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EFFECTIVENESS OF MANDIBULAR ADVANCEMENT DEVICES IN THE MANAGEMENT OF MILD TO MODERATE OBSTRUCTIVE SLEEP APNEA: A PROSPECTIVE INTERVENTIONAL STUDY

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ABSTRACT

Background: Obstructive sleep apnea (OSA) is a common sleep-related breathing disorder characterized by recurrent upper airway collapse during sleep, leading to intermittent hypoxia, sleep fragmentation, and excessive daytime sleepiness. Continuous positive airway pressure (CPAP) is the standard treatment; however, poor tolerance and compliance have increased interest in alternative therapies such as mandibular advancement devices (MADs), particularly for patients with mild to moderate disease.

Aim: To evaluate the effectiveness of mandibular advancement devices in improving polysomnographic parameters and clinical symptoms in patients with mild to moderate obstructive sleep apnea.

Materials and Methods: This prospective interventional study included 40 adults diagnosed with mild to moderate OSA based on overnight polysomnography. All participants were treated with a custom-made adjustable mandibular advancement device and followed for three months. Baseline and post-treatment assessments included Apnea–Hypopnea Index (AHI), oxygen saturation parameters, Epworth Sleepiness Scale (ESS), total sleep time, and sleep efficiency. Pre- and post-intervention values were compared using paired statistical analysis.

Results: Following MAD therapy, there was a significant reduction in mean AHI from 18.6 ± 6.4to 10.9 ± 4.8 events/hour ($p < 0.001$). Significant improvements were also observed in oxygen desaturation index, minimum and mean oxygen saturation, ESS scores, total sleep time, and sleep efficiency ($p < 0.05$). Thirty percent of participants achieved normalizationof AHI. Good compliance was reported in 85% of patients, with only mild and transient adverse effects.

Conclusion: Mandibular advancement devices are an effective and well-tolerated treatment option for patients with mild to moderate obstructive sleep apnea, resulting in significant improvements in both objective sleep parameters and subjective symptoms.

KEYWORDS: Obstructive sleep apnea; Mandibular advancement device; Oral appliance therapy; Apnea–Hypopnea Index; Epworth Sleepiness Scale; Polysomnography

INTRODUCTION

Obstructive sleep apnea (OSA) is a chronic sleep-related breathing disorder characterized by recurrent episodes of partial or complete upper airway obstruction during sleep, resulting in intermittent hypoxemia, hypercapnia, and repeated arousals from sleep. These physiological disturbances lead to fragmented sleep architecture and excessive daytime sleepiness, significantly impairing quality of life and cognitive performance. OSA is also strongly associated with systemic complications including hypertension, coronary artery disease, stroke, metabolic syndrome, and increased all-cause mortality[1,2].

The pathophysiology of OSA is multifactorial and involves anatomical narrowing of the upper airway, reduced neuromuscular control during sleep, and unfavorable craniofacial morphology. Collapse most commonly occurs at the level of the oropharynx due to posterior displacement of the tongue and soft tissues during sleep. Therapeutic strategies for OSA are therefore aimed at maintaining upper airway patency throughout the sleep period [3].

Continuous positive airway pressure (CPAP) therapy has long been regarded as the gold standard treatment for OSA due to its ability to effectively eliminate apneic and hypopneic events. However, despite its physiological efficacy, long-term adherence to CPAP is often suboptimal because of discomfort, nasal symptoms, claustrophobia, and inconvenience, leading many patients to seek alternative treatment modalities[4] .

Mandibular advancement devices (MADs) are oral appliances designed to protrude the mandible forward during sleep, thereby enlarging the upper airway and reducing its
collapsibility. These devices have gained increasing acceptance as a non-invasive treatment option, particularly for patients with mild to moderate OSA and for those intolerant of CPAP therapy[5].

OSA represents a major global public health burden. Epidemiological studies estimate that approximately 9–38% of the adult

population worldwide is affected by OSA, with prevalence varying according to age, sex, body mass index, and diagnostic criteria used [6]. The disorder is more common in middle-aged and older adults and occurs more frequently in men than women, although the gender difference narrows after menopause [7].

In developing countries, including India, the prevalence of OSA has increased significantly over recent decades, paralleling rising rates of obesity, sedentary lifestyle, and metabolic disorders. Community-based studies in the Indian population have reported OSA prevalence ranging from 4% to 13%, with a substantial proportion of cases remaining undiagnosed[8] . Given the chronic nature of the disease and its long-term health consequences, early diagnosis and effective management of OSA are essential to reduce morbidity and healthcare burden.

