Free Communications: Abstract 2

Evaluation of the clinical effectiveness of a sleep position trainer in patients with positional sleep apnea

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Study Objectives. The objective of this clinical trial was to assess the overall clinical effectiveness of a chest-worn sleep position trainer (SPT) in patients with positional obstructive sleep apnea (POSA). In addition, the aim was to evaluate how many patients were willing to purchase the device after a trial period of one month.

Material & methods. The SPT (NightBalance™, the Netherlands, Delft), evaluated in this clinical trial, is a small chest-worn device that vibrates when the patient is in supine position. Patients with an established diagnosis of POSA based on a type 1 sleep study, polysomnography in hospital setting, underwent a 1-month trial period with the SPT. Type 3 portable sleep monitoring was performed at baseline in order to confirm POSA and during the SPT trial period. Data are presented as median (quartile 1, quartile 3) or as mean ± standard deviation.

Results. Two hundred patients were included in the study. Fifty-four patients were diagnosed with positional snoring while POSA could be confirmed in 101 participants. Seventy-nine patients (81% male; mean age 52 ± 12 years; median body mass index 27 (25, 28) kg/m2; baseline apnea/hypopnea index (AHI) 11 (8, 16) events/h) completed the study protocol. A significant reduction in the overall AHI to 5 (3, 10) events/h was observed with the SPT as compared to baseline ($p < 0.001$). The median percentage of supine sleep decreased significantly from 27 (20, 48)% at baseline to 7 (2, 20)% with SPT ($p < 0.001$). Adjusted adherence (the percentage of the SPT use in hours per night divided by the total sleep time derived from polysomnography) was found to be 95 ± 8%. The overall clinical effectiveness in terms of mean disease alleviation (MDA) in the responder group of 45 patients (AHI reduction ≥ 50%) was 68% for reduction in AHI and 72% for reduction in supine position. Forty-four patients (56% out of the 79 patients that completed the study; 22 responders and 22 non-responders) decided to continue treatment and purchased the SPT. The most important reasons for not purchasing the SPT were insufficient objective results, intolerance for the vibrations, the cost price of the device, persistent daytime sleepiness or the fact that the patients preferred other treatment.

Conclusions. In the reported trial, treatment with the SPT came with high adherence rates and was effective in reducing AHI and supine position. In addition, a trial period with the SPT is of utmost importance, in order to avoid that patients who do not benefit from the therapy purchase the SPT. Further research on the long-term effectiveness of the SPT, including the evaluation of subjective symptoms such as excessive daytime sleepiness and sleep quality, is currently ongoing.