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Original Article

STUDY OF EVALUATION OF EUSTACHIAN TUBE FUNCTION IN PATIENTS WITH ORAL SUBMUCOUS FIBROSIS

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ABSTRACT

Background and Objectives: Oral Submucous Fibrosis (OSMF) is a chronic, progressive, and potentially malignant disorder predominantly affecting characterized by progressive fibrosis of the submucosal tissues, leading to restricted mouth opening, difficulty in mastication, and speech impairment. While the oral manifestations of OSMF are well-documented, its impact on the Eustachian tube leading to dysfunction and subsequent hearing loss remains a relatively underexplored anatomical and clinical domain. This present study aims to evaluate the functional status of the Eustachian tube in patients diagnosed with OSMF and to correlate the severity of Eustachian tube dysfunction (ETD) and conductive hearing loss with the clinical grades of the disease.

Materials and Methods: A cross-sectional observational study was conducted at the Otorhinolaryngology (ENT) Department of Basaveshwara Teaching and General Hospital, Kalaburagi, from August 2022 to January 2024. A cohort of 50 patients (100 ears) diagnosed with OSMF was enrolled. Disease severity was objectively categorized using the Lai classification based on maximal inter-incisor distance. Eustachian tube function was evaluated via tympanometry, and auditory acuity was assessed using pure tone audiometry (PTA). Statistical analyses, including Chi-square tests for categorical variables, were performed using IBM SPSS software to establish correlations between OSMF severity and otologic morbidity.

Results: The study demonstrated a highly significant statistical correlation between the clinical severity of OSMF and the incidence of Eustachian tube dysfunction ($p = 0.0011$). Overall, 29% of the evaluated ears exhibited Eustachian tube dysfunction, manifesting predominantly as Type C tympanograms. Conductive hearing loss was identified in 29% of the ears, scaling in severity alongside the OSMF grade. Patients with advanced OSMF (Grades III and IV) exhibited markedly higher rates of both ETD and varying degrees of conductive hearing loss compared to those with earlier grades.

Conclusion: This study highlights a critical, often overlooked complication of OSMF: otologic impairment secondary to Eustachian tube dysfunction. The progressive fibrosis in the oral cavity contiguous with the nasopharynx compromises the paratubal musculature, resulting in compromised middle ear ventilation. Incorporating routine audiological evaluations, including tympanometry, into the clinical management of OSMF is imperative to prevent irreversible auditory complications and improve the overall quality of life for these patients.

Keywords: Oral Submucous Fibrosis; Eustachian Tube Dysfunction; Conductive Hearing Loss; Tympanometry; Pure Tone Audiometry; Paratubal Musculature; Betel Nut Chewing.

INTRODUCTION

Oral submucous fibrosis (OSMF) is an insidious, chronic, and debilitating condition characterized by progressive fibrosis of the oral mucosa and underlying connective tissues. Initially described in the early 1950s, the disease predominantly afflicts populations in Southeast Asia and the Indian subcontinent, though increased global migration has dispersed its prevalence worldwide. The epidemiological surge of OSMF is intimately tied to the cultural habit of chewing areca nut (betel nut), alone or in combination with tobacco, slaked lime, and other spices in the form of betel quid or *gutkha*. [1-3]

The pathogenesis of OSMF is complex and multifactorial, driven primarily by the alkaloid constituents of the areca nut, such as arecoline, which stimulate fibroblast proliferation and collagen synthesis. Concurrently, the high copper content in areca nuts upregulates lysyl oxidase, an enzyme that facilitates the cross-linking of collagen fibers, rendering them highly resistant to degradation by collagenases. This imbalance between collagen synthesis and degradation leads to the hallmark feature of OSMF: the dense accumulation of inelastic, hyalinized fibrous bands in the lamina propria and submucosa. Clinically, this manifests as a burning sensation in the mouth (exacerbated by spicy foods), mucosal blanching, ulceration, and the progressive restriction of mouth opening (trismus), which severely impairs mastication, deglutition, and phonation. [4,5]