Subsequent studies comparing MADs with CPAP have shown that although CPAP achieves greater reductions in AHI, overall clinical effectiveness may be comparable due to better adherence with MAD therapy [9]. Barnes et al. observed similar improvements in daytime sleepiness and quality of life between MAD and CPAP users, despite differences in objective respiratory outcomes[10].

Clinical practice guidelines from the American Academy of Sleep Medicine and other professional bodies now recommend oral appliance therapy as a first-line treatment for patients with mild to moderate OSA who prefer an alternative to CPAP or are unable to tolerate it[5] .

Despite the growing support for mandibular advancement devices (MADs) in treating obstructive sleep apnea (OSA), there is variability in patient treatment responses due to differences in individual characteristics, device design, and treatment protocols. The available data from prospective studies on the Indian population is limited, especially studies that utilize comprehensive polysomnographic evaluations before and after MAD therapy. With the rising incidence of OSA and issues surrounding CPAP adherence, it is crucial to explore alternative treatment methods that are both effective and acceptable in everyday clinical settings. This prospective interventional study focuses on assessing the efficacy of MADs for patients with mild to moderate OSA by objectively measuring changes in polysomnographic parameters, oxygen saturation levels, and subjective reports of daytime sleepiness. The goal is to provide region-specific insights that will aid in informed clinical decisions regarding the use of oral appliance therapy for managing OSA.

Aim:

To evaluate the effectiveness of mandibular advancement devices (MADs) in patients with mild to moderate obstructive sleep apnea.

Objectives

1. To assess the change in severity of obstructive sleep apnea, as measured by the Apnea–Hypopnea Index (AHI), before and after the use of mandibular advancement devices.
2. To evaluate the improvement in clinical symptoms and sleep-related parameters (such as daytime sleepiness using Epworth Sleepiness Scale and oxygen saturation parameters) following treatment with mandibular advancement devices.

METHODOLOGY

This was a prospective interventional (before-and-after) study conducted to evaluate the effectiveness of mandibular advancement devices (MADs) in patients with mild to moderate obstructive sleep apnea (OSA), carried out in the Department of ENT at a tertiary care teaching hospital.

The study was conducted over a period of 12–18 months, with 40 Patients aged 18–65 years with diagnosed cases of mild to moderate obstructive sleep apnea, confirmed by overnight polysomnography , and Patients willing to use mandibular advancement device and comply with follow-up were included in the Study. They were initiated with Consecutive sampling**.**

Patients with Severe OSA , Central sleep apnea , Edentulous patients or those with insufficient dentition to support MAD , Temporomandibular joint disorders or severe mandibular dysfunction, Craniofacial anomalies affecting jaw advancement , Pregnant Patients were Excluded from the Study.

Change in Apnea–Hypopnea Index (AHI) following mandibular advancement device therapy was the Primary Outcome Variable.

A custom-made, adjustable mandibular advancement device was fabricated for each participant using dental impressions. Initial fitting was performed by a trained dental specialist and Patients were instructed to wear the device every night during sleep

Gradual advancement of the mandible was done over 2–4 weeks based on Symptom relief , Patient comfort and Absence of jaw pain or TMJ symptoms.Follow-up visits at 2 weeks, 1 month, and 3 months with Assessment of Device compliance, Adverse effects (jaw pain, tooth discomfort, excessive salivation) and Subjective improvement in symptoms.

Standard overnight attended polysomnography was performed using a computerized sleep recording system, following American Academy of Sleep Medicine (AASM) guidelines With Baseline PSG Before MAD initiation and Follow-up PSG After 3 months of regular MAD use, with the device in situ during the study night.

Primary Outcome was measured in terms of Change in Apnea–Hypopnea Index (AHI) before and after MAD therapy.

Secondary Outcomes measured in terms of Change in Epworth Sleepiness Scale (ESS) score, Minimum and mean oxygen saturation , Oxygen desaturation index , Sleep architecture parameters (total sleep time, sleep efficiency).

Paired t-test was used to compare pre- and post-intervention continuous variables and p- value < 0.05 was considered statistically significant

RESULTS

Table 1: Baseline Sociodemographic and Clinical Characteristics of the Study Participants (n = 40)

Variable	Value
Age (years), mean ± SD	46.8 ± 9.7
Sex	
• Male	28 (70.0%)
• Female	12 (30.0%)
Body Mass Index (kg/m²), mean ± SD	27.6 ± 3.4
Neck circumference (cm), mean ± SD	38.9 ± 2.8
Smoking history	
• Yes	14 (35.0%)
• No	26 (65.0%)
Severity of OSA	
• Mild (AHI 5–14)	22 (55.0%)
• Moderate (AHI 15–29)	18 (45.0%)

Figure 1. Baseline sociodemographic and clinical characteristics of the study participants.

