*ORIGINAL ARTICLE*

# Exploring the Efficacy of Hypoglossal Nerve Monitoring and Stimulation in Treating Obstructive Sleep Apnea

**J of Neurophysiological Monitoring 2023; 1(2): 12-19.** ISSN 2995-4886

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**KEYWORDS:** Hypoglossal nerve, obstructive sleep apnea, apnea, IONM EMG, neurophysiology.

**CITE AS:** Nadeem W, Qayum A, Jahangiri RH, Hasnain S, Mumtaz M. Jahangiri FR. Exploring the Efficacy of Hypoglossal Nerve Monitoring and Stimulation in Treating Obstructive Sleep Apnea. J of Neurophysiological Monitoring 2023; 1(2): 12-19. doi: 10.5281/zenodo.10214346.

**ABSTRACT**

Sleep disorders are a widespread health concern that affects millions of people around the world. Common sleep disorders include insomnia, obstructive sleep apnea, restless legs syndrome, and narcolepsy. Insomnia is characterized by difficulties falling or staying asleep and can be acute or chronic. Obstructive sleep apnea causes repeated breathing pauses during sleep due to airway blockages, which can result in disrupted sleep and daytime sleepiness. Restless legs syndrome causes unpleasant leg sensations and an urge to move them, often at night, disrupting sleep onset. Narcolepsy involves excessive daytime sleepiness and sudden sleep attacks and is caused by a lack of the hypocretin neuropeptide that promotes wakefulness. The treatment of sleep disorders varies depending on the specific condition. Cognitive behavioral therapy is often used to treat insomnia by improving sleep habits and modifying thoughts that interfere with sleep. Medications like benzodiazepines, nonbenzodiazepines, or melatonin may also be prescribed temporarily for insomnia. Continuous positive airway pressure therapy is the standard treatment for obstructive sleep apnea, which involves wearing a mask and using a machine. Restless legs syndrome is often treated with medications such as dopaminergic agents or opioids. Narcolepsy treatments include wakefulness promoting agents, selective serotonin reuptake inhibitors, and stimulant medications to manage daytime sleepiness. Innovative treatments like hypoglossal nerve stimulation (HGNS) offer a cutting-edge solution for obstructive sleep apnea with a success rate of 75% over five years. HGNS targets the genioglossus muscle, which causes the tongue to protrude and helps alleviate airway obstruction during apneas. This advanced therapy option is highly effective at improving sleep quality and reducing the frequency and severity of OSA symptoms.

## INTRODUCTION

Apnea is a sleeping disorder marked by complete (apnea) or partial (hypopnea) absence of inspiration for a minimum of 10 seconds. This results in a drop in arterial oxyhemoglobin saturation and arousal from sleep [1]. It is classified into obstructive and central, both resulting from a decrease or absence of neural stimulation of upper airway muscles (genioglossus) and/or lower thoracic inspiratory pump muscles (diaphragm and intercostal muscles) [2]. Obstructive sleep apnea (OSA) is more common, affecting one billion people globally and being prevalent in Hispanic, Black, and Asian Populations [1]. Obstructive sleep apnea (OSA) is a universally prevailing disease that continues to grow in population, involving 15–30 % of males to 10–15 % of females in North America [3]. OSA affects more males (three to seven percent) than females (two to five percent of the adult population) [4]. Evidence-based studies indicate that the incidence of OSA is increasing due to the worldwide escalation in obesity, making it one of the major risk factors [5]. The major risk factors include anatomical and non-anatomical factors [1].

A few comorbidities are associated with OSA, including hypertension, diabetes mellitus, coronary artery disease, stroke, congestive heart failure, atrial fibrillation [4], pulmonary hypertension [1], and sudden death [2]. Furthermore, excessive daytime sleepiness is linked to an increased risk of motor vehicle accidents [1]. Untreated OSA imposes a significant threat not only to the quality of life [4] but also lessens the overall life expectancy of patients compared to the general population [1].

