Hypoglossal Nerve Stimulation: How to incorporate into your practice

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OBJECTIVES

• Learn how to incorporate hypoglossal nerve stimulation (HNS) into your practice
• Provide examples of marketing HNS for your practice
• Provide examples of how patient flow may occur in practice
• Learn about value of ENT provider and how to partner with them
• Learn about ENT’s role with HNS
• Learn about follow up care for the patient
Steps to Success

• Contact your local rep (or regional rep if no local exists)
• Partner with an ENT
  • Preferably with experience in Head and neck surgery
  • Some knowledge/experience with sleep apnea surgery
• Get your providers and staff on board and motivated!
  • Consider PA/NP to be a champion of this for CPAP follow up patients
• Find a lead day tech or nurse and lead night tech
• Organize your intake of patients
• Organize your clinic flow and referral process
• Marketing/Advertise
• Obtain a tablet programmer for the device
• Hospital approval for surgical procedure
• Let the games begin!
Motivate your providers!

Despite improved technology CPAP adherence still low, often estimated at 40-60%:
  • Mask Fit and leaking
  • Pressure tolerance
  • Skin Irritation
  • Convenience – setup, cleaning, travel
  • Nasal Congestion
  • Aesthetics/Lack of Intimacy

• What can we do for these patients??
It works!

STAR Trial Overview – 5 Year Follow-Up Complete

STAR Trial Design
- Multi-center prospective
- 126 patients at 22 centers
- Randomized Control Therapy Withdrawal ARM

AHI response at 12 Month
- AHI ≤ 5: 41%
- AHI ≤ 10: 65%
- AHI ≤ 15: 78%
- AHI ≤ 20 & 50% reduction: 81%

Epworth Sleepiness Scale (ESS)

12 month STAR results published in the New England Journal of Medicine, 2014

Mean ESS reduced from baseline of 11.8 ± 5.5 to 6.7 ± 4.7 at 12 months
Reference: ESS < 10 considered free of symptoms for excessive daytime sleepiness
Hypoglossal Nerve Stimulation Success Rates

- STAR Trial – 79% decrease in respiratory events
- 41% patients “cured” – AH< I< 5
- 78% AH< I< 15 (mild sleep apnea range)

Epworth Sleepiness Scale (ESS)

Mean ESS reduced from baseline of 11.8 ± 5.5 to 6.7 ± 4.7 at 12 months
Reference: ESS < 10 considered free of symptoms for excessive daytime sleepiness
Hypoglossal Nerve Stimulation Effect

No Stimulation

Mild Stimulation

Base of Tongue

Palindrome

Base of Tongue

Palindrome
It’s Covered! – BCBS/BCN, Aetna, UHC

Hypoglossal nerve stimulation:
- Member is 22 years of age or older; AND
- AHI is 15-65 events per hour; AND
- Total number of central and mixed apneas are less than 25% of the total AHI; AND
- Member has a minimum of 30 days of CPAP documentation monitoring that:
  - Demonstrates CPAP failure (AHI greater than 15 despite usage of 4 or more hours per night, 5 nights per week), OR
  - Demonstrates CPAP intolerance (usage is less than 4 hours per night, 5 nights per week); AND
- A drug-induced sleep endoscopy (DISE) demonstrates absence of complete concentric collapse at the soft palate level; AND
- Body mass index (BMI) is less than 32 kg/m²; AND
- The sleep study used for the AHI is performed within 24 months of the first consultation for the hypoglossal nerve stimulator

Implantable hypoglossal nerve stimulation is proven and medically necessary in an adult patient with moderate to severe OSA when all of the following criteria are met:
- 22 years of age or older; and
- Body Mass Index of (BMI) less than or equal to 32kg/m²; and
- Apnea hypopnea Index (AHI) of 15 or greater and less than or equal to 65 as determined with polysomnography; and
- Absence of complete concentric collapse at the soft palate level, and
- Failure or intolerance of Positive Airway Pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines)
  - PAP failure is defined as an inability to eliminate OSA (AHI of greater than 20 despite PAP usage) and PAP intolerance is defined as:
    - Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of usage per night), or
    - Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it)
More patients than you think will qualify

• HNS therapy was FDA-approved in 2014 and is in use by 6,000 patients worldwide.

• Specifically for patients who:
  • Have moderate to severe Obstructive Sleep Apnea
    • AHI > 15
    • Less than 25% central and mixed apneas
  • Unable to use or get benefit from CPAP
    • CPAP intolerance
    • Not fully effective (AHI >15-20 despite CPAP use)
    • Not compliant
  • Not obese – BMI < 32 is ideal candidate
  • Age 22+
It’s safe and easy to use

- Safe outpatient procedure – 3 skin incisions
- Fast Recovery; typically OTC pain meds
- 11 year battery life
- Small device

- Easy to use, NOT painful
- Adjustable Stimulation
- Daily monitoring/compliance on cloud
Patients like it and are compliant!