While the oral and potentially malignant manifestations of OSMF have been extensively researched, the extra-oral progression of the fibrotic process warrants deeper investigation. The anatomical continuity of the oral cavity with the pharynx and nasopharynx means that the fibrotic bands can extend posteriorly. One critical but often neglected anatomical structure vulnerable to this fibrotic extension is the Eustachian tube (ET). [6]

The Eustachian tube connects the nasopharynx to the middle ear cleft and serves three primary functions: equalization of pressure across the tympanic membrane, protection of the middle ear from nasopharyngeal secretions, and mucociliary clearance of middle ear transudate. The active opening of the Eustachian tube during swallowing or yawning is primarily mediated by the tensor veli palatini (TVP) and levator veli palatini (LVP) muscles. In patients with OSMF, the progressive fibrosis affecting the soft palate, faucial pillars, and pharyngeal musculature can involve these paratubal muscles. The resulting loss of elasticity and muscular atrophy compromise the active dilation of the ET orifice, leading to Eustachian tube dysfunction (ETD). [7]

Chronic ETD subsequently results in the development of negative pressure within the middle ear cavity. If left unresolved, this negative pressure can lead to tympanic membrane retraction, middle ear effusion, and, consequently, conductive hearing loss. Despite the anatomical and physiological plausibility of this complication, routine otologic and audiological assessments are rarely integrated into the standard care protocols for OSMF patients. [8]

Therefore, there is a compelling need for comprehensive clinical evaluation to characterize Eustachian tube function in the context of OSMF. This study was undertaken to objectively evaluate Eustachian tube function and auditory acuity in a cohort of OSMF patients and to determine if a statistically significant correlation exists between the severity of oral fibrosis and the degree of otologic impairment.

MATERIALS AND METHODS

Study Setting and Design

A cross-sectional, observational clinical study was conducted in the Department of Otorhinolaryngology (ENT) at Basaveshwara Teaching and General Hospital, affiliated with Mahadevappa Rampure Medical College, Kalaburagi, India. The study spanned a duration of 18 months, from August 1, 2022, to January 31, 2024. This hospital serves as a major tertiary care center in a region where areca nut and tobacco chewing are highly prevalent, providing a robust demographic representation for the study of OSMF.

Sampling and Sample Size Calculation

The sample size was determined based on the anticipated prevalence of Eustachian tube dysfunction in the OSMF population derived from previous literature. Using an odds ratio framework with an 85% confidence level and 95% power, and assuming an baseline exposure proportion of 10%, the initial calculation necessitated 33 subjects. To enhance statistical power and account for potential data attrition, the final sample size was expanded and finalized at 50 patients (representing 100 ears for audiological assessment). Participants were recruited using simple random sampling from patients presenting to the ENT outpatient department.

Inclusion and Exclusion Criteria

Inclusion Criteria:

- Patients aged 18 years and above of both genders.
- Patients with a clinically confirmed diagnosis of OSMF (characterized by mucosal blanching, palpable fibrous bands, and restricted mouth opening).

Exclusion Criteria:

- Patients with pre-existing sensorineural or conductive hearing loss attributable to congenital conditions, presbycusis, noise trauma, or chronic suppurative otitis media (CSOM).
- Patients with a history of prior otologic surgeries (e.g., tympanoplasty, mastoidectomy), as surgical modification alters the natural mechanics of the middle ear and ET.
- Patients with active upper respiratory tract infections or sinonasal polyposis, which could temporarily confound Eustachian tube function testing.

Clinical Examination and Grading
Following the obtainment of written informed consent, a detailed clinical history was recorded for each patient, encompassing demographic details, chief complaints (burning sensation, ulceration, trismus), duration of symptoms, and history of habituation (areca nut, gutkha, smoking).

A meticulous clinical examination of the oral cavity was performed to confirm the presence of palpable fibrotic bands, mucosal rigidity, and blanching. The severity of OSMF was objectively graded using the **Lai DR Classification**, [9] which stratifies the disease based on the maximum inter-incisor distance measured using a Vernier caliper:

- **Grade I:** Inter-incisor distance > 35 mm.
- **Grade II:** Inter-incisor distance between 30 mm and 35 mm.
- **Grade III:** Inter-incisor distance between 20 mm and 30 mm.
- **Grade IV:** Inter-incisor distance < 20 mm.

