients who reported increased awakenings did not have worse PSQI-PT scores. Still, our adaptation and adherence outcomes were less favorable than those reported in the literature[10,14,15,17].

Our cohort included patients with mild–moderate OSA, as well as one participant with severe E-POSA. In the latter case, although PT led to an AHI reduction of eight episodes per hour, the treatment was unsuccessful. This result contradicts the current evidence suggesting that PT is effective for mild–moderate OSA. Including this patient also negatively impacted the group's average AHI and ODI[10–18].

Concurrent with the findings of Van Maanen and de Vries[14], our study identified both

responders and non-responders to PT, with outcomes consistent with those in the literature[14–16]. We found no statistically significant differences in baseline patient characteristics that predicted PT success, which may be attributed to our limited sample size. Among responders (fou r with mild and three with moderate POSA), there was an average reduction in the AHI (from 15.11 to 5.07; p = 0.001), ODI (from 15.03 to 7.1; p = 0.002), and time in the supine position (from 47.2% to 80.8%; p = 0.002). Additionally, the PSQI-PT score improved by 2 points, from 9 to 7. Van Maanen and de Vries[14] analyzed 31 patients with mild–moderate OSA using thoracic vibration bands for one month, and found that the time in supine sleep decreased from 49.9% to 0% and AHI from 16.4 to 5.2, with 15 patients achieving an AHI <5. In a subsequent study[15], they found a reduction in supine sleep to 3% and lower average ESS (from 11 to 8) and PSQI-PT (from 8 to 6) scores. However, their study did not assess the AHI after PT. Bignold et al.[16] evaluated15 patients with OSA with an average AHI >15 who underwent PT with a thoracic vibration band for 1 week followed by 1 week of rest. They found a reduction in supine sleeping (from 19.3% to 0.4%) and AHI (from 25 to 13.7) but no improvement in the prevalence of snoring. In our study, the rate of snoring decreased among patients with mild OSA (from 22.9% to 16.7%) and responders (from 17.3% to 11.7%); however, these reductions were not statistically significant.

Some authors have suggested PT as a valid alternative to CPAP in patients with mild–moderate POSA[10,17,18], reporting good adherence and AHI reduction. Berry et al.[10] compared NightBalance® with CPAP in patients with mild–moderate OSA and found that although the AHI was higher in the NightBalance® group (7.29 vs. 3.71), adherence was greater (345.3 vs. 286.98 nights) and patients reported higher comfort and usability . Skinner et al.[17] compared CPAP and PT (anti-supine thoracic band) for one month in 20 patients with mild–moderate OSA and found that despite CPAP being more effective at lowering the AHI (4.9 vs. 12), both groups showed similar improvements in sleepiness and quality of life, with higher adherence in the PT group. Similarly, Permut et al.[18] found PT to be as effective as CPAP in normalizing AHI among patients with mild–moderate OSA. As observed in our study, where one-fourth of the patients discontinued therapy, and as reported in the literature[13–18], PT adherence in the medium and long term may be suboptimal. Thus, careful selection of suitable candidates is essential for treatment success.

This study has certain limitations. Evaluations were conducted using type 3 PSG in an outpatient setting, with positional sensors placed at the abdominal level, without video confirmation of the patient's positioning. According to Kesteren et al.[19], apnea and hypopnea depend both on the trunk and head position, which may explain why some patients had higher AHI values in the non-supine position in post-PT assessment. Furthermore, type 3 PSG may underestimate the AHI, as it lacks electroencephalogram and electrooculogram results to verify sleep onset[1]. However, we consistently used type 3 PSG for both baseline and post-PT assessments, in line with recommendations for diagnosing high pretest probability OSA cases. Another limitation was the absence of serial PSG recordings before and after PT, which may have helped to capture the intra-individual variability in OSA[5,20].

The results of this prospective study may be considered as preliminary. The study is ongoing, and future data collection will provide more robust conclusions with a more representative sample.

Conclusion

The results of this study support the use of NightBalance® PT as a valid and effective treatment option for patients with mild–moderate POSA.

We observed a statistically significant reduction in the AHI, with 64% participants classified as responders experiencing more than 50% reduction in the AHI. Among

responders, 57% achieved an AHI <5, effectively no longer meeting the criteria for sleep apnea. These patients also demonstrated statistically significant improvements in the AHI, ODI, and time in the non-supine position. The PSQI-PT score improved by an average of 2 points; however, this difference was not statistically significant.

No correlations were found between patient characteristics and PT response.

Notably, only 36.36% participants reported no discomfort with the device. Approximately 45% experienced nocturnal awakenings due to vibration and 18% reported lower back pain from prolonged lateral decubitus positioning. However, as is the case with CPAP therapy, which often requires a lengthy adaptation period, sometimes lasting several months; we believe this initial discomfort with NightBalance® may be overcome with continued use.

This study is ongoing, and the authors aim to refine the identification of optimal candidates for PT.

Conflicts of interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

Data Confidentiality

The authors declare having followed the protocols used at their working center regarding patient data publication.

Protection of humans and animals

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and the 2013 Helsinki Declaration of The World Medical Association.

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Availability of scientific data

There are no datasets available, or publicity related to this work.

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