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SCIENTIFIC INVESTIGATIONS

Efficacy and long-term follow-up of positional therapy by vibrotactile neck-based device in the management of positional OSA

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Study Objectives: Different therapeutic strategies have been investigated for the treatment of positional obstructive sleep apnea, but more evidence is needed about efficacy and compliance. The objective of this study was to describe the efficacy of vibrotactile neck-based treatment in patients with positional obstructive sleep apnea with different degrees of obstructive sleep apnea severity who were followed for 6 months.

Methods: This is a retrospective study including 162 patients with positional obstructive sleep apnea undergoing vibrotactile neck-based positional therapy. We compared polysomnographic data obtained at baseline and during positional therapy after 1 month. We performed a subgroup analysis based on obstructive sleep apnea severity. Furthermore, we analyzed follow-up data in 84/162 (51.8%) patients with particular focus on discontinuation and complications related to the device.

Results: We observed a significant difference between mean baseline obstructive apnea-hypopnea index (OAHI; 21.9 ± 9.9 events/h) and during positional therapy (12 ± 9.2 events/h; $P < .01$). Moreover, 87/162 (54.9%) patients showed a reduced baseline OAHI of at least 50% and 38/162 (23.4%) achieved complete disease control (OAHI < 5 events/h). At subgroup analysis, at least 50% reduction from baseline OAHI was observed in 56.8% of patients with mild, 55% with moderate, and 47.4% with severe OAHI, whereas complete control of disease was achieved in 50% of patients with mild, 22.5% with moderate, and 7.9% with severe OAHI. At a 6-month follow-up, only 35/84 patients (41.6%) were regularly using the device, with a mean of 5.9 ± 1.2 days per week.

Conclusions: Our results on the efficacy and long-term adherence to vibrotactile neck-based positional therapy showed that positional therapy can be an efficient first-line treatment option for mild positional obstructive sleep apnea and in selected cases of moderate disease. Long-term compliance is limited because of complications and low satisfaction in some patients.

Keywords: OSA, obstructive sleep apnea, POSA, positional OSA, positional therapy, Nightshift, vibrotactile neck-based device

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BRIEF SUMMARY

Current Knowledge/Study Rationale: Many modalities for positional therapy for patients with positional obstructive sleep apnea exist, although there is disagreement about the efficacy and long-term outcomes. To our knowledge, this is the largest study to date assessing the effectiveness and long-term compliance of vibrotactile neck-based positional therapy in patients with different severities of positional obstructive sleep apnea.

Study Impact: We observed that patients with mild and selected moderate positional obstructive sleep apnea may be successfully treated by vibrotactile neck-based positional therapy, although achieving good long-term results may be limited by mild complications. In our series, 41.6% of patients were regularly using the device at 6 months. Accurate counselling should be performed prior to vibrotactile neck-based positional therapy to motivate patients toward better adherence to therapy.

INTRODUCTION

Obstructive sleep apnea (OSA) is a chronic multifactorial disease burdened by a wide spectrum of complications. Age-related tissue loss of collagen, obesity, metabolic changes, muscular dysfunctions, alcohol abuse, and oropharyngeal diseases/deformities can play a role. Proper evaluation and diagnosis are critical to determine a suitable treatment plan. Polysomnography (PSG) is typically necessary for diagnosis and staging of the disease. Continuous positive airway pressure (CPAP) therapy is considered the gold standard, although many patients consider it intrusive. Acceptance and compliance are moderate for this reason, and many alternative treatment options for OSA presently exist.[1] There is no set of standards of care for treatment of OSA, and treatment should be tailored to clinical aspects of the disease and specific anatomy. A useful strategy to evaluate dynamic upper airways obstruction is drug-induced sleep endoscopy[2] that can help in the selection process of the best alternative treatment. such as oral device[3,4] or multi-level surgery, if indicated.

Recently, interest in positional OSA (POSA) has been increased with the idea that a large percentage of patients may respond to changes in position during sleep.[5] POSA seems to be quite common among OSA patients, especially those with mild

Table 1—Demographic data for the entire population and 3 subgroups.

	All Cases (n = 162)	Group A (n = 44)	Group B (n = 80)	Group C (n = 38)	*P* Value
Age, year: Mean ± SD (range)	57.9 ± 12.1 (18–84)	60.4 ± 12.0 (40–84)	57.7 ± 11.5 (18–81)	55.3 ± 12.9 (22–80)	NS
Female, % (M:F)	22.8 (4:1)	34 (1.9:1)	20 (4:1)	15.8 (5.3:1)	< .05
BMI: Mean ± SD (range)	26.6 ± 2.7 (19.9–36.5)	26.7 ± 2.4 (21.4–32.9)	26.4 ± 2.9 (19.9–36.5)	27.2 ± 2.6 (21.5–32.0)	NS
ESS ± SD (range)	11.5 ± 5.9 (3–24)	7.4 ± 3.1 (3-10)	11.1 ± 5.2 (4–24)	16.1 ± 6.1 (8–24)	< .05

Statistical significance of the intergroup comparisons with the ANOVA was reported and assumed when $P < .05$. BMI = body mass index, ESS = Epworth Sleepiness Scale, M:F = male:female, NS = not significant, SD = standard deviation.

