ORIGINAL ARTICLE

Comparative evaluation of therapeutic efficacy of Thornton adjustable positioner with Karwetzky activator in the management of obstructive sleep apnea syndrome

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Abstract

Background: Mandibular advancement devices (MAD) are recognized as an effective option in the management of obstructive sleep apnea (OSA). Thornton adjustable positioner (TAP) allows gradual forward titration of mandible to optimize treatment outcome. Karwetzky activator is a fixed MAD and titration is not possible. Therefore a study was under taken to compare the therapeutic efficacy of TAP with Karwetzky activator in the management of OSA.

Methods: Twenty polysomnography diagnosed OSA patients were prescribed TAP (Group I) and another twenty were prescribed Karwetzky activator (Group II). The therapeutic efficacy was evaluated on Apnea-Hypopnea Index (AHI) and Epworth Sleepiness Scale (ESS).

Results: The percentage improvement in AHI scores in Group I was 52.48% compared to 42.37% in Group II. Statistically significant improvement (P<.001) in AHI and ESS scores was observed in Group I and Group II.75% and 55% positive responders (AHI improvement of >50) in Group I and Group II respectively were observed.

Conclusion: Therapeutic efficacy and clinical acceptance of TAP was superior to Karwetzky activator. Superior performance of TAP can be attributed to gradual titration and optimum mandibular positioning.

Keywords: Obstructive sleep apnea, Thornton adjustable positioner, Karwetzky activator

Introduction

Mandibular advancement devices (MAD) are recognized as an effective option for treatment of obstructive sleep apnea (OSA). Many studies have reported the rates of treatment success for OSA patients with the use of MAD. The previous results reported in the literature have varied from 50 % - 80% depending on the definition of success and the type of MAD [1,2,3,4,5, 6,7]. Some patients do not achieve an acceptable improvement in the apnea hypopnea index

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(AHI) with MAD. Fixed MAD is often required to be re-fabricated to bring out the requisite mandibular advancement for achieving maximum therapeutic efficacy. This results in increased chair side time, lab time and increased man hours. Clinically the concept of gradual forward titration of the mandible to obtain optimal treatment outcome with a MAD is appealing. Anterior mandibular positioning lacking sufficient and precise adjustments might under estimate the efficacy of MAD. If the position of the mandible could be titrated similar to as with continuous positive air pressure (CPAP), where nasal pressure is usually adjusted for each patient, OSA symptoms could be more effectively improved [8]. It was also not clear from our earlier studies as to why some cases did not respond to treatment [7]. Hence, we undertook a study to compare and evaluate the therapeutic efficacy and patient acceptance of Thornton Adjustable Positioner (TAP) which is a titratable/adjustable device with Karwetzky activator which is a fixed mandibular advancement appliance with the following aims and objectives.

- To compare the therapeutic efficacy of Thornton Adjustable Positioner (TAP) with Karwetzky activator in the management of obstructive sleep apnea syndrome.
- Evaluation of percentage improvement of AHI in all the study subjects.
- Comparison of base line and post treatment AHI and Epworth sleepiness scale (ESS) scores in patients treated with TAP and Karwetzky activator.

Patients and methods

Thirty adult patients presenting with polysomnography (PSG) diagnosed OSA were considered for treatment with TAP (Group- I). Ten of these cases were lost to follow up. The study subjects treated with Karwetzky activator (Group II) included in the present study were 12 cases from our previous study [7]. Eight new cases treated with Karwetzky activator were included in this group along with the former. The detail of cases was recorded on a sleep disordered breathing examination form which was inclusive of body mass index (BMI), neck size, alcohol consumption, sedative usage details, sleep position, frequency and intensity of snoring, Epworth sleepiness scale (ESS), tongue size, airway grading, periodontal examination, TMJ evaluation, blood pressure history, maximum mandibular protrusion and clearance between central incisors at maximum opening. All the study subjects were subjected to lateral cephalometry for craniofacial and upper airway analysis.

The criteria for patient selection are as follows:-

Inclusion criteria

- Adult patients.
- Mild to moderate OSA cases i.e. (AHI not exceeding 30/ h).
- Severe OSA cases not amenable to CPAP therapy or surgery (AHI >30/sleep h)

Exclusion criteria.

- Primary central apneas and hypopneas.
- Anatomically caused upper airway obstruction.
- Pre existing tempero mandibular pain/dysfunction.
- Maximum mandibular protrusion less than 5 mm.
- Bilateral distal edentulousness.
- Complete edentulousness.
- Advanced periodontal disease with multiple mobile teeth.

