Original Research Article

Comparison of upper airway post oral appliance therapy in patients with obstructive sleep apnea using 3 different modalities (lateral cephalogram, acoustic pharyngometry and CBCT)- A prospective clinical study

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ARTICLE INFO

ABSTRACT

Introduction: Obstructive Sleep Apnea (OSA) is a condition that results due to partial or complete obstruction of airway when patient assumes a supine position and goes to sleep.
Aim and Objective: of study was to compare the changes in upper airway resulting with oral appliance in treatment of OSA using lateral cephalogram, Acoustic Pharengometry (AP) and CBCT and correlate with AHI changes.
Results: OSA subjects treated with oral appliance therapy (OAT) had a significant improvement in upper airway diemensions.
Conclusion: Study assessed the changes in upper airway following oral appliance for treatment of OSA using Lateral cephalogram, AP and CBCT and correlated the changes with AHI. The following conclusions can be drawn from this study (a)There is a marked improvement in mean volume, mean area and minimum distance of constriction in upper airway following OAT assessed using Lateral cephalogram, AP and CBCT. (b) Among the above 3 modalities, CBCT shows a statistically significant correlation with change in AHI following OAT.

1. Introduction

Obstructive Sleep Apnea (OSA) is a condition that results due to partial or complete obstruction of airway when patient assumes a supine position and goes to sleep. OSA is characterized by episodes of apnea hypopnea during sleep associated with various signs and symptoms, most important being loud audible snoring and excessive daytime sleepiness. An increase in neck circumference and obesity among patients has been related with OSA and an imbalance of the upper airway anatomy is noticed.[1–3] Craniomaxillofacial abnormality is a well-recognized risk factor for patients with OSA, if untreated they are at risk of association with cardiovascular disorders and high blood pressure.[4] Overnight Polysomnography (PSG) i.e.,Type 1 PSG, Lab set up attended sleep study, showing various parameters of Apnea Hypopnea Index (AHI) is the gold standard for diagnosis of OSA, however the assessment of craniofacial risk factors include upper airway assessment using lateral cephalogram, Acoustic Pharyngometry (AP), and Cone beam computed tomography (CBCT).[1,5]

Lateral cephalogram helps in two dimensional (2D) evaluation of upper airway dimensions, and its accuracy in diagnosis and evaluation of results is well documented. However, it evaluates the upper airway in sagittal plane only.[6] AP is a non-invasive diagnostic technique, works

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on the principle of acoustic reflection (AR). AP modality is used to asses and quantify the volume and area of upper airway without any radiation exposure. The AR technique has been found to be accurate and reproducible in measuring airway dimensions.[7–9] Cone-beam computed tomography (CBCT) is a commonly used three-dimensional (3D) imaging technique introduced to dentistry in 1998. It provides linear as well as volumetric changes of a dynamic 3D airway space. When utilizing a large field of view (FOV), the upper airway is visible within the CBCT volume and thus CBCT is a useful diagnostic tool for evaluation of the airway.[10] Assessment of the upper airway in individuals with OSA is essential, as they have reportedly smaller upper airways than individuals without OSA.[11] Furthermore, evaluation of the upper airway is essential due to the reported increase in the frequency of airway collapse in individuals with narrower and longer airways.[12]

The treatment of OSA involves conservative management, non surgical and surgical management. The non surgical management of OSA involves usage of continuous positive airway pressure (CPAP) and oral appliances. In the last few decades mandibular advancement devices (MAD) have been extensively used in the treatment of mild to moderate OSA.[13,14]

Lateral Cephalogram, AP and CBCT have been extensively used for assessing the parameters of upper airway in patients with OSA being managed by OAT. However no study has compared the same with the changes in AHI using the above modalities in a single study. Thus, aim of study was to compare the changes 'if any' in upper airway resulting with oral appliance in treatment of OSA using lateral cephalogram, AP and CBCT and correlate with AHI changes.

