






Hypoglossal Nerve Stimulators For Obstructive Sleep Apnea

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Disclosure

- I have no actual or potential conflict of interest in relation to this program/presentation.

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Learning Objectives

- Understand obstructive sleep apnea (OSA) and its prevalence
- Discuss previous treatment options for OSA
- Knowledge of location and mechanics of upper airway stimulation (UAS) devices
- Review UAS data, patient care and therapy options
- Anesthesia considerations

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The Basics.....

- Obstructive sleep apnea (OSA) is characterized by repetitive upper airway collapse during sleep which leads to oxygen desaturation and hypercarbia.
- These intermittent desaturations lead to nighttime awakening; manifesting into chronic sleep deprivation and subsequent daytime somnolence.

BACK TO BASICS

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The Numbers....

- OSA is extremely common. Prevalence = diabetes or asthma worldwide.
- 25 million in the USA. Over 1 billion people worldwide.
- Only 25% are currently being treated.
- Gold standard is Continuous Positive Airway Pressure (CPAP)

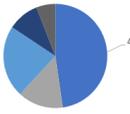
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The Numbers....

Global Sleep Disorder Market Share, by Disorder Type, 2022 (%)



Disorder Type	Market Share (%)
Sleep Apnea	48%
Restless Legs Syndrome (RLS)	~15%
Narcolepsy	~10%
Others	~27%

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Why Do We Need An Alternative To CPAP?

• ≥10 million patients own CPAP machines in North America.

• Studies have shown that **almost half do not comply with CPAP** (Weaver et al. 2008)

1. Mask discomfort
2. Claustrophobia
3. Pressure intolerance
4. Dry or irritated nasal membranes
5. Eye irritation from air leakage around the mask (Pawloski & Shelgikar, 2017).



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Untreated OSA

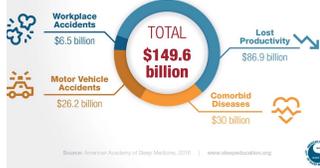
➢ If left untreated, OSA can result in

- Hypertension
- Diabetes mellitus
- Coronary artery disease
- Stroke
- Congestive heart failure
- Atrial fibrillation
- Death

➢ Increased cancer incidence, increased mortality, and increased neurodegeneration (Lim & Pack, 2017)

Undiagnosed Sleep Apnea: A Hidden Health Crisis

In the U.S. the estimated economic cost of undiagnosed obstructive sleep apnea was nearly \$150 billion in 2015.



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Alternatives To CPAP For Treating Sleep Apnea

1. Weight Loss and Exercise
2. Sleep Position
3. Avoiding Alcohol
4. Mandibular Advancement Devices
5. Tongue Retaining Devices
6. Myofunctional Therapy
7. Surgery (variable success 35-75%)
 - a) Maxillomandibular advancement
 - b) Uvulopalatopharyngoplasty (UPPP)
 - c) Adenotonsillectomy



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Introduction Of The Hypoglossal Nerve Stimulator (HGNS)

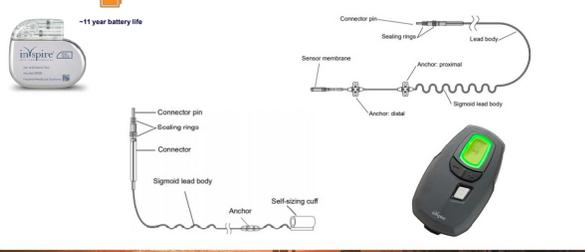
• Initial patents filed in the 1990s with Inspire founded in 2007 and FDA approval in 2014 for the treatment of OSA.



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Components Of The Inspire System

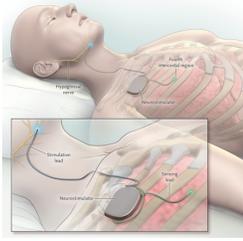


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How It Works

- The stimulation electrode is placed on the hypoglossal nerve to recruit tongue-protrusion function
- The sensing lead is placed between the internal and external intercostal muscles to detect ventilatory effort
- The neurostimulator is implanted in the right ipsilateral mid-infraclavicular region.



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The Hypoglossal Nerve Innervation

All the intrinsic muscles and all but one of the extrinsic muscles (genioglossus, styloglossus, and hyoglossus) of the tongue.

