Hypoglossal Nerve Stimulator Surgery for treatment of OSA

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Disclosures

• I do not have any relevant financial disclosures at this time.

Hypoglossal Nerve Stimulation

• A new, clinically proven, treatment for patients unable to use CPAP
• Selection criteria
  – Moderate to Severe Apnea (AHI 20-65)
  – BMI <33
  – Age >18
  – **Sleep endoscopy** evidence of velopharynx and oropharynx anterior-posterior collapse
Airway Obstruction

Sites of Airway Obstruction
- Nasal
- Palate
- Tongue base
- Epiglottis

Intraoperative Examination

SLEEP NASOENDOSCOPY
[Drug induced sleep endoscopy (DISE)]
- 1st described by Croft and Pringle in 1991
- Pt sedated with propofol to a level sufficient to induce snoring.
- Operator examines upper aerodigestive tract in supine position to determine levels of obstruction.
- Anaesthetist must be present with full cardiac monitoring and resuscitation facilities.
- Respiratory stimulants can be used to encourage snoring.

Examination

- View of the velopharynx
  The velopharynx is bounded by the soft palate (top), the back of the throat, and a muscle complex on each side.
- View of the oropharynx and hypopharynx
  This is the part of the upper airway that contains the tonsils and the tongue.
Drug Induced Sleep Endoscopy

Hypoglossal Nerve Stimulation

Stimulation Timed With Breathing
The Distal Hypoglossal Nerve

Clinical Evidence

- 126 patients were recently studied in the STAR trial
- 22 centers across both the US and Europe

**Reduction in Sleep Apnea**

<table>
<thead>
<tr>
<th>Baseline</th>
<th>Month 8</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>9.8</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Improvement in Quality of Life**

<table>
<thead>
<tr>
<th>Epworth Sleepiness Score</th>
<th>Baseline</th>
<th>Month 24</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>6.6</td>
<td>4.4</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Serious event rate ≤ 2%


**Reduction in Snoring**

Source: Inspire STAR pivotal trial

- 85% of best snoring reported
- 85% of worst snoring improved
Hypoglossal Nerve Stimulation Process

Assessment | Implant | Follow Up
---|---|---
Sleep profile | Typically outpatient | Therapy activation
Anatomy check | Therapy optimization | Routine annual follow up

Hypoglossal Nerve Stimulation Surgery

Therapy affects the airway at multiple levels

Tx OFF - Palate

Tx ON - Palate

OFF – Tongue Base

ON – Tongue Base

Palate tonsils
Epiglottis
Posterior oropharyngeal wall
Tongue base
Lingual tonsils
Inspire Therapy Procedure Overview

• Typically an Outpatient Procedure
  — General anesthesia

• Pain Management
  — Mild discomfort and swelling at the incision sites for a few days after the procedure, usually managed with over-the-counter pain medication

• Recovery
  — Return to regular diet and most activities of daily living immediately after the procedure
  — Avoid strenuous activities for a few weeks

Incisions After Healing is Complete

*Photos used with patient consent*
What Does Inspire Therapy Feel Like?

• Patients describe feeling a tingling sensation or mild muscle contraction when first activating Inspire therapy
• Inspire therapy is adjustable for patient comfort
• Most patients acclimate well to Inspire therapy within the first month of use
• In the STARR Trial at 1 year:
  – 86% of patients reported using Inspire therapy every night
  – 93% of patients reported using Inspire therapy five or more nights per week

Living with Inspire Therapy

With the sleep remote, patients can:
- Start therapy
- Stop therapy
- Pause therapy
- Increase or decrease energy

Inspire Therapy Contraindications*

• Screening sleep study shows > 25% central+mixed apneas
• Anatomical assessment findings that could compromise the performance of Inspire such as complete concentric collapse (CCC) at the palate
• Pre-existing conditions that have compromised neurological control of the upper airway
• Patients who are unable or do not have the necessary assistance to operate Inspire therapy
• Patients who are pregnant or plan to become pregnant
• Patients who will require MRI
• Patients with another implantable device (i.e. pacemaker) should consult the device manufacturer to assess possibility of interaction

*Indications approved by the United States Food & Drug Administration, April 2014