2. Materials and Methods

This prospective study was conducted at the Department of Orthodontics and Dentofacial Orthopaedics of a tertiary care government teaching institute. A convenient sample of 15 patients with moderate OSA was selected. Ethical clearance for the study was obtained from the institutional ethical committee, and a written informed consent was obtained from the subjects

2.1. Inclusion criteria

1. Type 1 PSG diagnosed cases of OSA with AHI > 5
2. Cases showing improvement in airway with mandibular anterior protrusion as seen from AP
3. Those who have minimum mandibular protrusive movement of 3-5 mm
4. Adequate number of anterior and posterior teeth to support the oral appliance

2.2. Exclusion criteria

1. Central OSA
2. Systemic conditions/diseases affecting airway including thyroid swelling, nasopharyngeal carcinoma etc.
3. Temporomandibular disorders
4. Syndromes affecting airway including cleft lip and palate
5. Poor oral hygiene with severe periodontal disease including chronic aggressive periodontitis

The treatment records for all patients were obtained at following time frames:
T0 - Pretreatment records
T1 - 03 months post OAT

3. Procedure Methodology

The pre-treatment AHI was recorded from the PSG records available with the patients. Standard orthodontic treatment records taken at T0 included photographs (intra oral & extra oral), study models, lateral cephalogram, OPG, AP recorded in mandibular rest & mandibular protruded position, CBCT. The lateral cephalogram, OPG and CBCT were taken in standard method using the dental radiography and CBCT machine manufactured by M/s Cefla Dental Group Italy, Model - NEW TOM GIANO: G-XR-46893. AP was recorded using the Eccovision$^{(R)}$ Acoustic Pharyngometer manufactured by Sleep Group Solutions, 2035 Harding St. #200, Hollywood, FL 33020 [Fig 1].

Manual tracings of the lateral cephalogram were done and various upper airway linear parameters of VAS, PAS, HAS were measured [Fig 2]. The acoustic pharyngometry produces an instant graph (Acoustic pharyngogram) which elicits the mean area, mean volume and minimum distance [Fig 3]. CBCT was generated records were exported in DICOM 3.0 format using NEWTOM.NNT analysis software. The CBCT data was transferred to the Horos^{TM} software [GNU Lesser general public license, Version 3 (LGPL-3.0), Horos Project, Annapolis, MD, USA] for assessment. The CBCT orientation was done in relation to McRae (a line joining median point of the anterior margin of the foramen magnum- Basion and median point of the posterior margin of the foramen magnum- Opisthion) in the mid sagittal section of multi planar reformation view.[15] After orientation was done, palatal plane (a line joining ANS and PNS) was marked. The digital tracing process of upper airway was done by marking the region of interest (ROI) in the mid sagittal section. It was traced anteriorly along curvature extending from PNS to tip of epiglottis, posteriorly traced along the posterior wall of pharynx, superiorly by line extending from palatal plane to posterior wall of pharynx and inferiorly by base of epiglottis to posterior wall of pharynx. The palatal plane was marked in all the sagittal section. Based on the anatomical outline of

the ROI, the Horos™ software automatically calculates the area of ROI and is depicted on to the screen . To assess the volume of the upper airway, a series of sagittal section were selected from the multiplane reformation (MPR) view of CBCT. The segmentation process included the mid sagittal section and at the best possible level of mandibular first molar, first premolar, canine of both sides. The ROI digital marking of airway was done in each section. Based on marked ROI, the software automatically combines the series of ROI and defines the outline of upper airway with a 3D image. Airway volume is generated by the software based on ROI compiled [Fig 4].

4. Treatment Progress

Based on the chief complaint, clinical features and pre-treatment records assessment, an appropriate treatment plan was formulated and OAT was planned for the patients. MDSA Pty Ltd (Australia), an adjustable mandibular advancement device having a titratable screw was selected for the patients as OAT and was delivered to the patients. At T1, all the records were again taken in the same standardized technique. CBCT and lateral cephalogram was taken with oral appliance placed in the mouth, and the AP was carried out in predetermined mandibular protruded position within normal physiological limit. Data of Type 1 PSG showing the AHI was also collected at T1.


