A Comparison of Surgical Procedures (Inspire vs. Genio) for the Treatment of Obstructive Sleep Apnea

David C. Lashbrooke, Jr, MS
Marian University College of Osteopathic Medicine, Indianapolis, IN

Background

- Obstructive sleep apnea (OSA) is a prevalent sleep disorder that typically arises when the muscles responsible for regulating the upper airway excessively relax, ultimately causing narrowing or constriction of the throat
    - This muscle relaxation causes the tongue to fall backwards leading to airway blockage
- Sleep apnea can lead to a variety of serious health issues such as:
    - Hypertension
    - Increased resistance to insulin
    - Increased risk for cancer
    - Cognitive impairment or dementia
    - Neurodegeneration
    - Cardiovascular disease

References

Treatment

- The objective of treating OSA is to prevent narrowing or collapsing of the airway, ensuring unobstructed airflow throughout the night
- Continuous positive airway pressure machine (CPAP)
    - Considered the “gold standard” treatment
    - Not well tolerated
- Hypoglossal nerve stimulation (HNS)
    - Facilitates the control of tongue movement to maintain the airway during sleep
- Inspire is a unilateral HNS system
    - Holds the only current Food and Drug Administration (FDA) approval
    - Generator is surgically implanted in the right chest superficial to the fascia of the pectoralis major muscle and just below the inferior border of the clavicle
    - Respiratory sensing lead is placed between the external and internal intercostal muscles on the lateral thoracic wall
    - Stimulation lead is inserted below the mandible, travels through the neck and connects to the hypoglossal nerve
- Genio is a bilateral HNS system
    - Not FDA approved and is primarily used in Europe
    - Externally worn on the submental region during sleep
    - Adhesive disposable patch transdermally stimulates the hypoglossal nerve bilaterally

Results

STAR Trial and Patient Outcomes (Inspire)

- In 2014, 126 patients participated in a study that aimed to investigate the effects of HNS on:
    - Apnea hypopnea index (AHI)
    - Oxygen desaturation index (ODI)
    - Epworth Sleepiness Scale (ESS)
    - Functional Outcomes of Sleep Questionnaire (FOSQ)
- After 12 months of Inspire use, productive changes in all four outcomes listed above were observed compared to the baseline
- Median ESS scores fell to less than 10.0 indicating a reduction in daytime sleepiness
- Median FOSQ scores increased at least 2.0 points indicating an improvement of overall quality of life

Figure 1. Inspire Medical System Remote and Generator
Source: Inspire Medical System

BLAST Trial and Patient Outcomes (Genio)

- In 2017, 27 patients participated in a study nearly identical to that of Inspire
- Because the Genio device is still relatively new, studies have been limited thus far
- Similar productive changes in the aforementioned outcomes were observed after 6 months of Genio use
- Median ESS scores also fell to less than 10.0 indicating a reduction in daytime sleepiness
- Median FOSQ scores increased by 1.9 points also indicating an improvement of overall quality of life

Figure 2. Genio Submental Patch
Source: Genio Sleep

Comparison

- Inspire stimulates the genioglossus and geniohyoid muscles while Genio only stimulates the protruding genioglossus muscle to keep airway open during sleep
- Inspire uses a sensing lead which detects the patient’s breathing to deliver stimulation while Genio delivers stimulation at a fixed rate
- At this time, no conclusion can be made on the benefits of bilateral versus unilateral stimulation in terms of patient outcomes
    - Additional studies are needed due to small sample sizes

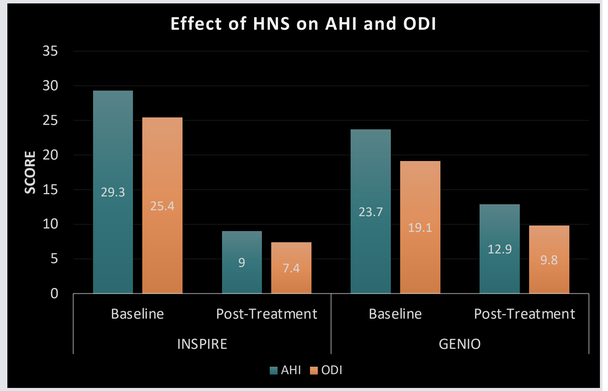

Figure 3. Effects of HNS on AHI and ODI
Source: Eastwood, National Library of Medicine

Inspire Adverse Events and Complications

- Following the 12-month STAR Trial, patients experienced a variety of adverse events and complications
- Postoperative complications due to the procedure are as follows:
    - 26% reported general discomfort around the incision site
    - 18% reported tongue soreness and weakness
    - 12% reported sore throat due to intubation
- Inspire device related complications are as follows:
    - 40% reported discomfort due to the electrical stimulation
    - 21% reported tongue abrasion
    - 10% reported mouth dryness
    - 6% reported pain associated due the mechanical activity

Genio Adverse Events and Complications

- Postoperative complications due to the procedure are as follows:
    - 19% reported hematomas around the incision site
    - 19% reported general discomfort around the incision site
- Genio device related complications are as follows:
    - 30% reported impaired or painful swallowing
    - 30% reported skin irritation around the submental region where the disposable patch is worn each night
    - 26% reported trouble speaking due to muscle weakness
    - 11% reported tongue abrasion
    - 11% reported tongue fasciculation
    - 11% reported discomfort due to electrical stimulation