Sleep Medicine 99 (2022) 18–22

Contents lists available at ScienceDirect

Sleep Medicine

journal homepage: www.elsevier.com/locate/sleep

Use of the Complete Airway Repositioning and Expansion (CARE) approach in 220 patients with Obstructive Sleep Apnea (OSA): A retrospective cohort study

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ARTICLE INFO

Article history:
Received 10 March 2022
Received in revised form
30 June 2022
Accepted 4 July 2022
Available online 11 July 2022

Keywords:
Sleep apnea
Dentistry
Oral appliance

ABSTRACT

Objective/Background: Obstructive sleep apnea (OSA) is a prevalent disease with significant health repercussions. While many effective OSA treatment modalities exist, Complete Airway Repositioning and Expansion (CARE) represents an emerging approach that leverages gradual airway expansion, with or without mandibular advancement. We conducted a retrospective study of patients who underwent CARE with a dental provider and examined how their sleep study data changed, with a focus on apnea hypopnea index (AHI).

Patients/Methods: A retrospective database of 220 adult patients was examined. Demographic data and radiographic and sleep study data were compared in patients before and following at least 6 months of treatment with one of two possible dental devices.

Results: The median age of patients in this cohort was 50 years, and evenly split by gender. The median decrease in AHI was 49.0%, with a median pre-treatment AHI of 17.3 and median post-treatment AHI of 9.6 ($p<0.001$). Most participants (63.6%) demonstrated an improvement in their OSA severity class. Fifty-seven (25.9%) participants had complete resolution of their OSA. Post-treatment, 151 (68.6%) of patients had OSA severities of none or mild. Thirty-four (15.5%) of patients had in increase in AHI and 13 (6.0%) of these patients demonstrated an increase in OSA classification. One patient experienced an adverse event in the form of a loose molar tooth requiring repair. Overall findings were limited by missingness of BMI and clinical co-morbidity data, as well as quality of life measures.

Conclusions: In this large, but data limited retrospective series, CARE seems to be an effective and safe approach to OSA management that may be a useful alternative to current mainstays of OSA management. Further investigation is warranted.

1. Introduction

Obstructive Sleep Apnea (OSA) is a prevalent and rising source of morbidity worldwide, affecting up to 25% of men and 9% of women [1,2]. While the pathophysiology of the disease primarily relates to airway collapse, the consequences of OSA have ramifications through all organ systems of the body with attendant risks of morbidity and mortality and profound public health repercussions [3–8]. The current mainstays of treatment include continuous positive airway pressure (CPAP) machines, surgical interventions, and mandibular advancement devices (MADs) [9–11]. Each of these treatment modalities has strengths and weaknesses, and there is space for additional OSA treatment that increase the armamentarium of sleep medicine providers [9,12–14].

Abbreviations: CARE, Complete Airway Repositioning and Expansion.

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https://doi.org/10.1016/j.sleep.2022.07.005

One emerging approach to OSA is Complete Airway Repositioning and Expansion (CARE), a dental provider-guided system that leads to gradual increases in airway volume [15–18]. The devices used as part of CARE have been shown in several case reports to lead to airway expansion and improved sleep quality [15–18]. The potential strength of this approach is the combination of benefits seen in many of the previously mentioned options (e.g., well-tolerated, non-invasive), without the lifelong need for CPAP or a MAD, nor the risks and pain of surgery [19]. Indeed, the ultimate goal with CARE is that patients will not need to wear their device on a daily basis if and when successful therapy is completed.

To date, no large cohort trials examining CARE have been performed in order to determine whether similar results are observable in multiple patients undergoing treatment in real-world settings. In this study, we examined a retrospective cohort of 220 patients who completed CARE, and who had data in the Vivos Airway Intelligence System (AIS), a proprietary patient data warehouse. We sought to determine the effectiveness of CARE in these adults, as measured by changes in their apnea-hypopnea index (AHI) before and after therapy.

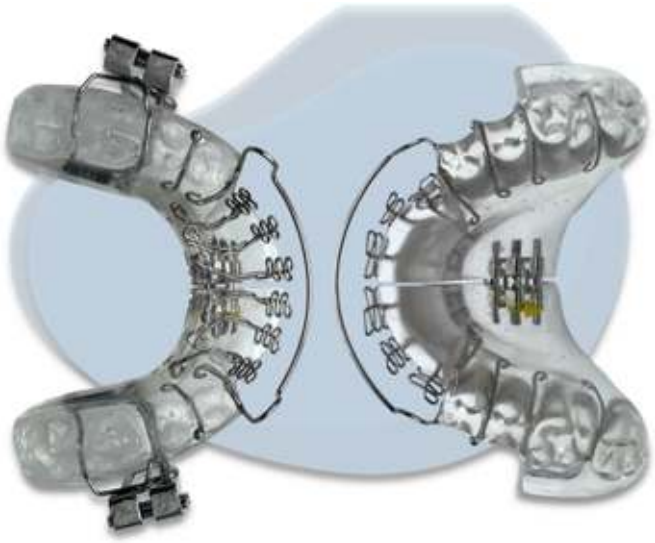

Fig. 1. Mandibular-repositioning nighttime appliance (MRNA).

