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Assessment of pharyngeal airway space with MRI In oral submucous fibrosis: A cross-sectional observational study[☆]

Ragavendiran Anandan^{*}, Krithika C. Lakshmi, Anuradha Ganesan, Yesoda Aniyank

Department of Oral Medicine and Radiology, SRM Dental College, no.1 Bharathi Salai, Ramapuram, Chennai, 600089, India

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ABSTRACT

Introduction: Oral submucous fibrosis (OSMF) alters the pharynx, which may affect airway size. MRI will be useful for diagnosing pharyngeal abnormalities. MRI is used to evaluate pharyngeal airway and soft palate changes in OSMF patients.

Materials and methods: This study is a cross-sectional observational study that included a sample size of 42 patients. Group A consisted of 21 patients with OSMF, while Group B consisted of 21 volunteers without OSMF, who served as the control group. The patients with OSMF were classified into Stages I, II, and III according to the categorization established by Pindborg JJ in 1989, Stop-Bang questionnaire was employed to assess obstructive sleep apnoea. Magnetic Resonance Imaging (MRI) was utilized to acquire evaluations of the pharyngeal airway, encompassing measurements in the midsagittal, cross-sectional width, length planes, and cross-sectional area with volume, for all participants. The Shapiro-Wilk test determines distribution normality. We utilized one-way ANOVA to compare the means between groups.

Results: The average age of OSMF patients was 45.9 ± 8.16 , while the control group was 39.19 ± 4.21 . Stage I of OSMF had the highest mean Stop Bang questionnaire score (2.75), followed by stage III (2.22), and stage II (1.75). Statistically significant differences ($p < 0.001$) were seen in volume, linear midsagittal planes, cross-sectional width and length planes, cross-sectional area, and soft palate breadth and length between OSMF and control groups.

Conclusion: MRI can effectively examine early changes in the pharyngeal airway of patients with OSMF thereby serving as a constructive diagnostic and motivational tool.

1. Introduction

Oral submucous fibrosis (OSMF) is a pre-cancerous condition recognized for its chronicity and challenging treatment. Patients commonly report a gradual constriction of the mouth due to the accumulation of inflexible fibrous tissue in the regions of the oral mucosa. They also experience a sense of burning when consuming spicy meals. Additional clinical characteristics linked to this condition encompass pallor of the oral mucosa, the formation of ulcers, a sense of discomfort, decreased movement of the soft palate and tongue, reduced ability to taste, and occasional slight hearing loss caused by blockage of the Eustachian tube.¹ Areca nut, known as pan-masala/gutkha, is increasingly used, especially by young Indians. Pan-masala is made from areca

nut, tobacco, areca lime, catechu (kattha), tannin, and flavorings. These additives make the areca nut more carcinogenic and addictive, causing physical dependence.²

The global prevalence of OSMF was estimated to be 2.5 million cases. This condition can affect individuals between the ages of 11 and 60 years. Despite numerous case-finding studies, especially in South and Southeast Asia, OSMF is not classified as a notifiable disease, and there is a lack of population-based data. In India, the occurrence of OSMF has been calculated to be between .2 % and 2.3 % in males and between 1.2 % and 4.6 % in females.³

OSMF has a notable impact on the oropharynx, leading to major alterations in the structure of the soft palate and the pharynx. This study will employ an evidence-based approach to detect obstructive sleep

[☆] All the co-authors listed in the manuscript have made substantial contributions to the research and preparation of the manuscript and have reviewed and approved the final version of the paper.

^{*} Corresponding author.

E-mail addresses: dr.raghaven@aol.com (R. Anandan), krithika.sekar@gmail.com (K.C. Lakshmi), anug77@yahoo.com (A. Ganesan), yesoda.aniyank@gmail.com (Y. Aniyank).

