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Hypoglossal nerve stimulation (HGNS) for obstructive sleep apnea (OSA) A systematic review and meta-analysis of patient-reported outcomes (PROMs)

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OBJECTIVE

Patient-reported outcome and patient-reported experience (PROM, PREM) measures have become increasingly important in the health sciences over the past decade, particularly in the development and evaluation of new medical technologies during market introduction. Hypoglossal nerve stimulation (HGNS) emerged as an alternative treatment for patients with obstructive sleep apnea (OSA) a decade ago, and numerous studies have demonstrated substantial improvements in disease severity and improving quality of life (QoL). The objective of this review was to evaluate PROM and PREM with HGNS therapy in a systematic review and meta-analysis.[1]

METHODS

MEDLINE, Cochrane, and Web of Science were systematically searched to identify randomized controlled and observational studies reporting outcomes relevant to HGNS therapy in patients with OSA. Of 406 articles screened, 55 publications were assessed for eligibility and risk of bias using the ROBINS-I tool. Meta-analysis using a fixed-effects model was performed when > 2 studies with data on a specific outcome were available [Fig. 1][1].

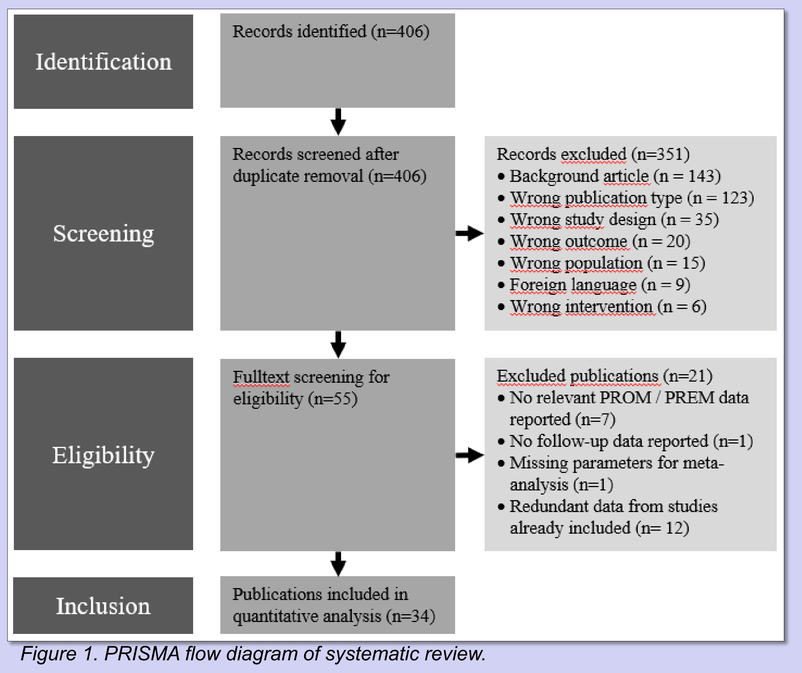

Figure 1. PRISMA flow diagram of systematic review.

PROM instruments used in included research articles

Instrument	Outcome domain	Scale	Direction	Minimal important difference (MID)
Epworth Sleepiness Scale (ESS)	Assessment of daytime sleepiness in OSA	0-24	↑	2.0 points
Functional Outcomes of Sleep Questionnaires (FOSQ)	Impairment of daytime activities due to sleepiness or fatigue	5-20	↓	1.8 points
Fatigue Severity Scale (FSS)	Impact of fatigue	1-7	↑	0.45 points
Pittsburgh Sleep Quality Index (PSQI)	Sleep quality and sleep disturbances	0-21	↑	4.4 points
Calgary Sleep Apnea Quality of Life Index (SAQLI)	Impairment of different functions due to sleep apnea	0-5	↓	1.0 points
Insomnia Severity Index (ISI)	Assessment of severity and impact of insomnia	0-28	↑	6.0 points
Patient Health Questionnaire (PHQ-9)	Quantify depression symptoms and monitor severity	0-27	↑	5.0 points

