Short Communication

Short-term effects of a vibrotactile neck-based treatment device for positional obstructive sleep apnea: preliminary data on tolerability and efficacy

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Background: Positional supine obstructive sleep apnea syndrome (OSAS) characterizes a subgroup of patients suffering from OSAS. Several devices designed to limit supine position have been developed, but evidences of their efficacy and safety are lacking. It is unclear whether a neck-worn vibrating device could induce positional change in patients with positional OSAS. We evaluated the efficacy of a neck-worn device to induce supine avoidance positional feedback over a short-term trial in OSAS patients and its impact on sleep quality and polysomnographyc indexes.

Methods: Twenty patients with positional apneas/hypopneas were prospectively studied. Baseline characteristics of daytime somnolence and risk of sleep apnea were screened and the efficacy of a 3-day trial of supine-avoidance therapy by vibrotactile neck worn device assessed by reporting the self-perceived change in quality of sleep and performing cardio-respiratory polysomnography. Comparison between baseline and treatment results was performed.

Results: The neck device produced a reduction in overall apnea-hypopnea index (AHI) (mean AHI pre =16.8/h and post =4.4/h, P<0.0001), oxygen desaturation (pre =13.7/h and post =3.8/h, P<0.0001) and Respiratory Disturbance Indexes (RDI) (20.0/h *vs*. 5.2/h; P<0.0001).The time spent in supine position decreased from 62.1% to 33.7% of the total (P<0.001). However, the impact on the perceived quality of sleep was unpredictable.

Conclusions: The neck position therapy device is effective in restricting supine sleep, improving AHI and related polysomnographic indexes. However, at least in a short-term trial, it seems unable to improve the patient's sleep quality.

Keywords: Positional obstructive sleep apnea; positional therapy (PT); sleep quality; polysomnography

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Introduction

Positional obstructive sleep apnea syndrome (POSAS) occurs in approximately 56% of patients with obstructive sleep apnea syndrome (OSAS) (1) independently from body habitus (2). Furthermore, respiratory pauses are more severe when lying supine in over 70% of subjects with mild to moderate OSAS (3). Avoiding the supine sleeping position, via positional therapy (PT), in whichever form, has a substantial influence on OSAS severity (4,5), and this may be sufficient to reverse, over time, the cardiovascular, metabolic and neurologic consequences of OSAS, and to improve long-term survival (4). One of these approaches, the so-called "tennis ball technique" (a tennis ball fastened to the back with a belt) has resulted in a significant decrease of supine sleep time and reduction in apnea-hypopnea index (AHI) (4). Unfortunately, compliance is poor, with only

38% of patients still using the device after 6 months and less than 6% at 2.5 years. Given the unsatisfactory outcome, this kind of therapy is not considered a first choice approach by most clinicians (4).

Several other devices designed to limit supine position have been recently developed, but definitive evidence of their efficacy and safety is lacking. Few data exist related to a neck-worn vibrating device (Night shift™ Advanced Brain Monitoring, Carlsbad, CA, USA) intended to induce positional change in patients with POSAS. Recently, a 4-week long assessment of the use of this device has provided the first evidence on its tolerability and efficacy in treating POSAS (6). However, these results do not provide any information on the short-term effect of this approach. Indeed, traditional PT (i.e., by using a chest worn sleep positional trainer) has been proved to usually take up to 9 days to determine a satisfactory reduction in percentage of supine sleep time (7). Reducing the time needed to induce positional change is one of the aims of the research of new positional devices.

We therefore evaluated the efficacy of a neck-worn device to induce supine avoidance positional feedback over a short-term 3 days adaptation trial in a population of POSAS patients and its impact on sleep quality and polysomnographyc indexes of disease severity.

Materials and methods

Twenty patients with a high prevalence of positional apneas/hypopneas (86.3% of the total number of apneas; SD 5.8) were prospectively studied. Baseline characteristics of daytime somnolence and risk of sleep apnea were screened by administrating the Epworth sleepiness scale (ESS) and the STOP-BANG questionnaires. The efficacy of a 3 days trial of supine-avoidance therapy by vibrotactile neck worn device was assessed by collecting the self-perceived changes in quality of sleep and performing cardio-respiratory polysomnography. Comparison between baseline and treatment results was performed. Participants with chronic mild to moderate neck dysfunctions (neck pain or functional limitation related to head, or cervical spine, muscular or radicular diseases) were included in the study in order to assess their tolerability to a vibrotactile stimulation.

