



University Hospitals

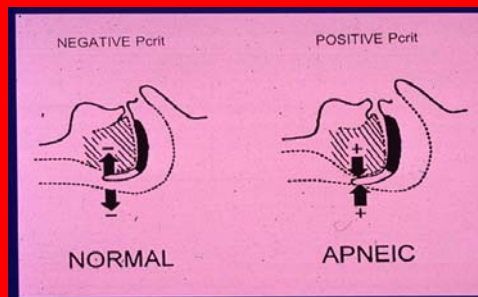


CASE WESTERN RESERVE UNIVERSITY
SCHOOL OF MEDICINE

Management Issues in Hypoglossal Stimulation for OSA

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A Sleep Medicine view of surgery

Sensitivity of the ventilatory control system
loop gain



Sleep
(low arousal threshold)



Obstructive Sleep Apnea
Hypopnea Syndrome

Decker et al 1993

Disclosures

Inspire Medical

- Site PI for the STAR Trial, and Inspire Post-Approval and Registry Studies
- Consultant on FDA application

NIH and VA research Awards on Causes and Consequences of Sleep Apnea

Galvani Bioelectronics (Consultant)

Sommetrics (Consultant and Research Support)

Summary

Hypoglossal Stimulation is a somewhat predictable treatment option for some.....

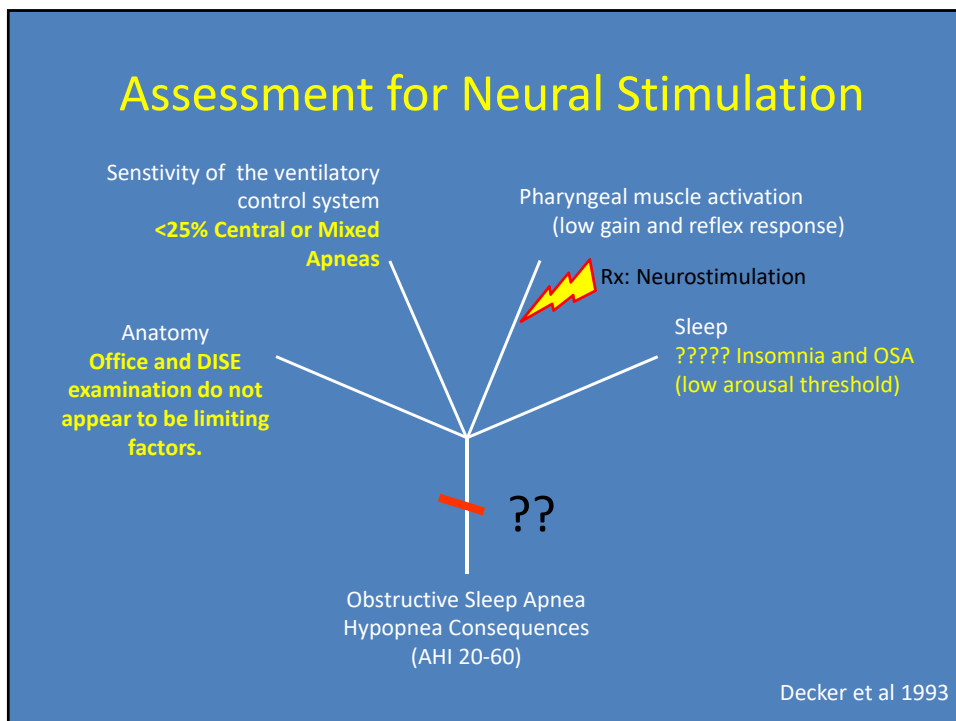
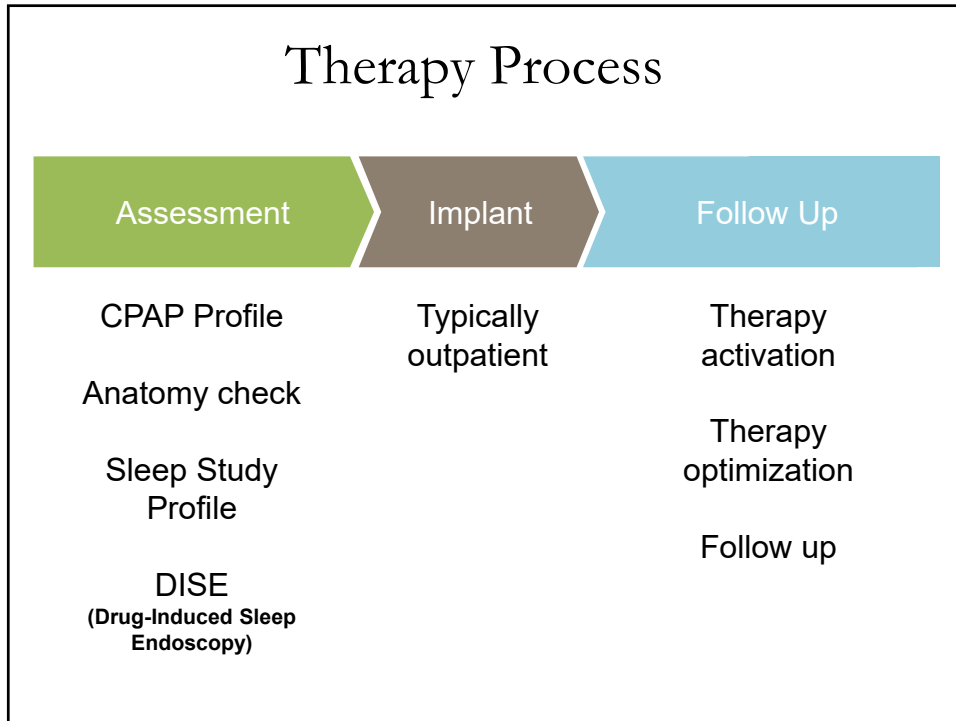
Who:

