Subjective Sleep Outcomes after Hypoglossal Nerve Implant
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INTRODUCTION

General anesthesia with three surgical incisions (submandibular A implantable device (Inspire II system, Inspire Medical, Minneapolis, MN) stimulates the Hypoglossal nerve (CN XII) to prevent upper airway collapse and obstruction in Obstructive Sleep Apnea (OSA). Prior studies have demonstrated that CN XII stimulation reduces apnea hypopnea indices (AHI). The current report describes secondary outcomes at two and six months post implant.

OBJECTIVE

The objective of this study was to assess improvements in subjective sleep outcomes in patients with obstructive sleep apnea undergoing hypoglossal nerve stimulation using a multicenter academic setting feasibility trial.

METHODS AND MATERIALS

Inspire™ II consists of three implantable components and two external programs:

1) Implantable Pulse Generator (IPG),
2) External Control System (ICS),
3) Directional Pressure Sensing Lead (pressure differential placed near the plica saliens to sense thoracic pressure).

Thirty one subjects underwent placement of a unilateral hypoglossal nerve implant (two explanted). Fifty five percent of all subjects at 6 months were AHI responders (AHI < 20/hr. and 50% reduction). Selection criteria were modified: BMI ≥ 32 kg/m², AHI ≤ 50/hr, and without complete obstructive collapse at the level of soft palate as determined by DSE for Phase II. In this group, 80% of subjects were responders with AHI reduced ≤ 2.5 to 11.0 (1-6 months).

In the entire group, ESS improved (baseline = 10.4(4.0), 2 months = 7.7(4.1), p< 0.005). At baseline, 2 months and 6 months: ESS improved in both responders (10.4 to 8.0 to 6.6) and non-responders (11.8 to 9.4 to 8.9), and FOSQ improved and normalized in responders (15.6 to 17.1 to 18.0, p< 0.05) but not non-responders (13.6 to 14.2 to 15.2, p= NS).

Sleep outcomes improved using a hypoglossal nerve implant. Consistent with other interventions, ESS improvements were unrelated to change in AHI. FOSQ improvements were observed in responders but not non-responders. Data support a clinical device effect but highlight the need for controlled studies to evaluate sleep outcomes in surgical trials.

CONCLUSIONS

OSA results from a complex interaction of a vulnerable upper airway structure and unstable ventilatory control. The goal of both medical and surgical treatments are stability of airway without obstruction. The current intervention creates a stable airway by augmenting pharyngeal upper airway muscle tone using external afferent stimuli. In contrast to traditional surgical procedures which directly modify soft tissue and stabilize the upper airway, hypoglossal nerve stimulation (HNS) is a treatment that creates a stable airway independent of AHI. The goal of the current study was to assess functional and sleep outcomes.

REFERENCES

Therapy Titration

Stimulating pulses are adjusted to be synchronous with each respiratory cycle. At 1 month, 2 months and 3 months: for nerve capture (voltage amplitude to elicit a percept), muscle recruitment (lowest voltage to elicit detectable tongue advancement), and sub-decubitus (voltage above which elicited a patient report of discomfort) were assessed. Therapy was adjusted to maintain stable, non-flow limited airflow patterns and to alleviate sleep apneas and hypopneas without electroencephalographic arousal.

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