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apnoea in patients with oral submucous fibrosis (OSMF) at an early stage. Recent research has shown changes in the soft palate's structure using lateral cephalogram and CBCT imaging techniques.^{4,5} Previously, the assessment of alterations in the pharyngeal airway space has been limited to using only lateral cephalogram, which has certain drawbacks. That includes its two-dimensional analysis with overlapping elements and its main purpose of evaluating hard tissues, MRI can surpass these restrictions. This study is the first to use MRI for evaluating the soft palate and pharyngeal airway space in oral submucous fibrosis, as there is currently no existing literature on this topic.

Magnetic resonance imaging (MRI) is a medical imaging technique that does not require any intrusive procedures and does not use ionizing radiation. It provides excellent contrast for visualizing soft tissues and has a high level of detail in terms of spatial resolution. Additionally, it can serve as a means of screening and motivating individuals to cease their habit of eating areca nuts. The purpose of the study is to utilize MRI to assess the morphology of the soft palate and the airway space in the pharynx in individuals diagnosed with oral submucous fibrosis.

2. Materials and Methods

2.1. Ethical consideration

Case-controlled cross-sectional observational research was carried out in the period between April 2022 and December 2023. The study was initiated following approval from the institutional review board with reference number SRMDC/IRB/2021/MDS/NO.903. Prior informed consent was obtained from the study participants, based on Helsinki Declaration. The research has been registered with the Clinical Trial Registry of India (CTRI) with the reference number REF/2023/01/062847.

2.2. Study participants

A total sample of 42 participants categorized into two groups of 21 in each was determined with a confidence interval of 95 %, and an alpha error of .05. Group A consisted of patients diagnosed with oral submucous fibrosis, fulfilling the criteria of inclusion. Group B consisted of age and sex-matched volunteers without OSMF who were undergoing an MRI of the head and neck region for other diagnostic purposes. The study participant's comprehensive dental and medical histories were documented.

2.3. Criteria of inclusion

Male patients aged between 20 and 60 years with no systemic illnesses were recruited. Individuals diagnosed with cleft lip and palate, skeletal malalignment with airway obstruction, craniofacial diseases, abnormal growth, tobacco users, other oral lesions, patients with metallic implants, pacemakers, or claustrophobia, cochlear implants, body mass index (BMI) greater than 30, patients diagnosed with asthma, anemia, who have undergone surgery within the past 8 weeks, high-risk of OSA patients (as determined by a score of 4–6 on the Stop Bang questionnaire), were excluded from the study, non-compliant patients who decline to engage in the study were also excluded.

2.4. The stop bang questionnaire

The STOP-Bang questionnaire is an OSA screening tool with four self-reportable questions (snoring, tiredness, observed apnea, and high blood pressure) and four demographic questions (Bang: Body mass index, age, neck circumference, and gender). The scoring will be categorized as; low risk: 0–2, intermediate risk: 3–4, high risk: 5–8. Volunteers with low and intermediate risk were recruited.⁶

2.5. MRI technique

MRI scan of the pharyngeal airway was carried out while the person was awake using a GE Signa creator 1.5 T MRI scanner manufactured by GE Health Care. The MR images were obtained in a standardized manner, with 50 slices taken in the sagittal plane. The images were weighted using T1 and were centered around the mid-sagittal plane of the airway. Each slice had a thickness of 3 mm and a matrix size of 272 by 512. The field of view measured 240 mm, with a repetition time (TR) of 645 ms and an echo time (TE) of 14 ms. Axial sections of the pharyngeal airway were obtained using a technique that involved acquiring 36 slices, each with a thickness of 3 mm. The images were captured using a matrix size of 224 by 512 and a 240 mm field of view (FOV). The repetition time (TR) and an echo time (TE) were 649 ms and 15 ms respectively, and 3D Slicer v4.10.1 was used for analysing and measuring the pharyngeal airway space in DICOM files.⁷ Measurement of the pharyngeal airway was performed in four planes.

2.6. Image analysis

The images were subjected to the following sequential processing steps: i) segmentation of the airway, ii) determination of volume, iii) measurement of linear dimensions, and iv) measurement of cross-sectional dimensions.⁸ (Fig. 1).

