A Randomized Cross-over Evaluation on Effects of Pressure Relief Control Device on Obstructive Sleep Apnea with Automatic Continuous Positive Airway Pressure Therapy

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Objective:

To evaluate the effects of a novel device of pressure relief control in automatic continuous positive airway pressure (auto-CPAP) therapy for obstructive sleep apnea (OSA) patients.

Methods:

We conducted a prospective, randomized, cross-over study to compare CPAP therapy with and without pressure relief control device (SensAwake™, SA) when detecting wakefulness during sleeping in OSA patients. Patients with diagnosed OSA and with experience of taking off the mask during CPAP therapy were enrolling in this study. Participants would be randomized into two groups and received treatment for 4 weeks, then crossed-over to the other group for another 4 weeks treatment. Data were collected at the baseline, the end of the 4th and the 8th week. Objective data from auto-CPAP including used time, percentage of used day, compliance, average and 90th percentile pressure, average and 90th percentile leak, and residual AHI. Subjective data including results of Epworth Sleepiness Scale (ESS), Pittsburgh Sleep Quality Index (PSQI), and Nasal Obstruction Symptom Evaluation Scale (NOSE).

Results:

Of 25 participants completed the full study, 12 participants in group 1 started with SA on, and the other 13 participants in group 2 started with SA off. The gender, age, body mass index, neck circumference, polysomnography data and previous CPAP using condition have no significant difference between two groups.

The average pressure and 90th percentile pressure were significant lower when SA ON (SA ON vs OFF 6.9±2.7 vs 7.3±2.6, p=0.032; 8.6±3.0 vs 9.2±2.9, 9=0.002, respectively). The used time, used day, compliance, average and 90th percentile leak, and residual AHI record from auto-CPAP were no significant change between SA ON and OFF. In subjective evaluation, PSQI, ESS and NOSE were no significant difference between SA ON and OFF. Compared with baseline ESS was significant reduced when SA ON (SA ON vs baseline 11.1±6.1 vs 13.2±6.0, p=0.023).

Conclusion:

For OSA patients with experience of taking off mask during CPAP therapy, pressure relief control device can help to improve the sleepiness in this study. But the condition of CPAP usage, sleeping quality, and nasal symptoms showed no significant changes. It still needs further study to evaluation the effects of pressure relief control for CPAP therapy.

中文題目：運用壓力釋放裝置於阻塞性睡眠呼吸中止症患者接受陽壓呼吸器治療之隨機交叉試驗

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