MAK HILL Publications Research Journal of Medical Sciences

Research Article
doi: 10.36478/makrjms.2024.7.299.303

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Key Words
Oral submucous fibrosis (osmf), eustachian tube dysfunction, hearing loss, tympanometry, middle ear function

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Received: 25 April 2024
Accepted: 18 June 2024
Published: 20 June 2024

Citation: Bonagiri Sandeep, Tirumala Radha, Siva Subba Rao Pakanti and Md. Adil Faizan, 2024. Assessment of Eustachian Tube Function and Hearing Status in Oral Submucous Fibrosis: A Cross-Sectional Study. Res. J. Med. Sci., 18: 299-303, doi: 10.36478/ makrjms.2024.7.299.303

Assessment of Eustachian Tube Function and Hearing Status in Oral Submucous Fibrosis: A Cross-Sectional Study

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Abstract
Middle ear function is altered by OSMF because it results in fibrotic alterations in the paratubal muscles. Restricted mouth opening also interferes with the proper functioning of the Eustachian tube. A hospital-based Descriptive Cross-Sectional study was carried out at a Tertiary Care Hospital from June 1, 2022 to January 30, 2024 after approval from Institutional Ethics Committee. Patients with a clinical diagnosis of oral submucous fibrosis, regardless of age or gender, who visit the ENT outpatient department and are willing to take part in the study were included. A total of 60 subjects (120 ears) were included in the study. Age range of study subjects was 18-60 years with a mean age of 33.25 ± 16.2 years. Majority of patients were in 3rd and 4th decade of life (70%) and Male: Female ratio was 4.45:1. Burning sensation in mouth (86.01%) was the most common complaint followed by reduced mouth opening (42.92%) and ulcers in mouth (21.97%). Eustachian tube function is impaired in advanced stages of oral submucous fibrosis due to involvement of paratubal musculature. This has clinical implications in hearing assessment of these patients, hence mandating a routine otoscopic and audiological examination in these patients.

INTRODUCTION

The chronic illness known as oral submucous fibrosis (OSF) results in tissue fibrosis, precancerous lesions and scarring. The buccal mucosa is where it usually appears[1]. Chronic inflammation, localized inflammation in the lamina propria or deep connective tissues, excessive collagen deposition in the connective tissues underneath the oral mucosal epithelium and degenerative alterations in the muscles are pathological features[2]. Reduced tongue movement and depapillation, a leathery, blanched oral mucosa, a gradual decrease in mouth opening, and shrunken uvula are further characteristics of OSMF[3]. According to estimates, the incidence of OSMF in India spans a wide age range, from 11 to 60 years old and ranges from 0.2-2.3% in males and 1.2-4.6% in females[4].

Following the extensive marketing of commercial tobacco and areca nut products, commonly referred to as Gutkha and sold in single-use packets, a notable rise in incidence of oral submucosal fibrosis has been noted[5]. Autoimmunity, insufficient amounts of vitamin B, C, and iron, chewing betel nut, eating spicy meals, HPV infection and genetic mutations are among the causes of OSF. According to epidemiological research, one of the biggest risk factors for OSF is chewing betel nut[6]. Additional research verified the synergistic effect of eating betel nut and alcohol consumption on OSF induction[7].

Middle ear function is altered by OSMF because it results in fibrotic alterations in the paratubal muscles. Restricted mouth opening also interferes with the proper functioning of the Eustachian tube[8].

It's not always required to do a biopsy or obtain histological confirmation because the clinical characteristics are almost pathognomic. Furthermore, the biopsy site may heal with scar formation due to decreased vascularity and impaired collagen synthesis in the mucosa, which could exacerbate the disease condition by further restricting the mouth opening. Furthermore, there is always a chance that the biopsy will act as an irritant in the form of mechanical trauma. While numerous research investigations have documented fibrosis and hyalinization in the oral cavity and pharynx's epithelium, only few studies have been reported regarding its effect on Eustachian tube function and hearing status. The purpose of the study was to assess the Eustachian tube function and hearing status of patients with oral submucous fibrosis and to link these findings with different disease groups.

MATERIALS AND METHODS

A hospital-based Descriptive Cross-Sectional study was carried out ata Tertiary Care Hospital from June 1, 2022 to January 30, 2024 after approval from Institutional Ethics Committee. Patients with a clinical diagnosis of oral submucous fibrosis, regardless of age or gender, who visit the ENT outpatient department and are willing to take part in the study were included. The study excluded patients with middle ear diseases such as cholesteatoma, tympanic membrane perforation, ossicular pathologies, external or inner ear pathology, damage to the ear, nasopharyngeal mass, cleft lip, or cleft palate. OSMF patients were examined using tympanometry to evaluate the functioning of the Eustachian tube.