Figure 1: Recording of acoustic pharyngometry

5. Data Compilation and Statistical Analysis

The data of variables is shown as N (% of cases) and the data on continuous variables is presented as mean and standard deviation (SD). The inter-group statistical comparison of means of continuous variables was done using independent sample t test. The intra-group statistical comparison of means of continuous variables was done using paired t test. The underlying normality assumption was tested before
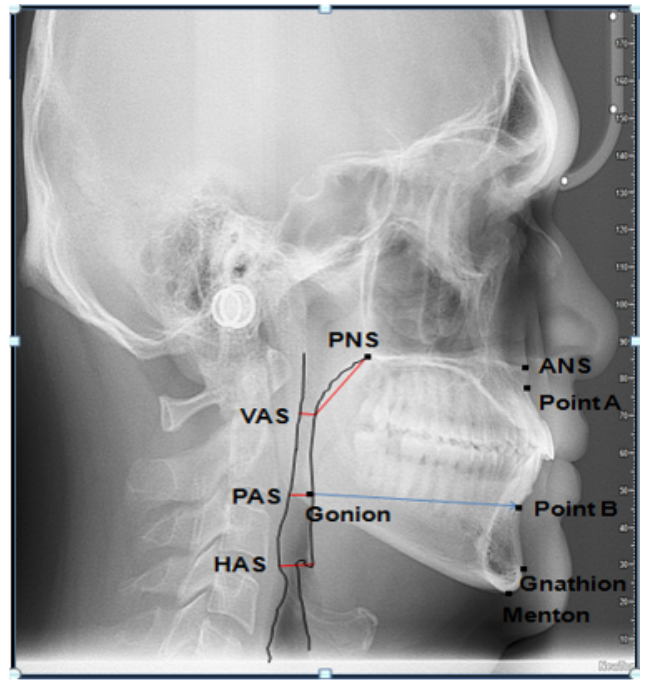
Figure 2: Cephalometric points and measurements
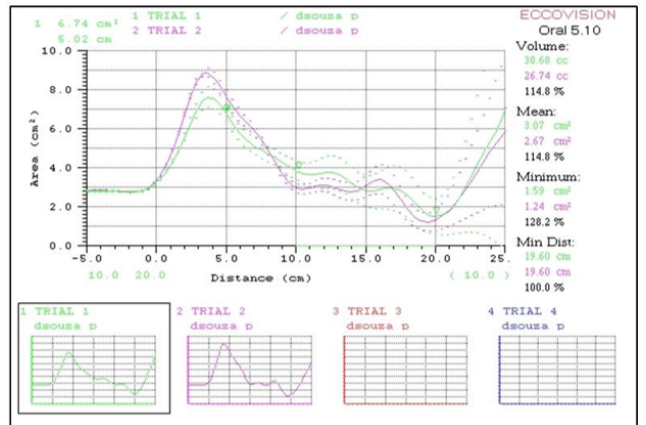
Figure 3: Acoustic Pharyngogram showing mean volume, mean area and minimum distance (Trail 1: Purple line – T0 Pretreatment, Trail 2: Pink line- mandibular protruded position)
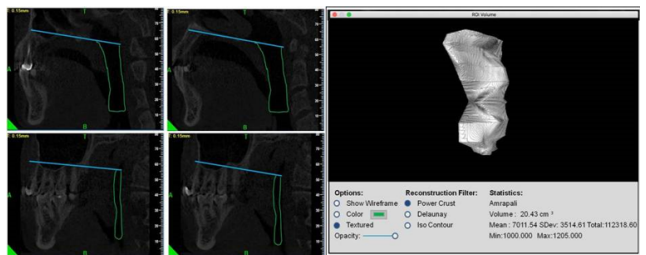
Figure 4: Assessment of upper airway area and volume using Horos™ software

