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Original Article

Comfy Dormir Appliance: A Miracle in OSA Management – A Cross-Sectional Study

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Abstract

Aim: The aim is to compare the efficacy of the all-new comfy dormir appliance (CDA) made by us with some of the current obstructive sleep apnea **(**OSA) snore management oral appliance, mandibular advancement device (MAD), tongue repositioning device (TRD), and palatal lifter. This original article is a pilot study done on a specific place, specific area, and the samples taken were mild-to-moderate snorers within age limits of 18–60 years irrespective of gender. It is an *in vivo* trial survey of the CDA.

Material and Methods: The subjects were recruited from and near the Kalka Dental College, Partapur, Meerut. Reference sources include interns, college students, faculties, doctors, and local nearby village populations. The survey was made from the samples of patients with mild or moderate diagnosis OSA (OSA [AHI]>, 15 events/h). The study population was distributed into five different groups – Group I: No appliance used, Group II: Mandibular advancement device used, Group III: Tongue repositioning device, Group IV: Palatal lifter, and Group V: CDA. Measuring parameters include sleep cycle records of snore scores done in the application "sleep plus" app or "snore lab" app which are available on Android as well as IOS platforms. Samples were instructed to wear the appliance for 3 months and readings were recorded by the application "Sleep plus" or "Snore lab" App on a monthly basis by itself.

Statistical Analysis Used: SPSS software version 11 was utilized for the analysis of the data. The comparison was made using a one-way ANOVA test and *post hoc* test.

Results: After comparing the groups, the results indicated the lowest mean value for snore count among patients with CDA (Group V) CDA (5.20+2.5). The mean difference among the five groups was found to be statistically highly significant using a one-way ANOVA test ($P < 0.05$). Pairwise comparison among different groups using *post hoc* test was found to be statistically significant ($P < 0.05$).

Conclusions: Group V which used CDA had a very positive result as compared to other Groups. The means snore count decreased from 83% to 5.2%.

Key words: Comfy dormir appliance, Mandibular advancement device, Tongue repositioning device, Palatal lifter, Continuous positive airway pressure

INTRODUCTION

Rationale

Obstructive Sleep Apnea (OSA) is a frequent disorder marked by recurrent pharyngeal collapses that last at least 10 s and occurs 5 or more times each hour of sleep. Significant health effects such as hypertension, stroke, and early mortality are linked to the resulting hypoxemia sympathetic activation and sleep disruption.[1] With an incidence of 17% in adult women and 34% in adult men,[2] it is a serious systemic disorder that, if untreated may hamper the onset of new commodities, fatigue, and daytime sleeplessness, all of which affect cognitive function, quality of life, and risk of occupational and traffic accidents.[1]

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Objective

To treat cases of mild-to-moderate OSA in addition to the standard continuous positive airway pressure (CPAP)

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therapy, the automatic positive airway pressure and bi-level treatment have also become a routine, choice, independent of the cause of the apnea, and the location of or the characteristics of the patient. Oral appliances are recommended first for people with mild-to-moderate OSA and a back option for individuals with snore.[1]

The purpose of this study was to determine clinical practical protocol in a pragmatic study, although significantly more patients would experience a complete or partial response when a tongue positioning device compound and "Palatal lifter" components were added to a "Mandibular Advancement device" than with the comfy Dormir appliance (CDA) appliances used alone.

Available Treatment options for OSA

1. Mandibular Device

MADs Seeks to slightly, advance the jaw forward and downward to expand the upper airway and prevent it from collapsing, which will lesser snoring and OSA. The design of these devices is tailored to the dental material used for manufacturing - occlusal coverage, and the way in which they are fastened in the maxillary and mandibular teeth in a protruded position. Additional Non-Customized Boil and bite "MADS" with supple material that is malleable in hot water sold over the counter.[3,4]

2. Tongue Repositioning devices

TRD s devices Sucks in front of the Tongue into the frontal bulb and opens on expands the dimensions of the upper respiratory tract so that it prevents relapse this reduces obstructive sleep apnea.[1] The TRD has a mouth piece that covers the upper jaw and mandibular arches compute with definite mandible high light air transfer of the tongue section of the device creates a negative pressure therefore lift the tongue slightly forward.[5] Wall Mouth breathing becomes easier through the holes on the side of the device.