and moderate OSA, accounting for up to 50% of cases,[6] and newer criteria seem to improve sensitivity, expanding the prevalence of POSA among patients with OSA.[7–9] POSA is commonly defined as a total apnea-hypopnea index (AHI) ≥ 5 events/h and a ratio supine AHI to nonsupine AHI of ≥ 2.[10] Exclusive POSA is defined when nonsupine AHI is normalized. Heinzer et al[11] demonstrated that exclusive POSA was present in 36–47% of patients with OSA, which has been confirmed by other authors.[12,13]

Different devices have been proposed for the treatment of POSA with poor results due to discomfort and low compliance.[14] De Vries et al[5] demonstrated in a series of 43 patients undergoing positional therapy (PT) that 65% of patients were no longer using it at 13 months. The vibrotactile neck-based device is a new PT modality, first used by Levendowski et al.[15] It is small and secured to the neck of the patient. This system has been validated in prior studies as a diagnostic and therapeutic tool on patients with POSA.[16] It is able to give useful information about the patients' position and activity, while providing a vibrotactile biofeedback inducing patients to avoid the supine position. The biofeedback does not disrupt sleep architecture and creates minimum arousals.[15]

The objective of this manuscript was to assess the efficacy of vibrotactile neck-based PT in patients with POSA with different degrees of OSA severity. The primary endpoint was to evaluate efficacy by analysis of polysomnographic data after 1 month of continuous treatment. The secondary endpoint was to evaluate follow-up data at 6 months, with particular attention to discontinuation of the device and complications.

METHODS

Study population and study design

This is a nonprofit observational retrospective study including 162 adult patients with POSA undergoing PT with a vibrotactile neck-based PT device. Patients were diagnosed and indicated for PT at the Rhinology Unit and Sleep Medicine Service of our institution ("A. Gemelli" University Hospital Foundation IRCCS - Catholic University of the Sacred Heart) between January 2018 and January 2020. Demographic data of patients are summarized in Table 1. Both Cartwright's criteria and the Amsterdam Positional OSA classification (APOC) were applied to the database.

Inclusion criteria were:

- Patients affected by POSA diagnosed, treated, and followed at our single institution with AHI ≥ 5 events/h.
- Positional component of OSA according to Grade I or II of the Amsterdam Positional OSA classification.[17,18]
- Patients who performed a control visit with PSG wearing the device after 1 month of treatment.

Exclusion criteria were:

- Previous sleep surgery.
- Contemporary oral device or ventilation therapy.
- Weight variations > 3 kg[19] between diagnostic PSG and PSG wearing the vibrotactile device.
- Timing interval between diagnostic PSG and indication for positional therapy > 3 months.

The work was carried out in accordance with Declaration of Helsinki for experiments involving humans and is in line with recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals by International Committee Medical Journal Editors (ICMJE).

Clinical data collection and outcomes

Data were directly extracted from our clinical database and medical records. Informed consent about privacy and review consultation of clinical data was obtained from patients at the time of original data collection. The data were anonymously analyzed. Clinical history, Epworth Sleepiness Scale scores, and body mass index were obtained by a screening visit that patients with OSA usually undergo at our institution before diagnostic PSG. Furthermore, socioeconomical status was determined according to declared occupation and educational attainment.[20] In our practice, patients suspected for positional OSA undergo a PSG at home (Somté HST, Compumedics Limited, Abbotsford, Australia) and are re-evaluated the day after. If the diagnosis of POSA is confirmed, PT may be indicated. Patients interested in Nightshift (Advanced Brain Monitoring, Carlsbad, CA) performed a first month of treatment. Efficacy was then evaluated by a new PSG while wearing the device. Adherence to PT is confirmed by daily sleep report analysis recorded by the device. If AHI decreased at least 50% from the baseline and patients wore the device for at least 5 hours for 5 nights, long-term use is recommended. The main outcomes analyzed in our study were: AHI index, obstructive AHI (OAHI) index,

Figure 1—The Nightshift device.

The Nightshift (Advanced Brain Monitoring, Carlsbad, CA) device is composed of a case attached to the back of the neck with an adjustable, latex-free, silicone rubber strap secured by a magnetic clasp.

minimal saturation, total time of desaturation < 90%, and sleep supine time < 10%.

We divided the population into 3 groups based on OSA severity: Group A, mild (AHI 5–14 events/h; n = 44); Group B, moderate (AHI 15–29 events/h; n = 80), and Group C, severe OSA (AHI > 30 events/h; n = 38).

Follow-up data

In our series, 89/162 (54.9%) of patients with mild and moderate POSA were indicated for long-term vibrotactile neck-based PT as an exclusive modality. Because 5 patients were lost to follow-up, 84 patients were analyzed for discontinuation and complications at 6 months. Clinical characteristics of this subgroup of patients were: women = 31; ratio of males to females = 4:1; mean age 54.5 years, range 18–80; mean body mass index 25.4 ± 2.5, range 19.9–36.5; Epworth Sleepiness Scale 5.7 ± 4.5. For severity, 66/84 (77.6%) of the participants had moderate OSA and 18/66 had mild disease (27.2%).

Follow-up data were obtained at the 6-month follow-up visit for patients with OSA in usual care. During that visit, patients are queried about compliance to the therapy and, in the case of PT, about discontinuation and complications. In case of discontinuation, patients are asked about the last time the device was used and the reasons for interruption; patients were re-evaluated with PSG if indicated and referred to other therapies. In 10 patients, relevant information at the 6-month follow-up was missing and the patients were contacted by telephone, asking predefined questions about their clinical status and treatment compliance.