Anterior two-thirds (oral)
 • General somatic afferent: hypoglossal nerve (XII)
 • Motor: hypoglossal nerve (XII)
 • Sensory: lingual nerve (V3) via chorda tympani

Posterior one-third (pharyngeal)
 • General somatic afferent: glossopharyngeal nerve (IX)
 • Motor: vagus nerve (X)

Motor Hypoglossal nerve (XII):
 • Genioglossus
 • Hyoglossus
 • Styloglossus
 • Palatoglossus — tongue nerve (X)

Mild Stimulation to Select Distal Branches during inspiration

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Hypoglossal Nerve Stimulation Effect An Increase In Cross Sectional Size Of Airway

No Stimulation **Mild Stimulation**

Base of Tongue **Palate** **Base of Tongue** **Palate**

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Requirements for HGNS Consideration

HOW SEVERE IS YOUR SLEEP APNEA?

AHI is the number of apneas or hypopneas recorded during the study per hour of sleep

<5 per hour	Normal
5-15 per hour	Mild
15-30 per hour	Moderate
>30 per hour	Severe

50% reduction in AHI to a value of <20

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Pre-op Anatomical Assessment Drug Induced Sleep Endoscopy (DISE)

- Used to determine eligibility for device implantation.
 - patients are excluded if DISE reveals complete concentric collapse
 - tongue's protrusion will not resolve this pattern of airway obstruction. (Gupta et al., 2018).
- Propofol (midazolam and dexmedetomidine) are the drugs of choice for DISE.
- The degree of sedation is important (BIS score in the mid 60's); a light sedation that most closely mimics sleep is ideal for accurate assessment of the upper airway.
- Collaborate with surgery PRIOR to the procedure.

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Pre-op Anatomical Assessment Drug Induced Sleep Endoscopy (DISE)

Good Candidate **Not a Good Candidate**

AP collapse at palate Complete concentric collapse at palate

Assess lateral wall collapse at genu of the soft palate

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Inspire STAR Trial (The Stimulation Therapy for Apnea Reduction Trial) Multicenter trial

Table 1. Characteristics of the Study Population at Baseline.^a

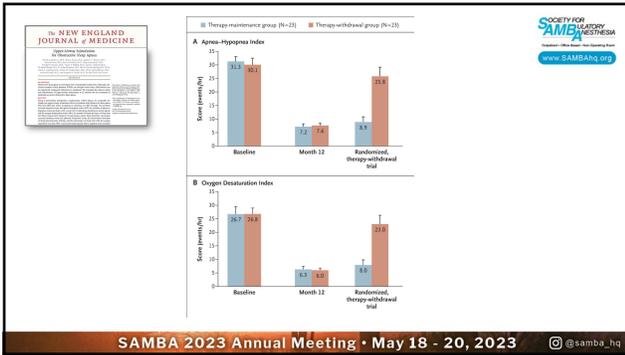
Characteristic	Participants (N=126)
Age — yr	54.5±10.2
Male sex — no. (%)	105 (83)
White race — no. (%)†	122 (97)
Body-mass index	28.4±2.6
Neck size — cm	41.2±3.2
Blood pressure — mm Hg	
Systolic	128.7±16.1
Diastolic	81.5±9.7
Hypertension — no. (%)	48 (38)
Diabetes — no. (%)	11 (9)
Asthma — no. (%)	6 (5)
Congestive heart failure — no. (%)	2 (2)
Uvulopalatopharyngoplasty — no. (%)	22 (17)

Table 2. Primary and Secondary Outcome Measures.^a

Outcome	Baseline	12 Months	Change	P Value
Primary outcomes				
AHI (no./h)	30.0±11.8	15.1±16.3	-16.4±16.7	<.001
Median	26.3	9.0	-17.3	
Interquartile range	23.7 to 38.6	4.7 to 22.5	-26.4 to -9.3	
ODI (no./h)	28.6±12.0	13.9±15.7	-14.6±15.8	<.001
Median	21.4	7.4	-13.7	
Interquartile range	19.3 to 36.6	3.7 to 20.5	-24.0 to -8.6	
Secondary outcomes				
FOIQ score†	14,3±3.2	17,3±2.9	2,9±3.1	<.001
Median	14.6	18.2	3.4	
Interquartile range	12.3 to 17.1	16.2 to 19.5	3.7 to 6.7	
Epworth Sleepiness Scale score†	11.6±3.0	7.0±4.2	-4.7±5.0	<.001
Median	11.0	6.0	-4.0	
Interquartile range	8.0 to 15.0	4.0 to 10.0	-8.0 to -1.0	
Percentage of sleep time with oxygen saturation <90%	8.7±10.2	5.9±12.4	-2.5±11.1	0.01
Median	5.4	0.9	-2.2	
Interquartile range	2.1 to 10.9	0.2 to 5.2	-6.6 to -0.3	