Statement of ethical approval and patient's informed consent

All patients accepted to participate in the study after having received a comprehensive description of the research design and signed an informed consent form. Being a proof of concept study without relevant ethical issues, it proceeded after the local institutional board of Campus Bio Medico University received notification (Prot. 47/11 ComEt CBM).

Description of neck-device

We tested a positional neck-worn device (Night Shift™) fastened on the back of the neck with an adjustable rubber strap secured by a magnetic clasp. The device measures snoring with a snore algorithm quantifying each snore based on shape and peak amplitude. The percentage of time snoring is determined by actigraphy. Neck positions are also reported. When used for PT, vibrotactile feedback starts 10-min after the device is turned on, to allow the user to fall asleep. The neck-device can record and provide vibrotactile feedback for 3 nights in a row before re-charging is needed. Further technical details have been described elsewhere (6).

Sleep evaluation

The suspected diagnosis of OSAS was tested through in-hospital cardio-respiratory polysomnography according to current international guidelines (8) by using a 12 channels dedicated device (Somnomedics; GmbH, Randersacker, Germany). As recommended by the American Academy of Sleep Medicine task force, the severity of sleep apnea was classified as mild if the AHI ranged from 5 to 15/h, moderate when the range was 15 to 30/h, and severe when the AHI was 30/h or more (9). Each epoch was classified as being either in the supine or non-supine postures (prone or lateral) and the patient was identified as having POSAS if there was a 50% reduction in the AHI between the supine and non-supine postures and the AHI in the non-supine posture was 5/h (2). Included were subjects suffering from POSAS not deserving (mild POSAS with AHI <20/h), or poorly compliant (rejection or intolerance) to continuous positive airway pressure (CPAP) therapy. Exclusion criteria were as follows: central sleep apnea syndrome, nasal obstruction or major facial or pharyngeal anatomic abnormalities likely to require surgery, night or rotating shift work, severe chronic heart failure, known history of a known cause of daytime sleepiness and severe sleep disruption (e.g., insomnia, periodic limb movement disorder, narcolepsy), seizure disorder, mental retardation, psychiatric disease, memory disorders.The self-perceived change in the quality of sleep after PT was assessed by

Table 1 Demographic and clinical features of the study population

Features	Value
Age (mean, SD)	64.8 (9.5)
Males (n, %)	15.0 (75.0)
BMI (mean, SD)	28.9 (4.0)
AHI at baseline (mean, SD)	16.8 (9.5)
% Prevalence of positional apneas/hypopneas (mean, SD)	86.3 (5.8)
ESS score at baseline (mean, SD)	6.8 (4.1)
STOP-BANG score at baseline (mean, SD)	4.8 (1.3)

BMI, body mass index; AHI, apnea-hypopnea index; ESS, Epworth sleepiness scale.

Table 2 Polysomnographic data at baseline and during positional therapy (PT)

PSG values	Baseline, mean (SD)	During PT, mean (SD)	P value
AHI events/h	16.8 (9.5)	4.4 (5.5)	<0.001
ODI events/h	13.7 (7.5)	3.8 (5.2)	<0.001
RDI events/h	20.0 (9.5)	5.2 (5.6)	<0.001
% time spent supine	62.1 (22.7)	33.7 (23.9)	<0.001

PSG, polisomnography; AHI, apnea-hypopnea index; ODI, oxygen desaturation index; RDI, respiratory disturbance index.

a Likert scale in which the patients had to score from 1 to 5 his sleep quality as improved (score 4 and 5), unchanged (score 3), or worsened (score 1 and 2). Finally the occurrence of neck discomfort induced by the vibratile device was systematically assessed.

Analytical approach

All data are expressed as means (± standard deviations, SD) for continuous variables, or as percentages for categorical variables. The Student's *t* test was used to detect differences within the groups. Mann-Whitney test was used to compare the changes in functional values between baseline and during PT.