Two designs of TAP appliance were used in the study-namely TAP-S and TAP-T (R) (Fig. 1,2,3). Out of the 20 cases TAP-S was used on 13 cases and in the remaining 7 cases TAP-T (R) was prescribed. Both the TAP versions used were custom adjustable oral appliance that is worn while sleeping. The splint bases were vacuum formed with biostar machine and were made of thermoplastic hard – soft composite material (Dura soft 2.5 mm). The standard clinical and laboratory protocol for fabrication of appliances was followed. The titration was conducted on a weekly basis till the patient reported good improvement subjectively. However, titration did not exceed 70 % of maximum mandibular protrusion. PSG was done with TAP-S / TAP-T(R) in-situ after completion of titration for objective assessment. Titrating assembly was replaced by locking plates after satisfactory objective assessment (Fig. 2). Karwetzky activator, made of autopolymerising resin, is a tooth-tissue borne activator which is split along the occlusal plane and joined by two 'U' loops in the lingual acrylic area of first molars (Fig. 4). Post treatment ESS scores were recorded in patients of both the groups. The data base was compiled on MS Excel work sheet and Mat lab 7.5 was used for statistical analysis.

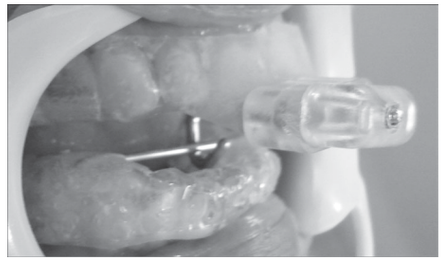

Figure 1 : Intra oral view of a patient with TAP-S

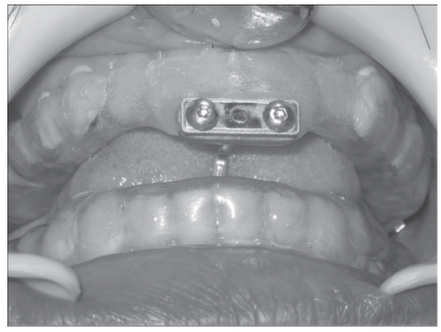

Figure 2 : Intra oral view of TAP-S at end of titration and objective assessment. The titrating assembly has been replaced by locking plates.

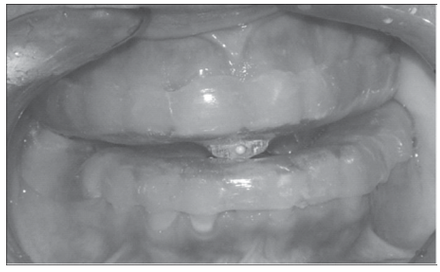

Figure 3 : Intra oral view of TAP-T (R)

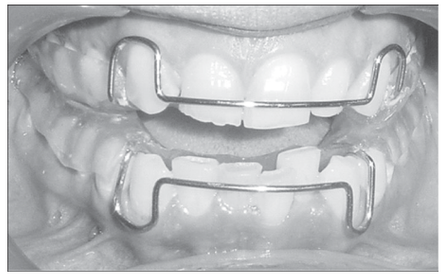

Figure 4 : Intra oral view of Karwetzky activator

Results and observations

In Group-I (n = 20), the age profile was 55.10 ± 12.76 years (mean ± sd) and mean BMI was equal to 27.62 Kg/m². The male to female ratio was 15: 5. The overall percentage improvement in AHI scores was 52.48%. Six cases (30%) did not respond positively (AHI % improvement < 50%) to treatment with TAP appliance. The percentage improvement of AHI scores for each patient in Group-I and response to the treatment in Group-I is summarized in Table-1. In Group-II (n = 20), the age profile was 47.65 ± 8.28 (mean ± sd) and mean BMI was 30.46 kg/m². The male to female ratio in this group was 12:8. The overall percentage improvement in AHI scores was 42.37%. Nine cases (45%) did not respond positively. The percentage improvement of AHI scores for each patient in Group-II is summarized in Table 1.

Intra group comparison of pre and post treatment AHI and ESS scores in both the groups showed statistically significant improvement (P<.001) (Table 2). In Group 1 statistically significant improvement (P<.001) in AHI and ESS scores was observed in cases treated with TAP(S) and TAP(R).However inter sub group comparison was not found to be statistically significant (P>.001) (Table 3).