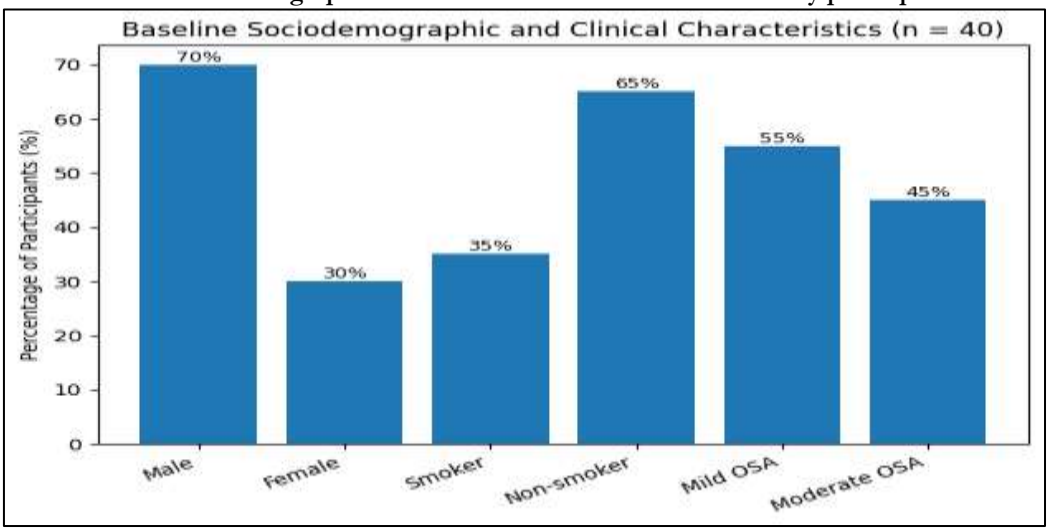


Table 2: Comparison of Polysomnographic Parameters Before and After MAD Therapy (n = 40)

Parameter	Baseline (Mean ± SD)	Post-MAD (Mean ± SD)	p- value
Apnea–Hypopnea Index (events/hr)	18.6 ± 6.4	10.9 ± 4.8	<0.001
Oxygen Desaturation Index (events/hr)	15.2 ± 5.9	8.7 ± 3.6	<0.001
Minimum SpO_2 (%)	82.4 ± 4.6	88.9 ± 3.8	<0.001
Mean SpO_2 (%)	93.1 ± 1.9	95.2 ± 1.6	<0.001

Figure:2 ***Comparison of polysomnographic parameters before and after mandibular advancement device (MAD) therapy.***

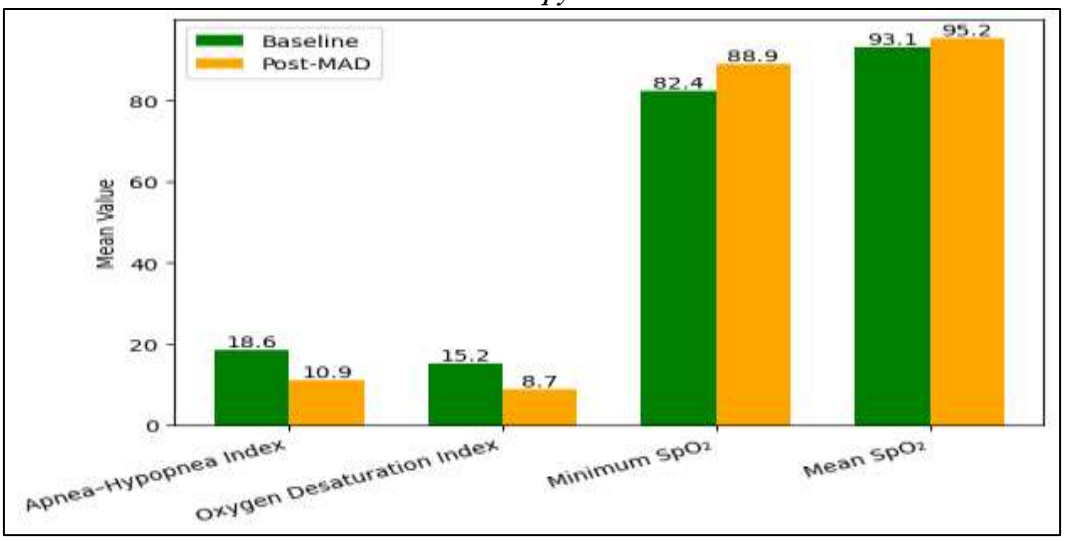


Table 3: Comparison of Daytime Sleepiness and Sleep Quality Parameters Before and After MAD Therapy (n = 40)