According to the American College of Physicians (ACP) guidelines, weight loss is recommended for all OSA patients, along with Continuous Positive Airway Pressure therapy (CPAP) being declared the standard first-line treatment [5]. Other treatment options include positional therapy (encouraging side sleeping), mandibular advancement devices, and surgery. Surgical options with a success rate varying from 35% to 86% have both conventional surgical procedures as well as bariatric surgery [4]

Hypoglossal nerve stimulation (HGNS) is the latest novel therapy option available for treating OSA, having a success rate of 75% at five years [4]. HGNS involves stimulation of the genioglossus muscle with resultant tongue protrusion (Figure 1), relieving the obstruction during apneas. HGNS stimulation setup involves intraoperative neurophysiological monitoring (IONM) with Electromyography (EMG) monitoring for precise placement of the electrodes and better postoperative outcomes. HGNS effectively treats CPAP refractory OSA by having better compliance and enhancing subjective and objective sleep outcomes [6].

## MATERIAL AND METHODS

### Patient selection:

Patients must be diagnosed clinically with OSA. It is recommended to include patients aged 18 years or above with a BMI less than 32 kg/m2. It is indicated for patients having apnea Hypoxia Index (AHI) of 15-

65 events/hour with no more than 25% of central or mixed events. There should be no complete concentric palatal collapse and failure to use continuous positive airway pressure.

**Anesthesia Regiment:**

The recommended anesthesia regimen includes general anesthesia with no muscle relaxation. Short-acting muscle relaxants such as succinylcholine may be used for intubation. Maintenance dose may include IV propofol and fentanyl. Inhalational agents such as isoflurane, desflurane, or sevoflurane may be used with less than Minimum alveolar concentration (MAC) of 0.5MAC. The level of muscle relaxants should be monitored by a train of four (TOF) from hand or foot muscles.

**Surgical technique:**

The Hypoglossal nerve stimulation (HNS) device consists of a cuff that stimulates the nerve, a sensory lead that detects pressure, a battery, and a pulse generator placed infraclavicularly. A two or three-incision approach can be utilized based on the surgeon's experience and comfort - a two-incision approach is highlighted. Careful consideration should be given to appropriate sterilization techniques to avoid infectious complications. The first incision is placed submandibularly, a finger breadth below the mandibular border and anterior to the palpated submandibular gland, approximately 2-4cm long. The second incision marked out is the chest incision, which is typically 4cm long and lateral to the sternum, overlying the rib space of the anterior chest, approximately 3cm below the clavicle. Electrodes are then placed in the tongue, one in the hyoglossus muscle to test for tongue retraction and one in the genioglossus for protrusion. The submandibular incision should be taken down through the skin and platysma, after which the hyoid bone is palpated and located along with the digastric muscle tendon. Once the posterior belly of the digastric muscle is identified and retracted, the mylohyoid muscle can be identified and retracted, after which the hypoglossal nerve can be identified. Once the hypoglossal nerve is identified, a microscope should be brought into the field for further dissection. The nerve should then be further dissected by identifying the inclusion and exclusion branches, including genioglossus and geniohyoid branches, and exclusion branches have styloglossus and hyoglossus branches. The cuff of the HNS device is then placed around the inclusion branch and secured with anchoring sutures to the digastric tendon.

Attention is then turned to the chest incision to place the pulse generator and sensing lead (Figure 1). The incision is taken down through the skin to the fascia of the pectoralis major muscle. Here, a pocket should be created for the pulse generator, with care not to make it too large to avoid seroma formation or migration. The pectoralis major muscle fibers can then be gently separated in the direction of the fibers down to the external intercostal muscle fibers. The external and internal intercostal muscles should be identified with the placement of the sensor between these two muscles - great care should be taken not to violate the plane of the internal intercostals due to the risk of pleural injury. An anchoring suture is placed, and the sensor lead is placed into the pocket between the internal and external intercostals, securing the lead into the pocket. The pectoralis major should be reapproximated. A tunneler and introducer should connect the space of the two incisions, which is done underneath the platysma from the neck to the chest incision. The lead wire can then be passed through using this tunneler. The leads should then be placed into the pulse generator and tested to ensure tongue protrusion (Figure 2). The pulse generator should be placed and anchored into the pocket above the pectoralis muscle. When testing the device, careful consideration should be paid to lower levels of stimulation to ensure no retrusion branches are being activated.  Both incisions should be washed with antibiotic solution and saline for infection prevention. The two incisions are then closed upon completion of the procedure.