Table 1: Characteristics of study sample at T0

Parameters		Statistical data
Age Group (years)	<50	3 (20.0%)
	50 – 60	10 (66.7%)
	>60	2 (13.3%)
	Mean ± SD (Min – Max)	51.80 ± 10.21 (28 – 62)
Sex	Male	10 (66.7%)
	Female	5 (33.3%)
BMI (kg/m^2)	18.50 – 24.99	2 (13.3%)
	25.00 – 30.00	13 (86.7%)
	Mean ± SD (Min – Max)	26.24 ± 1.49 (22.49 – 28.57)
Neck circumference (cm)	Mean ± SD (Min – Max)	41.20 ± 1.86 (38.0 – 44.0)
AHI per hour sleep	Mean ± SD (Min – Max)	17.96 ± 6.31 (12.3 – 29.5)
Upper airway parameters VAS (mm) PAS(mm) HAS(mm)	Mean ± SD (Min – Max)	6.27±1.03 (5.24-7.3) 7.13±0.99 (6.14-8.12) 11.40±2.23 (9.17-13.63)

subjecting the study variables to t test. Box-Whisker plot was used for graphical presentation of continuous variables studied. All results are shown in tabular as well as graphical format (bar graph and pie chart) to visualize the statistically significant difference more clearly. In the entire study, the p-values less than 0.05 were considered to be statistically significant. All the hypotheses were formulated using two tailed alternatives against each null hypothesis (hypothesis of no difference). The entire data was statistically analyzed using Statistical Package for Social Sciences (SPSS version 22.0, Armonk, IBM Corporation, New York- USA) for Microsoft Windows.

6. Results

6.1. Characteristics of the study sample At T0

The study sample consisted of 15 patients, out of which 10 were males and 05 were females. The overall mean age was 51.80 ± 10.21 years. The mean BMI was 26.24 ± 1.49 kg/m^2 and neck circumference was 41.20 ± 1.86 cm. The mean AHI score was 17.96 ± 6.31 per hour sleep. The mean upper airway parameters of VAS, PAS and HAS assessed on lateral cephalogram were 6.27±1.03 cm, 7.13±0.99 cm, 11.40±2.23 cm respectively; which were below the normal range. (Table 1).

6.2. Intra and Inter-operator agreement for CBCT and lateral cephalogram measurements

The data assessment for all 15 subjects was carried out by the same operator. Eight randomly selected CBCT records and lateral cephalogram were reassessed after one week by the same and another trained operator, in order to ascertain intra and inter-operator bias. The intra-class correlation (ICC) analysis for the measurements such as upper airway area, volume, VAS, HAS and PAS had significantly higher values of 0.897, 0.908, 0.872, 0.923 and 0.927 respectively (P-value<0.001 for all) indicating statistically significant

intra and inter-observer agreement for these parameters.

6.3. Change in Ap parameters of upper airway (Mean Area, Volume and Minimum Distance) from T0 To T1

At T1, there was a statistically significant increase in mean area, volume and minimum distance of upper airway compared to T0 (P-value<0.001). The mean change and % change at T1 in mean area, volume and minimum distance was 0.46 cm^2, 4.69 cm^3, 0.67 cm and 23.73%, 23.86%, 6.36% respectively (Table 2)

6.4. Change in CBCT parameters of upper airway (Mean Area and Volume) from T0 to T1

At T1, there was a statistically significant increase in mean area and volume of upper airway compared to T0. The mean change and % change at T1 in mean area and volume was 0.53 cm^2, 5.15 cm^3 and 24.16%, 25.87% respectively (P-value<0.001). (Table 2).

6.5. Change in lateral cephalogram parameters (VAS, PAS, HAS) of upper airway from T0 TO T1

At T1, there was a statistically significant increase in upper airway parameters of VAS, PAS, HAS compared to T0 (P-value<0.001). The mean change and % change at T1 in VAS, PAS, HAS was 1.73 mm, 1.53 mm, 2.00 mm and 27.87%, 22.65%, 22.62% respectively (Table 2).

6.6. Change in Ahi score from T0 To T1

=At T1, there was a statistically significant decrease in AHI score compared to T0 (P-value<0.001). The mean change and % change at T1 in AHI score was 14.29 and 78.20%, respectively (Table 2).

