

# Hypoglossal Nerve Stimulation in Veterans with Obstructive Sleep Apnea

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Anthony Fernandez, MD

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Elsa Mathew, MD

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S. Raman, MD

# Accreditation Statement

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of The American Academy of Sleep Medicine and The Virginia Academy of Sleep Medicine. The American Academy of Sleep Medicine is accredited by the ACCME to provide continuing medical education for physicians.

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No financial disclosures

# Why we embarked on this study

- The efficacy of positive airway pressure (PAP) therapy in the management of obstructive sleep apnea (OSA) is limited by inadequate patient adherence.
- Hypoglossal nerve stimulation (HNS) is an FDA approved PAP-alternate surgical treatment option that is available for patients with poor PAP tolerance.
- The purpose of this pilot study was to review outcome measures and usage data for patients treated with HNS therapy in a military veteran population.



# Anatomy of Upper Airway

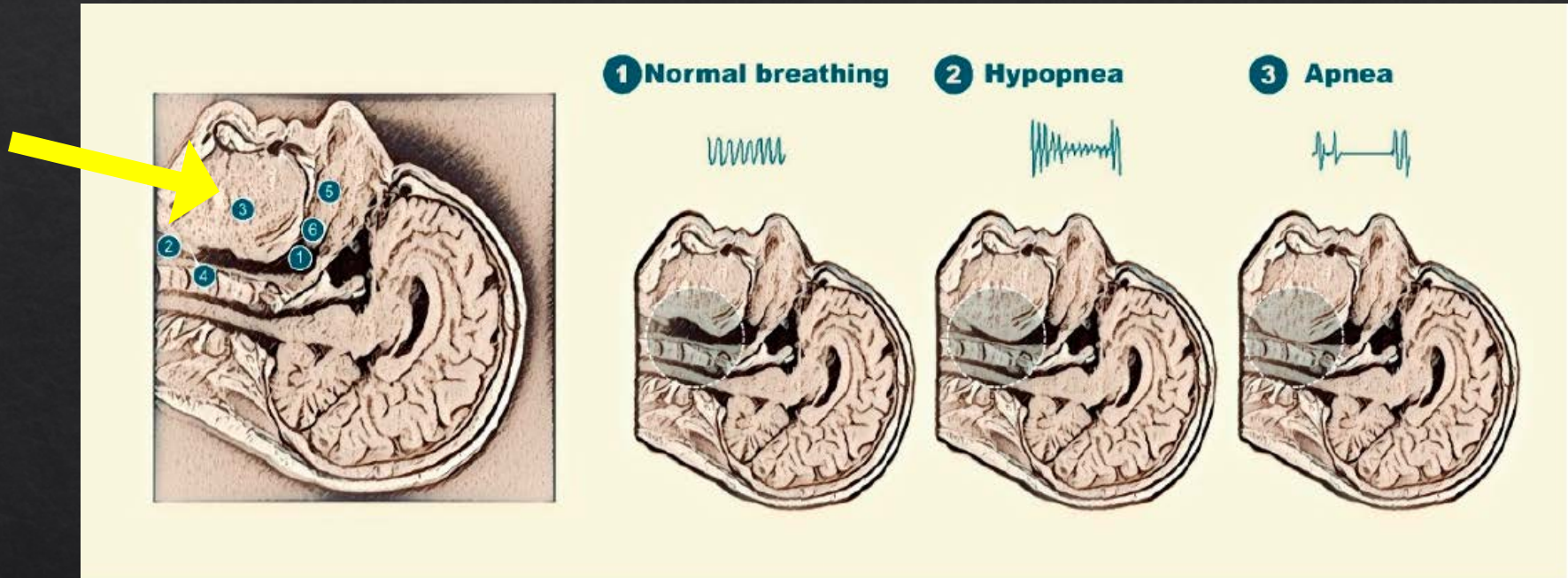
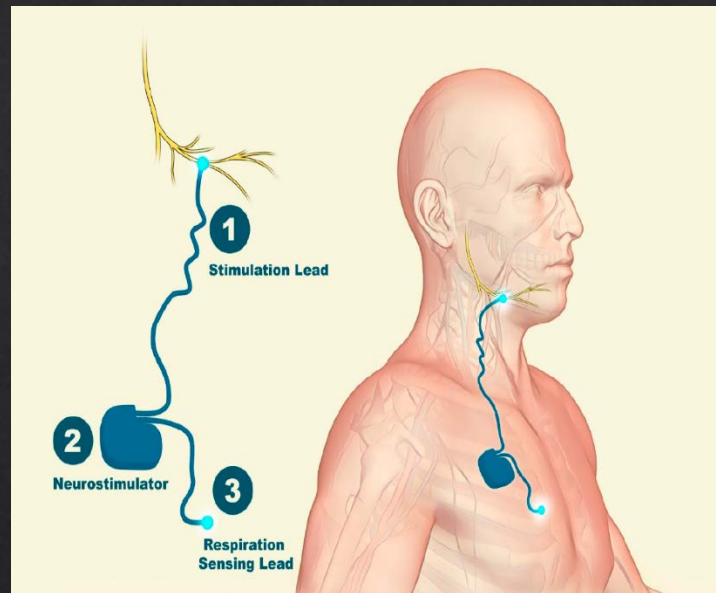


