Patient Selection for Hypoglossal Nerve Stimulation

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Disclosure

- None
Outline

- What is HGNS?
- How does it work?
- Who is the ideal candidate?
- Future directions

Obstructive Sleep Apnea

- 60-90% patients have multi-level collapse
- Contributors:
  - **Upper Airway Anatomy**
    - Collapsibility
  - Ventilatory Control
  - Arousal Threshold
  - Neuromuscular Control
Upper Airway Muscles in Sleep

- Increased Collapsibility
  - Anatomy
  - Neuromuscular Control
- Genioglossus = UA dilator
  - Improves upper airway patency
  - GGEMG declines in sleep – worse in OSA
  - Activation improves airflow and OSA

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Genioglossus stimulation

- Animal
  - Electrical stimulation of GG restores airway patency in sleep
- Human
  - GG stimulation associated with
    - Increased maximum inspiratory airflow, without arousals
    - Enlargement of retrolingual and retropalatal airway
  - Distal and proximal stimulation on XII can open airway and improve airflow

Hypoglossal Nerve Stimulation Systems

- Feasibility trials

![Graph showing hypoglossal nerve stimulation results](image)


Hypoglossal Nerve Stimulation

- FDA approved first device – Inspire II 4/2014
- Fully implanted system with sleep remote
- Unilateral (right) Hypoglossal Nerve stimulation
- Synchronized to inspiration

![Image of hypoglossal nerve stimulation](image)
Clinical Evidence

- STAR Trial: Strollo et al. NEJM 2014.
- 126 patients with mod-severe OSA
- Results @ 1 year:
  - AHI reduction
    - 1 yr: 66% responder
    - 3 yrs: 74%
  - ODI (25.4 to 7.4)
  - ESS normal in 75%
  - >80% soft to no snoring
  - Daily use: 86%

Long Term Data: AHI and Compliance

Clinical Indications for HGNS

- Patient goals and expectations
- CPAP intolerance
- BMI < 32-35
- PSG: AHI 15 to 65**
  - <25% Central apnea events
- Appropriate airway anatomy: DISE evaluation
  - Rule out complete concentric collapse at the palate
- Considerations:
  - MRI Conditional: MR head, neck, extremities only.
  - Surgical history: Prior implants, prior breast surgery

Preoperative evaluation DISE

- Rule out complete concentric collapse at soft palate (~15%)
- Vanderveken et al. J Clin Sleep Med 2013:
  - 21 pts – predictive value of DISE for HGNS outcomes
  - 16 pts without palate CCC: AHI 38 to 12
  - 5 pts with CCC: no change in postop AHI
Intraoperative – Hypoglossal Nerve

- Goal: unhindered tongue
  PROTRUSION and STIFFENING
- Include nerve branches for tongue:
  - Protrusion = oblique and horizontal genioglossi (GG)
  - Stiffening = intrinsic transverse/vertical (TV)
  - C1 = geniohyoid (if possible)
- Exclude
  - Retrusion = hyoglossus, styloglossus

Dedhia et al. Neuroanatomy of the tongue.
Electrode placement

IPG and Sensor Lead
Postoperative Care

- Reduced postoperative pain and medication use.
- 80% patients going home the same day.

- CXR
- Precautions: limit right arm elevation & heavy lifting x 2 weeks
- Dressings off POD #2
Activation and Acclimation

- **1 month postop: Activation**
- Activation Range tested and set (ie. 1.0V-2.0V)
- Assess different electrode configurations
- Patient goes home -> Self-titration
  - Every 3-7 days increases the amplitude

Titration PSG 2-4 months

- **Therapeutic Home Sleep Study in first year**
Awake Laryngoscopy with Stimulation
Airway Changes

- HNS stimulation increases retropalatal and retrolingual areas
- Higher levels of stim increases area with plateau


Inspire Device Outcomes

<table>
<thead>
<tr>
<th>Study</th>
<th>Cohort</th>
<th>Number</th>
<th>Overall response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Woodson et al. [21]</td>
<td>STAR 36 months</td>
<td>98/126</td>
<td>74%</td>
</tr>
<tr>
<td>Kent et al. [51]</td>
<td>UPMC</td>
<td>20</td>
<td>95% (AHI &lt; 15)</td>
</tr>
<tr>
<td>Heiser et al. [64]</td>
<td>Munich</td>
<td>31</td>
<td>97% (50% reduction)</td>
</tr>
<tr>
<td>Heiser et al.* [54]</td>
<td>German Multi-center</td>
<td>60</td>
<td>70% (AHI &lt; 15)</td>
</tr>
</tbody>
</table>

Patient Selection and Counseling

- Must meet the clinical criteria
  - AHI range, BMI, Central apnea evaluation
  - Sleep study within 3 years
- HGNS does involve a device which requires maintenance and compliance
  - 10 year battery life
- Getting the implant to work is a PROCESS
  - Settings may need to be adjusted in first 4-6 months.
  - Long term follow up every 6-12 months.
Patient Selection

- When HGNS does NOT work well:
  - Insomnia that is not concurrently managed
  - Sensitive sleepers
  - Upcoming MRI needs

- Some issues:
  - Does NOT replace or swap for CPAP
  - Borderline BMI
  - Tooth soreness/tongue abrasions – lower mouth guard
  - Nasal breathing is best – optimizes HGNS function
  - If pt fails DISE: consider expansion palatopharyngoplasty

Other Devices – Selective Nerve Stimulation

- **ImThera Medical (Aura6000)- Trial**
  - 6 electrodes, circumferential around main portion XII
  - Phase III trial

- **Nyoxah**
  - Bilateral stimulation
  - External rechargeable battery = MR compatibility
HGNS Advantages and Directions

- **Benefits:**
  - Addresses reduced neuromuscular tone
  - Can be titrated to effect and reprogrammed for comfort
  - Excellent safety profile, low morbidity
  - Provides effective multilevel therapy in properly selected patients

- **Disadvantages:**
  - Cost
  - Narrow inclusion criteria
  - Coverage with payors
  - Requires patient compliance
  - MRI incompatibility

Questions

- Email: jolie.chang@ucsf.edu

- Unanswered Questions
  - Who is the ideal candidate?
  - What is the optimal titration protocol?
  - What are the long term effects of chronic stim?
  - Where does HGNS fall in the OSA treatment paradigm?
  - How do we incorporate thinking about combined surgical therapies?