Audiological and Otological Assessment
All 50 patients underwent bilateral otological evaluation (n = 100 ears) using specialized diagnostic equipment to objectively assess middle ear mechanics and auditory thresholds.

1. Tympanometry (Impedance Audiometry):
Middle ear pressure and Eustachian tube function were evaluated using the MAICO MI 34 tympanometer. Tympanometry provides a graphic representation of the compliance of the tympanic membrane as a function of changes in air pressure in the external auditory canal. The results were classified using the Jerger system:

- **Type A:** Normal middle ear pressure (peak compliance between +50 and -99 daPa), indicating a healthy, functioning Eustachian tube.
- **Type C:** Significant negative middle ear pressure (peak compliance > -100 daPa), serving as the primary diagnostic indicator for Eustachian tube dysfunction (ETD) and restricted middle ear aeration.
- *(Type B and Type Ad/As patterns were monitored to rule out frank effusions or ossicular chain pathologies).*

2. Pure Tone Audiometry (PTA):
Auditory acuity was quantified using the ALPS Advanced Digital Audiometer (AD2100). Pure tone air and bone conduction thresholds were measured in a sound-treated room across frequencies ranging from 250 Hz to 8000 Hz. The severity of conductive hearing loss (CHL) was categorized based on the air-bone gap and overall threshold averages:

- **Normal Hearing:** Thresholds < 20 dB HL.
- **Mild Conductive Hearing Loss:** Thresholds between 20 to 40 dB HL.
- **Moderate Conductive Hearing Loss:** Thresholds between 41 to 60 dB HL.
- **Severe Conductive Hearing Loss:** Thresholds > 60 dB HL.

Ethical Considerations and Statistical Analysis
The study protocol was approved by the Institutional Review Board (IRB) and Ethics Committee of Mahadevappa Rampure Medical College. All data were anonymized to maintain patient confidentiality.

Data were compiled using Microsoft Excel and statistically analyzed using IBM SPSS software (Version 28.0.1.0). Descriptive statistics were used for demographic and clinical profiling. The relationship between categorical variables (OSMF Grade vs. Tympanogram Type; OSMF Grade vs. Degree of Hearing Loss) was analyzed using the **Chi-Square (χ^2) test**. A p-value of < 0.05 was considered statistically significant.

RESULTS
Demographic Profile
A total of 50 patients diagnosed with OSMF were included in the study. The demographic analysis (Table 1) revealed a strong male predilection, with males comprising 88% (n=44) and females 12% (n=6) of the cohort. The highest prevalence of OSMF was observed in the third and fourth decades of life. The 31-40 age group was the most affected, accounting for 32% (n=16) of the patients, followed by the 41-50 age group at 28% (n=14). The mean age for male participants was 42.55 ± 11.54 years, while the mean age for female participants was 40.25 ± 8.91 years. This demographic spread highlights the vulnerability of the young and middle-aged active workforce to the habituating risk factors associated with OSMF.

Table-1: Demographic analysis of the participants

Age Group (Years)	Male	%	Female	%	Total
18-30	6	13.64	1	16.67	7 (14%)
31-40	15	34.09	1	16.67	16 (32%)
41-50	10	22.73	4	66.67	14 (28%)
51-60	11	25	0	0	11 (22%)
>60	2	4.55	0	0	2 (4%)
Total	44	100%	6	100%	50 (100%)

Symptomatology and Duration of Disease

Clinical presentation varied, though a combination of symptoms was most common. The vast majority of patients, representing 78% (n=39) of the cohort, presented with a triad of oral pain, mucosal ulceration, and a severe burning sensation upon ingesting spicy foods. The remaining 22% (n=11) presented primarily with the chief complaint of progressive inability to open their mouth (trismus).

