UC DAVIS HEALTH | BETTY IRENE MOORE SCHOOL OF NURSING
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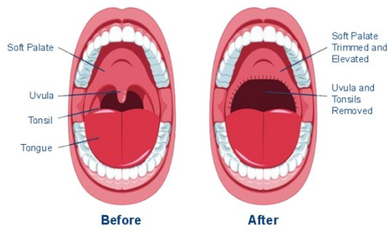
Investigating Inspire Hypoglossal Nerve Stimulation for Refractory OSA Treatment

Introduction

Background: Obstructive sleep apnea (OSA) is defined by an apnea-hypopnea index (AHI) ≥ 5/h accompanied by daytime sleepiness, unrefreshing sleep, extreme tiredness, and/or impaired quality of life related to sleeping. In the US, the prevalence of OSA in middle-aged adults varies with 10% for mild OSA, 3.8% for moderate OSA, and 6.5% for severe OSA.[1] A polysomnography (PSG), better known as a sleep study is necessary with an apnea-hyponea index (AHI) > 5/h being diagnostic. The gold standard and first-line treatment for OSA is continuous positive airway pressure (CPAP), though 46-83% of patients are unable to tolerate long-term therapy.[2,5] For patients who are intolerant of CPAP, surgical management can be the difference between waking up feeling refreshed or a lifetime of somnolence. Surgical managements can include but are not limited to uvulopalatopharyngoplasty (UPPP), tongue base reduction, maxillomandibular advancement (MMA), and upper airway stimulation (UAS) such as Inspire hypoglossal nerve stimulation (HNS).[2]

Risk Factors and Epidemiology of Obstructive Sleep Apnea (OSA):

- Strong association with cardiovascular and metabolic comorbidities (DM, HTN, CVD, CVA, obesity)
- Age and BMI increases risk of AHI ≥ 15
- Prevalence, 2:1 in men; rates equalize in menopausal women
- Hispanic & Asian populations have increased risk of OSA



Upper Airway Stimulation (Inspire Hypoglossal Nerve Stimulation)[3]	Uvulopalatopharyngoplasty (UPPP)[3]
• Moderate-to-severe OSA, intolerant to CPAP therapy • AHI ≥ 15/h • Absence of complete concentric collapse at soft palate during DISE • BMI ≤ 32kg/m^2	• OSA with anatomical obstructions in oropharynx, intolerant to CPAP therapy • Redundant tissue in the palate, oropharynx, tongue base • No BMI criteria

Case Study (Methods & Results)

HPI: 62-year-old male with PMHx significant for HTN, HLD, seasonal allergies, GERD, and severe OSA demonstrated on home sleep study with AHI of 33.3, intolerant of CPAP due to ongoing xerostomia and rhinitis sicca, referred by PCP to discuss potential surgical management.

Medications: Albuterol, Amlodipine, Azelastine, Cetirizine, Ezetimibe, Famotidine, Fluticasone, Montelukast, Pantoprazole **Allergies:** Penicillin, Atorvastatin, Benzoic Acid, Formaldehyde, Hydralazine, Balsam of Peru, Cocamidopropyl Betaine **FMHx:** HLD, HTN, Stroke (Father) **Social Hx:** Non-smoker, occasional EtOH	**FMHx:** HLD, HTN, Stroke (Father) **Social Hx:** Non-smoker, occasional EtOH **Review of Systems:** **Daytime:** + excessive daytime somnolence, non-restorative sleep, irritability, anxiety **Nighttime:** + snoring, witnessed apneas, waking up gasping/choking, xerostomia

T 36.4°C | BP 128/73 | HR 73 | RR 14 | BMI 25.78kg/m^2 | Pain Scale 0

A&Ox4, well-nourished, well-developed male in no apparent distress or discomfort. HEENT exam remarkable for bilateral caudal septal deviation, 1+ turbinate, 1+ tonsils with Mallampati score of 2, suggestive of normal airway, with low risk of obstruction. Oral cavity, ears, nose, and neck unremarkable with no lesions or masses visualized. Cranial nerves II-XII intact.