Figure 1: Lower component of comfy dormir appliance with mandibular advancement

3. Palatal lifters

Most patients experience, Snoring because they have excess or hanging tissues in the oropharyngeal area which blocks the airway. These lifting devices have adjustable acrylic handle that extend distally into the Soft palate and gently lifts the tissue, peening it from quivering when air passes during sleep. So, raising the palate significantly improves the dimensions of the upper respiratory tract helps to stop snoring and airway obstruction.[6]

MOA of Oral Appliances: The CDA incorporates a combination of MAD, tongue repositioning device, and palatal lifter innovatively put together. These components of the appliance forward the mandible and widen the lateral aspects of the upper airways to reduce airway collapse, hold the tip of the tongue forward using suction to open

Figure 2: Upper component of comfy dormir appliance with tongue retaining device positioned at the anterior part along with the split palatal lifter, all the component is incorporated along with the thermoplastic polymer material

Figure 3: Wire housing with protective rubber sleeves for mucosal safety, the housing keeps the components infact, provides rigidity and skeleton framework for the appliance, and keeps the appliance lightweight

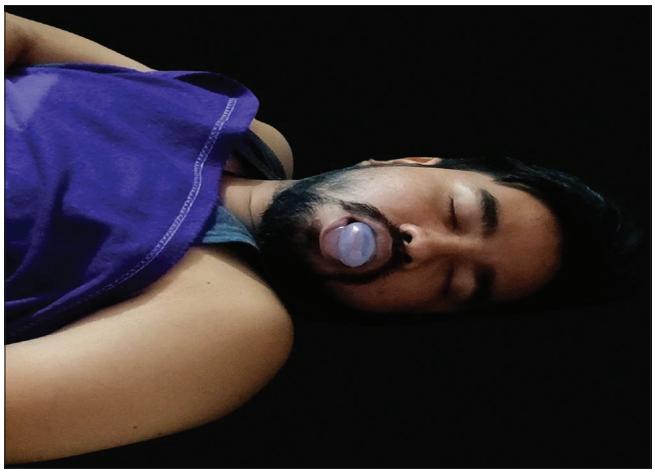

Figure 4: Patient using comfy dormir appliance appliance

airways, displace the soft palate superiorly and posteriorly to increase upper pharyngeal dimension [Figures 1-4].

MATERIALS AND METHODS

Study Design

A cross-sectional study.

Setting

Subjects were recruited from the Kalka Dental College, Partapur, Meerut, with a popular of 80,000. Reference sources at the center include interns, college students, faculties, doctors, and the local nearby village populations. Surveys were made to look out for the sample of patients with a mild or moderate diagnosis of OSA and those who failed or the individuals who are prohibited from CPAP are regularly offered the opportunity to consultation in relation to oral appliance therapy. The samples were instructed to wear the appliance for 3 months and readings were made with the help of the application "Sleep plus" or "Snore lab" App on a daily/monthly basis. This application provides the full information on the sleep cycle of the sample daily or monthly basis with the help of Chart 1. The following study was done after approval from the institutional ethics committee (Kalka Dental College and Hospitals) and a consent form was filled out before the recruitment of samples. All research instructions that include methods, study design, and sample selection process were thoroughly reviewed by the committee. All the potential risk factors associated with the study were been considered while the evaluation period. Proper criteria for sample selection have been given below.

Participants

The study population consists of 29 subjects from 176 referred during the recruitment period. Four samples did not follow up for the tests. The selection criteria were OSA sample mild to moderate [AHI] – 5–15 and 15–30 respiratory events/h; samples are 18+ age; both genders with OSA; dentulous samples only.

