The efficacy of oral appliances treatment for obstructive sleep apnea

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ABSTRACT
Obstructive sleep apnea (OSA) is a sleep disorder caused by upper airway obstruction. There are about one billion people worldwide affected by OSA; in the past decade, the number of people who seek treatment for OSA is increasing. Although *continuous positive airway pressure* (CPAP) is the gold standard for OSA treatment, the dentist also has a role in treating OSA using oral appliances (OA), especially for those who do not want to be treated using CPAP. However, the efficacy of OA treatment for OSA is varied so further study is needed. This scoping review ia aimed to evaluate the efficacy of OA treatment for OSA on adult patients with different severity based on the *apnea-hypopnea index* (AHI) which is classified as a mild, moderate, and severe group. It is concluded that OA effectively reduces the symptoms of OSA. It must be noted that objective examination through the AHI evaluation shows that AHI reduction is affected based on the OSA and BMI classification. Patients with high BMI demonstrated a smaller reduction in AHI, thus showing low effectiveness of OA.
Keywords: obstructive sleep apnea, adult, oral appliances, continuous positive airway pressure, treatment

INTRODUCTION

Obstructive sleep apnea (OSA) can be defined as a health problem where respiratory disturbance occurs during sleep.[1,2] OSA's main characteristic is the presence of partial or complete airway obstruction during sleep.[2] Numerous symptoms occurred during OSA, such as irregular loud snoring, grunting, gasping, unusual sleeping breath sounds, and long pauses in breathing during sleep. Other symptoms also include excessive sleepiness, fatigue, obesity tendency, headaches, and changes in emotion or behavior. An untreated OSA may cause 20 times increase in the risk of a heart, 3 times increase in the risk of a stroke attack, uncontrolled weight gain, hypertension, decline in memory, alertness, coordination, and even death.[3,4]

The predisposing factors for OSA are obesity, male gender, and age.[2] OSA is generally more common in men than women and while it can occur at all ages, even at birth, OSA is more common in middle age individuals.[3] Prevalence of OSA is 3% in women and 10% in men aged 30-49 years, 9% in women, and 17% in men aged 50-70 years.[4] The estimated global prevalence of OSA is nearly one billion persons.[5]

As mentioned above, an untreated OSA may cause a variety of negative effects. Therefore, proper management of OSA treatment is vital. The goal of OSA treatment is to reduce any symptoms that occur due to OSA and improve respiration by widening the respiratory tract or oropharynx, either by surgery or by opening the airway. Common treatments for OSA are the use of continuous positive airway pressure (CPAP) machine, soft tissue surgery of the throat, and the use of oral appliances (OA).[1] Dentist can also treat OSA by the means of OA fabrication.

The severity of OSA can be measured by using the apnea-hypopnea index (AHI) which is calculated by using polysomnography (PSG). Based on the AHI, mild OSA is at AHI 5-14, moderate OSA is at AHI 15-29, and severe OSA is when AHI more than 30.[4] According to the American Academy of Sleep Medicine, OA, specifically, mandibular advancement device (MAD), can be used for OSA treatment in mild to moderate OSA.[6] CPAP is the main treatment for patients with severe OSA, however, the use of CPAP is usually quite difficult for patients. If the patient cannot receive CPAP therapy, the use of OA can be considered to use with combination of treatment therapy with other fields like surgery.[1] According to existing studies, the effectiveness of OA itself varies greatly; 57-81% for mild and moderate OSA, while for severe OSA it is 14-61%.[1,4] This varying success rate of OA treatment is also influenced by various factors such as AHI, body weight based on body mass index (BMI), gender, and age.[4]

There are three types of OA, namely MAD, tongue retaining device (TRD), and oral positive airway pressure appliance (OPAP) (Fig.1). The mechanism of how OA works is to place the mandible and tongue in a protrusive position so that the oropharyngeal space expands and prevents the upper respiratory tract from collapsing.[6,7] MAD is a device that holds the mandible in a protrusive position. Usually, this device is made of acrylic with metal loops. In addition to MAD, there are also other

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devices that can be used for the treatment of OSA, namely TRD. This tool is shaped like a suction cup to position the tongue anteriorly; the patient is instructed to bite the device so that the tongue is held in the front position. However, this device is less comfortable to use when compared to the MAD. Contraindications of MAD and TRD are patients who cannot breathe through the nose. Besides MAD and TRD, another OA device known as OPAP can also be used for OSA treatment. This device is shaped like a retainer that is placed in the mouth and is connected to the CPAP tube and the machine. OPAP does not require head equipment like CPAP and since this device does not use a mask, it does not irritate the skin. The downside of using this device is excessive salivary production thus it is less comfortable for the patient. Also, patients with temporomandibular joint disorders are not recommended to use these devices.[3]