- Have moderate to severe OSA
- Struggle to get consistent benefit from CPAP
- Have a compatible airway anatomy profile
- Have a body mass index (BMI) <35, ideally <32

A team is best to determine if this invasive, non-anatomic therapy is right at this time for any given patient.

- Success is dependent upon its action to reduce the closing pressure of upper airway.
- In our hands, best success is when it opens the retropharyngeal space.

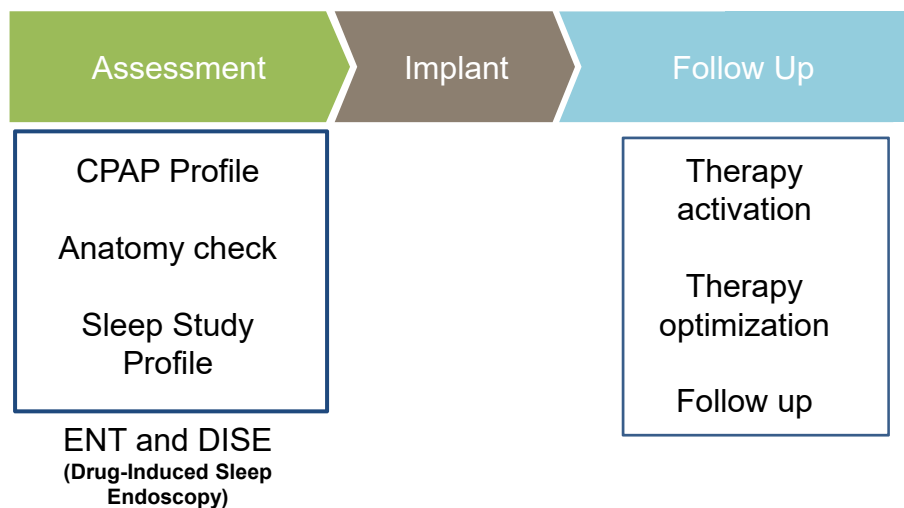
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Insurance/Cost Considerations

- Inspire therapy is FDA approved. Currently, the therapy is being reviewed by insurance companies on a patient-by-patient basis.
- The first step is to see if a patient qualifies for the therapy and then the work with the patient and/or an insurance company on the Inspire implant.