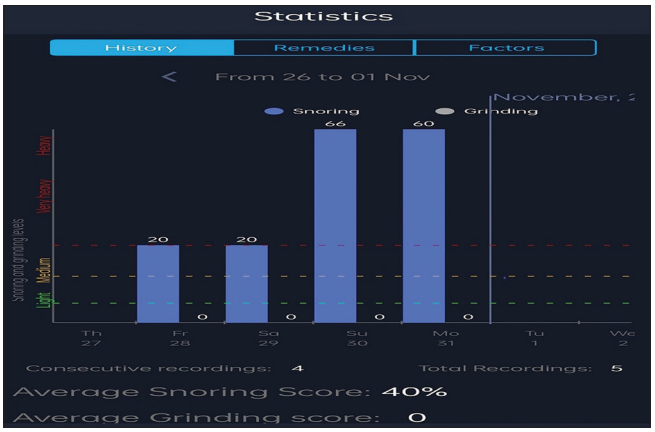

Figure 5: Statistical records of snoring with and without a comfy dormir appliance with the help of the application "sleep plus" or "snore lab" App

Figure 6: One of the recordings in graphical representation without a comfy dormir appliance

Figure 7: One of the recordings in graphical representation using comfy dormir appliance

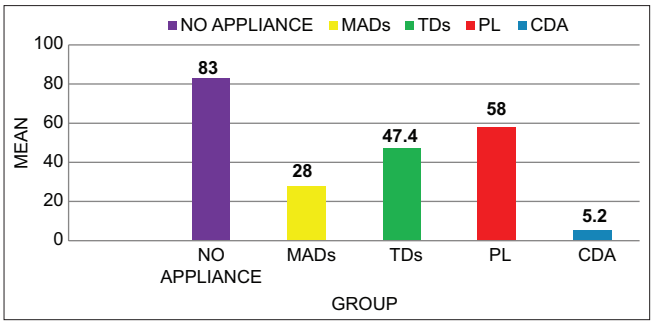

Chart 1: Snore count

The survey was made to look out for the sample of patients with a mild or moderate diagnosis of OSA and those who failed or the individuals who are prohibited from CPAP were regularly offered the opportunity to consultation in relation to the oral appliance therapy.

Putty impressions were taken, for each patient. The mandibular advancement device was made of thermoplastic polymer. The mandibular protrusion was achieved, by placing a triangular silicone material over the occlusal surface of the mandible and maxillary cast. The tongue retaining device along with palatal lifters was attached to the mandibular advancement device with the help of a wire housing in a silicone housing which embedded in a silicone housing which does not cause discomfort to the patient [Figures 1 and 3].

Variables

Snore count with four different appliances and one with no appliance (baseline).

Data Sources/Measurement

Samples were instructed to wear the appliance at night and were asked to record their sleeping cycle with the help of the application "sleep plus" app or "snore lab" app which is available on Android as well as IOS platforms [Figures 5-7]. The samples were instructed to wear the appliance for 3 months and readings were made with the help of the application "Sleep plus" or "Snore lab" app on a daily/monthly basis. This application provides the full information on the sleep cycle of the sample daily or monthly basis with the help of Chart 1.

The study population consists of 29 subjects from 176 referred during the recruitment period. Four samples did not follow up for the tests. The study population was distributed into five different groups.
Group I: No appliance used
Group II: MAD appliance used
Group III: TRD appliance used
Group IV: Palatal lifter appliance
Group V: CDA used (CAD).

BIAS

Serial number	BIAS	Limiting measures for BIAS
1	Selection bias	Scientific selection of sample
2	Observer bias	Triple blinding
3	Investigator bias	
4	Analyzer bias	
5	Measurement bias	Standardization of instrument
6	Reporting bias	Standardization of examiner

Study Size

Convenience sampling method.