Patients with a clinical diagnosis of oral submucous fibrosis, regardless of age or gender, who visit the ENT outpatient department and are willing to take part in the study were included. The study excluded patients with middle ear diseases such as cholesteatoma, tympanic membrane perforation, ossicular pathologies, external or inner ear pathology, damage to the ear, nasopharyngeal mass, cleft lip, or cleft palate.

Participants provided signed informed consent before clinical data, including demographics, chief complaints, history of addiction, history of hearing loss and an in-depth clinical examination, was collected. Using a Vernier Calliper, patients' inter-incisor distance was measured. For every person, three readings were obtained, the average was noted as the final reading. To control the inter-examiner and intra-examiner reliability, each step was performed by single examiner. Patients were divided into four groups according to Khanna and Angrade's Clinical classification[9,10] as follows:

- **Group 1:** Earliest stage without mouth opening limitations with an interincisal distance of >35mm and burning sensation in mouth or acute ulceration.
- **Group 2:** Patients with an interincisal distance of 26-35mm and marble like buccal mucosa, fibrosed areas with normal pink mucosa in between.
- **Group 3:** Moderately advanced cases with an interincisal distance of 15-25mm. Fibrotic bands are visible at the soft palate and anterior pillars of faucet.
- **Group 4A:** Trismus is severe with an interincisal distance of less than 15mm and extensive fibrosis of all the oral mucosa, tonsils and uvula are also fibrosed and shortened.
- **Group 4B:** Disease is most advanced with premalignant changes throughout the mucosa.

Using a Pure Tone Audiometer, an audiological evaluation was conducted. The tested frequency span from 250 Hz to 8000 Hz. The kind and extent of hearing loss were determined. The degree of hearing impairment was divided into the following categories:

- 10-15 dB Normal hearing
- 16-25 dB Minimal hearing loss

- 26-40 dB Mild hearing loss
- 41-55 dB Moderate hearing loss
- 56-70 dB Moderate to Severe hearing loss
- 71-90 dB Severe hearing loss
- >90 dB Profound deafness

A graph representing the compliance was produced by impedance audiometry. Three different graph types were obtained: Type A is normal, but Types B and C are aberrant and may indicate middle ear illness. It was determined how the compliance shifts peak at normal, negative and positive pressures. Compliance peaks with a shift show optimal Eustachian Tube function, while compliance peaks without a shift indicate ineffective Eustachian Tube function. The purpose of data collection was statistical analysis.

Using Microsoft Windows and Epi InfoVersion 7.0, statistical analysis was carried out. The standard deviation (SD), range and mean of the baseline demographics were displayed. The results of pure tone and impedance audiometry were expressed as percentages and frequencies. The relationship between hearing loss and Eustachian Tube Function with varying OSMF grades was evaluated using the Pearson Chi-Square test. A 5% threshold for significance was established.

RESULTS AND DISCUSSIONS

A total of 60 subjects (120 ears) were included in the study. Age range of study subjects was 18-60 years with a mean age of 33.25 ± 16.2 years. Majority of patients were in 3rd and 4th decade of life (70%) and Male: Female ratio was 4.45:1. Burning sensation in mouth (86.01%) was the most common complaint followed by reduced mouth opening (42.92%) and ulcers in mouth (21.97%). Hard of hearing was reported as associated complaint by 34% patients. Study subjects had addiction of one or more addictive substances. Kharra/Gutkha was the most common substance consumed in 85 % patients followed by tobacco chewing (65%), supari (38.33%) and Pan consumption (35%). Mouth opening (Inter-incisor distance) of >35mm was found in 38.33% patients, while it was 35-26mm in 26.66% patients, 25-15 mm in 23.33% and < 15mm in 11.66%. Clinically, all patients (60) had involvement of buccal mucosa followed by soft palate in 32(53.33%) patients. Involvement of hard palate was seen in 16(26.66%) patients, anterior pillar in 12(20%) patients, uvula and retromolar trigone in 4(6.66%) and 2(3.33%) patients respectively (Table 1).