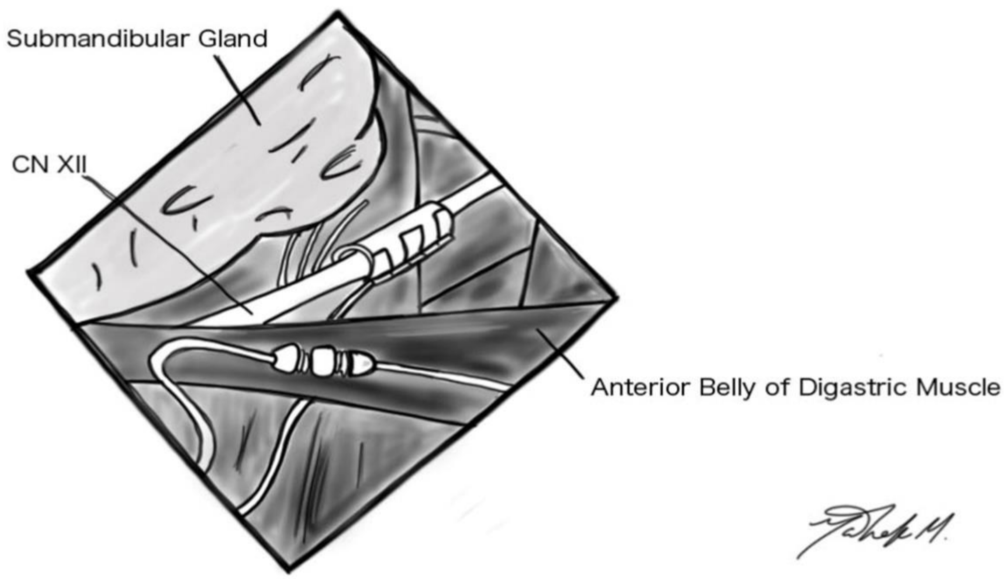


**Figure 1.** To provide airway opening during sleep, a hypoglossal nerve stimulation implant requires the placement of a stimulation lead. The lead is positioned in a schematic diagram with the cuff electrode placed on the medial branch of the hypoglossal nerve, also known as CN XII. (Medical illustration by Mahek Mumtaz).