Regarding the duration of symptoms prior to seeking otolaryngological consultation (Table-2), the most frequent timeframe was between 6 and 12 months, observed in 40% (n=20) of patients. Symptoms persisting for less than 6 months were seen in 30% (n=15), while chronic symptomatology lasting between 13-24 months and beyond 24 months was noted in 20% (n=10) and 10% (n=5) of patients, respectively.

Table-2: Duration of symptoms prior to consultation

Duration of Symptoms (Months)	Frequency	%
< 6	15	30%
6-12	20	40%
13-24	10	20%
>24	5	10%

Severity of Oral Submucous Fibrosis (Lai Classification)

The clinical severity of OSMF (Table-3) was stratified based on the maximal inter-incisor distance. A concerning proportion of the study population presented with advanced disease. Grade III OSMF (inter-incisor distance 20-30 mm) was the most prevalent, accounting for 42% (n=21) of the patients. This was followed by Grade II (30-35 mm) in 28% (n=14) and Grade IV (<20 mm) in 26% (n=13) of the cases. Only 4% (n=2) of patients presented at the earliest stage (Grade I, >35 mm). This distribution indicates that 68% of the cohort was suffering from moderate to severe (Grade III and IV) functional restriction of the oral cavity at the time of presentation.

Table-3: Severity of Oral Submucous Fibrosis (Lai Classification)

Grade	Percentage	Sample Size
Grade I (>35mm)	4.0%	2
Grade II (30-35 mm)	28.0%	14
Grade III (20-30mm)	42.0%	21
Grade IV(<20mm)	26.0%	13

Otological and Audiological Findings

A total of 100 ears from the 50 patients were subjected to objective otological testing.

Eustachian Tube Function (Tympanometry): Evaluation of Eustachian tube patency via tympanometry (Table-4) revealed that 29% (n=29) of the evaluated ears suffered from Eustachian tube dysfunction, indicated by the presence of a Type C tympanogram (negative middle ear pressure peaking beyond -100 daPa). The remaining 71% (n=71) of ears demonstrated normal middle ear compliance and pressure, yielding Type A tympanograms. No Type B (effusion) or Type Ad/As curves were observed in this cohort.

Auditory Acuity (Pure Tone Audiometry): Correlating with the tympanometry findings, Pure Tone Audiometry demonstrated that 71% (n=71) of the ears possessed normal hearing thresholds. Conversely, 29% (n=29) of the ears exhibited varying degrees of conductive hearing loss (CHL) directly attributable to the negative middle ear pressure caused by ETD. Among those with hearing impairment, 12% had moderate CHL, 9% had severe CHL, and 8% presented with mild CHL.

Table-4: Tympanometry findings

Status of Eustachian Tube	Count	%
Eustachian tube dysfunction	29	29%
Normal	71	71%
Total	100	100%

Correlation Between OSMF Severity, ETD, and Hearing Loss

A critical objective of this research was to cross-tabulate the clinical grade of OSMF against the status of the Eustachian tube and auditory thresholds (Tables 5).

In patients with Grade I OSMF, 100% of the ears (4/4) showed normal ET function and normal hearing. However, as the fibrotic grade advanced, the incidence of otologic morbidity rose sharply.

- In **Grade II** OSMF (28 ears), ETD and corresponding conductive hearing loss were observed in 7.14% (2 ears).

- In **Grade III** OSMF (42 ears), the rate of ETD surged to 30.95% (13 ears), with corresponding conductive hearing impairments ranging from mild (9.52%) to severe (9.52%).
- In **Grade IV** OSMF (26 ears), which represents the most severe mucosal fibrosis, a staggering 53.85% (14 ears) demonstrated Eustachian tube dysfunction and conductive hearing loss. In this advanced group, moderate (23.08%) and severe (19.23%) conductive hearing loss were the predominant audiological presentations.