2.7. Segmentation of airway

The segmentation location was carefully determined using the thresholding tool. A mask was generated and employed throughout segmentation to maintain uniformity. The “paint” tool was used to separate the pharyngeal airway. The “un-paint” tool, and “smoothing” tool were used to remove all non-pharyngeal airway structures. A three-dimensional representation of the pharyngeal airway was generated (Fig. 2a)

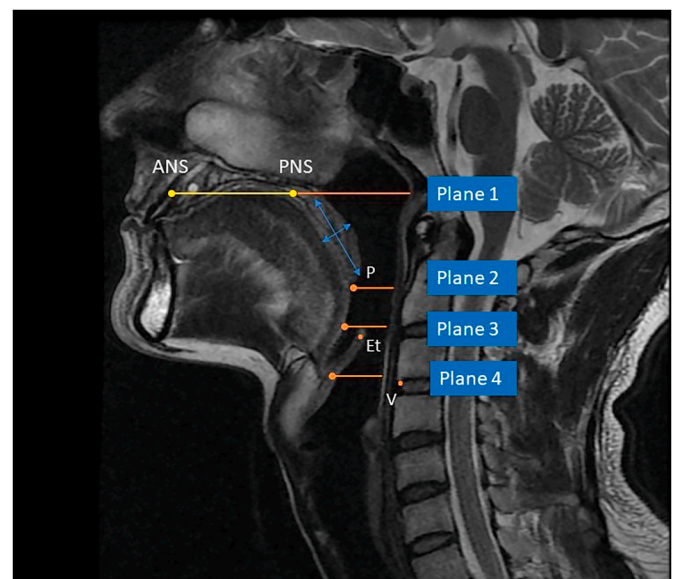


Fig. 1. Measurements planes of the Pharyngeal airway. Planes 1–4 (orange) are airway-measuring planes that run parallel to the palatal plane, ANS-PNS (Yellow). Plane 1 is situated at the level of the PNS. Plane 2 is located at the same level as point P. Plane 3 is located at the same elevation as point Et. Plane 4 is located at the V-point level. The blue arrow represents the dimensions of the soft palate, both its length and width. All the planes run parallel to the palatal plane and plane 1 extends from PNS to (Posterior pharyngeal wall) PPW, plane 2 extends between anterior and PPW at the level of point P, plane 3 extends between anterior and PPW at the level of Et, and plane 4 extends between anterior and PPW at the level of point V.