2. Materials and methods

After IRB exemption by the Program for Protection of Human Subject at the Icahn School of Medicine at Mount Sinai (STUDY-21-01561), we conducted a retrospective review of the Vivos Airway Intelligence Service (AIS) database, a prospectively collected, clinical database. Patient data were anonymized for use by the research group. Data entry into the AIS was performed by participating dental providers. Adult patients (ages 18 and older) with OSA who underwent CARE for that primary indication between 2015 and 2020 for at least 6 months were included. Demographics, pre- and post-treatment sleep study parameters, and cone beam CT (CBCT) parameters for *trans*-palatal width (TPW) and total 3-dimensional (3-D) airway volume were recorded. Of note, all pre-treatment and post-treatment sleep studies were conducted without an oral appliance in place. If either the pre or post-treatment AHI data were gathered while the patient wore their appliance, that patient was excluded from the study. Wear time was self-reported. Once all data was compiled and anonymized for release to the study group, only patients with complete pre- and post-treatment AHIs were included (n = 337), and those with sleep studies of differing reference values were excluded (n = 117). This led to a final patient cohort of 220 patients out of the original database of 2257 patients.

The course of therapy for each these patients followed a standard approach for patients undergoing CARE for OSA. Briefly, patients presenting to their Vivos dentist and complaining of sleep issues were referred for sleep studies, to be interpreted by a licensed sleep specialist. Sleep specialists could then recommend treatments according to standards of care based on results of the sleep studies, although many patients seeking treatment with a Vivos provider would have had CPAP therapy in the past without successful treatment of their OSA. Patients were offered CARE by their Vivos dentist as part of their treatment plan and were fitted for one of two types of oral appliance: either a maxillary, day and night appliance (DNA) or a mandibular-repositioning nighttime appliance (MRNA), which is a combination device that adds a MAD to the DNA. The DNA device is an FDA registered product for palatal expansion. The mRNA device is an FDA cleared device to treat mild to moderate OSA and snoring in adults (Fig. 1).

MRNA device with mandibular (left) and maxillary (right) components shown.

The maxillary (DNA) portion of both devices consists of polymer subunits with embedded metallic coils designed to increase airway volume over time. The DNA appliance has the ability to be expanded in the anterior-posterior as well as lateral dimensions. The type of device utilized was decided upon pragmatically, by the patient and dentist, based on the severity of OSA and/or patient preference and likelihood of adherence. Patients wear their appliance nightly (although the DNA can be worn throughout the day as well) and they adjust it serially during use, in order to gradually expand the device and allow maxillary expansion. Vivos dentists provide guidance and periodic exams for troubleshooting as well as additional adjustments. Repeat assessments via sleep studies are performed at intervals decided upon by the patient, their Vivos dentist, and their sleep specialist. Courses of therapy are typically completed by 18 months, but variability exists, and many patients can complete therapy earlier. The current patient cohort was made up entirely of patients who completed at least 6 months of therapy, as indicated by their provider.

2.1. Statistical analysis

Data fields were collated and inspected for outliers as well as normality of distribution. Normally distributed variables are reported as mean (SD) while non-normally distributed variables are reported as median [interquartile range, IQR]. Paired testing was utilized when applicable (pre-post treatment). For paired non-normally distributed variables the related samples Wilcoxon Signed Rank test was utilized in addition to the Related Samples Hodges-Lehman Median Difference test for the estimated difference and 95% confidence intervals. Categorical variables were tested via Chi-square or Fischer's exact test based on samples. Statistical models for associations with improvement in OSA severity were performed via binary logistic regression. Multivariate models were constructed using stepwise binary logistic regression. Variables were excluded from the model if their p value was greater that 0.2. The model was considered final once all variables were either statistically significant or borderline. All statistics were performed using SPSS Version 24 (IBM, Aramonk, NY). For OSA classification, we used the following schema:

- Normal sleep: An AHI of fewer than five events per hour
- Mild OSA: An AHI of five to 14.9 events per hour
- Moderate OSA: An AHI of 15–29.9 events per hour
- Severe OSA: An AHI of 30 or more events per hour [11].