Table 2: Change in AP, CBCT, Lateralcephalogram and AHI parameters from T0 to T1

N=15	Acoustic pharyngometry Parameters						CBCT Parameters				Lateral cephalogram parameters						AHI Score Per hr sleep	
	Mean Area (cm²)		Mean Volume (cm³)		Minimum Distance (cm)		Mean Area (cm²)		Mean Volume (cm³)		VAS(mm)		PAS(mm)		HAS(mm)			
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
T0	1.99	0.25	19.96	2.48	10.47	0.57	2.23	0.21	20.45	2.39	6.27	1.03	7.13	0.99	11.40	2.23	17.96	6.31
T1	2.50	0.27	25.05	2.72	11.13	0.60	2.76	0.22	25.60	2.63	8.00	0.84	8.67	0.90	13.40	2.09	3.68	0.92
Change	0.46	0.18	4.69	1.79	0.67	0.06	0.53	0.14	5.15	1.98	1.73	0.46	1.53	0.83	2.00	0.53	14.29	5.94
% Change	23.73%	–	23.86%	–	6.36%	–	24.16%	–	25.87%	–	27.87%	–	22.65%	–	22.62%	–	78.20%	–
P-value (Paired data) T0 vs T1	0.001***		0.001***		0.001***		0.001***		0.001***		0.001***		0.001***		0.001***		0.001***	

P-value by Paired t test. P-value<0.05 was considered to be statistically significant. ***P-value<0.001.

Table 3: Correlation analysis of AP, CBCT,Lateral cephalogram parameter changes with change in AHI.

			AHI	
			r-value	P-value
Acoustic pharyngometry	Mean area	T0	0.115	0.684[NS]
		T1	0.206	0.462[NS]
	Mean volume	T0	0.118	0.674[NS]
		T1	0.203	0.469[NS]
CBCT	Mean area	T0	0.335	0.222[NS]
		T1	0.512	0.048*
	Mean volume	T0	0.501	0.057[NS]
		T1	0.557	0.031*
Lateral Cephalogram	VAS	T0	0.419	0.120[NS]
		T1	0.476	0.073[NS]
	PAS	T0	0.127	0.653[NS]
		T1	-0.439	0.102[NS]
	HAS	T0	0.266	0.337[NS]
		T1	0.119	0.673[NS]

Correlation by Pearson's method. P-value<0.05 is considered to be statistically significant correlation. *P-value<0.05, NS – Statistically non-significant.

6.7. Correlation analysis of Ap, CBCT, lateral cephalogram parameter changes with change in AHI

At T1, there was a statistically significant correlation between AHI score and CBCT parameters (P-value<0.001), however the values of AP and lateral cephalogram parameters were statistically non significant (Table 3).

7. Discussion

OSA is an upper airway sleep disorder characterized by occurrence of five or more episodes of complete apnea or partial hypopnea. It further leads to irregularities in sleep and excessive daytime sleepiness. Disharmony in the craniofacial region is an important risk factor for OSA.[16,17] The pathophysiology of OSA is due to the physical obstruction of upper airway leading to a cascade of events resulting in hypoxia, hypercapnia followed by oxygen desaturation. To counter this effect on normal physiology of breathing, there is increase in heart rate, blood pressure, hyper activity of pharyngeal dilator muscles leading to opening of upper airway. This leads to abrupt breaks in the sleep as the cascade of events continue repeatatively.[18] The most important predisposing factor in patients with OSA can be obesity, craniofacial abnormalities like tonsilar enlargement, micrognathia.[3] The diagnostic workflow in patients with OSA involves history taking, clinical & craniofacial examination, PSG, AP and radiological examination & analysis. BMI and neck circumference forms the best predictors for clinical assessment of OSA and was measured in the present study revealing an increase in both the values compared to normal standards (Table 1).The medical approach for diagnosis of OSA includes: Home sleep test, Nasopharyngoscopy, Mullers maneuver, dynamic sleep MRI, drug induced sleep endoscopy, however the gold standard remains the type 1 PSG (Lab set up attended sleep study, showing various parameters of AHI).[1,18] All the 15 patients in the present study had undergone type 1 PSG, and had AHI > 5 (Table 1).