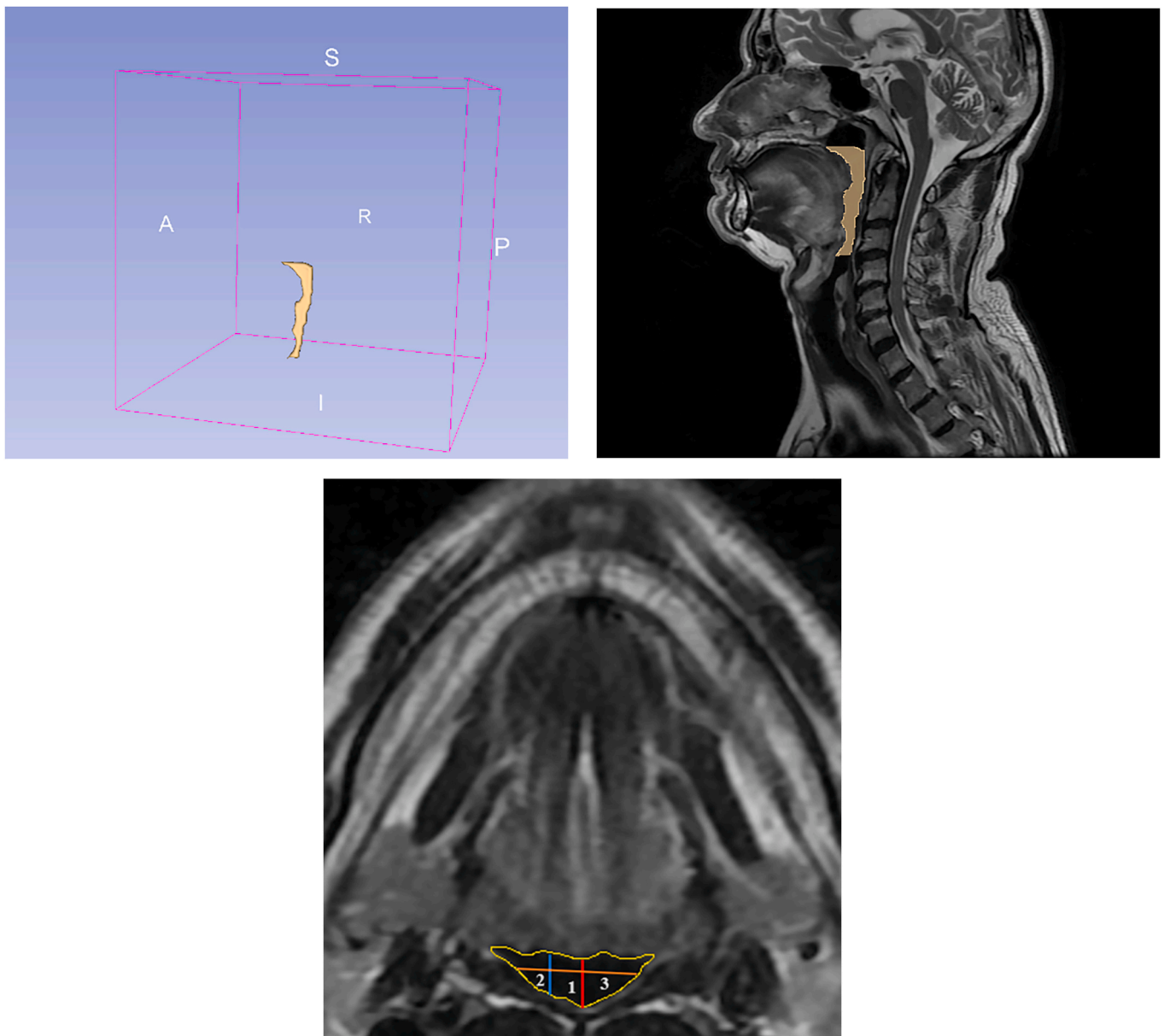


Fig. 2a and b. MRI image shows borders of the 3D volumes by presenting a pharyngeal airway segmentation for volumetric analysis. **Fig. 2c** shows A view of a measurement plane from the axis. The midsagittal plane is represented by the red line. The yellow line delineates the airway space. 1 = measurement along the midsagittal plane (Red). 2 = Represents a measurement of length taken in a cross-sectional plane (Blue). 3 = The measurement of the width in a cross-sectional view (Orange).

2.8. Determination of volume

The volume of the pharyngeal airway plane 4 is measured as the lower limit, while plane 1 as the upper limit. The inner pharynx soft tissue wall defined the lateral limits. Volume was determined using the Segment statistics tool (Fig. 2b).