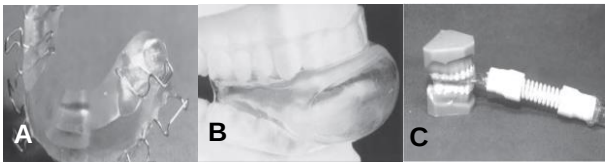

Figure 1A The MAD, **B** the TRD, **C** the OPAP.[3]

Today, OSA is a common health problem. The global prevalence of OSA is enormous, estimated at almost one billion. An untreated OSA can cause various kinds of negative impacts. Therefore, clinicians, including dentists, should pay more attention to the management of OSA so that the patient's quality of life can be maintained or even improved. The use of OA appliance is one of the OSA treatments that can be performed by dentists. The purpose of this scoping review is to find out how effective OA is for treating OSA based on the existing literature. In addition, this scoping review also aims to increase the dentists' knowledge and understanding of OSA and OA.

LITERATURE STUDIES

This scoping review paper summarizes and evaluates the results of existing studies on the effectiveness of the oral appliance for treating sleep apnea. The steps taken in this paper are determining study questions, conducting study selection, collecting data in a chart, and compiling a summary as well as evaluating the results of the study. The writing of this scoping review is based on the guidelines from Arksey and the Preferred Reporting Items for Systematic Review Extension for Scoping Review (PRISMA-ScR).[8,9]

The research question in this scoping review is *How effective oral appliance in reducing the symptoms of sleep apnea*?. The selected population is adult patients with OSA. The concept used is treated with an OA. The context set is the effectiveness of the appliance.

The literature search which is relevant to the research questions were carried out using the internet from three sources, namely PubMed, Wiley Online Library, and EBSCO. The keywords used to search were ("oral appliance" AND "sleep apnea" OR "sleep apnea"). The literature searched was literature published 2016-2021, in English, and carried out on adult people. The inclusion and exclusion criteria used are shown in table 1.

After the articles were searched according to the criteria, screening was carried out because there were some duplicated articles. Screening is also done by reading abstracts in each journal to pay attention to the inclusion and exclusion criteria. Appropriate literature will be included in this scoping review. The literature search yielded a total of 8 articles with PubMed with 38 articles, EBSCO with 28 articles, and Wiley literatures with 21 articles. Then duplicated articles were checked and there were 10 duplicated articles. The exclusion of literature that is not relevant to this scoping review was also carried out in terms of titles and abstracts leaving 57 articles. After obtaining the relevant literature, the literature was read again and 13 articles did not match the predetermined criteria so they were eliminated. The final results obtained eight articles that will be used in this scoping review. The results of the literature used in this scoping review can be seen in Table 1.

Table 1 Inclusion and exclusion criteria

Criteria	Inclusion	Exclusion
Time	Published January 2016 – September 2021	Published before January 2016
Language	English	Other than English
Subject	Sleep apnea in adult patient	Pediatric patients (under 18 years), experimental animals, laboratory samples
Concept	Treatment using oral appliance	Treatment using CPAP or surgery
Context	Efficacy of oral appliance reported	Efficacy of oral appliance unreported
Design	Randomized clinical trial, prospective study, retrospective study, cross-sectional study	Case report, finite element analysis, systematic review, meta-analysis, literature review
Full Text	Available	Not available

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Table 2 The efficacy of oral appliances treatment for obstructive sleep apnea in the past five years