3. Results

A final dataset of 220 patients was obtained from the initial survey of available AIS data. Table 1 shows the demographics of this patient cohort, which was evenly split by gender with a median age of 50 years. Most participants (60.5%) had undergone therapy with a DNA device with a median treatment period of 13 months (See Table 1). BMI data for the cohort was largely missing. In the pre-treatment cohort, the median BMI in 106 available entries was 26.0 kg/m^2 (Interquartile range [IQR] 24.1–29.4). Post-treatment BMI was 26.8 kg/m^2 (IQR 23.8–29.3) with 161 (73.2%) missing. The average total wear time was the same for each group, at 12h per day.

AHI and OSA data presented as pre- and post-treatment values are seen in Table 2. Overall, the pre-treatment group was categorized by AHI as having moderate sleep apnea, with a median AHI of 17.3 [10.4–35.1]. Post-treatment, the group's average OSA severity was classified as mild, with a median AHI of 9.6 [4.25–16.9]. Differences between OSA severity before and after treatment were statistically significant ($p<0.001$).

Most participants (63.6%) demonstrated an improvement in their OSA severity class. Fifty-seven (25.9%) participants had complete resolution of their OSA, and 102 (46.4%) participants demonstrated a greater than 50% reduction in AHI. The median decrease in AHI was 49.0% (IQR 17.5 to 74.4). Post-treatment, 151 (68.6%) of patients had OSA severities of none or mild (Fig. 2). The median increase in airway volume was 13.2% (IQR 2.0–29.5%) for the DNA group and 12.6% (IQR 0.0–33.8%) for the MRNA group ($p = 0.868$).

Univariate analysis for significant associations with improvement in OSA severity are found in Table 3. Of the variables investigated, only the pre-treatment AHI/pre-treatment OSA severity were significantly predictive of improvement in OSA classification. A multivariate model was attempted, however, only the aforementioned variables remained in the final model as well. Increasing pre-treatment AHI increased the likelihood of improving OSA classification. Likewise, those with mild OSA were less likely than those with moderate or severe OSA to see improvement in their OSA classification post-treatment.

Associations between variables to predict an increase in AHI score were also investigated. Only pre-treatment AHI (Odds ratio 0.944 [0.910–0.978], $p= 0.002$) and OSA severity of mild compared to severe (OR 5.72 [1.87–17.43]. $p = 0.002$)] were predictors of having an increase in AHI during treatment. Thirty-four (15.5%) of patients had in increase in AHI and 13 (6.0%) of these patients demonstrated an increase in OSA classification. In patients where AHI increased, the median AHI change was 4.7 [IQR 0.57–8.7] and 70.6% of patients who experienced an increase in AHI had a pre-treatment classification of mild. Those patients who had pre-treatment classifications as mild and experienced an increase in AHI had median AHI increases of 3.35 [IQR 0.50–7.77]. Changes in AHI stratified by initial OSA severity are illustrated in Fig. 3. There was one reported adverse event in the cohort in which a patient experienced a loosened molar tooth that was repaired. Minor events such as hyper-salivation or chewing/bite changes with initial device use were reported in 58 patients (26%), but did not preclude treatment.

Table 1
Demographic data.

Variable	Study Population (n = 220)
Age (years)	50 [39–60]
Gender n (%) Male	104 (47.3)
Months of Treatment	12.95 [9–16.53]
Treatment Device	
DNA n (%)	133 (60.5)
MRNA n (%)	87 (39.5)

4. Conclusions

While several evidence-based treatment modalities for OSA exist, there is a need for newer modalities that address the shortcomings of the current mainstays of therapy [13,20]. In this retrospective analysis, we found that patients who underwent CARE had improvements in their OSA severity, as measured by changes in AHI, irrespective of the device they wore nor the duration of therapy past 6 months. A significant proportion of patients experienced resolution of their OSA or had improvements in their OSA severity. Airway volume increases were observed, and very few adverse events were recorded. Overall, these findings are encouraging for the possibility that CARE may provide an alternative or adjunct to treatment for patients (either as first-line therapy or for patients who have difficulties with CPAP or MADs, or for whom surgery is not desired, or is contraindicated).