Device characteristics

We used the Nightshift device, which is composed of a case attached to the back of the neck with an adjustable, latex-free, silicone rubber strap secured by a magnetic clasp (**Figure 1**). It measures snoring with an acoustic microphone, and a snore detection algorithm quantifies each snore based on the shape and the peak amplitude prior to conversion to decibels (dB). Loud snoring is defined as at least 1 snore with a magnitude ≥ 50 dB in a 30-second interval of recording. The percentage of time snoring ≥ 50 dB is then determined for overall, supine, and nonsupine epochs of sleep. A 3-axis accelerometer is used to determine neck position and perform an actigraphy-based classification of sleep. Neck positions are reported as upright, supine, lateral left, lateral right, and prone. Two 1G haptic motors provide vibrotactile feedback when the supine position is detected. Positional feedback is modulated by setting the number of motors to be excited (one or both) and varying the duration of motor functioning. Feedback starts with low-frequency duration and increases until the user exits the supine position. The feedback can be optionally paused for a predefined time interval or completely turned off. A total of 7 levels of feedback are delivered.[15] We choose the Nightshift device because it is the only one available on the Italian market that provides an overnight report, with all the characteristics needed for treatment and follow-up. The device, in fact, is able to record an overnight report, which contains information about sleep position, snoring level (dB), duration, and quality of sleep. All reports are saved daily into the device and can be downloaded and analyzed with specific software by the clinician during the follow-up visit.

Statistical analysis

PSG and demographic data are expressed as mean ± standard deviation. AHI, OAHI, minimal saturation, and total desaturation time between baseline and 1-month PSG wearing Nightshift were compared in each group. Complete disease control was assumed if an OAHI < 5 events/h was achieved during PT. Partially controlled diseased was defined if a reduction of at least 50% from the baseline OAHI was observed during PT. Kaplan-Meier function was used to analyze discontinuation of the device over the 6 months. The data were analyzed using IBM SPSS 24 System. Firstly, a Kurtosis and symmetry test was performed to choose the more appropriate test. Wilcoxon signed-rank test was used to analyze the total time spent under baseline saturation, while a Student's *t* test was used for paired samples. Differences were considered significant when P was < .05.

RESULTS

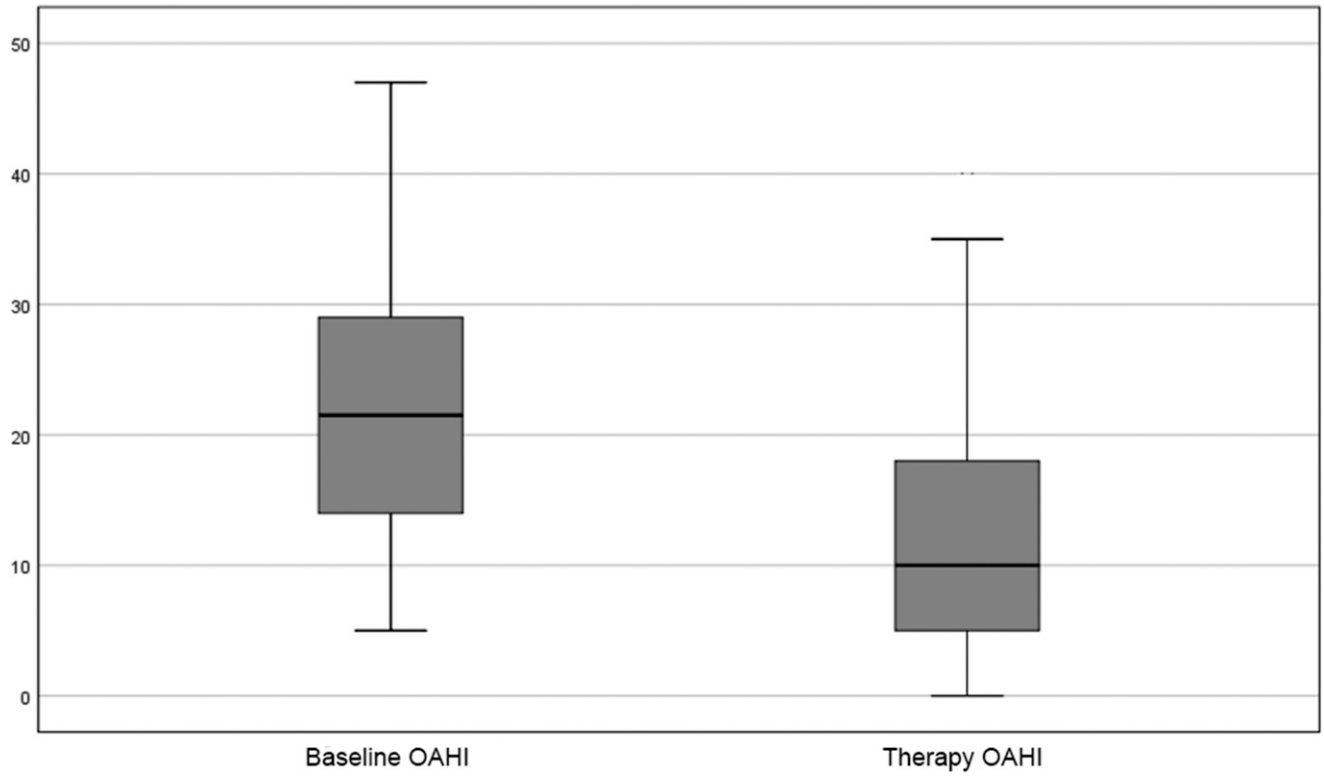
Baseline characteristics of the entire population and different groups based on OSA severity are reported in **Table 1**. PSG data at baseline and during positional therapy at 1-month follow-up in the entire population and in the different groups are reported in **Table 2**. We found a significant difference between baseline AHI (22.1 ± 9.9 events/h) and during PT (12.1 ± 9.3 events/h; $P < .01$) . The difference was also significant for OAHI (21.9 ± 9.9 vs 12.0 ± 9.2 events/h; $P < .01$) (**Figure 2**) for desaturation time (5.1 ± 7.5% vs 2.4 ± 7.5%; $P < .01$), minimal saturation (81.4 ± 6.0% vs 85.5 ± 7.0%; $P < .01$), and average supine sleep time (31.3 ± 4.2% vs 5.2 ± 0.7%; $P < .01$). The differences

