OXFORD Sleep Research Society®

SLEEP, 2024, **47**, 1–2
https://doi.org/10.1093/sleep/zsad290
Advance access publication 8 November 2023
Editorial

Editorial

The need for coordinating efforts to improve the global evidence of the long-term effectiveness of adult obstructive sleep apnea surgical therapies

Olivier M. Vanderveken[1,2,*,] and Frédéric Gagnadoux[3,4]

[1]Department of Otorhinolaryngology, Head and Neck Surgery, Antwerp University Hospital, Edegem, Belgium,
[2]Department of Otorhinolaryngology, Head and Neck Surgery, Translational Neurosciences, Faculty of Medicine and Health Sciences, University of Antwerp, Antwerp, Belgium,
[3]Department of Respiratory and Sleep Medicine, Angers University hospital, Angers, France and
[4]INSERM, CNRS, MITOVASC, Equipe CarME, SFR ICAT, University of Angers, Angers, France

[*]Corresponding author. Olivier M. Vanderveken, Full Professor and Chair, ENT-HNS Department, Antwerp University Hospital, Drie Eikenstraat 655, 2650 Edegem, Belgium. Email: olivier.vanderveken@uza.be.

Positive airway pressure (PAP) is usually considered as the standard first-line treatment of obstructive sleep apnea (OSA) [1]. However, adherence is a major issue with long-term PAP therapy. In a recent French Nationwide Database Analysis, almost 50% of patients who were prescribed PAP for OSA had discontinued the therapy at 3 years, the PAP termination rate being particularly high in female and younger patients [2]. Furthermore, only a minority of patients who discontinued PAP were referred to an alternative OSA therapy. So, although there is now an extensive list of non-PAP therapies, there remains an unmet need for more effective and personalized treatment options of OSA [3].

The most used non-PAP option is mandibular advancement device (MAD) treatment and from the available evidence it can be suggested that upper airway surgery, bariatric surgery, positional therapy, maxillomandibular advancement, and hypoglossal nerve stimulation (HGNS) can be effective in well-selected patient groups and should be prescribed, whether as single or multimodal therapy, more readily in clinical practice [3–7]. Although PAP is superior in reducing the apnea–hypopnea index (AHI), the findings of subjective and objective health outcomes are not in favor of PAP with improvements generally equivalent under non-PAP therapies including MAD or HGNS [8, 9].

In this issue of the Journal *SLEEP*, Pinczel et al. report the long-term results of the sleep apnea multi-level surgery (SAMS) trial investigating the maintenance of the multi-level surgery (MLS) effect in adults with moderate or severe OSA in whom PAP therapy failed [10]. The protocol of the SAMS trial has been described in detail as a randomized clinical trial including 102 patients with symptomatic moderate or severe OSA with PAP failure or refusal [11]. Eligible participants were randomly assigned to MLS consisting of modified uvulopalatopharyngoplasty and minimally invasive tongue volume reduction via radiofrequency ablation, or to continue with medical management including further trial of PAP, or initiation of MAD, weight loss, positional therapy, or other nonsurgical strategies [11]. In their 6-month follow-up report of the SAMS study, the authors already reported that the MLS group showed sustained decreases in AHI, self-reported daytime sleepiness, and other secondary measures of OSA impacts, with rare serious surgery-related morbidity compared to the best ongoing medical management in the control group [12].

To further improve knowledge regarding long-term outcomes of MLS for OSA, the authors were able to organize follow-up of both cohorts up to 2 years after inclusion in the randomized clinical trial [10]. In patients who underwent polysomnography (PSG) 2 years after MLS, mean ESS decreased from 12.3 +/– 3.5 at baseline to 5.5 +/– 3.9 while the average AHI decreased from 41.2 +/– 22.7 per hour to 21.4 +/– 18.2 [10]. The 24.2 events per hour decrease in AHI 2 years after MLS corresponds to a per protocol mean disease alleviation of 59% [10, 13] which is slightly superior to that previously reported with PAP and MAD (around 50%) at 1-year follow-up [14, 15], and quite similar to that observed in the 1-year and 5-year follow-up studies of the Stimulation Therapy for Apnea Reduction trial in sustained users of HGNS therapy [7, 16].

