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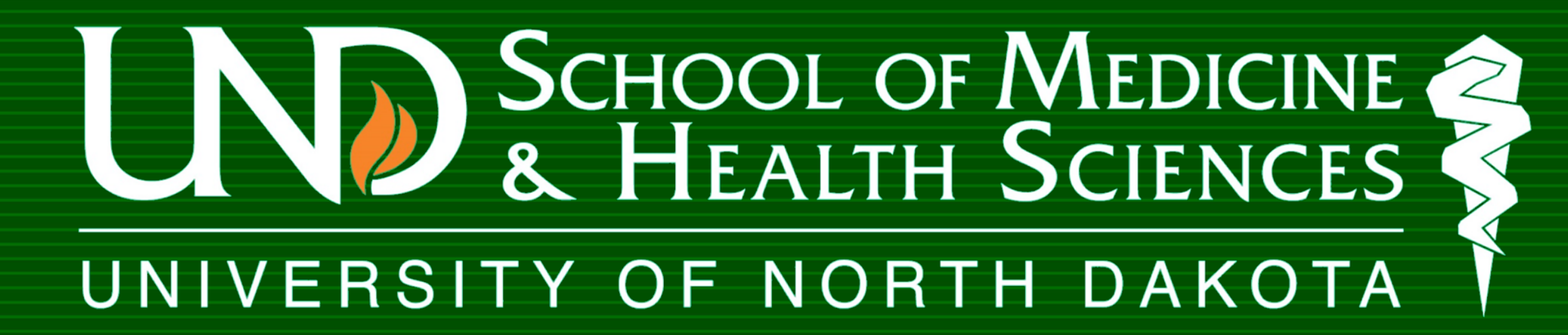
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Hypoglossal Nerve Stimulation Therapy in Obstructive Sleep Apnea

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Abstract

- Obstructive sleep apnea (OSA) is a disorder that results in loud snoring, gasping respirations, and excessive daytime sleepiness.
- OSA also has the potential to progress to other significant diseases such as hypertension, diabetes mellitus, stroke, and pulmonary hypertension.
- Continuous positive airway pressure (CPAP) has been the first line treatment for OSA since the early 1980's. Unfortunately, despite the ability of CPAP to significantly improve symptoms of OSA, a large amount of patients struggle to comply with this treatment.
- A new alternative treatment for OSA is hypoglossal nerve stimulation therapy (HGNS), resulting in an increase in muscle tone to the oropharynx, keeping the airway patent during inspiration.
- This review of the literature will examine the efficacy and compliance rates of CPAP, as well as the safety and efficacy of HGNS.
- Research found that there is in fact a need for an alternative therapy for OSA due to high CPAP noncompliance rates.
- The findings also indicate that despite favorable outcomes in clinical trials, more research is needed to determine the prolonged safety and efficacy of HGNS surgery.

Introduction

- OSA is a disorder that has a large variety of potential long term complications.
- OSA is often easily recognized with a thorough history and physical.
- Diagnosis and severity is made with polysomnography while measuring the apnea/hypopnea index (AHI).
- Several clinical studies are referenced which show the efficacy of CPAP versus current alternative treatments, as well as the efficacy and safety of hypoglossal nerve stimulation.

Statement of the Problem

- There is a significant need for a reliable alternative treatment for OSA when patients are intolerant of CPAP therapy and oral appliances.
- Papadakis & McPhee, 2014 explains that only about 75% of patients continue to use their CPAP device after the first year.

Research Questions

- How significant is noncompliance to CPAP treatment?
- In patients diagnosed with OSA who are intolerant of CPAP, is hypoglossal nerve stimulation therapy a safe and efficacious alternative treatment?

Literature Review

Epidemiology and Pathophysiology of OSA

- OSA is defined as the repetitive obstruction of the upper airway tissues during inspiration, resulting in an obstructed airway during sleep.
- Physical exam will most commonly show obesity, large neck circumference, sleepiness, and/or nasal-sounding speech.
- Lee et al. 2008 suggests up to 80% of moderate to severe OSA sufferers are thought to be undiagnosed.

