

Hypoglossal Nerve Stimulation in Obstructive Sleep Apnea: A Systematic Review

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Objectives

This study is aimed to investigate the efficacy (including Patient Reported Outcomes (PROs)) and safety of Hypoglossal Nerve Stimulation (HGNS) as reported in the literature to assess its significance for the treatment of Obstructive sleep apnea (OSA) across different stimulation technologies.

Background

Obstructive sleep apnea, as the most common form of sleep-disordered breathing, is a major burden on the individual and society. Severely affected patients in particular suffer from excessive daytime sleepiness, reduced quality of life and various comorbidities (e.g. cardiovascular diseases)^{1,2} resulting in significant direct and indirect costs to healthcare and society³.

- > Continuous positive airway pressure (CPAP) therapy is the gold standard but is limited in its effectiveness due to low acceptance and adherence.
- > Hypoglossal Nerve Stimulation therapy is a neurostimulation treatment for OSA that involves various technologies and is used as 2nd line therapy after CPAP failure.

Conclusion

- > Comprehensive systematic review of 33 publications consistently confirms HGNS as an effective and safe treatment alternative for OSA after unsuccessful CPAP therapy (including 2 RCTs and Real-World Data).
- > High adherence underscores the importance of HGNS versus CPAP.
- > Different HGNS technologies with comparable effects on PROs offer the opportunity to optimize therapy in individual cases.
- > Further effects (medical and health economic) of HGNS should be evaluated by using RWD with long term follow up.

Methods

- > Systematic literature research using PICOS and PRISMA in the Medline (PubMed) and Cochrane Library databases on HGNS in OSA treatment.
- > Systematic evaluation of essential outcome parameters: **daytime sleepiness**, **quality of life** (QoL), **adherence**, apnea-hypopnea index (**AHI**), oxygen desaturation index (**ODI**) and **safety**.

Results

	Daytime sleepiness	QoL	Adherence	AHI	ODI	Safety
Number of publications reporting	29	21	20	30	23	26
Result under HGNS treatment	<ul style="list-style-type: none">> RCTs: significant difference vs. control> Epworth Sleepiness Scale (ESS) scores within the normal range in all studies	<ul style="list-style-type: none">> RCTs: significant difference vs. control> Consistently increasing with the duration of HGNS, up to the normal range	<ul style="list-style-type: none">> At least above CPAP minimum usage threshold (e.g., double of weekly use threshold after 36 months, daily use in 80% after 60 months)	<ul style="list-style-type: none">> RCTs: significant difference vs. control> Consistent improvement compared to baseline in all studies	<ul style="list-style-type: none">> RCTs: significant difference vs. control> Consistent improvement compared to baseline in all studies	<ul style="list-style-type: none">> Mostly temporary, non-serious (e.g. simulation-related) adverse events (AEs)> Serious AEs typically resolved by device repositioning, exchange, or removal

- > Inclusion of 33 publications from 818 hits from the years 2011 – 2021, including 2 randomized controlled trials (RCTs) level Ib, 1 comparative cohort study level IIb, and 30 non-comparative studies level IV.

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