Image of the upper airway seen by magnetic resonance and its collapsibility in patients with OSA and anatomical description of the upper airway (left); representation of (1) normal breathing: 1: the pharynx; 2: the larynx; 3: the **genioglossus muscle**; 4: the epiglottis; 5: the hard palate; and 6: the soft palate; (2) partial upper airway obstruction; and (3) complete obstruction of the upper airway.

# Hypoglossal Nerve Stimulation



**Figure 2.** Hypoglossal nerve stimulation devices. (1) An electrode wrapped around the hypoglossal nerve attached to (2) an Implantable pulse generator (IPG) surgically placed in a subcutaneous pocket; the IPG is attached to a respiration-sensing lead (3).

# Methods

- Retrospective chart review of
- N= 30 PAP intolerant cases referred for HNS treatment
- Inclusion criteria:
  - Body Mass Index (BMI) < 32 kg/m<sup>2</sup>,
  - Apnea Hypopnea Index (AHI) of 15-65/h and
  - Drug induced sleep endoscopy (DISE) showing A-P pharyngeal collapse.
- Variables for analysis:
  - BMI
  - Epworth sleep scale (ESS)
  - DISE results
  - Pre- and post-treatment AHI
  - Adherence data.



# Sample Characteristics

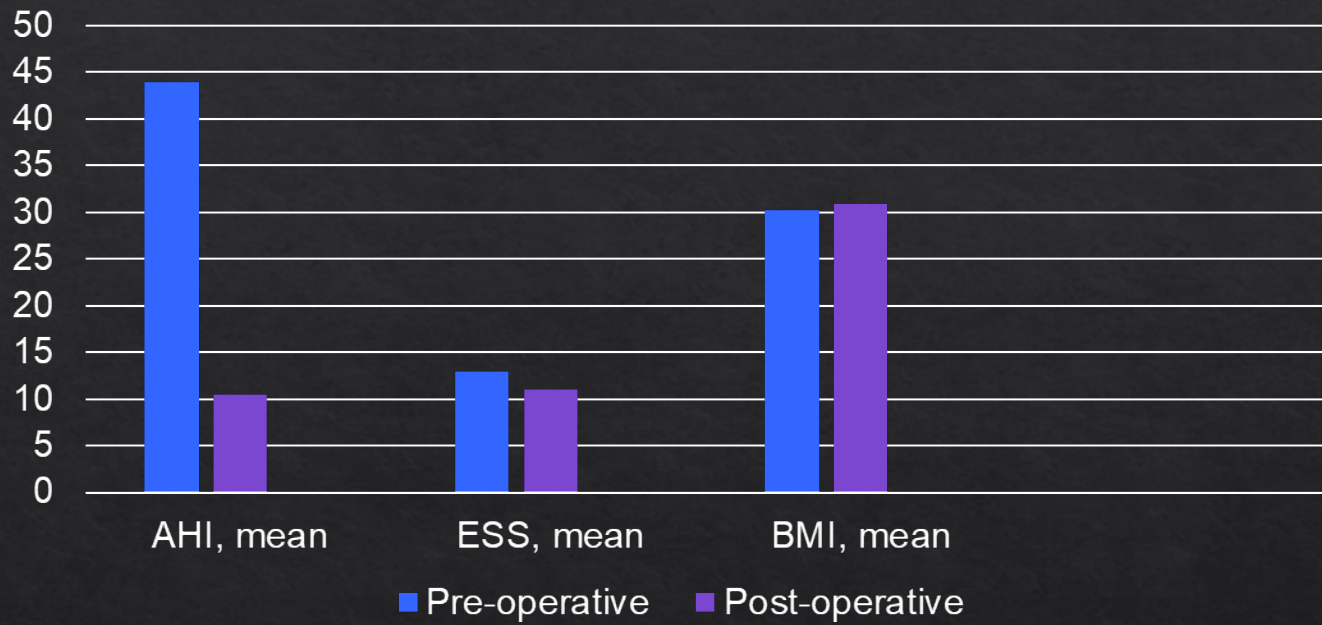
Characteristic	Value
Age, mean $\pm$ SD (yrs)	57 $\pm$ 11
Male:Female ratio	29:1
BMI, mean $\pm$ SD, kg/m <sup>2</sup>	30.3 $\pm$ 3.04
AHI, mean $\pm$ SD	43.95 $\pm$ 22.12
O2 nadir, mean $\pm$ SD (%)	80.47 $\pm$ 8.24
Time with saturation <89, mean $\pm$ SD (min)	29.72 $\pm$ 45.75
ESS, mean $\pm$ SD	13 $\pm$ 5

# Results

- 30 veterans – PAP intolerant
- 17 proceeded to Drug Induced Sleep Endoscopy