Results

Amongst the 20 participants, 15 (75%) were males, with a mean age of 64.8 (SD 9.5) years and BMI of 28.9 (SD 4.0) (see *Table 1*, for demographic and clinical data of the study population). Four patients were complaining for a mild neck dysfunction before the treatment was initiated (two were reporting chronic cervical pain due of muscular origin, and two remaining had a diagnosis of occasional "stiff neck"), but none of them, as well as any of the study participants reported worsened symptomatology or neck discomfort. The only highly prevalent comorbidities were hypertension and obesity (prevalence of 45% and 52%, respectively). Data at baseline and during PT are resumed in *Table 2*. Shortly, patients had mild to moderate POSAS (mean AHI 16.8±9.5/h) and had only mild excessive daytime sleepiness (ESS score at baseline 6.8±4.1). In all participants the neck device produced a highly significant reduction in overall AHI, (mean AHI pre and post of 16.8-SD 9.5 and 4.4-SD 5.5, respectively P<0.0001). The oxygen desaturation index (ODI) (pre and post of 13.7-SD 7.5 and 3.8-SD 5.2, respectively P<0.0001) and the Respiratory Disturbance Index (RDI) (20.0-SD 9.5 *vs.* 5.2-SD 5.6, P<0.0001) also decreased significantly. The time spent in supine position decreased from 62.1% (SD 22.7) to 33.7% (SD 23.9) of the total (P<0.001). However, the impact on the perceived quality of sleep was unpredictable. Only 7 out of 20 (28.6%) of patients reported a clear subjective improvement. Five (25%) reported no significant changes and another seven (28.6%) found their sleep quality to be somehow worsened. Interestingly, we registered two cases with an increment in the time spent in supine position despite the use of the vibratile device. Indeed, in these cases the accidental

rotation of the piezoelectric neck sensor that misidentified the body positions. In both cases, in fact, we confirmed a significant reduction in obstructive apnea indexes and a technician/nurse reported the patients maintained a non-supine position during their visual controls despite an inappropriate activation of the vibrotactile stimulus. In another couple of cases, we observed an increase in AHI and in the other related indexes despite an effective reduction in the time supine. In this occasion we found that the patient had a positional prone obstructive component that was concealed at the first examination but was revealed by the forced change to an other-than supine position.

Discussion

This preliminary report shows that a neck based vibrotactile positional device might benefit selected OSAS patients. Vibrotactile positional stimulation proved to reduce polysomnographic indexes of sleep apnea by decreasing the sleep time amount spent at a supine position. It is unclear whether this may improve the sleep quality and restore the physiologic sleep architecture. Indeed, this short-term proof of concept trial aimed only at demonstrating the ability of vibrotactile stimulation to induce positional changes and, consequently, reduce apneas, hypopneas and oxygen desaturations. Collaterally, we also verified the impact of therapy on self-perceived sleep quality because it is reported that even short term use of CPAP is often able to improve it and reverse metabolic changes induced by OSAS (10,11). It is likely that the awakening caused by vibration, and the consequent need to change position when sleeping is more disturbing for the patient than snoring and apneas/hypoxemia since he often is completely unaware of the latter. However, attempts at restoring the supine position and the ensuing discomfort for the patients are expected to become less frequent with time (7).

The self-perceived sleep quality changes after PT was assessed by not validated questionnaires based on a visual-analogic scale, this making the result non completely reproducible; indeed, also previously validated questionnaires investigating the overall quality of sleep, such as the Pittsburgh Sleep Quality Index, failed to correlate with the polysomnographic indexes (12) and it is therefore unlikely that the use of this instrument might have added further information in our population. However, we have reported that short-term compliance and tolerance was satisfactory, although data in literature demonstrate that long-term use by using classical tools (tennis ball or pillows) was disappointing due to patient's self-perceived ineffectiveness, backache, discomfort, and no improvement in sleep quality or daytime alertness (13). Of note, the rate of discontinuation was lowest in patients with mildly severe OSAS. Indeed, compliance data related to the neck based vibrotactile device are not available and deserve further investigation. A recent study (14) described improved short-term efficacy of a sleep position trainer compared to the tennis ball technique. In another (15), use of PT was effective in decreasing the amount of supine sleep and resulted in decreased measures of OSA severity. Finally, Levendowski and colleagues experienced acceptable compliance rates over a 30 days use of the night shift device (6). Unfortunately, no study investigated longer term compliance on the use of a neck based device. We cannot exclude that this device may help the patients to maintain acceptable compliance with the treatment over a long time, since we are aware that poor compliance represents a major issue in long-term PT for POSAS (16).

Limitations of this study deserve consideration. First, the sleep recordings were performed with limited channel recorders [without electroencephalography (EEG)] and did not allow assess the sleep structure. An impairment of sleep quality due to the positional device cannot be excluded and we therefore are not able to confirm that the lack of relief of OSAS symptoms might be due to a persisting altered sleep structure. Indeed, Permut *et al*. found no effect of their positional device on sleep efficiency, sleep duration, sleep architecture, and arousal index (17). Second, our study lacks a control untreated group. Also, we cannot exclude that OSAS severity might be changed in between the first and the second measurement. Indeed, this is unlikely, since the very short interval between diagnosis and therapy.

