The Many Faces of Equal Effectiveness When Comparing CPAP and MAD Therapy for OSA

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In 1965, Gastaut et al. provided the first comprehensive account of obstructive sleep apnea syndrome (OSAS), describing polysomnography in obese hypersomnolent patients with frequent nocturnal apneas.¹ In 1978, Remmers et al. reported on a nocturnal cyclic ventilatory pattern that consisted of a series of regular inspiratory efforts against an occluded airway alternating with a period of regular breathing with the pharynx, and not the larynx, being the site of upper airway occlusion during sleep.² The main pathophysiological feature of OSAS is indeed obstruction in the collapsible segment of the pharynx during sleep leading to nocturnal hypoxemia and sleep fragmentation.3 OSAS is associated with cardiovascular co-morbidities, and overall increased cardiovascular mortality, as well as metabolic dysfunction.⁴ The prevalence of this chronic disease is remarkably high with prevalence of moderate-to-severe OSAS reported to be as high than 23% in women and 50% in men, respectively.⁵ It remains to be established whether treating OSAS can fully reverse its chronic consequences.⁴

Apart from tracheostomy, that has the potential to bypass the collapsible segment but is highly invasive, continuous positive airway pressure (CPAP), first described in 1981 by Sullivan, is regarded as the standard treatment for OSAS.^{6,7} The adherence to CPAP, however, is highly variable and relatively low, with reported CPAP termination rates ranging from 12.4% at 3 months to 47.7% at 3 years, respectively.^{8,9} When combining the results of the Sleep Apnea Cardiovascular Endpoints (SAVE) study and the 47.7% termination rate in the French nationwide CPAP database, it could be speculated that the true long-term clinical effectiveness of CPAP is only 20%.⁹⁻¹¹

The first-line non-surgical alternative for CPAP is treatment of OSAS with custom-made, titratable mandibular advancement devices (MAD). 12-14 There is strong evidence demonstrating MAD treatment improves OSAS in most subjects, including patients with more severe disease, while generally being well tolerated. 12 Phillips *et al.* reported on the health outcomes of optimal MAD and CPAP treatment in patients with moderate-to-severe OSAS being similar and suggested that these results could be explained by greater efficacy of CPAP being offset by inferior compliance relative to MAD, resulting in similar effectiveness. 15 Therefore, comparable

effectiveness of MAD and CPAP could be attributed to higher efficacy in terms of reducing apneic events with CPAP being counteracted by greater treatment adherence with MAD.¹²

The CHOICE study was a multicenter, double-randomized cross-over trial offering CPAP and MAD to all participants. At one month follow-up, the average adherence per night with MAS was significantly higher than with CPAP. Interestingly, in the observational phase of the trial, most participants utilized both CPAP and MAS interchangeably supporting the necessity for having access to both CPAP and MAD for improved long-term management of OSAS. Once again, the CHOICE study results illustrate that multimodality treatment can contribute to personalized medicine approach for OSAS, and that combination therapy should not be a taboo. 16,17

In a recent noninferiority trial 220 participants with moderate-to-severe OSAS were randomized to either MAD or CPAP with a primary outcome being the difference between the 24-hour mean arterial BP at baseline and 6 months. 18 Based on the results the authors concluded that MAD was noninferior to CPAP for reducing the primary outcome in OSAS patients with hypertension and increased cardiovascular risk. 18

The results of the prospective clinical trial called "the First Line Obstructive Sleep Apnea Treatment (FLOSAT)" evaluating the clinical effectiveness of MAD therapy as first-line treatment option compared to second-line CPAP therapy in the same patients' cohort suggest that MAD therapy demonstrates good efficacy and high adherence resulting in non-inferior effectiveness compared to CPAP. FLOSAT includes 94 patients with moderate-to-severe OSA that completed all study visits and underwent three months of MAD therapy followed by a two-weeks wash-out period and three months of CPAP therapy. Most of the patients preferred MAD. 19

In conclusion, we could argue that the comparison of effectiveness between CPAP and MAD for the treatment of OSAS has many dimensions and faces. In recent clinical trials, MAD therapy demonstrates good efficacy and high adherence resulting in non-inferior effectiveness compared to CPAP. In addition, OSAS therapy should be tailored to individual patient needs. The interchangeable use of therapies that led to a similar improvement and comparable

clinical effectiveness on patient-centered outcomes while increasing overall adherence to treatment is highly important for future approaches.

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