Parameter	Baseline (Mean ± SD)	Post-MAD (Mean ± SD)	p-value
Epworth Sleepiness Scale (ESS)	13.4 ± 3.2	7.6 ± 2.8	<0.001
Total Sleep Time (minutes)	342.5 ± 48.6	381.2 ± 44.3	0.002
Sleep Efficiency (%)	74.6 ± 8.9	82.8 ± 7.4	<0.001

Figure:3 Comparison of Daytime Sleepiness and Sleep Quality Parameters Before and After MAD Therapy

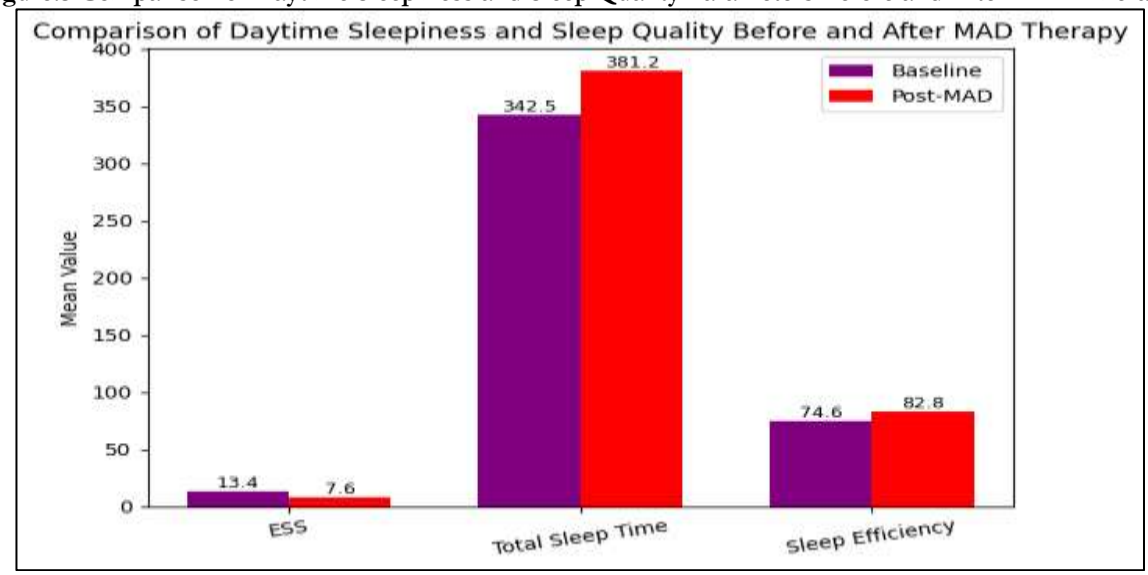


Table 4: Reduction in Severity of Obstructive Sleep Apnea After MAD Therapy (n = 40)

OSA Severity	Baseline n (%)	Post-MAD n (%)
Normal (AHI < 5)	0 (0.0%)	12 (30.0%)
Mild OSA (AHI 5–14)	22 (55.0%)	20 (50.0%)
Moderate OSA (AHI 15–29)	18 (45.0%)	8 (20.0%)
Severe OSA (AHI ≥ 30)	0 (0.0%)	0 (0.0%)

Figure:4 Distribution of obstructive sleep apnea severity at baseline and after mandibular advancement device therapy.