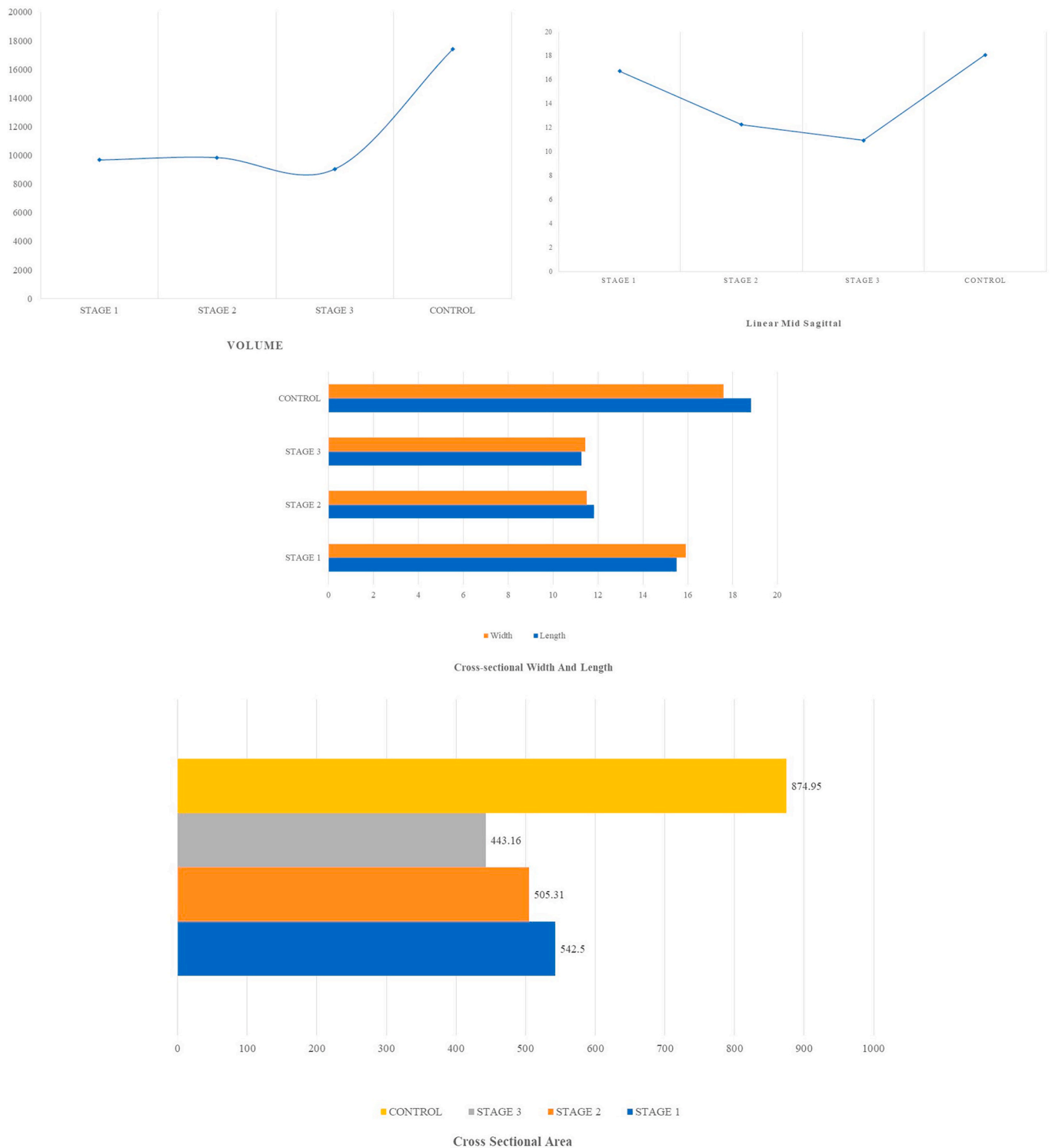
2.9. Midsagittal measurements

The MRI image was viewed from a multiplanar perspective. Utilizing the anterior nasal spine (ANS) as a reference guide slicing was done to evaluate the linear measurements in the midsagittal planes. 1, 2, 3, and 4, respectively, and the length and width of the soft palate were assessed using the measurements tool. The Midsagittal Length was measured as the anterior-posterior distance in the planes (1,2,3,4) between the anterior and posterior pharyngeal walls in the midsagittal plane

(Fig. 2c).

2.10. Cross-sectional measurements

We measured the length, breadth, and cross-sectional area of every plane. In the axial sections, the “magnetic lasso” and “mask statistics” tools were used to acquire cross-sectional measurements. The area was calculated in mm² after marking the radiolucent pharyngeal airway with a sequence of points till returning to the initial location. The cross-sectional length was measured as the longest anteroposterior distance, perpendicular to the midsagittal plane and the width was measured as the greatest distance between the lateral pharyngeal walls perpendicular to the midsagittal plane was used to determine the width (Fig. 2c).