CPAP and Alternative Treatments for OSA

- CPAP, which is the first line treatment for OSA, is a nasal or oral-nasal mask which pushes pressurized air upon inspiration.
- Notable alternative treatments currently used are oral mandibular devices and uvulopalatopharyngoplasty (UPPP).
- Common reasons for noncompliance of CPAP include claustrophobia, mask leaks and skin irritation.
- Doff et al. 2013 reports significant improvements in AHI with CPAP and oral appliance therapy (as shown in Figure 1).
- 27% of the 103 participants in the Doff et al. study were lost to noncompliance or unsuccessful treatment with CPAP and oral appliances.

Hypoglossal Nerve Stimulation Therapy

- HGNS is a new procedure where a stimulating device, similar to a pacemaker, is implanted in the chest and connected to the hypoglossal nerve, thus stimulating the genioglossus muscle (shown in Figure 2).
- Two single-arm, open-label studies evaluated patients with moderate to severe OSA who underwent HGNS surgery; compliance (hours used per night), safety (adverse events), AHI, and several subjective symptoms were assessed.
- Eastwood et al. studied 21 participants who underwent HGNS implantation; of the 19 who completed the study, improvement was made as AHI was reduced from 43.1 ± 17.5 to 19.5 ± 16.7 .
- Similarly, a study from Mwenge, Rombaux, Dury, Lengele, & Rodenstein followed 13 participants following successful HGNS implantation; AHI improved from 45.2 ± 17.8 to 21.0 ± 16.5 .
- Notable adverse events for the two studies include one patient with hematoma and infection, two patients with ipsilateral hemi-tongue paresis with full recovery, and one patient with post-operative swelling.
- Defective equipment were noted between the two studies including broken leads and a failed pulse generator.

Discussion

- Obesity is the largest contributing factor in the development of OSA. It is broadly understood that the best management is prevention through healthy diet and regular exercise.
- CPAP is found to be very effective in patients who are able to tolerate the many disabling side effects.
- In order to increase the compliance rates of CPAP, patients need accessibility and education regarding the use and management of CPAP.
- As for all other diseases, a safe and efficacious alternative treatment is necessary for those who do not comply with CPAP.
- As Figure 3 illustrates, HGNS appears to be capable of creating a more patent airway compared to no treatment.
- HGNS therapy showed success in subjective and objective testing in both studies referenced.
- However, more clinical research is necessary to guarantee the efficacy, safety, and reliability of the product being used.