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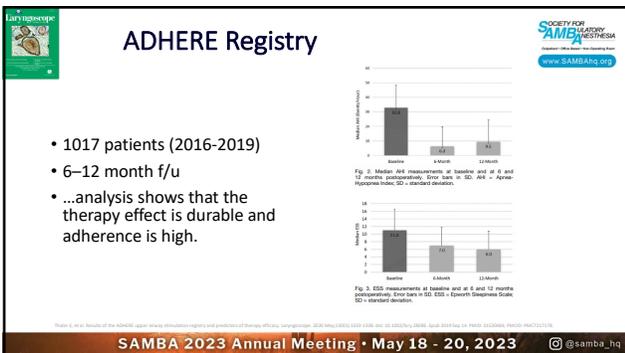


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ADHERE Registry - Enrollment goal of 5,000
Goal: Collect real-world outcomes data

Outcome Measure	Baseline	Month 12	Month 36	Month 60
AHI	Mean ± SD: 23.0 ± 11.8	Mean ± SD: 15.3 ± 16.1	Mean ± SD: 11.5 ± 14.0	Mean ± SD: 12.4 ± 16.3
ResAHI	Mean ± SD: 27.3	Mean ± SD: 25.0	Mean ± SD: 26.0	Mean ± SD: 24.4
ODI (R)	Mean ± SD: 28.9 ± 18.2	Mean ± SD: 14.0 ± 15.6	Mean ± SD: 9.1 ± 11.7	Mean ± SD: 9.9 ± 14.5
ESS	Mean ± SD: 14.2	Mean ± SD: 10.2	Mean ± SD: 11.0	Mean ± SD: 10.7

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Post-operative Complication Rate Comparison Between Airway Surgery and Upper Airway Stimulation Using NSQIP and ADHERE

...the study concluded that hypoglossal nerve stimulator patients had...

- shorter hospital stays
- lower 30-day return to the operating room (0.1% of HNS vs. 4.8%)
- lower surgical site infections (0.13% HNS vs. 0.9%)
- All despite an older HNS cohort and subsequent higher prevalence of comorbidities.

1623 UAS procedures in ADHERE
310 in NSQIP (National Surgical Quality Improvement Program NSQIP)

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Sleep and Breathing
International Journal of the Science and Practice of Sleep Medicine

- Neruntarat et al. (2021) performed the most recent meta-analysis
- 990 patients participating in randomized trials or observational studies.
- Inspire HNS implant vs traditional OSA surgeries (UPPP, Transoral robotic surgery and various palatal procedures).
- Hypoglossal nerve stimulation >> traditional OSA surgeries.
 - AHI reduction (23.9 vs. 15.8, P< 0.001)
 - They also had shorter hospital stays, lower readmission rates, and a lower incidence of adverse events.

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Anesthetic Management Concerns

Technical Guidance

For questions contact Inspire Therapy Support at: 1-844-OSG-HELP (1-844-672-4382, option 3)

Overview
This document describes the considerations for patients with an Inspire system who may undergo surgical procedures. The purpose is for team preoperative planning.

Preoperative Effects
Surgical procedures and the use of anesthetic agents can cause damage to an implanted Inspire system. The considerations are listed in order of priority below.

Estimated Frequency

Concern	Estimated Frequency
Damage to the nerve due to anesthetic administration using the Inspire Therapy	None
Damage to the Inspire system	None

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Anesthetic Management concerns

- Similar to a patient with a cardiac pacemaker
- Preoperative radiologic films



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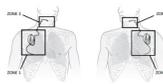
Anesthetic Management concerns

Table 1. Generator Scan Eligibility

Model*	X-ray ID**	Serial Number Prefix	Eligibility Details
3028	IMS1	A0000000X	MR Conditional at 1.5T
3024	NCR	N0000000X	Not eligible for MRI

* All require lead model numbers are MR conditional and are eligible for the scan conditions outlined in this manual.
 ** Reference "Appendix B: X-ray ID Tag" on page 18 for location and examples of the X-ray ID tag.
 The following table lists the approved locations for implanted components. Sensor location does not impact MRI eligibility. Generator and stimulation lead can be implanted on either the right or left side of the body.