Conclusions

Based on a short-term trial, the neck position therapy device Night shift™ is effective in restricting supine sleep, improving AHI and related polygraphic indexes, but not in improving the patient's perceived sleep quality. Only a long-term case control trial including objective sleep measurement might definitively prove its efficacy. Present data show that such a trial is worthy of being done. In the event of confirmatory results, PT might be largely used, given that POSA is highly prevalent in mild to moderate forms of OSAS which account for the vast majority of OSAS patients.

In conclusion, a comfortable positional device could

be considered as a therapeutic option in mild to moderate OSAS and in patients insufficiently treated with CPAP. However, larger studies assessing the effect of this type of treatment on objective sleepiness and cardiovascular comorbidities, as well as defining the impact of vibrotactile stimulation on sleep quality and architecture are needed before positional treatment can be considered as a long term valid and safe first line treatment for patients with OSAS.

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None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

References

1. Oksenberg A, Silverberg DS, Arons E, et al. Positional vs nonpositional obstructive sleep apnea patients: anthropomorphic, nocturnal polysomnographic, and multiple sleep latency test data. Chest 1997;112:629-39.
2. Mador MJ, Kufel TJ, Magalang UJ, et al. Prevalence of positional sleep apnea in patients undergoing polysomnography. Chest 2005;128:2130-7.
3. Benoist LB, Morong S, van Maanen JP, et al. Evaluation of position dependency in non-apneic snorers. Eur Arch Otorhinolaryngol 2014;271:189-94.
4. Randerath WJ, Verbraecken J, Andreas S, et al. Non-CPAP therapies in obstructive sleep apnoea. Eur Respir J 2011;37:1000-28.
5. Oksenberg A, Silverberg D, Offenbach D, et al. Positional therapy for obstructive sleep apnea patients: A 6-month follow-up study. Laryngoscope 2006;116:1995-2000.
6. Levendowski DJ, Seagraves S, Popovic D, et al. Assessment of a neck-based treatment and monitoring device for positional obstructive sleep apnea. J Clin Sleep Med 2014;10:863-71.
7. van Maanen JP, de Vries N. Long-term effectiveness and compliance of positional therapy with the sleep position trainer in the treatment of positional obstructive sleep apnea syndrome. Sleep 2014;37:1209-15.
8. Fleetham J, Ayas N, Bradley D, et al. Canadian Thoracic Society 2011 guideline update: diagnosis and treatment of sleep disordered breathing. Can Respir J 2011;18:25-47.
9. Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. Sleep 1999;22:667-89.
10. Callahan CY, Norman RG, Taxin Z, et al. Multinight recording and analysis of continuous positive airway pressure airflow in the home for titration and management of sleep disordered breathing. Sleep 2013;36:535-545F.
11. Antonelli Incalzi R, Pennazza G, Scarlata S, et al. Comorbidity modulates non invasive ventilation-induced changes in breath print of obstructive sleep apnea syndrome patients. Sleep Breath 2015;19:623-30.
12. Scarlata S, Pedone C, Curcio G, et al. Pre-polysomnographic assessment using the Pittsburgh Sleep Quality Index questionnaire is not useful in identifying people at higher risk for obstructive sleep apnea. J Med Screen 2013;20:220-6.
13. Bignold JJ, Deans-Costi G, Goldsworthy MR, et al. Poor long-term patient compliance with the tennis ball technique for treating positional obstructive sleep apnea. J Clin Sleep Med 2009;5:428-30.
14. de Vries GE, Hoekema A, Doff MH, et al. Usage of positional therapy in adults with obstructive sleep apnea. J Clin Sleep Med 2015;11:131-7.
15. Eijsvogel MM, Ubbink R, Dekker J, et al. Sleep position trainer versus tennis ball technique in positional obstructive sleep apnea syndrome. J Clin Sleep Med 2015;11:139-47.
16. Ravesloot MJ, van Maanen JP, Dun L, et al. The undervalued potential of positional therapy in position-dependent snoring and obstructive sleep apnea-a review of the literature. Sleep Breath 2013;17:39-49.
17. Permut I, Diaz-Abad M, Chatila W, et al. Comparison of positional therapy to CPAP in patients with positional obstructive sleep apnea. J Clin Sleep Med 2010;6:238-43.

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