Tab 1. PROM instruments. ↑ = Higher scores indicating larger negative effects; ↓ = Lower scores indicating smaller negative effects

RESULTS

Seven different PROM instruments [Tab. 1] were identified from the included studies (n = 34). All studies used the Epworth Sleepiness Scale (ESS) [Fig.2] as a measure of daytime sleepiness in OSA patients, seven reported changes in daytime functioning as measured by the Functional Outcomes of Sleep Questionnaire (FOSQ) [Fig. 3]. The Calgary Sleep Apnea Quality of Life Index (SAQLI) was used in three studies [Fig. 4] and the Pittsburgh Sleep Quality Index (PSQI) in two studies [Fig. 5]. The Insomnia Severity Index (ISI), the Fatigue Severity Scale (FSS), and the Patient Health Questionnaire (PHQ-9) were identified too but could not be included in this analysis because only one study per PROM was documented.

Thirty-four studies with a total of 3,785 patients and a mean follow-up of 11.8 ± 12.2 months were identified and included in the meta-analysis. The fixed effects model showed a pooled effect size of 4.59 points improvement in daytime sleepiness as measured by the ESS questionnaire (Z= 42.82, p < .001), 2.84 points improvement in daytime functioning as measured by the FOSQ score (Z= 28.38, p < .001), and 1.77 points improvement in sleep quality as measured by the PSQI questionnaire (Z= 2.53, p = .010). PROMs were positive in all identified studies, adding relevant information about care processes and perceptions of therapy.[1]