According to clinical classification of Khanna and Angrade, out of 60 patients, 23(38.33%) belonged to Group I OSMF followed by 17(28.33%) patients in Group II, 13(21.66%) in Group III, 5(8.33%) patients in Group IVA and 2(3.33%) patients in Group IVB (Table 2).

Audiological evaluation was performed in 60 patients (120 ears). Out of 120 ears, hearing level was normal in 84(70%) ears, minimal loss in 10(8.33%) ears, while mild and moderate hearing loss was found in 12(10%) and 14(11.66%) ears respectively. No patient had severe or profound hearing loss. (Table III) Correlation between Groups of OSMF and degree of hearing loss was evaluated. In Group I OSMF, there was no hearing loss found in ears of any patient. In Group II, 75.75% ears had normal hearing, 18.18% ears had minimal hearing loss, 3.03% and 3.03 % had mild and moderate hearing loss. In Group III OSMF, maximum number of ears i.e., 36.36% had mild hearing loss followed by 31.81% ears with moderate and 18.18% with minimal hearing loss. 13.63% ears had normal hearing in Group III patients. In Group IVA OSMF, 4(66.67%) ears had moderate hearing loss and 2(33.33%) ears had mild hearing loss out of 06 ears. In Group IVB, out of 3 ears, 1(33.33%) ears had moderate hearing loss and 2(66.66%) had mild hearing loss. There was statistically significant correlation seen between the Group of OSMF and Hearing loss (Chi-square test, $p < 0.05$)(Table 3).

Normal Type A tympanogram was found in 88(73.33%) ears, abnormal Type B curve in 18(15%) and Type C curve in 14(11.66%) ears. (Table IV) All subjects belonging to Group I of OSMF (56 ears) had normal i.e., Type A tympanogram. In Group II, 87.5% subjects showed normal Type A tympanogram while 6.25% ears showed abnormal Type B and 6.25% subjects showed Type C tympanogram. In Group III, only 13.63% subjects showed normal Type A tympanogram while 54.54% subjects showed abnormal Type B and 27.27% subjects showed Type C tympanogram. In Group IVA, 33.33% and 66.67% subjects showed abnormal Type B and Type C tympanograms, respectively. In Group IVB, Type B and C curve in Tympanometry was seen in 50% of ears each. On correlating tympanometry curves with different groups of Oral Submucous Fibrosis, a significant relation was found between the two.

On Eustachian Tube function test, 33 ears (15%) had no shift in compliance peaks meaning poor eustachian tube function while 73.33% ears showed good eustachian tube function (Table 5). All ears (56) of subjects belonging to Group I disease had good Eustachain tube function. 03 ears of Group II, 19 ears of Group III, 06 ears of Group IVA and 04 ears of Group IVB had poor Eustachian Tube function. As the severity of the disease increased, frequency of involvement of Eustachian tube also increased leading to its dysfunction and this was statistically significant corelation. (Table V)

OSMF is a well-known chronic progressive disease affecting the oral cavity and oropharynx. It involves the palatal and paratubal muscles, which cause eustachian

Table 1: Distribution of patients of OSMF according to demographic characters and clinical presentation (n=60)

Variables	Frequency	Percentage
Gender		
Male	49	81.66
Female	11	18.33
Male: Female	4.45:1	
Age in years (Mean + SD) in Years	33.25+16.2	
Consumption of addictive Substances*		
Gutkha	51	85
Tobacoo	39	65
Supari	23	38.33
Pan	21	35
Inter-incisor Distance in mm		
>35	23	38.33
35-26	16	26.66
25-15	14	23.33
<15	7	11.66
Mean +SD (in mm)		
Area of Oral Cavity involved*		
Buccal mucosa	60	100
Soft palate	32	53.33
Hard palate	16	26.66
Anterior pillar	12	20
Uvala	4	6.66
Retromolar Trigone	2	3.33

Table 2: Distribution of study subjects according to Group of OSMF (n=60)

Group of OSMF	Frequency (N)	Percentage (%)
I	23	38.33
II	17	28.33
III	13	21.66
IVA	5	8.33
IVB	2	3.33
Total Patient	60	100

Table 3: Distribution of Ears of patients according to degree of hearing loss in various Groups of OSMF and their correlation (n= 120 ears)