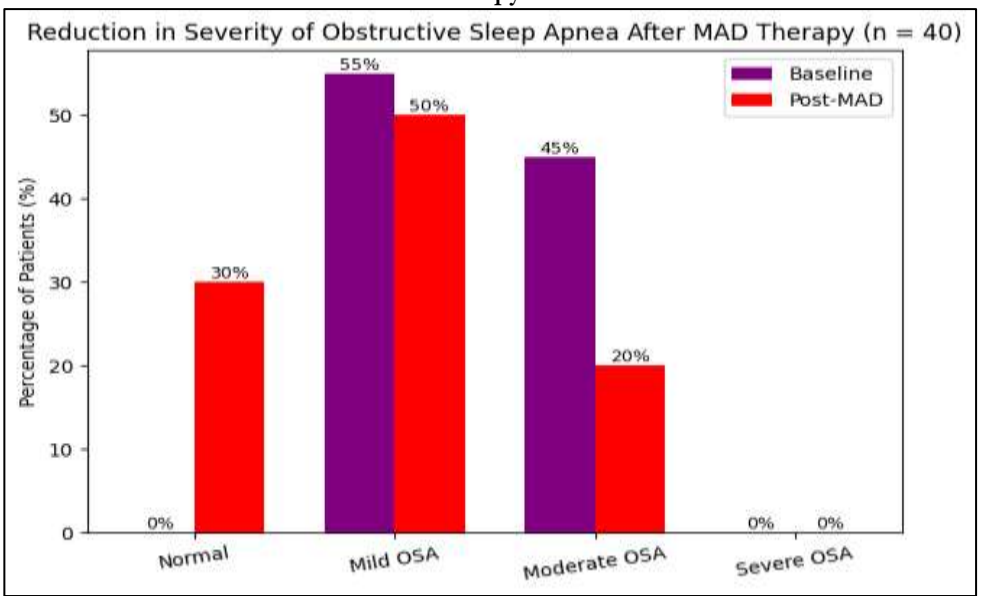
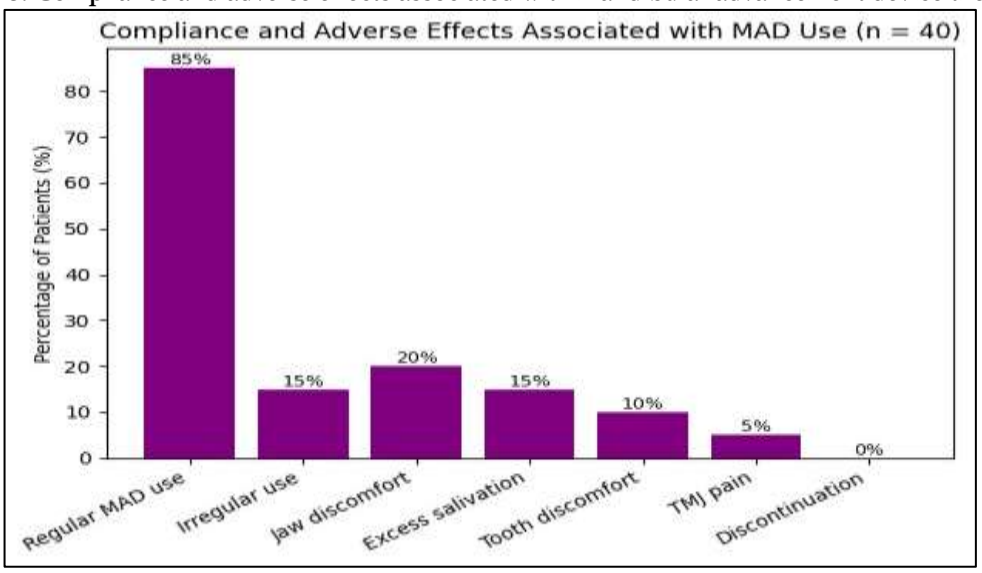


Table 5: Compliance and Adverse Effects Associated with Mandibular Advancement Device Use (n = 40)

Variable	n (%)
Regular MAD use (>5 nights/week)	34 (85.0%)
Irregular use	6 (15.0%)
Adverse effects	
• Jaw discomfort	8 (20.0%)
• Excess salivation	6 (15.0%)
• Tooth discomfort	4 (10.0%)
• Temporomandibular joint pain	2 (5.0%)
Discontinuation due to adverse effects	0 (0.0%)

Figure 5. Compliance and adverse effects associated with mandibular advancement device therapy



DISCUSSION

Obstructive sleep apnea (OSA) is a common sleep-related breathing disorder associated with repeated upper airway collapse during sleep, leading to intermittent hypoxia, sleep fragmentation, and excessive daytime sleepiness. Although continuous positive airway
pressure (CPAP) remains the gold standard treatment, suboptimal adherence has driven interest in alternative therapeutic options such as mandibular advancement devices (MADs), particularly in patients with mild to moderate OSA. The present prospective interventional study evaluated the effectiveness of MAD therapy and the findings are discussed in relation to previously published literature.