No	Author (Year), R.Design, OSA Classif,	Objective	Result	Conclusion
1	Guillaume et. al. (2021)[7], Retrospective, Samples: 347, Moderate Severe	To determine the predictive factors of OA efficacy. The secondary objective was to measure the efficacy rates and determine OAs' tolerance and dropout	The 50% AHI reduction rate after OA was 65.2%, the AHI ≤5/hr rate after OA was 26.1%, and the <50% AHI reduction and residual AHI > 10/hr rate was 50.1%. OA significantly reduced AHI (−14.9/hr, P<.0001). In 7.8% of patients, AHI increased with OA. Seven patients (1.5%) experienced adverse effects, 37 (7.8%) patients stopped using OA mainly because of its ineffectiveness.	OA is an effective and well-tolerated treatment for moderate to severe OSA. This treatment was effective for reduction of the AHI ≥50% in ⅔ of cases studied and it should be considered in more cases.
2	Okuno et. al. (2020)[4] Cross-sectional, Samples: 442, Mild moderate severe	The purpose of this cross-sectional study was to investigate the success rate of OA for OSA patients.	After OA treatment, the mean AHI decreased from 22.6 ± 13.8 to 10.0 ± 10.2/h and the mean rate of decrease in the AHI was 52.5 ± 38.4%. The success rate of OA treatment decreased according to the increase in OSA severity, obesity level (higher BMI), and older age.	OA can reduce 52.5% AHI. The treatment success rate of OA on multiple criteria according to OSA severity, BMI, and age
3	Lu et. al. (2020)[10] Cross-sectional, Samples: 30, Mild Moderate	To investigate the clinical effectiveness of adjustable oral appliance on older adult patients with OSAS.	By using oral appliance, AHI had decreased from (27.65±1.31) per hour to (6.74±0.75) per hour (P<0.05); the maximum apnea time (MAT) decreased from 43.82±2.69 to 21.37±3.18 s (P<0.05). CBCT showed that the minimal sagittal diameter, the volume of the palatopharynx, and volume of the glossopharynx significantly increased.	OA had considerable clinical efficacy and comfort in older adult OSAS patients by enlarging the palatopharynx and glossopharynx.
4	Byun et. al. (2019)[11] Prospective, Samples: 50, Moderate Severe	To determine the efficacy of OAs for the first-line treatment of Korean patients with moderate or severe OSA.	The patients were aged 47.4±12.1 years (mean±SD) and their AHI at baseline was 29.7±10.9/h. After OA treatment the AHI had reduced by 63.9± 25.8%, with the reduction was similar between the moderate and severe OSA. Overall 31.1% of the patients achieved a normal AHI (<5/h), and 64.4% had an AHI of ≤10/h after the treatment. The body mass index (BMI) was the most reliable factor for predicting the percentage reduction in the AHI	The OAs were effective in patients with moderate or severe OSA. The OAs reduced the mean AHI to 63.9% of the baseline value, and this reduction was influenced by the BMI.
5	Skalna et. al. (2019)[12] Clinical experimental, Samples: 58, Mild Moderate Severe	To verify the effectiveness of current OSA treatment by objective measurements, and to assess by means of a questionnaire patients' satisfaction with OA.	Average AHI reduction in the entire group was 10.4; 31% of patients experienced AHI reduction by at least 50%. Significant AHI reduction was proven when using the appliance. Appliances affect the reduction of AHI and patients tolerate the appliances well.	OA complement positive-pressure treatment and do not interfere with it in any way. OA can be used if the patient refuses to do CPAP treatment.
6	Enrique et. al. (2017)[13] *Case-control,* Samples: 35, Moderate Severe	To investigate outcomes including efficacy, quality of life, and levels of inflammatory markers of a MAD for moderate-to-severe OSA.	At 6 months, the MAD significantly improved AHI and lowest oxygen saturation (P<.01), non–rapid eye movement (N)1 and N3 sleep stages (P<.05), ESS score (P<.05), FOSQ total score (P<.01), interleukin 1b (P<.05), and TNF-a (P<.01) compared with the untreated group. In the overall, moderate, and severe OSA groups, 63.3%, 75%, and 50%, respectively, achieved at least a good response	The use of a MAD significantly improved polysomnographic parameters, quality of life, and some inflammatory markers (CRP, IL-b, and TNF-a). MAD may be a viable alternative therapy in with moderate-to-severe OSA who refuse continuous positive airway pressure.
7	Nikolopoulou et. al. (2017)[2], Randomized placebo-controlled trial, Samples: 219, Mild Moderate	To compare the effects of a MAD with those of nasal continuous positive airway pressure (nCPAP) on self-reported symptoms of common sleep disorders and sleep-related problems in mild and moderate OSAS patients	The MAD group showed significant improvements over time in symptoms of common sleep disorders and sleep-related problems (P: 0.000–0.014). These improvements in symptoms were, however, not significantly different from the improvements in symptoms observed in the nCPAP and placebo groups (P: 0.090–0.897).	There is no significant difference between MAD & nCPAP in their positive effects on self-reported symptoms of common sleep disorders & sleep-related problems in mild and moderate OSAS; may be a result of placebo effects
8	Nordin et. al. (2016)[1] Cross-sectional Samples: 738	To survey the care and patient experiences and the self-reported effectiveness of OSA treatment with an OA incorporating mandibular advancement	Treatment with OA gave relief of symptoms in 83%. Quality of life, somatic and cognitive symptoms improved significantly in patients who used the appliance frequently (P < 0.001). Daytime sleepiness decreased significantly (P < 0.001). Treatment satisfaction and willingness to recommend a similar treatment to a friend were high (>85%).	User of OA frequently reported improvement in quality of life, somatic, and cognitive symptoms. Excessive daytime sleepiness was reduced in the majority of the patients under treatment.

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DISCUSSION

This scoping review aims to evaluate the efficacy of oral appliance treatment for OSA in adult patients with different severity based on the AHI in the last five years. In the eight literatures that match the inclusion criteria, there are differences in research design, OSA classification, and evaluation methods, therefore these can lead to inconsistencies in the summary.