Table 2—Polysomnographic data for the entire population and subgroups obtained during baseline polysomnography and positional therapy.

	All Cases (n=162)			Group A (n=44)			Group B (n=80)			Group C (n=38)		
	Baseline	Therapy	*P*	Baseline	Therapy	*P*	Baseline	Therapy	*P*	Baseline	Therapy	*P*
AHI (events/h)	22.1 ± 9.9	12.1 ± 9.3	< .01	10.6 ± 2.9	6.7 ± 5.5	< .01	21.9 ± 4.1	11.8 ± 7.9	< .01	36.1 ± 4.6	19.2 ± 10.8	< .01
OAHI (events/h)	21.9 ± 9.9	12.0 ± 9.2	< .01	10.4 ± 2.9	6.5 ± 5.3	< .01	21.7 ± 4.2	11.8 ± 7.9	< .01	35.8 ± 4.5	19.0 **±10.7**	< .01
Total desaturation time (%)	5.1 ± 7.5	2.4 ± 7.5	< .01	1.9 ± 2.6	1.1 ± 3.8	< .05	6.1 ± 9.8	2.8 ± 9.8	< .01	6.6 ± 6.8	3.3 ± 4.9	< .01
Minimal saturation (%)	81.4 ± 6.0	85.5 ± 7.0	< .01	85.1 ± 3.0	86.2 ± 10.6	NS	80.8 ± 5.5	85.3 ± 5.1	< .01	78.4 ± 6.9	83.5 ± 4.8	< .01
Supine sleep time (%)	31.3 ± 4.2	5.2 ± 0.7	< .01	32.5 ± 5.1	5.1 ± 0.7	< .01	30.09 ± 4.5	5.0 ± 0.4	< .01	31 ± 4.2	5.8 ± 1.2	< .01

All data were expressed as mean ± SD. Statistical significance between baseline and treatment data was reported and assumed when $P < .05$. AHI = apnea-hypopnea index, AHI = apnea-hypopnea index, NS = not significant, OAHI = obstructive apnea-hypopnea index, SD = standard deviation.

Figure 2—Difference between OAHI index from baseline polysomnography to positional therapy for the entire population.