The authors are to be congratulated on their important contribution to the field, the rigor with which they have carried out the study protocol and the way they achieved the 2-year follow-up. The results highlight the role of MLS as an effective treatment option for OSA when patients have a history of nonadherence to PAP therapy. Long-term follow-up data following surgical therapy for OSA are needed to provide sufficient basis for management recommendations [3, 10, 16]. Non-PAP therapies should learn from the PAP field as most reported studies of outcome with non-PAP approaches have been marked with relatively low power in terms of number of included patients in the trials [6, 7, 10–13,

15, 16]. Current innovation in OSA monitoring on a nightly basis represent promising methods to provide evidence of the long-term effectiveness of OSA surgical therapeutic options considering adherence and the effect of the therapy on the OSA-related comorbidities and mortality [17–19].

For sure, the field of OSA treatment in adults needs to evolve from a "PAP treatment fits all" to a more individualized approach [3, 20]. The key question should be on the right OSA treatment for a specific patient with an individualized and evidence-based upfront selection upon diagnosis, moving away from "trial and error" and "one size fits all" approaches.

The SAMS trial and its presented 2-year follow-up study (published in this issue of *SLEEP*) provide encouraging results on the effectiveness of MLS [10, 11]. The field seeks more evidence regarding long-term impact of OSA surgery and, by extension, more big data analyses are needed in all the OSA therapeutic options including facts on adherence to the therapy and the correlation between therapeutic effectiveness and the impact on OSA-related morbidities.

Disclosures Statement

Financial Disclosures: O.M.V. reports research support at Antwerp University Hospital from Cochlear, Med-El, Inspire Medical Systems, Nyxoah, Philips, ProSomnus, SomnoMed, at the Antwerp University Hospital and consultancy for GSK, Inspire Medical Systems and SomnoMed. O.M.V. holds a Senior Clinical Investigator Fellowship from the Research Foundation Flanders (FWO: 1833517N). F.G. reports personal fees from AIR LIQUIDE SANTE, ASTEN SANTE, INSPIRE, BIOPROJET, RESMED, SEFAM, outside the submitted work; payment or presentations from PHILIPS RESPIRONICS, JAZZ PHARMACEUTICAL, BIOPROJET, CIDELEC, RESMED. *Nonfinancial Disclosures:* support from ASTEN SANTE, outside the submitted work.