Figures

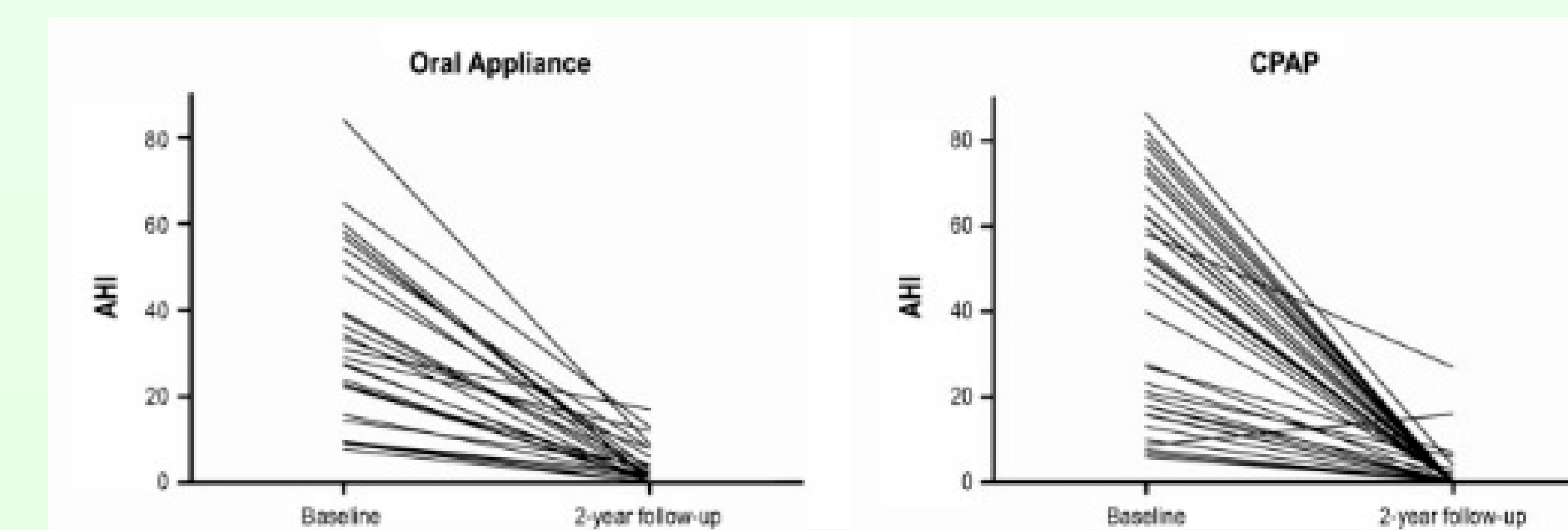


Figure 1. 2013 Associated Professional Sleep Societies, LLC.