Judging from the research design in the eight selected literatures, three literatures are cross-sectional[1,4,10], one prospective[11], one retrospective[7], one clinical experimental[12], one case-control[13], and one randomized placebo-controlled trial literature[2]. Based on the classification of OSA, two literatures evaluate mild, moderate, and severe OSA[4,12], two literatures evaluate only mild and moderate[2,10], three literatures evaluate moderate and severe[7,11,13], and the other one does not evaluate the AHI classification[1]. In these eight literatures, there were researchers who evaluate subjectively[1], objectively[4,7], and both[2,10-13]. These differences cause the result and conclusions to vary.

Nordin et.al evaluate that subjectively, OA can reduce symptoms in 83% of respondents. Quality of life and cognitive are also improved in patients who routinely use OA.[1] Okuno et al and Skalna et al objectively evaluate the effectiveness of OA against OSA in mild, moderate, and severe classification.[4,12] The results of Okuno et al's study showed that treatment with OA could reduce AHI from 22.6±13.8/h to 10.0±10.2/h with an average reduction of 52.5±38.4%, in addition, Okuno also found that OA success decreased as the increasing of OSA severity, BMI, and age.[4] The study conducted by Skalna et al said that OA can reduce AHI by as much as 10.4/h which is almost similar to the study conducted by Okuno. AHI reduction of 50% was found in 31% of patients, 14% did not experience any reduction, and the rest experienced a decreased AHI although it did not reach 50%. In this study, there was no significant difference between AHI, BMI, and age in each sample so the effects of AHI, BMI, and age can't be seen in this study.[12] From the efficacy perspective of OA against OSA, these two studies have similar results: OA can reduce AHI, which means it is effective for treating OSA.[4,12]

Research conducted by Lu, et al and Nikolopoulo et al in mild and moderate OSA also showed similar results.[2,10] According to research by Lu et al, the use of OA can reduce the AHI by 20.91± 0.56/h, from 27.65±1.31/h to 6.74±0.75/h after therapy. The results from Lu also show that the volume of the palatopharyngeal and glossopharyngeal also increased with the use of OA so the space of oropharyngeal and glossopharyngeal is wider, with this can be seen that OA became effective. Nikolopoulo, in his research also compared the effectiveness of OA against CPAP and placebo and all three showed a good response to treat OSA even though the value obtained using placebo was not as high as OA and CPAP, presumably this could be due to the placebo effect.[2]

Guillaume et al, Byun et al, and Enrique et al. conducted a similar study on moderate and severe OSA, these three researchers also showed similar results regarding the effectiveness of OA against OSA.[7,11,13] Guillaume et al. showed that the use of OA could reduce AHI by 50% in 65.2% of patients, decrease AHI <50% and AHI >10/h in 50.1% of patients, and AHI to <5/h in 26.1% of patients. On the other hand, Guillaume also said that increasing advancement was not significant in reducing AHI.[7] Similar results were obtained from a study conducted by Byun et al, after treatment with OA, AHI was reduced by 63.95%. 31.1% achieved normal AHI <5/h and 64.4% of patients achieved AHI <10/h.[11] According to Guillaume and Byun, the decrease in AHI is also influenced by BMI, the higher a person's BMI, the lower the effectiveness of OA.[7,11] Enrique et al stated that the use of OA has an effectiveness of 63.3%, that is not much different from the study conducted by Guillaume and Byun.[13]

The eight literatures used in this scoping review shows similar results, OA can effectively reduce symptoms in OSA. This remains the same even if the research is evaluated objectively, subjectively, or both. Research conducted subjectively on the literature used was only conducted by Nordin et al,[1] objective study was conducted by Byun et al. and Nikolopoulo et al,[4,7] and the rest used a combination of subjective and objective. [2,10–13]

The difference in AHI reduction in each literature is also different, this is influenced by the classification of OSA and also BMI. In studies conducted on all OSA classifications, whether mild, moderate, or severe, there was an average decrease in AHI of 10/h.[4,12] In studies that only examined mild and moderate OSA, the average decrease in AHI was 20/h, some patients can even almost reach normal AHI with the use of OA.[2,10] In modederate and severe OSA, achieving an almost normal AHI was only achieved by 25-30% of patients, while the rest experienced a decrease in AHI of 50-64.4%. According to Guillaume and Byun, the decrease in AHI is also influenced by BMI, the high-

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er a person's BMI, the lower OA effectiveness.[7,11]

It is concluded that OA effectively reduces the symptoms of OSA. It must be noted that objective examination through the AHI evaluation shows that AHI reduction is affected based on the OSA and BMI classification. Patients with high BMI demonstrated a smaller reduction in AHI, thus showing low effectiveness of OA. Considering the limitation of this scoping review, it is suggested that future reviews should be presented with a more uniform study design to reflect more accurate results regarding the efficiency of OA in treating OSA.

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