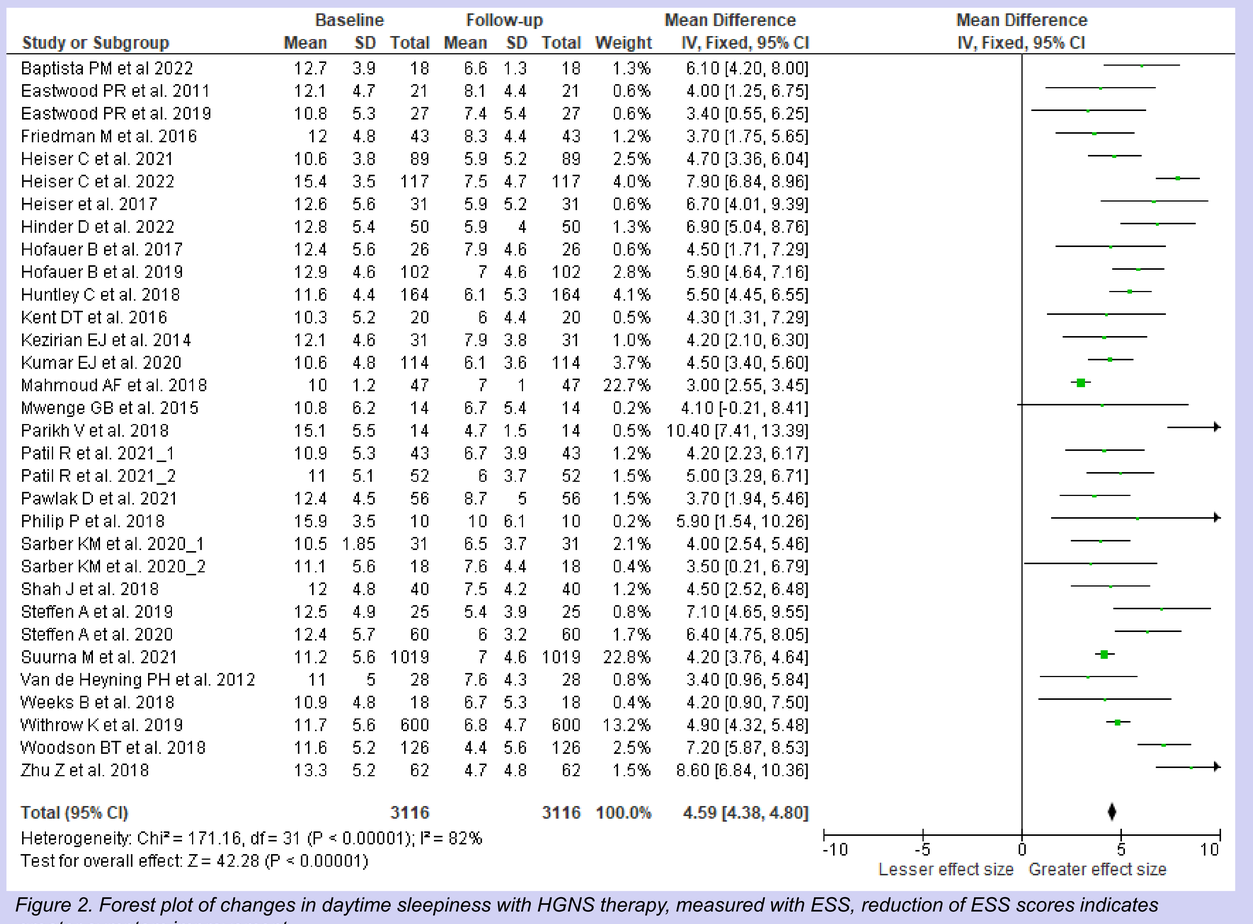

Figure 2. Forest plot of changes in daytime sleepiness with HGNS therapy, measured with ESS, reduction of ESS scores indicates greater symptom improvement

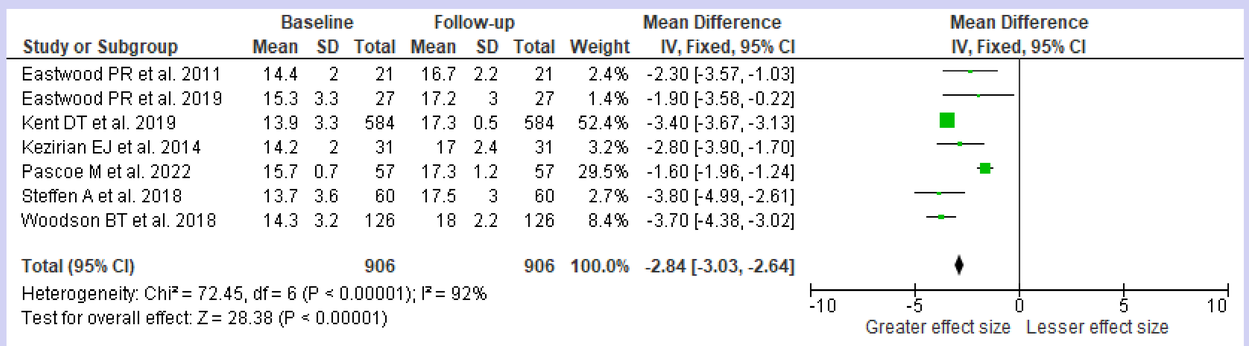

Figure 3. Forest plot on effects of HGNS therapy on daytime functioning, measured with FOSQ, increase of FOSQ scores indicates greater symptom improvement