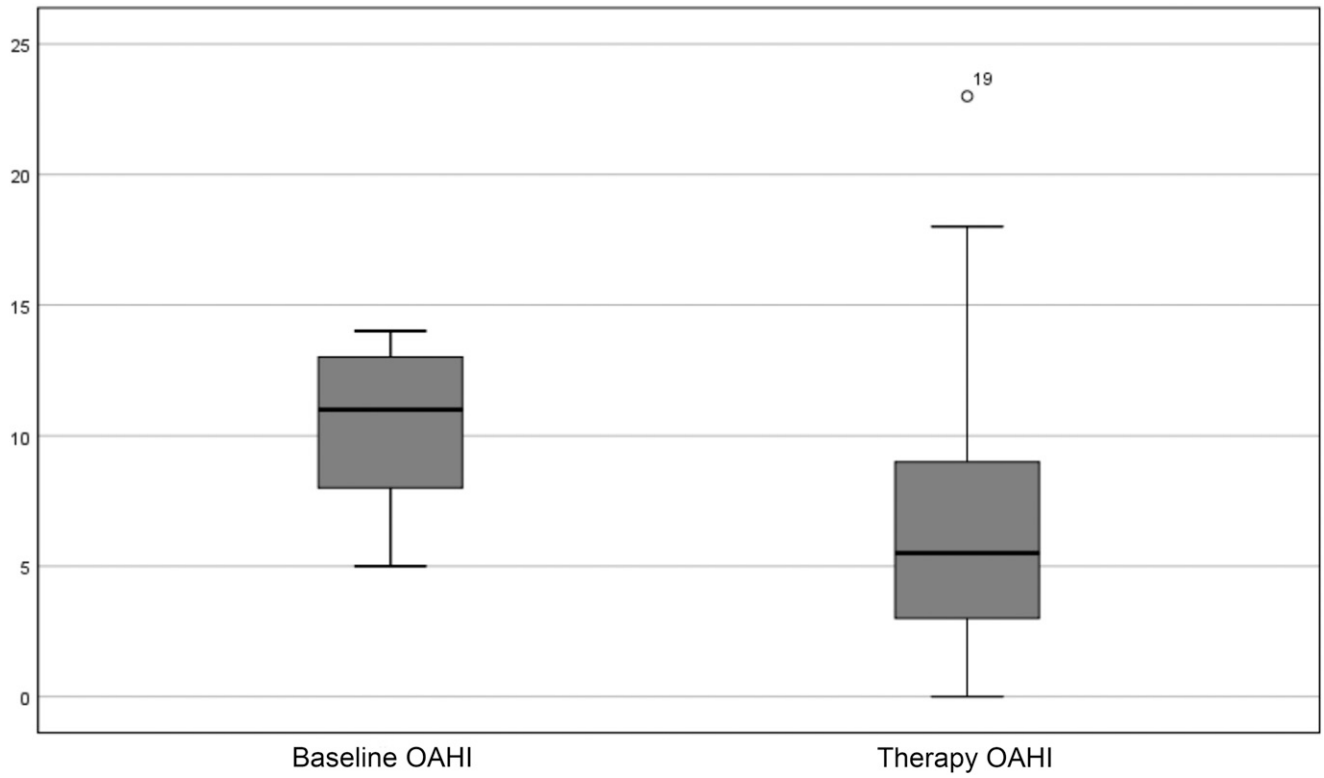


The dark line shows the median value, the box indicates I and IV quartile, and indicators show confidence intervals. Measurement unit is events/h. AHI = apnea-hypopnea index, OAHI = obstructive sleep apnea-hypopnea index.

between baseline and during PT for AHI, OAHI, supine sleep time, total desaturation time, and minimal saturation for groups A, B, and C are reported in **Table 2**. A significant difference between OAHI index from baseline PSG to PT in mild OSA is shown in **Figure 3**.

The number of patients who achieved complete disease control or partial disease control during PT in the entire population and subgroups is reported in **Table 3**. Patients reducing baseline OAHI by 50% were 87/162 (53.7%), of whom 38/162 (23.4%) achieved complete disease control. At baseline, the supine time was 45.2 ± 10.3% compared with 9.6 ± 7.2% during PT. In group A, 25/44 (56.81%) decreased baseline OAHI by 50% and 22/44 (50%) achieved complete control of disease. In group B, 44/80 (55%) patients decreased baseline OAHI by 50% and 18/80 (22.5%) achieved complete control of disease. In group C, 18/38 (47.4%) patients decreased 50% baseline OAHI and only 3/38 (7.9%) had complete disease control. The number of responders in terms of supine sleep < 10% is shown in **Table 4**. Finally, we performed a statistical linear regression analysis between baseline and therapy OAHI as shown in **Figure 4** (R: .468; $P < .01$). Baseline OAHI was the only significant predictor of therapy OAHI.

Figure 3—Difference between OAHI index from baseline polysomnography to positional therapy in patients affected by mild POSA.



The dark line shows the median value, the box indicates I and IV quartile, and indicators show confidence intervals. Measurement unit is events/h. AHI = apnea-hypopnea index, OAHI = obstructive sleep apnea-hypopnea index, POSA = positional obstructive sleep apnea.

Table 3—Control of the disease based on subgroups of patients.

	All Cases (n = 162)	Group A (n = 44)	Group B (n = 80)	Group C (n = 38)	Chi-square Significance
No. of patients with controlled disease (OAHI < 5 events/h)	38/162 (23.4%)	22/44 (50%)	18/80 (22.5%)	3/38 (7.9%)	< .01
No. of patients with partially controlled disease (after therapy OAHI < 50% of baseline OAHI)	87/162 (53.7%)	25/44 (56.8%)	44/80 (55%)	18/38 (47.4%)	NS
Uncontrolled	75/162 (46.3%)	19/44 (43.2%)	36/80 (45%)	20/38 (52.6%)	NS

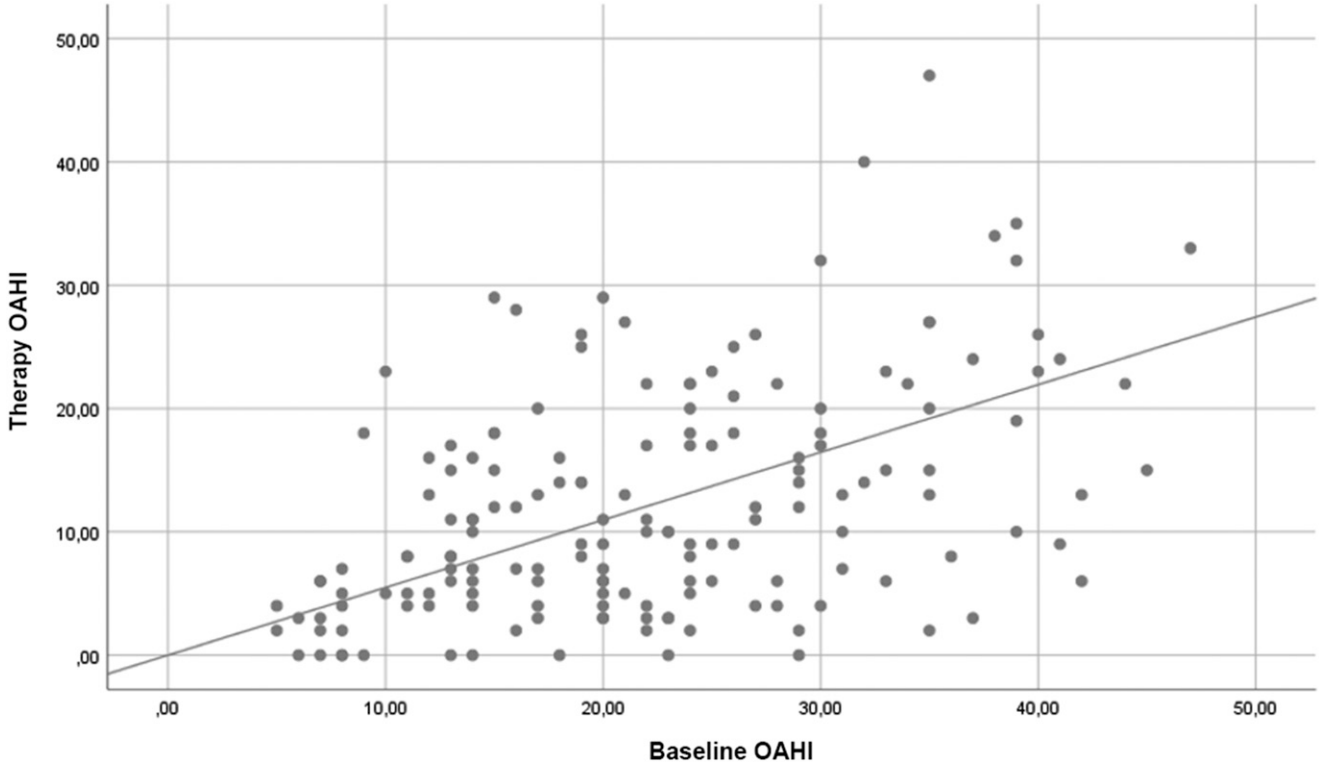
Statistical significance of the intergroup comparison was reported and assumed when $P < .05$. NS = not significant, OAHI = obstructive apnea-hypopnea index.