Quantitative Variables

Snore count.

Statistical Method

Data collected were tabulated using MS Office Excel. Data were analyzed using SPSS (Statistical Package for the Social Science) version 23. Descriptive statistic for explanatory and outcome variables was calculated by the mean, standard deviation for quantitative variables, frequency, and proportion. Comparison of mean and various parameters between two groups was carried out using an independent *t*-test and for three groups was carried out using ANOVA and *post hoc* test (with Bonferroni correction).

Statistical Mean and Standard Deviation

The statistical mean refers to the mean or average that is used to derive the central tendency of the data in question. It is determined by adding all the data points in a population and then dividing the total by the number of points. The resulting number is known as the mean or the average.

The standard deviation is a statistic that measures the dispersion of a data set relative to its mean. The standard deviation is calculated as the square root of variance by determining each data point's deviation relative to the mean.

The formula for calculating mean **x** is:

$$x = \sum x/n$$

The formula for calculating standard deviation (σ) is:

$$\sigma = \sqrt{1N\sum Ni=1(Xi-\mu)^2}$$

ANOVA (Analysis of Variance) is a statistical test used to analyze the difference between the means of more than two groups.

Commonly used for,

- Statistical difference between the means of more than two groups

Table 1: Descriptive statistics

				(*n*=5)			
Group	Mean	SD	SE	95% CI for mean		Minimum	Maximum
				Lower bound	Upper bound		
No appliance	83.00	4.950	2.214	76.85	89.15	76	89
MADs	28.00	6.403	2.864	20.05	35.95	17	33
TDs	47.40	3.507	1.568	43.05	51.75	42	51
PL	58.00	4.690	2.098	52.18	63.82	51	63
CDA	5.20	2.588	1.158	1.99	8.41	2	8

CI: Confidence interval, SD: Standard deviation, SE: Standard error, MADs: Mandibular advancement devices, CDA: Comfy dormir appliance

- Statistical difference between the means of more than two interventions
- Statistical difference between the means of more than two scores

A two-way ANOVA is used to estimate how the mean of a quantitative variable changes according to the levels of two categorical variables. Use a two-way ANOVA when you want to know how two independent variables, in combination, affect a dependent variable.

The Bonferroni Method

The Bonferroni *post hoc* test should be used when you have a set of *planned* comparisons you would like to make beforehand.

For example, suppose we have three groups – A, B, and C – and we know ahead of time that we are only interested in the following comparisons:

- $\mu_A = \mu_B$
- $\mu_B = \mu_C$

When we have a specific set of planned comparisons, we would like to make ahead of time like this, the Bonferroni *post hoc* test produces the narrowest confidence intervals, which means it has the greatest ability to detect a true difference between the groups of interest.

Note that the Bonferroni *post hoc* test can also be used whether or not the group sample sizes are equal.

RESULT

Participants

(a) Study population consists of 29 subjects from 176 referred during the recruitment period
- OSA sample mild-to-moderate [AHI]: 5–15 and 15–30 respiratory events/h
- Samples are 18+ age
- Both genders with OSA
- Dentulous samples only

Table 2: Multiple comparisons using one-way analysis of variance

Group	Mean	SD	*P*	Result
No appliance	83.00	4.950	0.000**	HS
MADs	28.00	6.403		
TDs	47.40	3.507		
PL	58.00	4.690		
CDA	5.20	2.588		

HS: Highly significant, SD: Standard deviation, MADs: Mandibular advancement devices, CDA: Comfy dormir appliance, **Highly significant

(b) 4 samples did not follow up for the tests due to their personal home affairs.