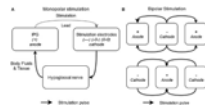
UAS Therapy Process



Sleep Medicine

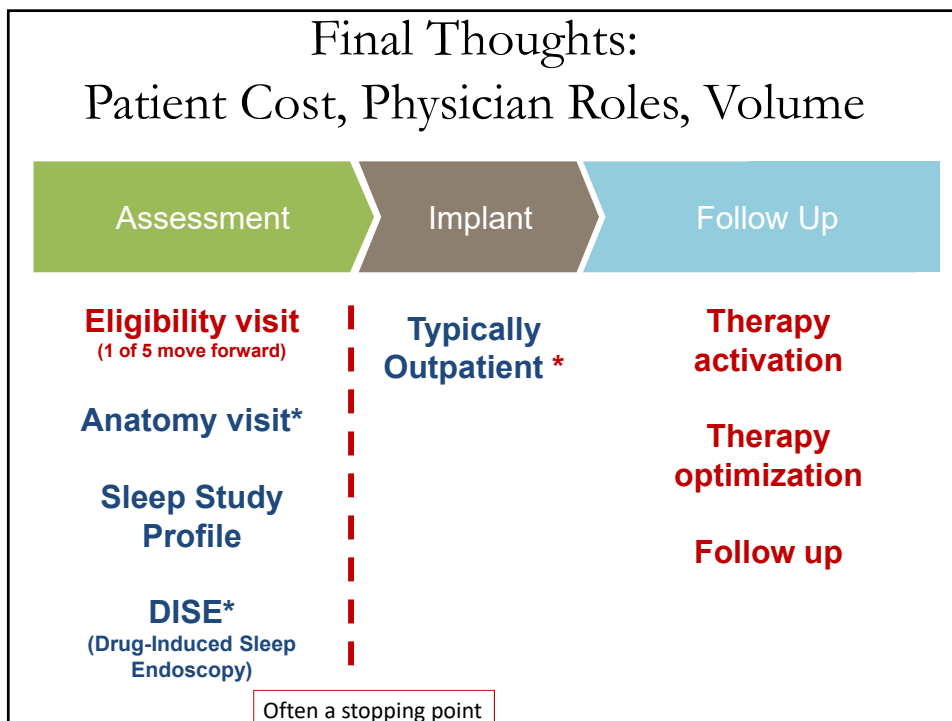
- Inclusion/exclusion criteria needs
- CPAP/oral appliance and documentation of attempts, reasons, and face validity of non-use (HNS is not a choice therapy) then
- Explanation of the purpose and manner of therapy including follow-up
- Restate the patient goals and assess committment
- Include some documentation by the patient of why they need it.

Post-Implant Management



| Implant | Activation Phase | Titration Phase | Long-term |
|------------------------|---|---|--|
| Post-op check @ 1 week | 1 month post-op | 2 month post-op | 6 months and Annually* |
| | Office Visit: <ul style="list-style-type: none"> • Stimulation • Thresholds Home Use: <ul style="list-style-type: none"> • Acclimatization | • Thresholds * In-lab tuning PSG 2-6 months • Stimulation Across states and positions | Office Visit: <ul style="list-style-type: none"> • Battery • Usage • Thresholds • Therapy Adjustment |
| | | | • HST in many cases are considered |

Final Thoughts: Patient Cost, Physician Roles, Volume



Checklist for a Center: Build a Team

OSA Common Knowledge Sleep

- Incidence/ prevalence/demographics
- Disease pathophysiology
- Outcomes of untreated OSA
- Inspire Mechanisms of Action

Inspire vs. Alternative Therapies

- Efficacy
- Safety profiles
- Patient selection
- Patient preference

Clinical Evidence

- Reduction AHI/ODI (%)
- Safety Profile
- Effect on Co-morbidities/mortality
- QOL/ADL

Health Economics

- Cost of Inspire vs. alternate therapies
- Cost vs. non-treatment
- Hospital economics
- Physician economics
- Reimbursement
- Coding

Assessment and Implant

- Surgical techniques
- Device follow-up and programming
- Post operative complications

Practice & Patient Mgmt

- Patient selection
- Clinical trials - best practices
- Medical management after implant
- Psychological issues

Question 1

What is the operational need to establish upper airway stimulation as an option for OSA?

1. A committed surgeon
2. A sleep laboratory that can focus on higher levels of recording and analysis
3. Research level sleep medicine group
4. Both 1 and 2
5. All factors

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Question 2

What is the hardest issue in the assessment of a patient who really wants hypoglossal stimulation?

1. Cost
2. Defining CPAP failure
3. Organizing DISE
4. Scoring the PSG for eligibility
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Question 3

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1. The hospital will not be worried about the cost.
2. The cost to the patient is more than they ever expected.
3. The routines in the ENT and Sleep Medicine sections for this therapy will mesh perfectly.

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