• High Overall Therapy Satisfaction
  • 95% would choose again
  • 96% would recommend to others
  • 94% were satisfied

• High Compliance Rates
  • About 6 hours of use every night on average
Lead tech responsibilities

• Take calls that come into clinic and schedule consults
  • We have separate option on our phone line for HNS therapy that goes straight to the tech
• Obtain old studies and screen patients
• Follow patients course until their surgery and arrange follow up
• Keep running list of all referred patient and where they are in the process
• Help with activation of device
• Call at scheduled intervals after activation until titration study
• Get trained on using the cloud and
• Lead night tech to perform HNS titration studies
Intake Form (tech screening patients)

**Patient Name:**

**D.O.B.:**

**Do You Use CPAP routinely now?**

| YES | NO |

**Last Sleep Study DATE**

**Do you Know your OSA Severity**

| Mild | Moderate | Severe |

*Patient to provide previous sleep study and bring to appointment*

*Sleep Study Should be within 2 years for insurance submission. Order sleep study if necessary (HST or PSG)*

**BMI Calculation**

| Height | Weight | BMI |

**Primary Care Physician**

**Previous Sleep Physician**

**Managing OSA**

**How did you hear about the Therapy**

| Radio | Social Media | Internet | Dr. Referral | Friend |

**Appointment Date**

**AHI (moderate – severe) AHI >15**

**BMI (normal body size / BMI <35)**

**Intolerant to CPAP**

*Advise Patient to learn more in preparation for appointment by:*

**Visit Website**

**Download App (on mobile device)**
Phone Call with Patient:

1. Are you using it every night?
   a. If yes: “That’s great, keep it up.”
   b. If no: “What is preventing you from using it every night?" 
      i. Uncomfortable = step down therapy or possible office visit 
      ii. Forgot = reminder to use “all-night, every-night” 
      iii. Review video book “Step Up” process

2. How many steps have you stepped up?
   a. Encourage the patient to keep stepping up Inspire if comfortable

3. Are you more rested during the day?
   a. If yes: “That’s great, keep it up.”
   b. If no: “It may take more time. Continue stepping up Inspire.”

Next Steps:

1. If the patient is using and sees a decrease in daytime sleepiness, then the patient should continue the step up process to prepare for the sleep study.

2. If the patient is not using (ex: less than 4 hours per night or uncomfortable), schedule an office visit with a healthcare provider to confirm initial settings are correct and make adjustments for comfort.
Advertising/Marketing

• Only start when you are ready and prepared!
• Send letter to all providers in system
• Send letter to noncompliant patients
• Hospital newsletters
• Radio ads
• Community talks
How does the flow work in clinic?

• For normal OSA patient consults - given flowsheet of apnea treatment

• For HNS consults
  • Review old study prior to appointment
  • Go through detailed history of PAP intolerance/ineffectiveness issues and DOCUMENT in detail – this can be important for insurance approval/appeals
  • If they are good candidate – give folder of information (Surgeon’s name/contact, patient advocates, information about device, FAQs)
  • Go through flowsheet of process
  • Place referral if meets criteria
  • Order new sleep study (If more than 2 years old) – can be PSG or HST
  • ALWAYS have a backup plan to get started on – eg. Retry CPAP, switch to BiPAP, mask desens, OMAD, other surgical option
  • If BMI out of range – give them a target weight that you will place referral at
    • Typically has to be less than 35 for me to refer with assumption they will get to 32 by surgery
    • Use BMI calculator
Follow up after surgery

• Therapy activation
• Physician Programmer
• Range from 0-5 Volts
• Set min to max voltage (1 V range) for patient home titration
  • Min – first tongue motion
  • Max – 1 V higher
  • 10 levels patient goes up on
    • 0.1 V each level
• Patient slowly titrates up at home over 2-3 months
• Sleep study titration after this
• Download compliance on cloud
Typical success

• About 70-80% of patients are successful with first titration in both AHI reduction (goal is <15) and clinic response (ESS scores) and are compliant.

• The remaining 20-30% may need further adjustment of settings
  • Pulse width, rate adjustments
  • Electrode configuration

• Sometimes awake endoscopy is needed to determine proper settings and what opens the airway the best
  • ENT may get involved again

• Can use combination therapy if needed
  • OMAD
    • Positional therapy (lateral position or neck extension)
Our clinic so far (in 1 year)

• Referrals –
• Implants – 6
• In line for implant –
• Titration study – 2
• More info on our referrals pending
QUESTIONS