Descriptive Data

In the present study, the mean value for snore count was recorded among participants of five groups with different appliances. It was found that the highest mean value for snore count was recorded among patients with no appliance (83.00 ± 4.9) in Group I, followed by Group IV with PL (58.00 ± 4.6), then by Group III with TDs (47.4 ± 3.5) and Group II with MADS (28.00 ± 6.4). It was found that the least count was recorded among the participants of Group 5 with CDA (5.20 ± 2.5) [Table 1]. The mean difference among the five groups was found to be statistically highly significant using a one-way ANOVA test ($P < 0.05$) [Table 2] and pairwise comparison among the different groups using *post hoc* test was found to be statistically significant ($P < 0.05$) [Table 3].

Outcome Results

The outcome of the result was that the sample in Group V which used CDA had a very positive result as compared to other Groups the means snore count decreased from 83% to 5.2%.

Main Results

In the present study, mean snore counts were recorded among participants in five groups using different appliances. The highest mean snore count was observed in Group 1, where participants used no appliance, followed by Group 4 using a Palatal Lifter, Group 3 using a Tongue Repositioning Device, and Group 2 using a Mandibular Advancement Device. The lowest mean snore count was

Table 3: *Post hoc* multiple comparisons

Multiple comparisons						
(I) group	(J) group	Mean difference (I−J)	SE	Significant	95% CI	
					Lower bound	Upper bound
No appliance	MADs	55.000*	2.919	0.000**	45.80	64.20
	TDs	35.600*	2.919	0.000**	26.40	44.80
	PL	25.000*	2.919	0.000**	15.80	34.20
	CDA	77.800*	2.919	0.000**	68.60	87.00
MADs	TDs	−19.400*	2.919	0.000**	−28.60	−10.20
	PL	−30.000*	2.919	0.000**	−39.20	−20.80
	CDA	22.800*	2.919	0.000**	13.60	32.00
TDs	MADs	19.400*	2.919	0.000**	10.20	28.60
	PL	−10.600*	2.919	0.017*	−19.80	−1.40
	CDA	42.200*	2.919	0.000**	33.00	51.40
PL	CDA	52.800*	2.919	0.000**	43.60	62.00

*The mean difference is significant at the 0.05 level. CI: Confidence interval, SE: Standard error, MADs: Mandibular advancement devices, CDA: Comfy dormir appliance, **Highly significant

recorded in Group 5, where participants used the Comfy Dormir Appliance [Table 1].

In the present study, the mean value for snore count was recorded among participants of five groups with different appliances. It was found that the mean difference among the five groups was found to be statistically highly significant using a one-way ANOVA test ($P < 0.05$) [Table 2] and pairwise comparison among the different groups using *post hoc* test was found to be statistically significant ($P < 0.05$) [Table 3].

The results showed that the Group using comfy Dormir appliance (Group V) experienced significantly positive outcome compared to other groups. The Means Snore count decreased dramatically from 83% to 5.2 %. This version clarified that Group V, which used the comfy Dormir appliance , had a substantial reduction in snoring compared to other groups in study

DISCUSSION

Oral appliances are increasingly used as a preventive treatment for OSA. They are recommended as 1st line of treatment for mild-to-moderate OSA and 2nd line of treatment for severe OSA conditions.

Key Results

The outcome of the result was that the sample in Group V which used CDA had a very positive result as compared to other groups; the means snore count decreased from 83% to 5.2%. OSA treatment using the CDA had renowned results as compared to the other appliance alone. Snore count decreased from 83% to 5.2%.

Limitations

The selected sample should have Mild to Moderate [AHI] – 5 to 15 & 15-30 respiratory events/hr.[7] Severe snoring, i.e., more than 15–30 respiratory events/h is not recommended for this oral appliance.

CONCLUSION

Despite evolving approaches to OSA, many issues remain unresolved. The goal of diagnosis and treatment of OSA improve the quality of life of the patient. Continuous follow-up and communication are essential for effective OSA management.

Patients are encouraged to participate in a healthier way to reproductive lifestyle modification programs such as physical activities and exercise for weight loss so that obesity decreases among the individual.

FUNDING

Nil.

CONFLICTS OF INTEREST

There are no conflicts of interest.

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