Table 1: Percentage improvement of AHI scores and response to treatment

Case Code	Group -I		Group -II	
	% Improvement	Response	% Improvement	Response
001	55.31	Positive	51.81	Positive
002	62.74	Positive	100	Positive
003	66.74	Positive	65.06	Positive
004	52.48	Positive	49.25	Negative
005	41.59	Negative	59.30	Positive
006	81.96	Positive	56.93	Positive
007	41.68	Negative	58.94	Positive
008	58.94	Positive	54.10	Positive
009	46.12	Negative	0.82	Negative
010	60.75	Positive	41.59	Negative
011	61.43	Positive	60.59	Positive
012	16.46	Negative	71.92	Positive
013	62.66	Positive	57.81	Positive
014	36.44	Negative	- 2.51	Negative
015	58.78	Positive	36.77	Negative
016	81.81	Positive	58.16	Positive
017	60.86	Positive	7.48	Negative
018	30.69	Negative	24.82	Negative
019	55.69	Positive	6.68	Negative
020	53.37	Positive	48.93	Negative

$$\% \text{ improvement} = \frac{\textit{Base line AHI} - \textit{Post treatment AHI}}{\text{Base line AHI}} \times 100$$

Table 2 : Statistical comparison between pre and post treatment among Group I & II

Thornton Adjustable Positioner				Karwetzky Activator			
Var	**Pre (A)**	**Post (B)**	**Sig A vs B**	**Var**	**Pre (A) (A)**	**Post (B) (B)**	**Sig A vs B**
AHI	46.22 ± 2.90	21.96 ± 2.78	P<0.001	AHI	46.40 ± 4.65	26.74 ± 4.65	P<0.001
ESS	13.05 ± 0.48	9.00 ± 0.32	P<0.001	ESS	12.95 ± 0.61	8.00 ± 0.56	P<0.001

Table 3 : Statistical comparison between pre and post treatment AHI scores between patients treated with TAP(S) and TAP-T(R) in Group I

TAP (S)				TAP-T (R)			
Var	**Pre (A)**	**Post (B)**	**Sig A vs B**	**Var**	**Pre (A) (A)**	**Post (B) (B)**	**Sig A vs B**
AHI	46.64 ± 12.71	22.62 ± 13.78	P >0.001	AHI	43.76 ± 14.11	20.72 ± 11.25	P >0.001

Statistical comparison of performance of Group-I and Group-II with respect to AHI and ESS showed no significant difference (P>.001). The same is summarized vide Table 4; however the percentage improvement of AHI scores in Group-I (52.48 %) was superior to Group-II (42.37 %). Positive responders in Group-I (75 %) were more than Group-II (55 %). We found better compliance, patient comfort, better stability and retention of MAD in Group-I. Some of the cases reported excessive salivation following initiation of treatment but improved subsequently. Seven cases in Group II reported pain/discomfort in the TMJ and masticatory muscles in the first week but improved subsequently on biting silastic shem in the morning for 10-15 minutes. Any two of the cephalometric findings namely reduced posterior airway space (PAS), increased hyoid distance (MP-H) and decreased SNB angle were observed in cases in Group-I.

Discussion

OSA is the cessation of air flow despite adequate effort to breathe caused by complete or partial airway obstruction during sleep.MAD helps in keeping the mandible forward in sleep. It prevents the tongue from approaching the posterior wall of the pharynx and causing obstruction. These appliances act by elevating the base of the tongue, tensing palatoglossus muscle and decompressing the tissues around the pharynx [9]. We studied fixed MAD and encountered uncertainty about selection of maximum dosage of mandibular advancement required to control OSA in individual patients [7]. The mean AHI decreased from 46.50/h to 23.37/h and the percentage improvement recorded was 49.75 %. The present study augmented the sample of the above study with eight more cases (Group-II). Although statistically significant improvement (P<.001) was observed with respect to AHI and ESS, the mean percentage improvement recorded on AHI was 42.37%. Therefore this cannot be considered an overall successful treatment outcome in Group-II as the mean percentage improvement was less than 50% AHI reduction. However 55% of patients in the first group recorded ≥50% improvement in AHI, thus being included as positive responders. According to experts in the field of dental sleep medicine, positive response with mandibular

Table 4 : Statistical comparison between treatments for AHI and ESS in Group-I and Group-II

AHI				ESS			
Var	**Thornton (A)**	**Karwetzky (B)**	**Sig A vs B**	**Var**	**Thornton (A)**	**Karwetzky (B)**	**Sig A vs B**
Pre	46.22 ± 2.90	46.40 ± 4.65	NS	Pre	13.05 ± 0.48	12.95 ± 0.61	NS
Post	21.96 ± 2.78	26.74 ± 4.17	NS	Post	9.00 ± 0.32	8.00 ± 0.56	NS

NS : Not Significant (P>.001)

advancement appliance is observed in approximately 63% of the cases [10]. The reason for only 55% positive responders may be explained by the fact that most of the cases were severe OSA and obese. The favorable mandibular position can not be ascertained with fixed MAD like Karwetzky as the bite is recorded and appliance is fabricated to the recorded bite only once thereby leaving no/minimal scope for adjustment.

One of the major physical findings in OSA is obesity. The increased body weight co-relates with increased frequency of apnea and severity of hypoxemia. However, the morbidly obese somnolent, hyper ventilating patient with corpulmonale represents a smaller number of sleep apnea patients. Lower BMI with obstructive sleep apnea often have more abnormal cephalometrics than obese people [11]. The mean BMI in Group-I was 27.62 Kg/m² and in Group-II was 30.46 kg/m². This difference was statistically significant (P<.05) and may have contributed to the better performance of MAD in patients in Group-I compared to Group-II in the present study.