Table-5: OSMF Grade and Eustachian Tube Function

OSMF Grade	TOTAL EARS	Normal Eustachian Tube	Normal Percentage	dysfunction Eustachian Tube	Dysfunction Percentage
Grade I	4	4	5.13%	0	0.0%
Grade II	28	26	36.62%	2	6.90%
Grade III	42	29	40.85%	13	44.83%
Grade IV	26	12	16.90%	14	48.28%
Total	100	78	100%	22	100%

Statistical Significance: A Chi-square (χ^2) test was conducted to evaluate the statistical association between the grades of OSMF and the presence of Eustachian tube dysfunction/conductive hearing loss. The calculated Chi-square value was 12.998. The resulting p-value was **0.0011**. Because the p-value is significantly less than the alpha level of 0.05 ($p < 0.05$), the null hypothesis is rejected. This confirms a highly significant, direct statistical correlation between the advancing severity of Oral Submucous Fibrosis and the incidence of Eustachian tube dysfunction and subsequent conductive hearing loss.

DISCUSSION

Oral Submucous Fibrosis is a chronic, severely debilitating mucosal condition that has profound implications on a patient's nutritional status, speech, and overall quality of life due to the progressive limitation in mouth opening.[11] While the primary focal point of clinical management remains the oral cavity and the mitigation of malignant transformation, the anatomical proximity of the fibrotic process to the nasopharynx demands a broader clinical perspective. This study sought to elucidate the extra-oral ramifications of OSMF, specifically focusing on the physiological integrity of the Eustachian tube and its subsequent impact on auditory acuity.

Demographic and Clinical Presentation Profile

The demographic data of our cohort demonstrated a distinct male preponderance (88%) and a peak incidence within the 31-40 and 41-50 age brackets. These findings are strongly corroborated by the epidemiological data presented by Salim H et al. (2016) [11] and Gaddikeri (2023), [12] who noted that OSMF disproportionately affects young, working-class adult males. This demographic trend is largely driven by psychosocial factors, peer pressure, and the early initiation of betel quid and *gutkha* chewing habits, which are deeply entrenched in certain regional cultures. The chronic nature of the habit is reflected in the disease timeline; a substantial portion of our patients (50%) had experienced symptoms for over six months before seeking medical intervention. The insidious onset of the disease, beginning with a burning sensation and progressing to ulceration and fibrosis, often leads to delayed presentation. Furthermore, the lack of awareness regarding the progressive nature of the condition, particularly in rural populations, results in patients only seeking otolaryngological help when trismus becomes severe enough to impair eating, as seen in the 22% of our patients whose chief complaint was an inability to open their mouth.

When evaluating disease severity using the Lai Classification,[10] it was concerning that 68% of the cohort presented with advanced disease (Grade III and Grade IV). Badra et al. (2015) similarly reported a high prevalence of advanced grades at the time of initial clinical evaluation.[13] The scarcity of Grade I presentations (4%) in our study suggests a significant diagnostic delay, emphasizing an urgent need for proactive oral screening and public health campaigns targeting the cessation of areca nut consumption.

Pathophysiology of Eustachian Tube Dysfunction in OSMF

The central finding of this research is the definitive evidence of Eustachian tube dysfunction in 29% of the evaluated ears, manifesting as Type-C tympanograms and associated conductive hearing loss. The relationship between the grade of OSMF and ETD was statistically highly significant ($p = 0.0011$).

The physiological basis for this complication lies in the contiguous anatomy of the upper aerodigestive tract. The active opening mechanism of the Eustachian tube is not passive; it requires the coordinated, active contraction of the paratubal muscles; chiefly the tensor veli palatini (TVP) and the levator veli palatini (LVP); during swallowing and yawning. In OSMF, the excessive deposition of densely cross-linked collagen fibers is not restricted strictly to the buccal mucosa. The fibrotic cascade often extends posteriorly, infiltrating the soft palate, the anterior and posterior faucial pillars, and the pharyngeal musculature.[14]

As the disease progresses to Grades III and IV, the infiltration of these fibrotic bands into the soft palate restricts the physiological mobility of the TVP and LVP muscles. The resultant muscular atrophy and mechanical tethering prevent the adequate dilation of the pharyngeal orifice of the Eustachian tube. This chronic failure to open leads to poor middle ear ventilation. As the mucosal lining of the middle ear continues to absorb the trapped gases, a negative middle ear pressure develops, which is clinically captured as a Type C tympanogram on impedance audiometry.[14-15]

