First-in-human Clinical Study to Investigate the Titration of Intra-oral Negative Air Pressure in Treating the Patient with Obstructive Sleep Apnea.

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Objective:

The intra-oral negative air pressure (iNAP) device was designed to decrease airway obstruction by retaining the tongue and the soft palate forward by providing a constant negative pressure (-40mmHg) within the oral cavity. The lasted studies demonstrate the response rate of iNAP could up to 60%. However, for those OSA patients with very high BMI or AHI, they may need higher pressure to achieve optimal treatment outcome. In this study we hope to select an optimal intra-oral pressure for an OSA patient during iNAP treatment by titration process.

Methods:

All the subjet had received two PSG, one is baseline PSG and the other one is iNAP titration PSG. When conducting the iNAP titration PSG, the initial treatment pressure is -40mmHg. iNAP presure should be increased by at least 10mmHg. with an interval no shorter than 15 min, with the goal of eliminating obstructive respiratory events

iNAP presure should be increased if(1) at least 2 obstructive apnea. (2) at least 3 hypopnea. (3) at least 3 min of loud or unambiguous snoring. The recommended maximum iNAP pressure should be -150mmHg.

Results:

Six subjects were consented and enrolled into the study. The mean age of all subjects was 45.33±10.46 years old and the mean BMI was 28.30±4.12 kg/m^2. The baseline AHI was 59.60±28.24, which decreased to 45.47±38.13 (p=0.0542) at initial pressure (-40mmHg). Comparing to baseline AHI, the AHI reduction without titration is 23.71%. After iNAP titration, the final tereatment AHI is 7.18±6.08 (p=0.0041). Comparing to baseline AHI, the AHI reduction with titration is 87.95%.

Conclusion:

This study is a First-in-human clinical trial to investigate the titration of intra-oral negative pressure in treating the patient with obstructive sleep apnea. The result show that titration could improve the efficacy of iNAP treatment, especial for the non-responder. The titration result was only available in 6 subjects, but even in this small sample we saw signifcant differences between baseline AHI and titration AHI. We believe further iNAP titration studies need to be performed to understand the side effect of higher pressure and the optimal pressure exploring process.

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