References

1. Sullivan CE, Issa FG, Berthon-Jones M, Eves L. Reversal of obstructive sleep apnoea by continuous positive airway pressure applied through the nares. *Lancet*. 1981;**1**(8225):862–865. doi: 10.1016/s0140-6736(81)92140-1
2. Pépin JL, Bailly S, Rinder P, Adler D, Szeftel D, Malhotra A, Cistulli PA, Benjafield A, Lavergne F, Josseran A, Tamisier R, Hornus P; On Behalf Of The medXcloud Group. CPAP therapy termination rates by OSA phenotype: A French Nationwide Database Analysis. *J Clin Med*. 2021;**10**(5):936. doi: 10.3390/jcm10050936
3. Verbraecken J, Dieltjens M, Op de Beeck S, *et al*. Non-CPAP therapy for obstructive sleep apnoea. *Breathe (Sheff)*. 2022;**18**(3):220164. doi: 10.1183/20734735.0164-2022
4. Chang JL, Goldberg AN, Alt JA, *et al*. International consensus statement on obstructive sleep apnea. *Int Forum Allergy Rhinol*. 2023;**13**(7):1061–1482. doi: 10.1002/alr.23079
5. Johal A, Hamoda MM, Almeida FR, Marklund M, Tallamraju H. The role of oral appliance therapy in obstructive sleep apnoea. *Eur Respir Rev*. 2023;**32**(168):220257. doi: 10.1183/16000617.0257-2022
6. Beyers J, Vanderveken OM, Kastoer C, *et al*. Treatment of sleep-disordered breathing with positional therapy: Long-term results. *Sleep Breath*. 2019;**23**(4):1141–1149. doi: 10.1007/s11325-019-01792-9
7. Strollo PJ, Jr, Soose RJ, Maurer JT, *et al*.; STAR Trial Group. Upper-airway stimulation for obstructive sleep apnea. *N Engl J Med*. 2014;**370**(2):139–149. doi: 10.1056/NEJMoa1308659
8. Sharples LD, Clutterbuck-James AL, Glover MJ, *et al*. Meta-analysis of randomised controlled trials of oral mandibular advancement devices and continuous positive airway pressure for obstructive sleep apnoea-hypopnoea. *Sleep Med Rev*. 2016;**27**:108–124. doi: 10.1016/j.smrv.2015.05.003
9. Pascoe M, Wang L, Aylor J, *et al*. Association of hypoglossal nerve stimulation with improvements in long-term, patient-reported outcomes and comparison with positive airway pressure for patients with obstructive sleep apnea. *JAMA Otolaryngol Head Neck Surg*. 2022;**148**(1):61–69. doi: 10.1001/jamaoto.2021.2245
10. Pinczel AJ, Woods CM, Catcheside PG, *et al*. Sleep Apnea Multilevel Surgery (SAMS) Trial: Long-term observational outcomes. *Sleep*. 2024;**47**(1):zsad218. . doi: 10.1093/sleep/zsad218
11. Carney AS, Antic NA, Catcheside PG, *et al*. Sleep Apnea Multilevel Surgery (SAMS) trial protocol: A multicenter randomized clinical trial of upper airway surgery for patients with obstructive sleep apnea who have failed continuous positive airway pressure. *Sleep*. 2019;**42**(6). doi: 10.1093/sleep/zsz056
12. MacKay S, Carney AS, Catcheside PG, *et al*. Effect of multilevel upper airway surgery vs medical management on the Apnea-Hypopnea Index and patient-reported daytime sleepiness among patients with moderate or severe obstructive sleep apnea: The SAMS randomized clinical trial. *JAMA*. 2020;**324**(12):1168–1179. doi: 10.1001/jama.2020.14265
13. Vanderveken OM, Dieltjens M, Wouters K, De Backer WA, Van de Heyning PH, Braem MJ. Objective measurement of compliance during oral appliance therapy for sleep-disordered breathing. *Thorax*. 2013;**68**(1):91–96. doi: 10.1136/thoraxjnl-2012-201900
14. Grote L, Hedner J, Grunstein R, Kraiczi H. Therapy with nCPAP: Incomplete elimination of Sleep Related Breathing Disorder. *Eur Respir J*. 2000;**16**(5):921–927. doi: 10.1183/09031936.00.16592100
15. Dieltjens M, Braem MJ, Vroegop AVMT, *et al*. Objectively measured vs self-reported compliance during oral appliance therapy for sleep-disordered breathing. *Chest*. 2013 Nov;**144**(5):1495–1502. doi: 10.1378/chest.13-0613
16. Woodson BT, Strohl KP, Soose RJ, *et al*. Upper airway stimulation for obstructive sleep apnea: 5-year outcomes. *Otolaryngol Head Neck Surg*. 2018;**159**(1):194–202. doi:10.1177/0194599818762383
17. Lechat B, Naik G, Reynolds A, *et al*. Multinight prevalence, variability, and diagnostic misclassification of obstructive sleep apnea. *Am J Respir Crit Care Med*. 2022;**205**(5):563–569. doi: 10.1164/rccm.202107-1761OC
18. Scott H, Lechat B, Guyett A, *et al*. Sleep irregularity is associated with hypertension: findings from over 2 million nights with a large global population sample. *Hypertension*. 2023;**80**(5):1117–1126. doi: 10.1161/HYPERTENSIONAHA.122.20513
19. Bailly S, Trzepizur W, Gagnadoux F. Cardiovascular protection in sleep apnea: Is it a question of CPAP adherence? *Arch Bronconeumol*. 2023;**59**(5):277–279. doi: 10.1016/j.arbres.2022.11.001
20. Vanderveken OM, Gagnadoux F. Comparative outcomes in obstructive sleep apnea therapy: Mean Disease Alleviation as a more appropriate measure - it's about time. *Sleep*. 2023;**46**(10). doi: 10.1093/sleep/zsad210