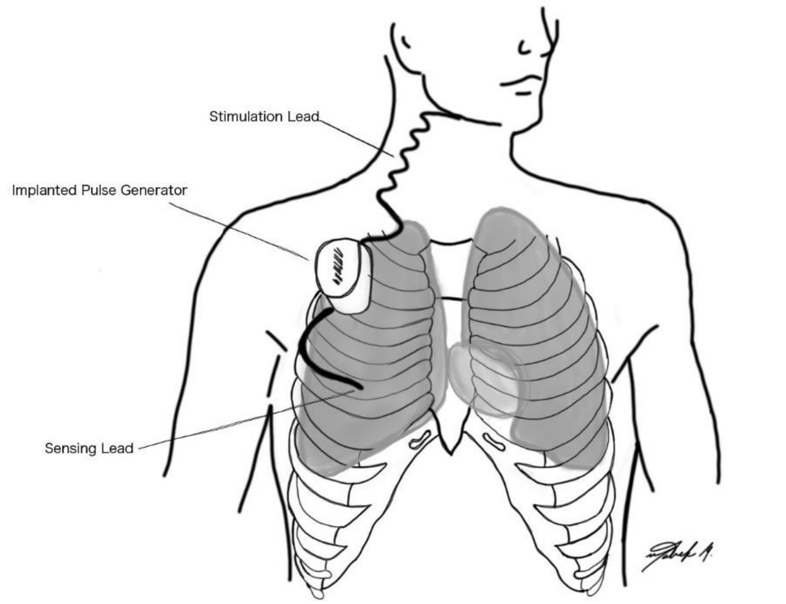


**Figure 2.** This figure shows a schematic diagram of an implant used to stimulate the hypoglossal nerve during sleep, which helps to keep the airway open. The system comprises an implantable pulse generator (IPG) and stimulation and sensing leads. The sensing lead detects the respiratory cycle and delivers stimulation through the stimulation lead to help keep the airway open. Medical illustration by Mahek Mumtaz).

**Electromyography (EMG):**

Electromyography (EMG) is performed to identify the cranial nerves supplying the target muscles and confirm the nerves' integrity. In this surgical procedure, Intraoperative Neurophysiological Monitoring (IONM) with spontaneous EMG (s-EMG) and trigger EMG (t-EMG) is used. This is done by placing subdermal needle electrodes in the muscles supplied by the nerves. The electrical activity is passively recorded via s-EMG without any stimulation electrode (Figure 3). Any nerve irritation can be detected by changing the s-EMG and informing the surgeons to take corrective steps to avoid any damage to the nerve.

Subdermal needle electrodes with a 90-degree angle are placed in the tongue muscles (genioglossus, hyoglossus, styloglossus) for hypoglossal nerve monitoring. These electrodes are taped to one side of the mouth to avoid interference during surgery. The EMG recordings are performed at 10 Hz for a low-cut filter, 5000 Hz for the high-cut filter, a sweep of 300 msec/division, 200 microvolts/division input gain, and 100-200 microvolts/division sensitivity. The t-EMG stimulation is performed with a hand-held probe. The stimulation parameters include a monophasic rectangular pulse, with a pulse of 100 microseconds (0.1 msec), a repetition rate of 1.79-2.91 Hz, an intensity of 0.05-2.0 mA, and a sweep on 2 msec/division.