Graph 1. Showing comparison of pharyngeal airway measurements in OSMF and control group.

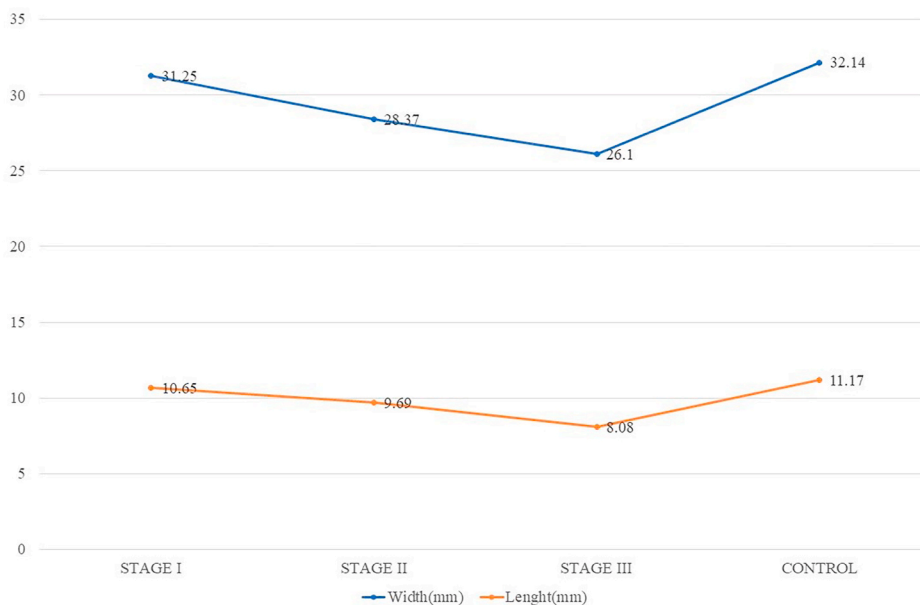
2.11. Statistical analysis

The Normality tests Kolmogorov-Smirnov and Shapiro-Wilks tests results reveal that values follow Normal distribution. Therefore, to evaluate the data, Parametric analysis was applied. Descriptive analysis was performed to assess the mean and standard deviation. To compare the mean between groups, one-way ANOVA was used, to analyse the data SPSS (IBM SPSS Statistics for Windows, Version 26.0, Armonk, NY: IBM Corp. Released 2019) was used. P-value <.05 is considered to be

statistically significant.

3. Results

The average age of OSMF patients was 45.9 ± 8.16 , while the control group averaged 39.19 ± 4.21 . Table 1 displays the stop-bang questionnaire results for both the OSMF group and the control group. The average was determined to be greater in OSMF stage I (2.75), followed by OSMF stage III (2.22), and the lowest average was seen in OSMF stage



Graph 2. Showing comparison of soft palate length and width In OSMF and control group.

Table 1
STOP-BANG questionnaire among OSMF and control group.

VARIABLES	OSMF GROUP			CONTROL GROUP
	I	II	III	
Mean	2.7500	1.7500	2.2222	2.1429
Std. Error of Mean	.47871	.31339	.22222	.17301
Std. Deviation	.95743	.88641	.66667	.79282
Variance	.917	.786	.444	.629
Range	2.00	3.00	2.00	3.00
Minimum	2.00	.00	1.00	1.00
Maximum	4.00	3.00	3.00	4.00

II (1.75). The mean and standard deviation indicate that the samples selected from the control and OSMF groups have a low likelihood of developing OSA, as determined by the stop bang questionnaire at the time of sample recruitment.

Table 2 shows a comparison of parameters between the groups by using one-way ANOVA, and Graph 1 displays a comparison of pharyngeal airway measures between the control group and the OSMF group. Graph 1(a) shows the comparison of volume measurements for stage I (9684.00), stage II (9855.75), stage III (9052.66), and the control (17415.42). Graph 1(b) illustrates the comparison of linear midsagittal measurements for stage I (16.71), stage II (12.26), stage III (10.94), and the control (18.08). Graph 1(c) presents the comparison of cross-sectional width and length for stage I (15.91, 15.51) and stage II (11.51, 11.83). The values for Stage III are 11.43 and 11.27, and for the

Table 2
Comparison of parameters between and within the groups by using one-way ANOVA.