7.1. Changes in upper airway assessed using lateral cephalogram

The 2D upper airway assessment using lateral cephalogram has been used traditionally, with the advantages of ease of access, low cost factor, and minimal radiation exposure.[19] The airway analysis of patients at T0 revealed that the reduction in airway parameters of VAS, PAS and SAS in comparison to standard norms (Table 2) and at T1 showed significant improvement (P-value<0.05).

7.2. Changes in upper airway assessed using AP

The mean area, mean volume and minimum distance at T0 showed significant narrowing of upper airway when compared to standard norms and is similar to studies documented by Kamal I.[20,21] who evaluated the pharyngeal airway through AP among males and females, apneoic and non apneoic snorers. The norms of mean area and volume were calculated and reduced value was documented in apneoic snorers. The results of present study point towards a significant increase in upper airway parameters at T1 when compared to T0 (Table 2). The mean area, mean volume and minimum distance at T1 showed significant improvement in upper airway from T0 (P-value<0.05). The literature on study of changes in upper airway post OAT using AP is ambiguous.[22,23] Hence, the correlation of the outcome of the present study to any previous studies was not feasible. However, the changes in upper airway post OAT using MRI,[17] CBCT,[24] CT[25] have shown overall mean increase

of the upper airway area and volume post oral appliance therapy.

7.3. Changes in upper airway assessed using CBCT

Patients with OSA present with a significant decrease in upper airway parameters which include area and volume and the accuracy of measuring the same is well established using CBCT modality.[15] The correlation between the volume of the upper airway and severity in patients with OSA using CBCT records showed that there was no correlation between the volume of the upper airway and severity.[25] However, a CBCT based study compared the upper airway dimensions of 16 patients with OSA and 16 control subjects showing significant reduction of average airway area, average airway volume, total airway volume, and mean airway width.[26] A systematic review and meta-analysis of CBCT derived cephalometric studies on craniofacial and upper airway morphology in adult OSA patients showed reduced pharyngeal airway space.[27]

Marked improvement in total upper airway volume along with reduction in AHI was documented in a CBCT based study which evaluated the upper airway in 10 patients with moderate or severe OSA treated with non-adjustable 2nd generation customized oral appliance.[28] A similar CBCT based study using custom made 2nd generation oral appliance was carried out on 44 patients with OSA, resulting in significant improvement in upper airway volume and area.[24] The present study also assessed the mean area and volume of upper airway using CBCT, however 3rd generation oral appliance was used. The results showed a significant improvement in upper airway volume and area from T0 (Mean area 2.23+ 0.21 cm^2, mean volume 20.4+2.39 cm^3) to T1 (Mean area 2.76+ 0.22 cm^2, mean volume 25.6+2.63 cm^3) (Table 2).

Correlating AP, CBCT, Lateral cephalogram parameter changes with the change in AHI, statistically significant correlation between AHI score and CBCT parameters (P-value<0.001) only, whereas the parameters of Lateral cephalogram and AP were statistically non significant. However, there is lack of studies that limit us to correlates the above 3 modalities together with the change in AHI.

8. Limitations of the Study

Statistically significant results were obtained for the objectives in the study; however the following limitations were noted:

1. Study sample size is relatively small. It is recommended to confirm the results with a larger sample and a multicentric study.
2. There is lack of uniform distribution in the male and female groups; hence the gender based comparison could not be carried out.

3. The present study is of a relatively short duration. It is recommended to have a long term follow up of the results obtained.
4. Acoustic pharyngometry evaluates the airway while in seated posture and also does not provide insights to detect the mechanism of underlying airway obstruction during sleep in supine position.

9. Conclusion

The present study assessed the changes in upper airway following OAT for treatment of OSA using Lateral cephalogram, AP and CBCT and correlated the the changes with AHI. The following conclusions can be drawn from this study –

1. There is a marked improvement in mean volume, mean area and minimum distance of constriction in upper airway following OAT assessed using Lateral cephalogram, AP and CBCT.
2. Among the above 3 modalities, CBCT shows a statistically significant correlation with change in AHI following OAT.

10. Source of Funding

None.

11. Conflict of Interest

None.

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