A POST HOC ANALYSIS OF THE COMPLIANCE OF A NEW FOREHEAD DEVICE ABOUT POSTURAL SLEEP APNEA PATIENTS

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INTRODUCTION

In 56-75% of patients with obstructive sleep apnea (OSA), the frequency of apneas and hypopneas are influenced by body position. A positional therapy device based on vibration and placed at the forehead has proven to be effective in reducing the apnea-hypopnea index (AHI) in these patients.

OBJECTIVES

The aim of the study was to analyze the differences in daily use, percentage of time in the supine position and patient satisfaction between patients using an active device (AD) and patients using an inactive device (ID).

METHODS

This is a post-hoc analysis of a multicenter, randomized, prospective, parallel controlled trial.

Study sample: 87 patients > 18 years, diagnosed as positional OSA and divided in two groups (AD and ID).

Follow-up time: 12 weeks.

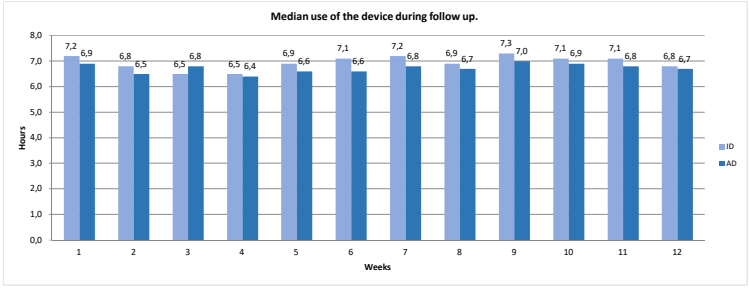
Data Collection: Data recorded in the devices were downloaded in each follow-up visit (weeks 4,8 ,12)

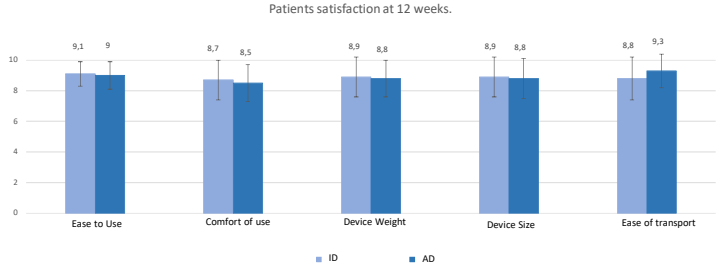
Questionnaires: were administered at the end of the study to evaluate patient satisfaction focusing the attention in Ease of use, Comfort, Device Weight, Device Size and Ease of Transport (scores between 1 - very bad and 10 - very good).

Randomization: Eligible patients were randomized to one of the two groups. An external unit generate the allocation sequence.

RESULTS

- The median (IQR) daily use of the device at week 12 was similar in both groups (6.8 h (2.6) for ID group and 6.7 h (1.8) for AD group; p > 0.05), being always above 6.4 h throughout the follow-up period in both groups.
- The percentage of days that the device was used more than 4 hours a day showed a compliance of 100% (85.7 – 100) in POSA patients with AD at the first month, and 85,7% at three months, with similar values in the ID group (p=0.896).
- The median percentage of time in the supine position (measured by the device at the head) was significantly lower in the AD group (between 2.3% and 3.1% along the follow-up period) than in the ID group (between 8,7% and 13,4%) (p <0.012 in all weeks). Noteworthy, this difference was observed even in the first week (2.6% (4.2) for AD group and 10.6% (14.8) for the ID group; p< 0.001).
- The better patient satisfaction score obtained in the AD group was for Ease of transport (9.3±1.1) and in the ID group was for Ease of use (9.1±0.8). All other satisfaction items received scores higher than 8.5 in both groups.





CONCLUSION

Daily use of the device and compliance rates were high in both groups and a significant reduction in the supine position was observed with the AD group compared to the ID group. Patient satisfaction was high in all items evaluated and in both groups.

The use of a vibrating forehead device is well tolerated by patients with positional OSA and could be considered as a treatment option in these patients.