Effect of MAD Therapy on Apnea–Hypopnea Index

In the present study, a statistically significant reduction in Apnea–Hypopnea Index (AHI) was observed following MAD therapy, with mean AHI decreasing from 18.6 ± 6.4 to 10.9 ± 4.8 events/hour. This finding is consistent with earlier studies that demonstrated a clinically meaningful reduction in AHI with MAD use in patients with mild to moderate OSA. A randomized controlled trial by **Barnes et al.** reported significant reductions in AHI among patients treated with mandibular advancement appliances, particularly in those with lower baseline disease severity[10] . Similarly, **Aarab et al.** observed sustained reductions in respiratory events with adjustable MADs, supporting their efficacy in reducing upper airway obstruction during sleep[11] .

The improvement in OSA severity classification observed in the present study, with 30% of patients achieving normalization of AHI, aligns with previous reports indicating that a subset of patients experience near-complete resolution of OSA following MAD therapy. These findings support the proposed mechanism by which mandibular advancement increases upper airway volume and reduces pharyngeal collapsibility during sleep.

Improvement in Oxygen Saturation Parameters

Significant improvements were also noted in nocturnal oxygenation parameters, including reductions in the oxygen desaturation index and increases in minimum and mean oxygen saturation levels. These findings are in agreement with previous polysomnographic studies demonstrating improved oxygen saturation following MAD therapy[12,13] . **Pitsis et al.** reported that mandibular advancement not only reduces the frequency of apneic events but also attenuates the depth of oxygen desaturation, thereby reducing the hypoxic burden associated with OSA[14] . Improved nocturnal oxygenation is clinically relevant given its association with reduced cardiovascular risk.

Reduction in Daytime Sleepiness

Daytime sleepiness, assessed using the Epworth Sleepiness Scale (ESS), showed a significant reduction following MAD

therapy in the present study. This improvement is consistent with earlier studies that reported significant subjective symptom relief with oral appliance therapy[10]. **Barnes et al.** demonstrated that improvements in daytime sleepiness with MAD therapy were comparable to those achieved with CPAP in patients with mild to moderate OSA, despite greater reductions in AHI with CPAP[10] . The reduction in ESS scores observed in the present study highlights the positive impact of MAD therapy on patient-reported outcomes and quality of life.

Changes in Sleep Architecture

The present study demonstrated significant improvements in total sleep time and sleep efficiency following MAD use. Similar improvements have been reported by **Gagnadoux et al.**, who observed reduced sleep fragmentation and improved sleep continuity with MAD therapy[15] . These findings suggest that reduction in respiratory events and arousals contributes to more restorative sleep, which may partially explain the improvement in daytime symptoms.

Compliance and Adverse Effects

High compliance rates were observed in the present study, with 85% of participants reporting regular device use. This finding is consistent with previous studies that have demonstrated higher long-term adherence to MADs compared to CPAP therapy [10]. Adverse effects reported were mild and transient, including jaw discomfort and excessive salivation, which are commonly reported in the literature. Importantly, no participants discontinued treatment due to adverse effects, underscoring the favorable tolerability profile of MAD therapy when appropriately prescribed and monitored.

Clinical Implications

The findings of the present study support existing evidence that MADs are an effective, well- tolerated, and patient-acceptable treatment option for mild to moderate OSA. Current clinical practice guidelines from the **American Academy of Sleep Medicine** recommend oral appliance therapy as a first-line treatment for patients with mild to moderate OSA who prefer alternative therapy or are intolerant to CPAP [5].

Limitations

The present study has certain limitations. The relatively small sample size and single-center design may limit the generalizability of the results. The absence of a control group or direct comparison with CPAP therapy precludes definitive conclusions regarding comparative efficacy. Additionally, the short follow-up period did not allow assessment of long-term outcomes or potential dental and skeletal changes associated with prolonged MAD use.

Future randomized controlled trials with larger sample sizes and extended follow-up are required to further establish long-term efficacy and predictors of treatment success.

CONCLUSION

The present study demonstrates that mandibular advancement devices are an effective and well-tolerated therapeutic option for patients with mild to moderate obstructive sleep apnea. Use of MAD therapy resulted in a statistically significant reduction in apnea–hypopnea index, improvement in oxygen saturation parameters, and marked reduction in daytime sleepiness as assessed by the Epworth Sleepiness Scale. Additionally, a substantial proportion of patients showed a shift to a lower severity category of OSA following treatment, with good compliance and minimal, transient adverse effects. These findings support the role of mandibular advancement devices as a practical, non-invasive alternative to continuous positive airway pressure therapy in appropriately selected patients, particularly those with mild to moderate disease or those intolerant to CPAP.

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