VARIABLES	STAGE 1	STAGE 2	STAGE 3	CONTROL	P-VALUE
VOLUME	9684.00	9855.75	9052.66	17415.42	.001*
LINEAR MIDSAGITTAL	16.71	12.26	10.94	18.08	.001*
CROSS-SECTIONAL LENGTH	15.51	11.83	11.27	18.81	.001*
CROSS-SECTIONAL WIDTH	15.91	11.51	11.43	17.59	.001*
CROSS-SECTIONAL AREA	542.50	505.31	443.16	874.95	.001*

control group are 17.59 and 18.81. In Graph 1(d), the values for stage I, stage II, stage III, and the control group are 542.50, 505.31, 443.16, and 874.95, respectively. Graph 2 shows the measurements of soft palate width and length at several stages: Stage I (31.25, 10.65), Stage II (28.37, 9.69), Stage III (26.1, 8.08), and the control group (32.14, 11.17).

4. Discussion

Oral submucous fibrosis is characterized by decreased tongue movement, loss of papillae on the tongue, blanching, and stiffness of the oral mucosa with a gradual decrease in mouth opening and shrinking of the uvula. Progressively this leads to alterations in the pharynx, which can result in alterations in the airway space.

MRI is more precise, and consistent imaging offering multiplanar evaluation without the use of ionizing radiation and any documented adverse effects.⁹ Cone beam computed tomography, though an ideal tool in assessing pharyngeal airway mandates a standing or sitting posture rather than a supine position which can lead to less reliable results due to gravity effects.¹⁰ MRI exhibits superior soft-tissue contrast in comparison to CBCT.

The study participants were all males owing to the fact that there is a significant prevalence of oral submucous fibrosis in male patients in the Chennai district, with a male-to-female ratio of 9.9:1.¹¹

Studies show that the STOP-Bang questionnaire is brief, effective, and reliable for OSA screening. It can improve resource allocation for diagnosing and treating undiagnosed OSA. The questionnaire has adequate sensitivity and diagnostic accuracy for detecting moderate to severe sleep apnoea across geographic region and notably the sensitivity and specificity was around 95 % around south and southeast Asian.¹² Patients recruited in the study belonged to low and intermediate-risk groups based on this questionnaire.

The causes of OSA are still unclear and it is more common among middle-aged adults. The pharynx’s anatomy changes during adulthood, according to studies in adulthood the soft palate has a propensity to elongate and thicken, whereas the oropharynx tends to narrow. This may explain the higher risk of OSA and related disorders.^{13,14} Significant variations in pharyngeal airway measurements and dentofacial morphology among developing individuals have been documented with distinct growth patterns.^{15–17} In addition, to physiological changes, pan chewing can cause mucosal alteration in the pharyngeal airway can

increase the risk of developing obstructive sleep apnea (OSA).

This study represents a pilot testing of alterations in airway dimensions observed in individuals with OSMF using MRI. A statistically significant ($P < 0.01$) change in the dimension of the pharyngeal airway was observed in OSMF patients. While assessing different stages of OSMF subjects, significant changes were specifically observed in stage III participants. These changes can be attributed to muscle fibrosis or muscle atrophy in the later stages of Oral Submucous Fibrosis (OSMF). Furthermore, it aligns with the findings acquired by Agrawal et al.¹⁸