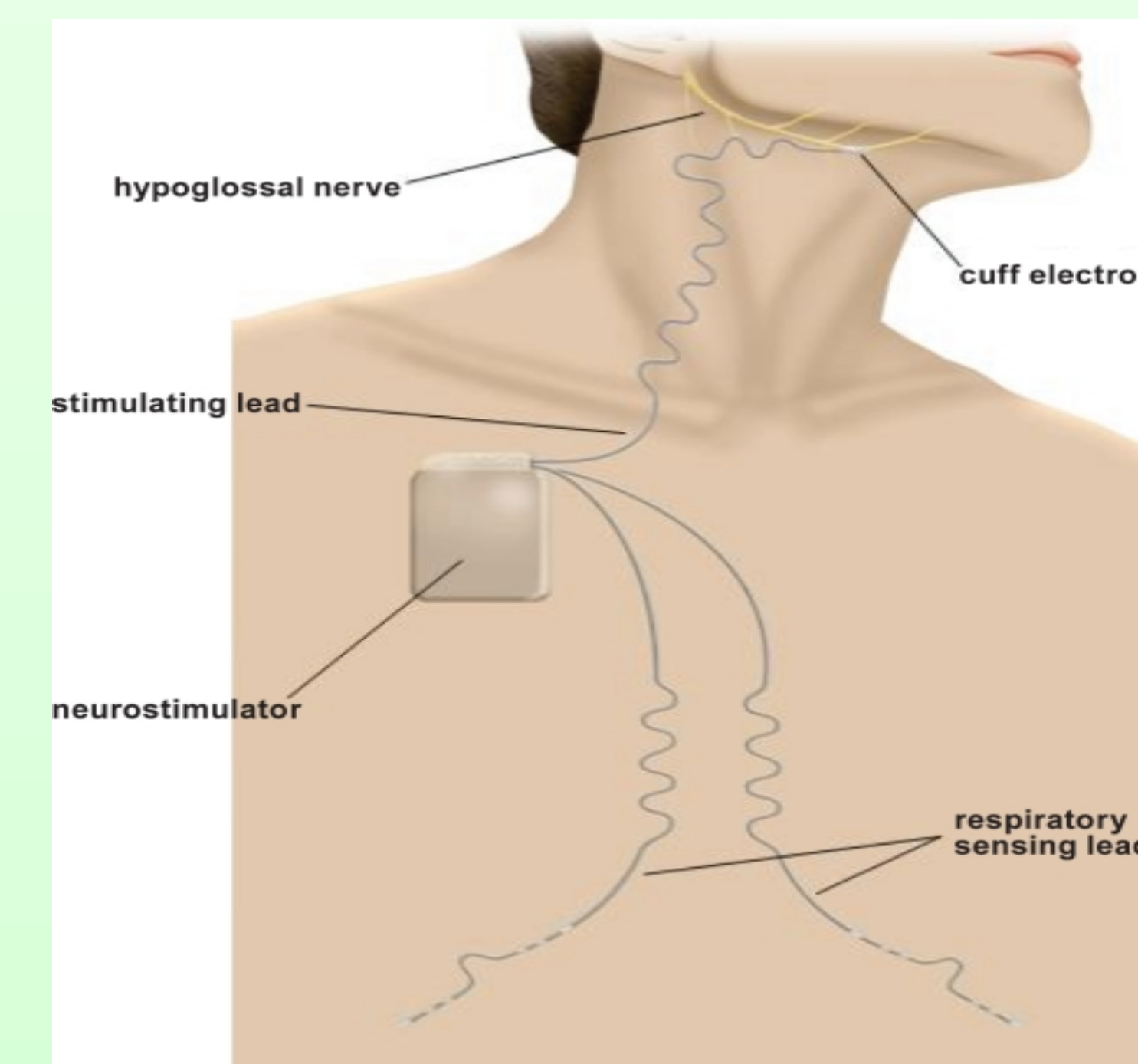


Figure 2. Eastwood et al., 2011

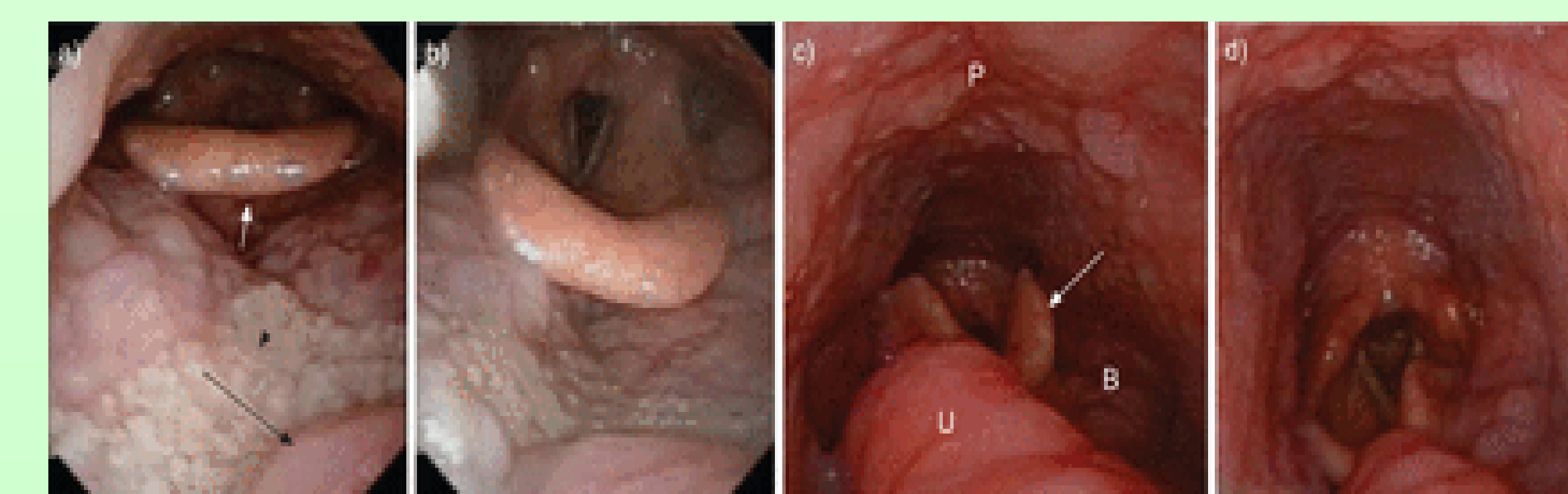


Figure 3. Mwenge, Rombaux, Dury, Lengele, & Rodenstein, 2013

Applicability to Clinical Practice

- Obstructive sleep apnea is a disease that is rapidly increasing in incidence, yet is relatively unknown to the general public.
- Providers need to be screening and catching this “not-so-silent killer” before it manifests into other significant comorbidities or a fatal accident.
- CPAP alternatives, such as oral mandibular devices and UPPP, often create their own significant side effects and are usually less effective.
- Instead of cycling between these treatments, extensive education is necessary for the compliance of CPAP. This includes finding an appropriately fitting mask and appropriate pressure settings.
- Despite favorable outcomes in the clinical studies for HGNS therapy, it is considered an extremely invasive alternative treatment.
- HGNS is in the very early stages to the road toward being a feasible alternative to CPAP, as there are very few physicians trained in the procedure or equipment.
- Considering the lack of research for HGNS, providers should be exhausting all efforts into assuring patients are adequately educated about the benefits of CPAP, including ways to overcome its many side effects.**

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