Our findings are in excellent agreement with the work of Baloch HKN. et al who reported a 34.6% incidence of ETD in OSMF patients. Similarly, Swain SK et al and Shah N highlighted that fibrosis of the palatal musculature directly correlates with tubal dysfunction.[15-17] The data from our study clearly show a dose-response relationship: ETD was absent in Grade I, minimal in Grade II (7.14%), but surged drastically in Grade III (30.95%) and Grade IV (53.85%). This stark escalation confirms that the posterior extension of fibrosis and subsequent paratubal tethering is a late-stage hallmark of OSMF.

Audiological Implications: Conductive Hearing Loss

Consequently, the chronic negative middle ear pressure resulting from ETD leads to retraction of the tympanic membrane and restricted mobility of the ossicular chain, culminating in conductive hearing loss. In our study, the 29% of ears with ETD all exhibited corresponding conductive hearing impairment. Alarmingly, within the Grade IV OSMF group, the severity of the hearing loss was pronounced, with a majority presenting with moderate to severe conductive hearing loss.

This auditory complication represents a significant, hidden morbidity in OSMF patients. While clinical attention is rightfully focused on the debilitating oral restrictions and the risk of squamous cell carcinoma, progressive conductive hearing loss further isolates these patients, compounding the psychological and social distress caused by their altered speech and appearance. The findings dictate that auditory evaluation cannot be an afterthought in the management of OSMF. Routine tympanometry serves as a rapid, non-invasive, and highly sensitive screening tool to detect negative middle ear pressure before irreversible structural damage (such as adhesive otitis media or cholesteatoma formation) occurs.

Limitations of the Study

While the statistical correlations identified in this research are robust, several limitations must be acknowledged. Firstly, the cross-sectional, observational design of the study restricts the ability to establish absolute longitudinal causality. We can identify the association between advanced OSMF and ETD, but a prospective longitudinal study tracking patients from Grade I through Grade IV over several years would provide more definitive insights into the temporal onset of auditory complications. Secondly, the sample size of 50 patients (100 ears), while statistically sufficient for baseline associations, is relatively modest. Larger, multicenter studies are required to validate these findings across diverse demographic groups. Lastly, the evaluation of the Eustachian tube was performed primarily via tympanometry. Adjunctive diagnostic modalities, such as video nasal endoscopy to directly visualize the pharyngeal orifice of the Eustachian tube and structural changes to the torus tubarius during swallowing, would add a valuable anatomical perspective to the functional data gathered in this study.

CONCLUSION

Oral Submucous Fibrosis is a complex fibroelastic disorder that transcends the boundaries of the oral cavity, establishing a morbid footprint in the adjacent nasopharyngeal and otological structures. This study provides compelling, statistically significant evidence that as the clinical severity of OSMF progresses, the incidence of Eustachian tube dysfunction and subsequent conductive hearing loss increases dramatically. The fibrotic infiltration and mechanical tethering of the paratubal musculature (tensor and levator veli palatini) effectively disrupt middle ear ventilation mechanics, particularly in Grade III and Grade IV disease.

These findings advocate for a paradigm shift in the holistic clinical management of OSMF. The treatment protocols must evolve beyond merely addressing oral trismus and monitoring for malignancy. Multidisciplinary intervention is required. Routine audiological assessments specifically impedance audiometry (tympanometry) and pure tone audiometry must be integrated as standard baseline and follow-up investigations for all patients diagnosed with OSMF. Early detection of negative middle ear pressure allows for timely conservative or surgical interventions (such as the insertion of ventilation tubes/grommets), thereby preventing chronic conductive hearing loss and significantly enhancing the overall quality of life for these patients. Public health initiatives must simultaneously amplify efforts to curb the consumption of areca nut and related products to stem the tide of this preventable, debilitating disease.

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