Treatment effectiveness is variable among existing modalities for OSA, largely due to measures used to rate effectiveness and to the very nature of how the different devices work. It is, however, important to consider the present results of CARE in the context of other available therapies. While CPAP is the gold standard and very effective at improving the sequelae of OSA, approximately 46–83% of patients with OSA have been reported to be CPAP nonadherent [21], and when adjusting for adherence, its effectiveness can be as low as 50% [22]. Pitarch et al., found MADs to be effective in 65.8% of patients [22]. However, long term adherence with MAD therapy has also been suboptimal, with some studies showing a wide range of adherence rates between 4 and 76% adherence after 1 year, possibly due to the need for continued device usage for an indefinite timeframe [23].

Similarly, surgical interventions have a wide range of success with significant limitations and risks. Hypoglossal nerve stimulator implantation had an effectiveness rate of 69% [24]. But limitations of this therapy can include: high cost, incompatibility of the therapy with magnetic resonance imaging, the need for two skin incisions, and a long-term non-responder rate of up to 25% [25]. Traditional upper airway surgeries designed to remove redundant tissue along the palate and tongue have a success rate of 50–65% but can have complications associated with bleeding, infection, pain, voice and taste change, dysphagia, and nasal regurgitation [24]. It must also be considered that when researchers and clinicians attempt to assess the severity of OSA and the impact of whatever treatment modality is being employed, they invariably do so with that device *in situ*. That is not the case with CARE.

Patients are increasingly seeking treatment that not only improves their sleep apnea, but also minimizes complications, improves quality of life, and allows for minimal disruption to their lives. While domains of dentistry and sleep medicine clearly intersect in the airway, physician-dental collaboration in the diseases of the airway is still in its infancy. Multiple studies have shown that rapid maxillary expanders (i.e., oral appliances that are either removable or semi-permanently cemented to the upper palate) can be successful in treating OSA in children [26]. Some smaller studies report similar success in adults as well [27,28]. CARE devices have been developed as enhanced versions of rapid maxillary expanders that harness the growth potential of the maxilla. While more studies need to be done, CARE potentially provides a therapy that allows for promising rates of effectiveness and the benefits of a MAD, without the need for long-term or lifelong usage where adherence with traditional MADs can drop significantly [23]. There is a potential for increasing space between teeth as a side effect, and indeed one patient in this cohort

Table 2
Pre and post-treatment measures of AHI and OSA severity.

Variable	Pre-Treatment (n = 220)	Post-Treatment (n = 220)	Difference and 95% CI	p-value
AHI, median [IQR]	17.3 [10.4–35.05]	9.6 [4.25–16.85]	−9.3 [-11.2 to −7.6]	<0.001
OSA Severity, N (%)			N/A	<0.001
None	0 (0)	57 (25.9)		
Mild	89 (40.5)	94 (42.7)		
Moderate	58 (26.4)	43 (19.5)		
Severe	66 (30)	19 (8.6)		
Missing	7 (3.2)	7 (3.2)		
Improved OSA Severity? N (% Yes)	N/A	140 (63.6)		

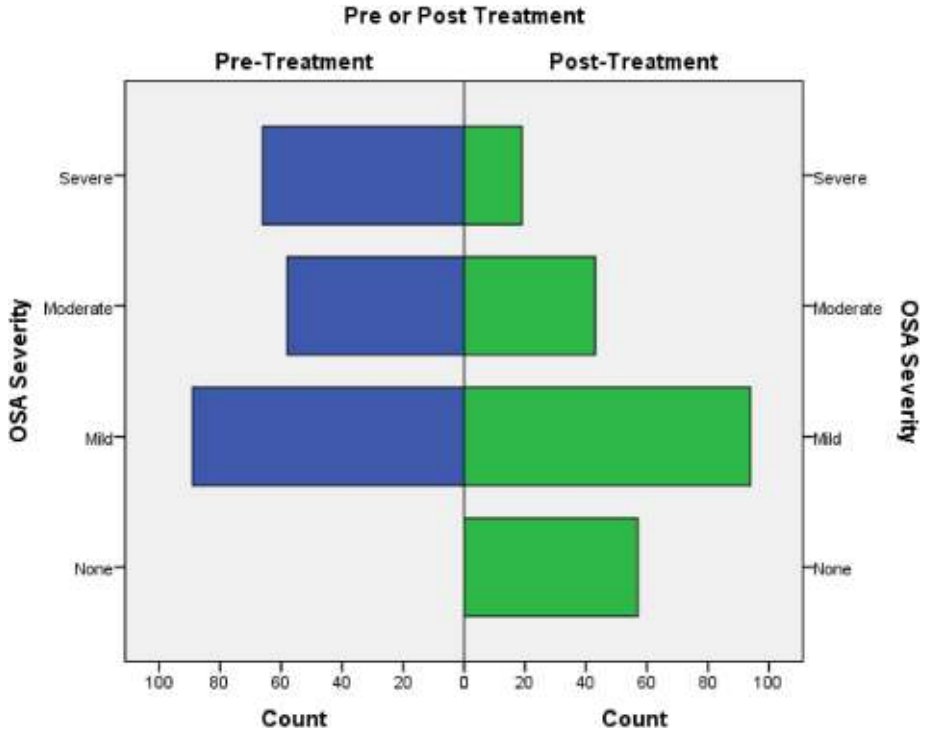

Fig. 2. Pre and post-treatment AHI class distribution.