Table 2. Approved Locations for Implanted Components



Appendix B: X-ray ID Tag

The X-ray images show how Generator Models 3028 and 3024, with specific reference to the location of the X-ray identification tag.

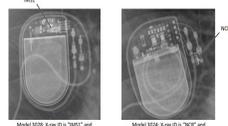


Figure 6. X-ray ID Tag Locations



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Anesthetic Management concerns

MRI Conditional Guidelines

Overview
 Patients implanted with the Inogen 3028 generator may undergo an MRI if specific guidelines are followed. These guidelines allow for imaging of the head, neck, arms, and legs with the use of a 1.5T or 3T MRI. The ability to perform an MRI depends on the location of the generator and the type of MRI equipment used.

Potential Risks
 The generator may heat up during the MRI scan. This may cause discomfort or pain. Patients should be monitored during the scan.

Scan Regions
 With the use of a 1.5T or 3T MRI, scans of the head, neck, arms, and legs of a patient implanted with the Inogen 3028 generator can be performed with MR. MR scans of the chest can be performed with the use of a breast receive head coil located on the patient's abdomen.

Required MRI Equipment
 A breast receive MR coil is required for all scans. An MR system that displays 0.1 TMS is required for head and neck scans.

Implant Configurations
 Patients with breast leads not connected to a generator cannot be scanned with MRI. Refer to the complete Inogen MRI guidelines for additional information. www.inogen.com



 MRI conditional labeling provides patients access to MRI scans at 1.5T*


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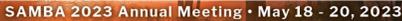
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Anesthetic Management concerns

- To avoid the risk of infection and damage to the implanted components, a 15cm (6 inches) separation between the components and the surgical procedure site is recommended by the manufacturer.
- If less call manufacturer for device interrogation
- Bipolar cautery preferred. If mono used → placement of pad important
- Postoperatively, electrolyte disturbances can affect lead sensing, and as such, checking a basic metabolic panel after surgery may be indicated. (Preston et al. Am J Cardiology)
- Check the device function post op prior to discharge!!!



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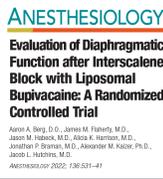
Anesthetic Management concerns

PERIOPERATIVE MEDICINE

ANESTHESIOLOGY

Evaluation of Diaphragmatic Function after Interscalene Block with Liposomal Bupivacaine: A Randomized Controlled Trial

Hemi-diaphragmatic Transient Phrenic Nerve Palsy.
 Paralysis resulting from local anesthetic traveling over the anterior scalene muscle to the phrenic nerve.
 Decrease in diaphragm function of 0 to 25% normal
 Decrease of 25 to 75% is partial paralysis
 Decrease of 75% or greater defines complete paralysis.



 Anesth A. Berg, D.O., James M. Flannery, M.D., Jason M. Hoback, M.D., Alicia K. Harrison, M.D., Jonathan P. Rosen, M.D., Alexander M. Nadeau, Ph.D., Jacob L. Rubenstein, M.D.
 Anesthesiology 2022; 136:531-41

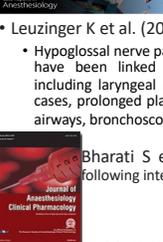

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Anesthetic Management concerns

Airway Anesthesiology

- Leuzinger K et al. (2021)
 - Hypoglossal nerve palsies, both isolated and in conjunction with other nerves, have been linked to numerous anesthesia-related iatrogenic etiologies including laryngeal manipulation during intubation or with ENT suspension cases, prolonged placement of the endotracheal tube, use of laryngeal mask airways, bronchoscopy, and shoulder surgery with utilization of chin straps.
- Bharati S et al. (2014) Ipsilateral paralysis of hypoglossal nerve following interscalene brachial plexus block.
 - Fritz et al. (2014) ...compression of the lateral tongue base during prolonged surgery or intubation.



 Bharati S et al. (2014) Ipsilateral paralysis of hypoglossal nerve following interscalene brachial plexus block.


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