Table 4—Control of disease based on supine sleep time ≤ 10%.

	No. of Patients with Controlled Disease (OAHI < 5 events/h)	No. of Patients with Partially Controlled Disease (After Therapy OAHI < 50% of Baseline OAHI)	Uncontrolled
Supine sleep ≤10%	36/38 (94.7%)	43/89 (48.3%)	16/73 (21.9%)
Supine sleep > 10%	2/38 (5.3%)	46/89 (51.6%)	57/73 (78.1%)

OAHI = obstructive apnea-hypopnea index.

Figure 4—Scatter plot.



Measurement unit is events/h. Dependence of OAHI during therapy from baseline for all patients is demonstrated with an R of .468 ($P < .01$). Baseline OAHI was the only significant predictor of therapy OAHI. AHI = apnea-hypopnea index, OAHI = obstructive sleep apnea-hypopnea index.

Long-term results

Data for 6-month follow-up were available in 84 patients. At 6 months, 35/84 patients (41.6%) were regularly using the device, with a mean of 5.9 ± 1.2 days per week and a mean of 6.1+1.3 hours per night (**Figure 5**). Among regularly users, at 6 months, 26/35 had moderate OSA (74.2%) and 9/35 had mild disease (25.7%). The remaining patients discontinued the device because of absence of self-reported benefit from therapy in 23/49 cases (46.9%), complications related to use of the device in 16/49 (32.6%), and finally, 10/49 (22.4%) patients were losing weight with a referred improvement of symptoms and decided to abandon Nightshift. Based on severity, the rate of discontinuation was 50% (9/18) in patients with mild OSA and 39.4% (26/66) in those with moderate disease.

Regarding complications referred by patients, the most frequent were difficulty in initiating sleep wearing the device, 56/84 (66.6%), and being awakened by the vibration in 51/84 (60.7%). Patients reported back (28/84; 33.3%) and neck pain (28/84; 33.3%), discomfort with the neck band (24/84; 28.6%), and trouble due to low battery charge of the device (20/84; 23.8%), while 6 patients (12/84; 14.3%) reported that vibration of the device disturbed the partner's sleep. All patients reported 1 or more than 1 simultaneous complication.

We performed a logistic regression for device use to identify risk factors of discontinuation, such as age, body mass index, sex, low socioeconomical status, AHI, and Epworth Sleepiness Scale before and after 1-week usage. However, no clear factors associated with device discontinuation were identified. The results of logistic regression are shown in **Table 5**.

Finally, among patients who discontinued PT with Nightshift, 35/84 (41.6%) were recommended for CPAP therapy, 19/84 (22.6%) were referred to a nutritionist for weight loss, 11/84 (13.1%) underwent surgery, and 5/84 (5.9%) started an oral device.