Table 3
Univariate analysis data.

Variable	Coefficient	95% Confidence Interval	p-value
Age	1.001	[0.98–1.02]	0.919
Gender (male)	0.925	[0.52–1.63]	0.788
Treatment Type	0.907	[0.50–1.62]	0.743
Months of Treatment	0.992	[0.94–1.03]	0.738
Pre-Treatment BMI	0.961	[0.88–1.04]	0.345
Pre-Treatment AHI	1.024	[1.00–1.04]	0.008
Pre-Treatment OSA Severity (Severe)			
Mild	0.220	[0.10–0.45]	<0.001
Moderate	1.292	[0.52–3.18]	0.577

experienced a loosened molar tooth, requiring repair.

This study has several limitations that should be considered. The retrospective, real-world nature of the data means that a well-controlled, matched comparison group adhering to other available treatments, especially CPAP, was not available. There may be confounding factors influencing the results we observed in ways we cannot delineate as well. While we chose to examine patients with at least 6 months of therapy and complete data sets, there is also a possibility that examining data on patients who are mid-therapy may have yielded different results in terms of effectiveness or adverse events. Given the size of the dataset, a "dose-response curve" could not be derived. The modest number of patients observed in this trial also limits the validity of the outcomes observed, as the dataset is not powered to explore multiple associations. Additionally, the limited nature of the data collected prevented us from exploring secondary outcomes more thoroughly like quality of life and impacts on medical conditions associated with OSA. In addition, this study lacked adequate power to

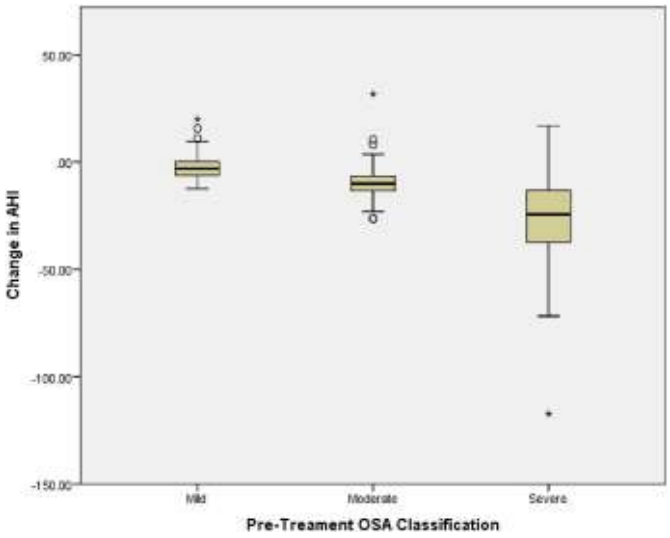

Fig. 3. AHI changes by OSA severity group.

determine whether the trajectories and/or magnitudes of AHI improvement were different between OSA severity classes. Missingness of data such as BMI and other relevant co-morbidities or quality of life data, also makes complete interpretation of our results limited. Selection bias is unable to be controlled for in this study design, as patients were enrolled based on real-world entry into treatment with a Vivos device. Many of the patients in the cohort were mid-treatment and it is possible that significant further changes and improvements or worsening could still occur, and are undetected in this cohort. As such, this may lead to better or worse results if the treated population is more, or less adherent with treatment, overall.

The above limitations notwithstanding, the results of this largest study on CARE are compelling and do suggest an association between CARE and improved OSA, as measured by AHI. Based on these results, further investigation through prospective, controlled trials and protocol-driven practice registry data is warranted. In addition, patient-centered data would help to define the place for CARE in the armamentarium of OSA treatment. Long-term follow-up data would also help elucidate the potential durability of CARE over 2 or even 5 years after therapy is completed. Finally, broader demographic data would better determine equity in outcomes through the lens of gender, race/ethnicity, and socioeconomic factors of great importance. Overall, CARE represents an emerging therapy in need of further study.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declaration of competing interest

Drs. DeMaria, Lin, Heckman and Kushida are members of the medical advisory board at Vivos Therapeutics.

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