Diagnostic Testing:

- Polysomnography (PSG)
- Flexible Fiberoptic Endoscopy (in-office)

Preoperative:

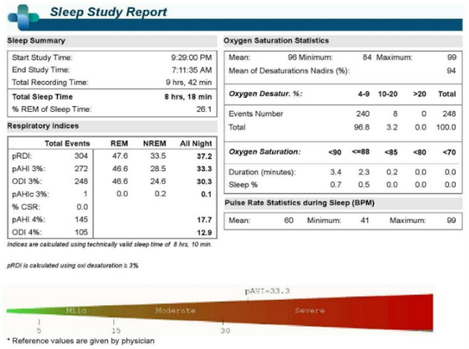
- Drug-Induced Sleep Endoscopy (DISE)
  - Favorable airway collapse
  - Candidate for hypoglossal nerve stimulation and satisfies all criteria for implantation

Operative:

- Insertion, Neurostimulator, Hypoglossal (Right)
  - Obstructive sleep apnea [G47.33]

Postoperative:

- Activation of Inspire HGN Stimulator, 1 month s/p
- Titration sleep study, 2 months s/p; evaluate & optimize device settings



Sleep Study Report

Sleep Summary

Start Study Time:	9:29:00 PM
End Study Time:	7:11:35 AM
Total Recording Time:	9 hrs, 42 min
Total Sleep Time	**8 hrs, 18 min**
% REM of Sleep Time:	26.1

Respiratory Indices

	Total Events	REM	NREM	All Night
pRDI:	304	47.6	33.5	**37.2**
pAHI 3%:	272	46.6	28.5	**33.3**
ODI 3%:	248	46.6	24.6	**30.3**
pAHic 3%:	1	0.0	0.2	**0.1**
% CSR:	0.0			
pAHI 4%:	145			**17.7**
ODI 4%:	105			**12.9**

Indices are calculated using technically valid sleep time of 8 hrs, 10 min.

pRDI is calculated using oxi desaturation ≥ 3%

Oxygen Saturation Statistics

Mean: 96 Minimum: 84 Maximum: 99
Mean of Desaturations Nadirs (%): 94

Oxygen Desatur. %:	4-9	10-20	>20	Total
Events Number	240	8	0	248
Total	96.8	3.2	0.0	100.0

Oxygen Saturation:	<90	<=88	<85	<80	<70
Duration (minutes):	3.4	2.3	0.2	0.0	0.0
Sleep %	0.7	0.5	0.0	0.0	0.0

Pulse Rate Statistics during Sleep (BPM)

Mean: 60 Minimum: 41 Maximum: 99

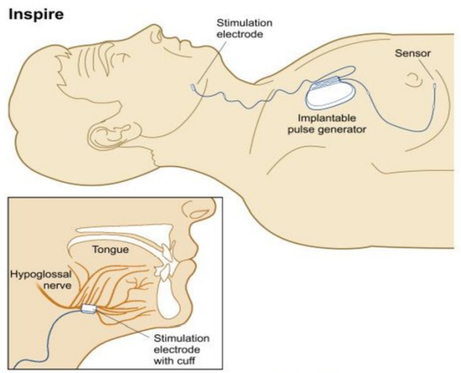
* Reference values are given by physician

***Post-activation, patient reported increased restful sleep, the ability to fall back asleep if woken, and reduction in snoring (per spouse).*

Discussion/Conclusions

OSA is a very common disorder that plagues many people all over the world. It is often undiagnosed and undertreated.[5] Inspire HNS is a minimally invasive outpatient procedure with a recovery time of ~7-14 days. It has the advantage of optimization through PSG-guided titrations, allowing experimentation with varying stimulation levels to reach therapeutic range.[7] In comparison, UPPP is irreversible with increased risk of 90-day readmission and post-operative complications; 4% vs 12% and 2% vs 21% respectively.[6] A systematic review and meta-analysis of 30 papers demonstrated HNS reducing AHI by -20.14 events/h and -15.91 events/h respectively in the short and long term.[4,7] Compared to UPPP with a mean AHI reduction of -14.0 events/h over 8-years, with efficacy decreasing over time.[5,8] These findings are consistent in determining Inspire HNSs favorability in comparison to UPPP for CPAP intolerance due to improved AHI reduction, patient satisfaction, and lower incidence of complications.[4,5,7]

Total nights used	Nights used ≥4 hours	Hours per night used	Avg. pauses per night
100% 30/30	**100%** 30/30	**8hr 22min**	**0.0**



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