DISCUSSION

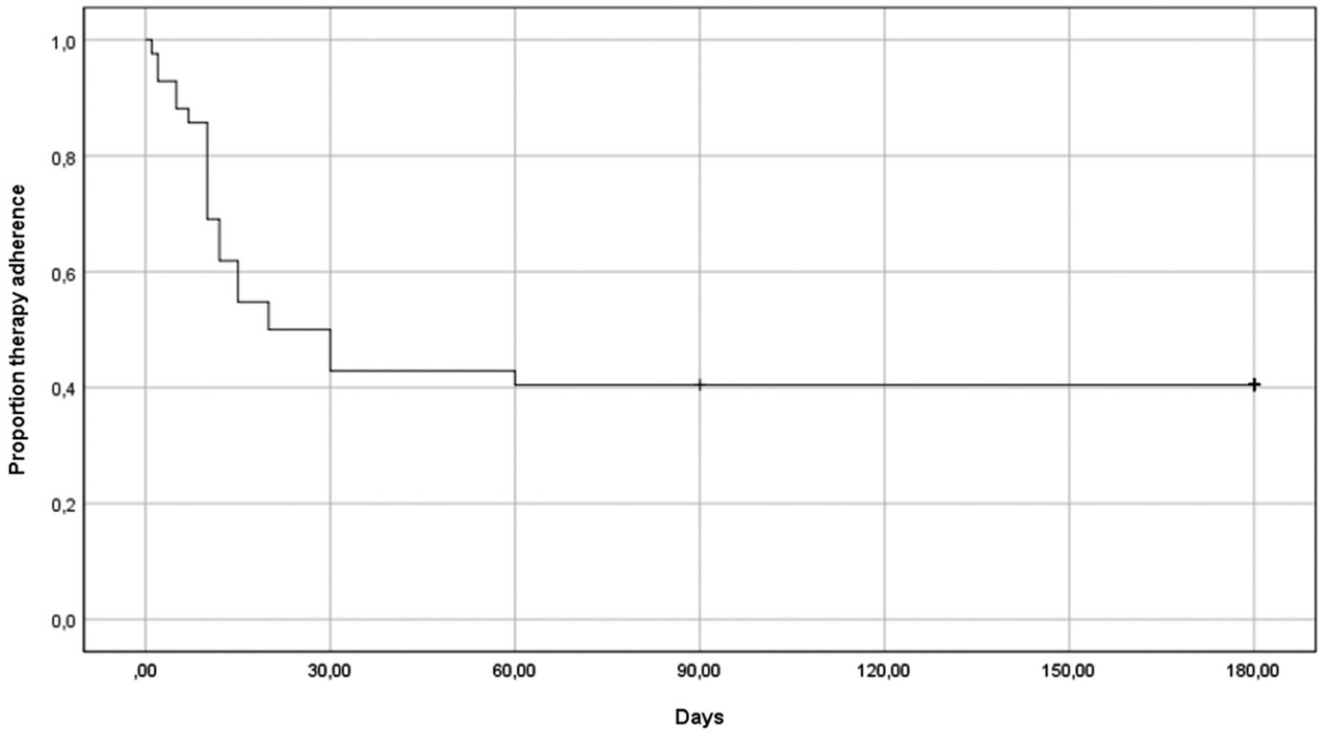
Treatment modalities of OSA aim to improve clinical symptoms and quality of life, decreasing disease-related problems, especially comorbidities. Therapy includes behavioral modification, CPAP, surgical options, and oral appliances. Less-invasive treatment options are preferred by patients and should be taken into consideration by physicians whenever possible. Behavioral modification includes avoidance of alcohol and sedatives for 3 hours before sleep, body weight control, and PT by changing the sleep position from the supine to the side position. One of the first techniques described was the so-called ''tennis ball technique,'' a tennis ball fastened to the back with a belt. This can prevent patients from turning to supine during sleep with a significant decrease in supine sleep time and reduction in the AHI, but fewer than 10% of patients continue long-term treatment due to discomfort or back pain.[21] The sleep position trainer is another device fastened to the chest that can

Table 5—Logistic regression analysis for device discontinuation.

	SE	Wald	df	Significance	Exp (B)
Screening AHI	.092	0.192	1	.661	0.960
AHI after 1-month trial	.204	1.881	1	.170	0.756
Age	.052	0.136	1	.713	1.019
BMI	.368	0.550	1	.458	1.314
Screening ESS	.376	1.082	1	.298	0.676
ESS after 1-month trial	.415	1.280	1	.258	1.599
Sex	.891	1.212	1	.853	1.912
Socioeconomic status	.456	1.100	1	.196	0.712

AHI = apnea-hypopnea index, BMI = body mass index, df = degrees of freedom, ESS = Epworth Sleepiness Scale, Exp (B) = exponentiation of the B coefficients, SE = standard error.

Figure 5—Kaplan-Meier function for long-term use of the device.



measure body position and vibrate when the patient lies supine and was considered useful to reduce quickly the average percentage of supine sleep time and improve sleep-related quality of life.[22] More recently, Eijsvogel et al[23] compared compliance in patients using either a sleep position trainer or tennis ball technique, reporting their effectiveness in the short term. A vibrotactile neck-based treatment device is a valid alternative and Scarlata et al[16] and Levendowski et al.[15,24] confirmed its positive impact on reducing AHI and showed a relation between OSA severity and rate of success of PT. Meoli[25] carried out a review on PT of OSA, defining this therapy as an attractive option from the standpoint of cost-effectiveness, even though it needs further investigation in terms of long-term compliance.

In this large series, we retrospectively analyzed the efficacy of vibrotactile neck-based PT in the management of patients with POSA considering severity of disease. Our results show that Nightshift can be a treatment that otorhinolaryngologists should consider as exclusive or combined with other modalities in management of positional OSA. In fact, we observed a 50% reduction of baseline OAHI in 53.7% of all patients with POSA during PT with Nightshift and complete disease control (OAHI < 5 events/h) in 23.4% of the entire cohort. More interestingly, based on OSA severity, we observed that it can be considered a valid option, especially for mild POSA and for selected patients with moderate disease. In fact, we observed complete control of the disease in 50% of patients with mild POSA and in 22.5% and 7.9% of those with moderate and severe cases, respectively. Moreover, we demonstrated a 50% reduction of OAHI from baseline in 56.8% of patients with mild POSA and in 55% and 47.4%, respectively, in those with

moderate and severe cases. These data are confirmed by the number of responders in terms of supine sleep < 10%, which was significantly higher in mild POSA. Furthermore, based on our results, the baseline OAHI was the only factor able to predict the efficacy of the device in reducing the OAHI during PT ($P < .01$).