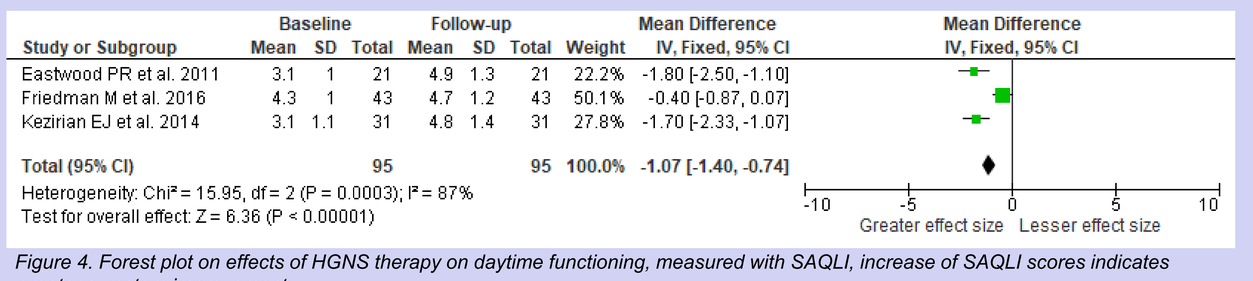

Figure 4. Forest plot on effects of HGNS therapy on daytime functioning, measured with SAQLI, increase of SAQLI scores indicates greater symptom improvement

Limitations

This study was not pre-registered in the PROSPERO database of the National Institute for Health and Care Research. Most articles reported data on breath-synchronized HGNS therapy, including the two RCTs representing the Inspire-Therapy, whereas only four continuous stimulation trials could be identified, which may have biased the results.[1]

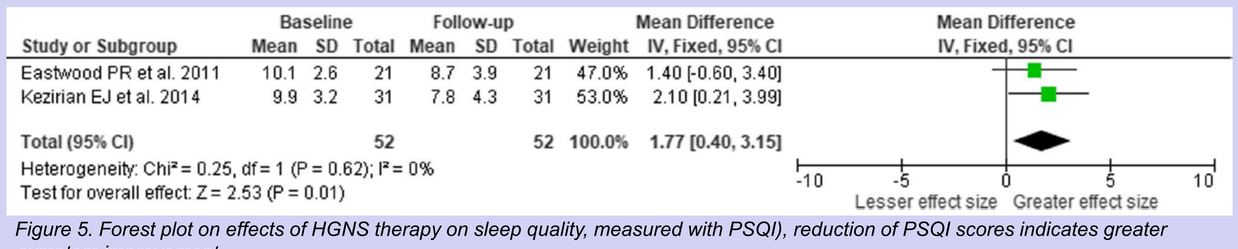

Figure 5. Forest plot on effects of HGNS therapy on sleep quality, measured with PSQI), reduction of PSQI scores indicates greater symptom improvement

CONCLUSIONS

The effects of HGNS therapy result in significant and sustained improvements in health-related quality of life in patients with OSA and reliably produce clinically meaningful changes in daytime sleepiness, daytime functioning, and sleep quality. The therapy consistently meets or exceeds the minimum clinically important differences defined for the respective instruments. HGNS therapy is well accepted by patients and results in significant and clinically meaningful improvements in self-reported QoL. Further research is warranted to examine subjective outcomes beyond improvements in daytime sleepiness and daytime functioning.

References

[1] Braun, M. et al. Patient-reported outcomes with hypoglossal nerve stimulation for treatment of obstructive sleep apnea: a systematic review and meta-analysis. Eur Arch Otorhinolaryngol 280, 4627–4639 (2023).

Access to full text & supplementary materials

Disclosures

M.W. received fees from SI-BONE (United States) a company unrelated to the research topic of this study and personal fees from Inspire Medical Systems (United States). C.H. was a consultant for Inspire Medical Systems (United States), received personal fees from Neuwirth Medical Products (Germany), and research grants from Sutter Medizintechnik (Germany), Löwenstein Medical (Germany), Nyxoah (Belgium) and Inspire Medical Systems (United States). C.S. received personal fees from ResMed (Australia). J.S. received personal fees from Inspire Medical Systems (United States) and from Neuwirth Medical Products (Germany), research grants from Sutter Medizintechnik (Germany), Löwenstein Medical (Germany), Nyxoah (Belgium) and Inspire Medical Systems (United States). M.B. is an employee of Onera Health (The Netherlands), a company unrelated to the research topic of this study.