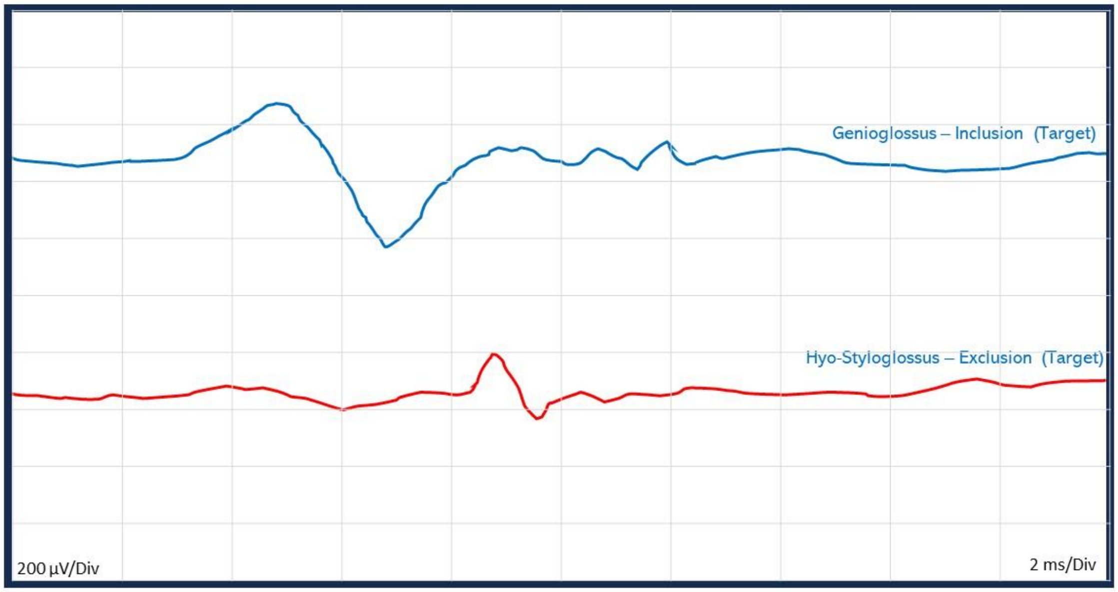


**Figure 3.** Good, triggered EMG responses were recorded from genioglossus muscles (inclusion criteria). Responses are absent in hyoglossus/styloglossus muscles (exclusion criteria).

## DISCUSSION

The prevalence of OSA is very high in the general population. It occurs due to obstruction of the airway tract during sleep. This harms the quality of life and increases the risk for other comorbidities. Various treatment modalities are available, but CPAP is preferred to treat OSA [7]. The available surgical treatment options include conventional surgeries like septoplasty, nasal polypectomy, adenoidectomy, tonsillectomy, uvulopalatopharyngoplasty, valvuloplasty, glossectomy, tongue base reduction, mandibular advancement, tracheostomy [4] and more advanced techniques like Hypoglossal nerve stimulation are also being employed with promising results.

According to Qaseem et al., a review of 10 studies on the effect of CPAP on quality of life indicated no significant improvement in most cases. Cognitive and psychological testing also revealed similar results. It also showed no difference in the incidence of cardiovascular events over 24 months (0% compared to 4.3%, P= 0.0161) and hypertension in OSA patients using CPAP instead of control groups. There was, however, a substantial improvement in the National Institute of Health (NIH) Stroke Scale scores (a score of 2.3 was achieved in the ten subjects with excellent CPAP adherence as opposed to 1.4 in 25 patients who were randomly assigned standard of care) and a decrease in the mortality rates with CPAP adherence. A common side effect of CPAP is dryness and irritation in the throat and nasal passages; however, models with builtin humidifiers prevent this from happening. The use of CPAP has also been reported to cause episodes of epistaxis, a distended abdomen, and chest discomfort [5].

Implantable hypoglossal nerve stimulation (HGNS) emerged as a novel therapy for treating moderate to severe OSA in patients who couldn't adhere to CPAP [8]. The benefit of HGNS, compared to other treatment options, is its ability to target multiple anatomical levels, hence resisting airway collapse simultaneously. Additionally, these devices have been shown to decrease the risk of dysphagia and throat pain [6]. Contraindications to the use of HGNS are central sleep apnea and sleep-related hypoxia or hypoventilation as associated with severe obstructive or restrictive pulmonary diseases [4]. The common adverse effects reported include tongue abrasion, pain, device malfunction [1], abnormal sensations, paresthesia, change in salivary flow, and lip weakness [6]. The use of HGNS has proved beneficial in trials conducted by several researchers. A study by Tiffany et al. included 68 patients who underwent HGNS surgery between 2015 and 2018. Treatment success was monitored by considering a postoperative AHI of less than 20 events per hour and a reduction of at least 50% of AHI. The success rate of HGNS was 79%, showing that most patients' OSA improved after undergoing HGNS [9].

Analysis of 39 patients carried out by Boorosan et al. also demonstrated that 79.5% of patients who underwent HGNS implantation showed improvement [10]. Another study conducted by Peter et al. included patients with moderate or severe OSA who failed to comply with previous CPAP treatments. A total of 21 participants were recruited for this study. Significant improvement was noted in patients who underwent HGNS implantation. The study concluded that HGNS had favorable efficacy compliance and results and can be used as a potential treatment for OSA [11].

## CONCLUSION

Studies have shown that using hypoglossal nerve stimulation (HGNS) is more effective in managing symptoms and improving long-term outcomes when compared to traditional methods like continuous positive airway pressure (CPAP) use. Therefore, we recommend using HGNS and intraoperative neurophysiological monitoring (IONM) to treat obstructive sleep apnea (OSA).

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