The prevalence of POSA in mild OSA is approximately 50%,[26,27] and our data confirmed the important role of PT, mainly with mild POSA and in selected moderate cases, expecting that PT alone could be sufficient to correct apnea, hypopnea, and oxygen desaturation, as demonstrated by significant differences in mean AHI, OAHI, and total desaturation time at baseline and during PT. We found a significant reduction of the PSG indexes in the other groups as well, although the device cannot be considered equally useful as exclusive treatment for severe POSA, especially if comorbidities are present. Making decisions on patients with moderate OSA may be more challenging, because selected cases may benefit from Nightshift therapy and there are no predicting factors of success. Future studies could clarify if patients with high AHI, especially those close to the cut-off of 30 events/h, can benefit from Nightshift therapy. It should be considered that patients with significant AHI and, in particular patients, with severe and longstanding OSA seem to develop spontaneous nonsupine sleeping strategies,[13] which can be underestimated by a single-night PSG, but which makes the clinician overestimate the PT effect. We can hypothesize that vibrotactile neck-based PT may be considered as a complementary therapeutic modality in patients with severe POSA. PT could be, in fact, combined with CPAP, oral device, distraction osteogenesis maxillary expansion, or surgery, opening a wide range of therapeutic options[22,28]; however, further studies are needed to confirm the efficacy of combined modalities.

Despite our interesting results, we cannot deny the therapeutic efficacy of CPAP in patients with POSA, especially in those with severe cases. Other authors[29,30] have compared different treatment modalities, demonstrating better results of CPAP in reducing AHI and increasing oxygen saturation in patients with POSA compared with PT; nevertheless, considering quality of life and compliance, the latter study concluded that PT may be associated with better compliance than CPAP, but long-term results are still lacking. On the other hand, a recent cross-sectional study by Mok et al[31]compared auto-CPAP versus PT, suggesting that the latter was inferior in terms of compliance and effectiveness for both PSG data and self-reported somnolence. Finally, some authors[15] hypothesized that PT could increase the risk of neck and shoulder lesions due to nonsupine sleep in patients with obesity and in the elderly.

In this series, we also provide interesting information about long-term use of the device and discontinuation. There is little information about long-term follow-up of patients treated with PT with the Nightshift device; only 1 study,[32] in fact, has investigated the durability of conditioning effects with promising results, but it enrolled patients who only used the device with continuity over a year. Our results show that adherence of PT with the Nightshift device is still lower than expected. We observed that after 6 months, only 35/84 patients (41.6%) were regularly using the device, with a mean of 5.9 ± 1.2 days per week. Most of patients who discontinued use of the device were directed to other therapeutic strategies.

Furthermore, we investigated possible complications that could induce patients to discontinue PT. It is important to highlight that patients with mild OSA are difficult to treat, because any complication, even if mild or minimal, can have a significant impact on compliance. In fact, based on severity, we found that the rate of discontinuation was 50% (9/18) in patients with mild OSA and 39.4% (26/66) in those with moderate OSA. In our study, we found no major complications, but we found that mild complications and discomfort, such as neck constriction or summer sweating due to the neck band, were sufficient to convince some patients to discontinue use of the device. Moreover, it was disconcerting to discover that several patients discontinued because of the absence of self-reported benefit from PT; all, in fact, were selected among patients with POSA who demonstrated an objective benefit by PSG while wearing the device. At the follow-up, they admitted substantial improvement in the quality of sleep and snoring, but probably the mild initial condition and the noncomplete resolution of snoring could be determining factors in the negative perception of results obtained using the device. Nevertheless, we believe that patients with mild OSA be encouraged to carry out PT, representing a subgroup of patients who may benefit most from this treatment. These findings lead to the need to establish precise protocols for PT with biofeedback devices to assess if the benefits of therapy are perceived by the patients, for example by enhancing counseling on OSA complications and risk to overcome discomfort and mild complications.

Some limitations of the present study must be pointed out. It is known that there is night-to-night variability of AHI in patients with OSA, and for this reason a single evaluation may not be meaningful. However, most studies on OSA, and in particular on Nightshift, have the same limitation related to observation in only 1 night.

CONCLUSIONS

In conclusion, our results of Nightshift in patients with POSA with different severity show that almost all patients had an improvement in AHI and OAHI, even if the proportion of patients who achieved complete control of disease was very high only in mild patients and in selected cases of moderate OSA. A 50% decreased in OAHI was observed in a large proportion of moderate and severe cases but was not sufficient to recommend PT as an exclusive modality for these patients. Some selected moderate cases could achieve complete control, but accurate counseling should be performed to motivate patients toward closer follow-up to verify long-term compliance. In fact, we observed that long-term compliance is limited because of complications and low satisfaction in some patients. Finally, Nightshift PT could be considered as complementary to other therapeutic options and its association should be tailored to the patient. We believe that future studies should focus on long-term compliance of PT with vibrotactile neck-based Nightshift PT to confirm our results and to identify potential predictive factors for discontinuation.

ABBREVIATIONS

AHI, apnea-hypopnea index
CPAP, continuous positive airway pressure
OAHI, obstructive apnea-hypopnea index
OSA, obstructive sleep apnea
POSA, positional obstructive sleep apnea
PSG, polysomnography
PT, positional therapy

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DISCLOSURE STATEMENT

All authors have seen and approved this manuscript. The authors report no conflicts of interest.