Trudo et al.¹⁹ investigated the retro-palatal distance and the retro-glossal space in both awake and asleep healthy individuals. It was identified that during deep sleep, the retropalatal distance of the patients significantly decreased, which can lead to a constricted upper airway during sleep. The study conducted by Matthias et al.²⁰ utilized MRI to evaluate the pharynx in individuals with the impaired neuromuscular transmission in the throat. Additionally, surface electromyography was employed to measure the upper airway dilator. It was identified that patients with the slightest change in neuromuscular transmission showed a reduction in retropalatal distance and retro-glossal space in comparison to healthy individuals. This reduction in muscular tension in the upper airway could lead to obstructive sleep apnea (OSA). These studies imply that the vital factor contributing to OSA is the structural or functional alterations of the soft tissue in the pharynx. These changes result in a reduction in the distance behind the palate and a decrease in the space behind the tongue, leading to constriction and collapse of the airway during inhalation. Our findings align with these results as fibrosis can extend to the pharyngeal region, resulting in structural alterations that could decrease the airway space in the pharynx. This could potentially induce symptoms such as snoring or sleep-disordered breathing.

Researchers have analyzed the morphology and structure of the soft palate in patients with OSMF and changes have been documented. The structural changes in the soft palate cause a significant impact on the morphology of the upper airway resulting in sleep disturbances.²¹ In digital lateral cephalometric evaluation, of the soft palate in OSMF patients researchers, have observed a discernible reduction in the anterior-posterior measurements and an increase in the superior-inferior measurements of the soft palate only in the advanced stages, while subtle changes that could occur between the early and the advanced stages could not be documented.^{22,23} We have accounted for a more accurate, detailed, non-ionizing, and three-dimensional evaluation of the soft palate and upper airway showing appreciable changes even in early OSMF.

It is essential to understand the diverse morphological changes of the soft palate in OSMF patients which can provide insights into disease progression. This in turn can aid in the development of treatment interventions based on clinical staging for a favourable outcome.²⁴

OSMF being a premalignant condition requires comprehensive management not only for the presenting symptoms but also for the ill effects that could affect the aero digestive tract. The comprehensive management of the condition will require additional diagnostic procedures like pharyngeal airway space assessment and endoscopic evaluation to determine the extent of the involvement.

The novelty of the current study is the use of MRI in oral submucous fibrosis patients. MRI exhibits superior soft-tissue contrast in comparison to CBCT, and multiple studies have reported the benefits of using MR images as a mainstay in the assessment of pharyngeal airway space.²⁵ The clinical validation and justification for using MRI to estimate airway space lies in its high accuracy and ability to serve as a supplementary screening and motivational tool in the comprehensive management of the condition, leading to enhanced treatment adherence, better prognosis, and improved quality of life in these patients rather than treating the presenting symptoms in the oral cavity alone.

Our study was a cross-sectional pilot testing of pharyngeal airway space in OSMF. Investigation with a larger sample at a multicentric level can provide an in-depth perception of the airway. The data was collected

at a single point in time, making it difficult to assess changes over time or establish temporal relationships between variables and assess treatment prognosis. The integration of polysomnography and surface electromyography could have enabled a more meticulous evaluation of patients before recruitment.

The current study results indicate that future research on a large scale can confirm its clinical utility and incorporate it as a standardized diagnostic imaging protocol, for monitoring disease progression over time, providing a non-invasive tool for evaluating the effectiveness of treatment interventions. Moving forward, the reliability of MRI pharyngeal assessment utilizing various softwares can be evaluated and the incorporation of artificial intelligence algorithms in MRI analysis tools can be less time-consuming thereby assisting in automating the detection and quantification of changes happening in the airway space.

5. Conclusion

The present study suggests that MRI can account for even subtle changes in the pharyngeal airway in individuals with OSMF. This will help implement proactive measures like quitting areca nut consumption earlier and prevent complications associated with advanced phases.

Patient consent

informed consent was obtained from all the patients.

Source of funding

Nil.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Abbreviation:

- OSMF: Oral submucous fibrosis
 MRI: Magnetic resonance imaging
 ANS: The most anterior point of the anterior nasal spine
 PNS: The most anterior point of the posterior nasal spine
 P: Palate point is the most inferior point of the soft palate
 Et: The most superior point of the epiglottis
 V: The most anterior inferior point of the third cervical vertebrae