Degree of Hearing Loss	Groups of OSMF						
	I n(%)	II n(%)	III n(%)	IVA n(%)	IVB n(%)	Total Ears	
Normal	56(100%)	25(75.75%)	3(13.63%)	0	0	84(70%)	
Minimal	0	06(18.18%)	4(18.18%)	0	0	10(8.33%)	
Mild	0	01(3.03%)	8(36.36%)	4(66.66%)	2(66.66%)	12(10%)	P-VALUE*
Moderate	0	01(3.03%)	7(31.81%)	2(33.33%)	1(33.33%)	14(11.66%)	<0.001
Total	56	33	22	06	03	120	

**Chi-square Test, p value< 0.05 -Statistically significant*

Table 4: Distribution of Ears of patients according to Type of Tympanogram and Groups of OSMF and their correlation (n= 120 ears)

Type of Tympanogram	Groups of OSMF						
	I n(%)	II n(%)	III n(%)	IVA n(%)	IVB n(%)	Total Ears	
Type A	56(100%)	28(87.5%)	4(13.63%)	0	0	88(73.33%)	
Type B	0	02(6.25%)	12(54.54%)	02(33.33%)	02(50%)	18(15%)	P Value*
Type C	0	02(6.25%)	6(27.27%)	4(66.66%)	02(50%)	14(11.66%)	<0.001
Total	56	32	22	06	04	120	

**Chi-square Test, p value < 0.05 -Statistically significant*

Table 5: Distribution of study ears based on Eustachian tube function in various Groups of OSMF (n=120)

Eustach Ian tube function	Groups of OSMF						
	I n(%)	II n(%)	III n(%)	IVA n(%)	IVB n(%)	Total Ears	
Good	56(100%)	28(87.5%)	4(18.18%)	0	0	88(73.33%)	P Value*
Poor	0	04(12.5%)	18(81.81%)	06(100%)	04(%100)	32(26.66%)	<0.001
Total	56	32	22	06	04	120	

**Chi-square Test, p value< 0.05-Statistically significant*

tube malfunction, leading to disturbed middle ear function and negative middle ear pressure. This study evaluates the hearing status and eustachian tube function in patients with oral submucous fibrosis along with their demographics.

In our study, oral submucous fibrosis showed a predominance in the 3rd and 4th decades, which is in accordance with the study of Harkare *et al*. However, a predominance in the 2nd and 3rd decades is seen in other studies by Siddiqui *et al*. and Shah et al. Most of these patients were males (4.45:1), similar to other studies. Furthermore, the usage of addictive substances is observed in almost all of the study subjects, with gutkha being the most commonly used, followed by tobacco and paan, which is consistent with findings in other studies as well.

Audiometric evaluation of 120 ears showed normal hearing in the majority (84 ears), with minimal loss in 10 ears, mild in 12 and moderate in 14 ears. In a study by Harkare *et al*., audiometric evaluation of

242 ears in 121 OSMF patients revealed that hearing was normal in 168 ears (69.42%), minimal conductive hearing loss was present in 20 ears (8.26%), mild conductive hearing loss was present in 26 ears (10.74%) and moderate conductive hearing loss was evident in 28 ears (11.58%). In Shah et al.'s study, Pure Tone Audiometry of 60 ears in 30 OSMF patients revealed normal hearing in 42 ears (70%), minimal hearing loss in 5 ears (8.33%), mild hearing loss in 6 ears (10%) and moderate hearing loss in 7 ears (11.66%). Gupta et al. found normal hearing in 79.2% of ears, mild to moderate hearing loss in 18.0% and sensorineural hearing loss in 2.8%. Shah M *et al*. reported that, out of 54 ears in their OSMF group, hearing was normal in 67%, mild hearing loss was found in 22% and moderate mixed hearing loss was present in 11%. Overall, our results are in line with the above studies. Additionally, there is a significant correlation between hearing loss and different groups of OSMF (p-value <0.001).

On performing tympanogram, Group I shows only type A, Group II shows 87% of type A, whereas type B & type C are in equal numbers. Group III showed the majority of them in type B and lastly, Group IV showed only type B & C. This indicates the alteration of tympanogram as the stage of OSMF advances, a finding similar to that seen in the study of Harkare et al. This suggests a direct relation between the progression of OSMF and hearing loss due to the involvement of palatal/paratubal muscles in the fibrotic process, leading to the shortening of muscle fibers. These degenerative changes impair the eustachian tube patency and ventilatory process of the middle ear, affecting the patient's hearing.

CONCLUSION

Eustachian tube function is impaired in advanced stages of oral submucous fibrosis due to involvement of paratubal musculature. This has clinical implications in hearing assessment of these patients, hence mandating a routine otoscopic and audiological examination in these patients.

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