In Group-I there was significant improvement (P<.001) with respect to AHI and ESS. The mean percentage improvement recorded was 52.48 % and is suggestive of successful out come. Seventy five per patients responded positively to TAP Therapy. The results clearly indicates TAP to be a better treatment option in the management of OSA than Karwetzky activator. However, the enigma with respect to reasons for certain patients not responding to MAD therapy remain unclear.

No significant difference (P>.001) was observed when the performance of TAP (S) and TAP-T(R) were compared. The fabrication of TAP-T(R) was much easier. Patient acceptance was also better. In TAP-S, during the titration phase the lips can not be closed as the titrating assembly protrudes between the lips. This disadvantage has been overcome by the TAP-T(R) design in which the titrating assembly is placed intra orally (Fig 1, 3).

Attempts are being made by investigators to crack the enigma of non responders to oral advancement (OA) therapy in OSA. A retrospective study in 2006 compared cephalometric variables between responders and non responders to a titratable MAD in a group of subjects matched for sex, pretreatment age and BMI [12]. In this study middle and inferior airway space and oropharyngeal airway cross sectional area were significantly larger in non responders. Position of the mandible, relative to cervical spine, was the only significant skeletal variable and was larger in non responders. There was a 2.9 % increase in BMI in non responders. The weight gain in non responders might also have reduced the effectiveness of MAD.

A study reported by Pancer and co-workers concluded TAP to be an effective treatment alternative for selected patients with snoring and OSA including severe OSA [5]. In this study the base line AHI was 44 $\pm$ 28/h which is comparable to the present study which recorded 43.76$\pm$ 14 /h. The study has reported a reduction in AHI to 10$\pm$ 9/h which is far greater when compared to the present study 21.96 $\pm$2.78/h. This is probably due to a sample size who underwent PSG with TAP (n=61).

A predictable AHI based results was achieved with TAP in a case control study which encompassed examination of initial effects of PSG in patients with OSA [13]. The base line AHI in this study was 19.2 $\pm$ 12.8/h and showed improvement to 3.3 $\pm$ 7.8/h. In the present study only two cases in Group-I , one each treated by TAP-S and TAP-T (R) showed similar response. The base line AHI which is comparable to the above study decreased from 22.5/h and 22/h to 8.4/h and 04/h respectively. This is reflective of better response of mild to moderate OSA to MAD therapy.

Based on scientific appraisals and international guidelines most of the sleep societies recommend oral appliance treatment for primary snoring, upper airway resistance syndrome, mild to moderate OSA (AHI up to 30/h) and in severe cases, not amenable to CPAP therapy. The above recommendations was supported in a study by Marklund and colleagues who specifically evaluated the efficacy of MAD in OSA patients with varying levels of severity [14]. In this prospective study they demonstrated a significant reduction in AHI in patients with wide range of OSA severities but the greatest improvement was observed in patients with mild and moderate cases. An excellent review by Kathleen Ferguson on oral appliances therapy for OSA has pointed out that most studies exclude the patients with severe OSA and include patients who failed other treatment modalities, thus there exists a significant source of bias [15]. In the present study this bias has been over come as severe OSA cases have been included. In a study by Henke and colleagues of 28 patients with OSA showed that severity of OSA and the site of airway closure did not predict the efficacy of the device. In this study patients with severe sleep apnea had a mean reduction of 53 % in their AHI scores which is comparable to the findings in the present study [16]. Base line AHI and percentage

AHI improvement in the present study are also comparable to the study by Henke and co-workers.

Karwetzky activator had to be refabricated in a few cases, either due to inadequate subjective response or lack of retention. TAP appliances were not refabricated in any case thus saving man hours. Ten cases in the Group-I were lost to follow up over a period of time and most of them had reported pain in TMJ, tenderness in masseter muscle and gag reflex in addition to poor subjective response. These cases did not report for follow up after a few weeks and PSG studies with OA in-situ. Patients who had reported pain in the TMJ and pain in masseter muscle were prescribed silastic shem. Affected patients were asked to bite on the silastic shem with the front teeth for approximately 15 minutes [17]. This resulted in reseating the condyle and disc within the fossa which contributed to dissipate edema in the joint that may have developed over night with the use of MAD.

Cephalometric findings like reduced PAS, increased MP-H and decreased SNB was observed in Group I. This clearly suggests a predominant craniofacial element. This may also have contributed to the better treatment outcome in Group I. This bias needs to be over come in future studies. We recommend further studies to evaluate the causes for non responders to MAD and dosage of mandibular advancement.

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