  - 15 had partial or complete AP collapse
  - 2 concentric collapse
- 12 veterans proceeded to HNS implantation
  - 6 veterans who completed HNS titration studies showed an average improvement of 77% from baseline AHI
  - mean AHI from 43.9/h → 10.5/h
  - The mean ESS 13 → 11
  - The mean compliance was 6.66 hrs/night.



HNS: Pre- and post operative



# The Stimulation Therapy for Apnea Reduction (STAR) trial

## Examined

- Safety and efficacy of the Inspire Medical Systems device
- 126 CPAP-intolerant patients with moderate to severe OSA.
- Inclusion criteria:
  - Body mass index (BMI) values < 32 kg/m<sup>2</sup>
  - AHI 20-50
  - Pattern of collapse (No Concentric collapse, nonsupine AHI>10).
- AHI decreased (p<0.0001)
- Falling from 29.3/h to 9.0 events/h and from 25.4 to 7.4/h
- improvements in quality of life as measured by the ESS and the Functional Outcomes of Sleep Questionnaire (FOSQ).
- Reductions in AHI (>50%) after 36 months and 48 months as well as improvements in subjective measures of sleepiness and quality of life

# Conclusions

- Electrical stimulation of oropharyngeal muscles is a promising and elective alternative to CPAP for the treatment of moderate to severe OSA.
- Hypoglossal nerve electrical stimulation significantly decreases AHI and ESS values.
- Our limited observational study supports that in carefully selected patients HNS is an effective treatment option for the management of PAP-intolerant patients with OSA.
- Our preliminary data suggests improved treatment adherence.
- Future prospective large-scale cohort studies should be considered.